Effective Health Care Program

Comparative Effectiveness Review
Number 26

Therapies for Children With Autism Spectrum Disorders

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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care. The EPCs now lend their expertise to the Effective Health Care Program by conducting Comparative Effectiveness Reviews (CERs) of medications, devices, and other relevant interventions, including strategies for how these items and services can best be organized, managed, and delivered.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strengths and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews are useful because they define the strengths and limits of the evidence, clarifying whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about systematic reviews, see http://effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that CERs will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. In addition, AHRQ is committed to presenting information in different formats so that consumers who make decisions about their own and their family's health can benefit from the evidence.

Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an e-mail list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly.

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Therapies for Children With Autism Spectrum Disorders

Structured Abstract

Objectives. The Vanderbilt Evidence-based Practice Center systematically reviewed evidence on therapies for children ages 2 to 12 with autism spectrum disorders (ASDs). We focused on treatment outcomes, modifiers of treatment effectiveness, evidence for generalization of outcomes to other contexts, and evidence to support treatment decisions in children ages 0-2 at risk for an ASD diagnosis.

Data. We searched MEDLINE,® ERIC, and PsycInfo.®

Review Methods. We included studies published in English from January 2000 to May 2010. We excluded medical studies with fewer than 30 participants; behavioral, educational, and allied health studies with fewer than 10 participants; and studies lacking relevance to treatment for ASDs.

Results. Of 159 unique studies included, 13 were good quality, 56 were fair, and 90 poor. The antipsychotic drugs risperidone and aripiprazole demonstrate improvement in challenging behavior that includes emotional distress, aggression, hyperactivity, and self-injury, but both have high incidence of harms. No current medical interventions demonstrate clear benefit for social or communication symptoms in ASDs. Evidence supports early intensive behavioral and developmental intervention, including the University of California, Los Angeles (UCLA)/Lovaas model and Early Start Denver Model (ESDM) for improving cognitive performance, language skills, and adaptive behavior in some groups of children. Data are preliminary but promising for intensive intervention in children under age 2. All of these studies need to be replicated, and specific focus is needed to characterize which children are most likely to benefit. Evidence suggests that interventions focusing on providing parent training and cognitive behavioral therapy (CBT) for bolstering social skills and managing challenging behaviors may be useful for children with ASDs to improve social communication, language use, and potentially, symptom severity. The Treatment and Education of Autistic and Communication related handicapped CHildren (TEACCH) program demonstrated some improvements in motor skills and cognitive measures. Little evidence is available to assess other behavioral interventions, allied health therapies, or complementary and alternative medicine. Information is lacking on modifiers of effectiveness, generalization of effects outside the treatment context, components of multicomponent therapies that drive effectiveness, and predictors of treatment success.

Conclusions. Medical interventions including risperidone and aripiprazole show benefit for reducing challenging behaviors in some children with ASDs, but side effects are significant. Some behavioral and educational interventions that vary widely in terms of scope, target, and intensity have demonstrated effects, but the lack of consistent data limits our understanding of whether these interventions are linked to specific clinically meaningful changes in functioning. The needs for continuing improvements in methodologic rigor in the field and for larger multisite studies of existing interventions are substantial. Better characterization of children in these studies to target treatment plans is imperative.

Contents

Tables

Figures

Appendixes

Executive Summary

Background

Autism spectrum disorders (ASDs) have an estimated prevalence of 1 in 110 children in the United States.[1] Disorders within the spectrum include Autistic Disorder, Asperger Syndrome, and Pervasive Developmental Disorder, Not Otherwise Specified (PDD-NOS).

Individuals with ASDs have impaired social interaction, behavior, and communication[2] including lack of reciprocal social interaction and joint attention (i.e., the ability to use nonverbal means such as pointing to direct others' attention to something in which the child is interested); dysfunctional or absent communication and language skills; lack of spontaneous or pretend play; intense preoccupation with particular concepts or things; and repetitive behaviors or movements.[3-5] Children with ASDs may also have impaired cognitive skills and sensory perception.[1,2]

Treatment for ASDs focuses on improving core deficits in social communication, as well as addressing challenging behaviors to improve functional engagement in developmentally appropriate activities.[4] In addition to addressing core deficits, treatments are provided for difficulties associated with the disorder (anxiety, attention difficulties, sensory difficulties, etc.). Individual goals for treatment vary for different children and may include combinations of therapies.[4]

Objectives

Population. We focused this review on children ages 2-12 with ASDs for Key Questions (KQs) 1-6 and children under age 2 at risk of ASD for KQ7.

Interventions. Treatments included behavioral, educational, medical, allied health, and complementary and alternative medicine (CAM) interventions (Table A).

Table A. Description of interventions

Intervention category	Brief description
Behavioral	• Interventions in the early intensive behavioral and developmental category have their basis in or draw from principles of applied behavior analysis (ABA), with differences in methods and setting. We included in this category two intensive interventions with published treatment manuals (manualized interventions): the University of California, Los Angeles/Lovaas model and the Early Start Denver Model (ESDM). We also included in this category interventions utilizing intensive ABA principles in a similar fashion to the UCLA/Lovaas model. Frequently these approaches included variations of the UCLA/Lovaas model, but we review this literature together because of overall similarities. An additional set of interventions included in this category use ABA principles to focus on teaching pivotal behaviors to parents rather than on directed intensive intervention. • Social skills interventions focus on facilitating social interactions and may include peer training and social stories. • Play- or interaction-focused interventions use interactions between children and parents or researchers to affect outcomes, including imitation, joint attention skills, or children's ability to engage in symbolic play. • Interventions focused on commonly associated behaviors attempt to ameliorate symptoms such as anxiety, often present in ASDs, using techniques including cognitive behavioral therapy (CBT) and parent training focused on challenging behaviors. • Additional interventions include techniques such as sleep workshops and neurofeedback.
Educational	• Educational interventions focus on improving educational and cognitive skills. They are intended to be administered primarily in educational settings and also include studies for which the educational arm was most clearly categorized. • Some interventions in educational settings are based on principles of ABA and may be intensive, but no interventions in this category used the UCLA/Lovaas or ESDM manualized treatments.
Medical and related interventions	• Medical and related interventions are those that include the administration of external substances to the body to treat symptoms of ASDs. • Medical treatments for ASD symptoms comprise a variety of pharmacologic agents, including antipsychotics, psychostimulants, and serotonin reuptake inhibitors (SRIs), and modalities such as therapeutic diets, supplements, hormonal supplements, immunoglobulin, hyperbaric oxygen, and chelating agents.
Allied health	• Allied health interventions include therapies typically provided by speech/language, occupational, and physical therapists, including auditory and sensory integration, music therapy, and language therapies (e.g., Picture Exchange Communication System [PECS]).
CAM	• CAM interventions include acupuncture and massage.

Note: ABA = applied behavior analysis; ASDs = autism spectrum disorders; CAM = complementary and alternative medicine; CBT = cognitive behavioral therapy; ESDM = Early Start Denver Model; PECS = Picture Exchange Communication System; SRI = serotonin reuptake inhibitor; UCLA = University of California, Los Angeles

Comparators. Comparators included no treatment, placebo, and comparative interventions or combinations of interventions.

Outcomes. Outcomes included changes in core ASD symptoms and in commonly associated symptoms (Figure A).

Key Questions

Key questions were:

KQ1. Among children ages 2-12 with ASDs, what are the short- and long-term effects of available behavioral, educational, family, medical, allied health, or CAM treatment approaches? Specifically,

KQ1a. What are the effects on core symptoms (e.g., social deficits, communication deficits, and repetitive behaviors) in the short term (≤6 months)?

KQ1b. What are the effects on commonly associated symptoms (e.g., motor, sensory, medical, mood/anxiety, irritability, and hyperactivity) in the short term (≤6 months)?
KQ1c. What are the longer term effects (>6 months) on core symptoms (e.g., social deficits, communication deficits, and repetitive behaviors)?
KQ1d. What are the longer term effects (>6 months) on commonly associated symptoms (e.g., motor, sensory, medical, mood/anxiety, irritability, and hyperactivity)?

KQ2. Among children ages 2-12, what are the modifiers of outcome for different treatments or approaches?
KQ2a. Is the effectiveness of the therapies reviewed affected by the frequency, duration, and intensity of the intervention?
KQ2b. Is the effectiveness of the therapies reviewed affected by the training and/or experience of the individual providing the therapy?
KQ2c. What characteristics, if any, of the child modify the effectiveness of the therapies reviewed?
KQ2d. What characteristics, if any, of the family modify the effectiveness of the therapies reviewed?

KQ3. Are there any identifiable changes early in the treatment phase that predict treatment outcomes?

KQ4. What is the evidence that effects measured at the end of the treatment phase predict long-term functional outcomes?

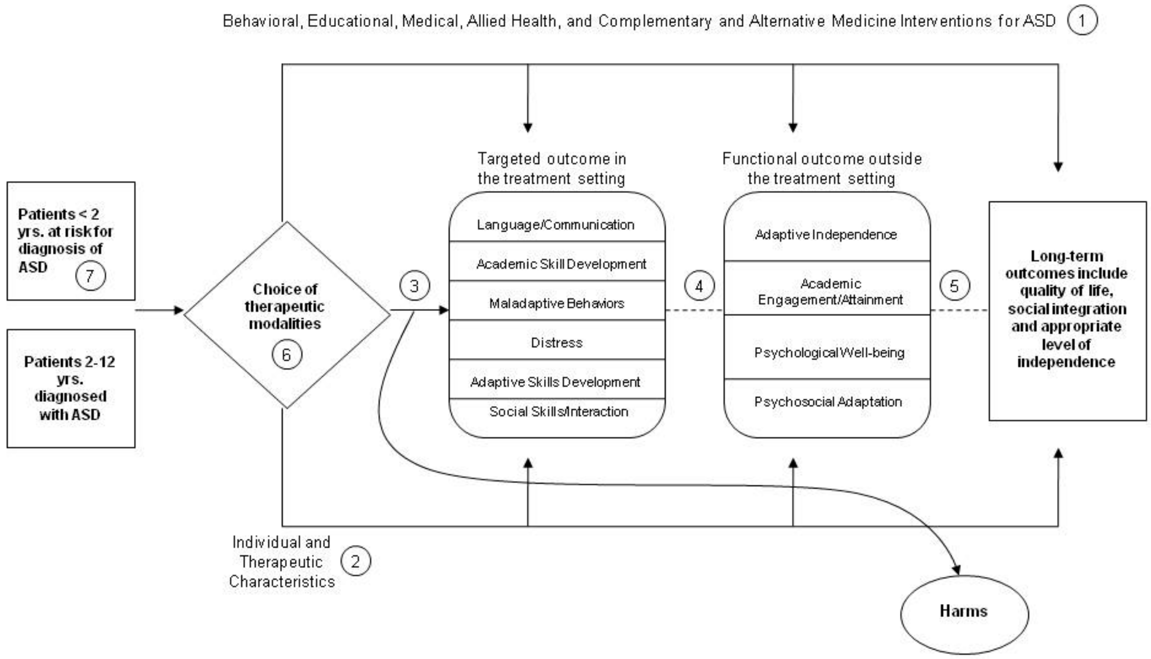
KQ5. What is the evidence that specific intervention effects measured in the treatment context generalize to other contexts (e.g., people, places, materials)?

KQ6. What evidence supports specific components of treatment as driving outcomes, either within a single treatment or across treatments?

KQ7. What evidence supports the use of a specific treatment approach in children under the age of 2 who are at high risk of developing autism based upon behavioral, medical, or genetic risk factors?

Analytic Framework

Figure A. Analytic framework for therapies for children with ASDs



The analytic framework summarizes the process by which families of children with ASDs make and modify treatment choices. Treatment choices are affected by many factors that relate to the care available. Treatment effectiveness may also be affected by factors related to the child (e.g., age, IQ) or the context of care. Ideally, treatment effects are seen both in the short term in clinical changes and in longer term or functional outcomes. Eventual outcomes of interest include adaptive independence appropriate to the abilities of the specific child, psychological well-being, appropriate academic engagement, and psychosocial adaptation. The circled numbers represent the report's key questions; their placement indicates the points in the treatment process in which they are likely to arise.

Methods

Input From Stakeholders

The topic was nominated in a public process. With key informant input, we drafted initial key questions and, after approval from the Agency for Healthcare Research and Quality (AHRQ), they were posted to a public Web site for public comment. Using public input, we drafted final key questions, which were approved by AHRQ. We convened a Technical Expert Panel to provide input during the project on issues such as setting inclusion/exclusion criteria and assessing study quality. In addition, the draft report was peer reviewed and made available for public comment.

Data Sources and Selection

We searched three databases: MEDLINE® via the PubMed interface, PsycINFO, and the Education Resources Information Center (ERIC) database. We hand-searched reference lists of included articles and recent reviews for additional studies. We excluded studies that:

- Were not published in English.
- Did not report information pertinent to the key questions.
- Were published prior to the year 2000, the time of the revision of the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)[2] and widespread implementation of gold standard assessment tools, including the Autism Diagnostic Observation Schedule (ADOS)[6] and the Autism Diagnostic Interview – Revised (ADI-R).[7]
- Were not original research.
- Did not present aggregated results (i.e., only presented data for each individual participant) or presented graphical data only.

We also excluded studies with fewer than 10 total participants for studies of behavioral, educational, allied health, or CAM interventions; or fewer than 30 total participants for medical studies. We believed that, given the greater risk associated with the use of medical interventions, it was appropriate to require a larger sample size to accrue adequate data on safety and tolerability as well as efficacy. In addition, most studies of medical interventions for ASDs with fewer than 30 subjects report preliminary results that are replaced by later, larger studies.

We accepted any study designs except individual case reports. Our approach to categorizing study designs is presented in Appendix F of the full report.

Two reviewers separately evaluated each abstract. If one reviewer concluded that the article could be eligible, we retained it. Two reviewers independently read the full text of each included article to determine eligibility, with disagreements resolved via third-party adjudication.

Data Extraction and Quality Assessment

Data extraction. All team members entered information into the evidence table. After initial data extraction, a second team member edited entries for accuracy, completeness, and consistency. In addition to outcomes for treatment effectiveness, we extracted data on harms/adverse effects.

Quality assessment. Two reviewers independently assessed quality (study design, diagnostic approach, participant ascertainment, intervention characteristics, outcomes measurement, and statistical analysis), with differences resolved though discussion, review of the publications, and consensus with the team. We rated studies as good, fair, or poor quality and retained poor studies as part of the evidence base discussed in this review. More information about our quality assessment methods is in the full report.

Data Synthesis and Analysis

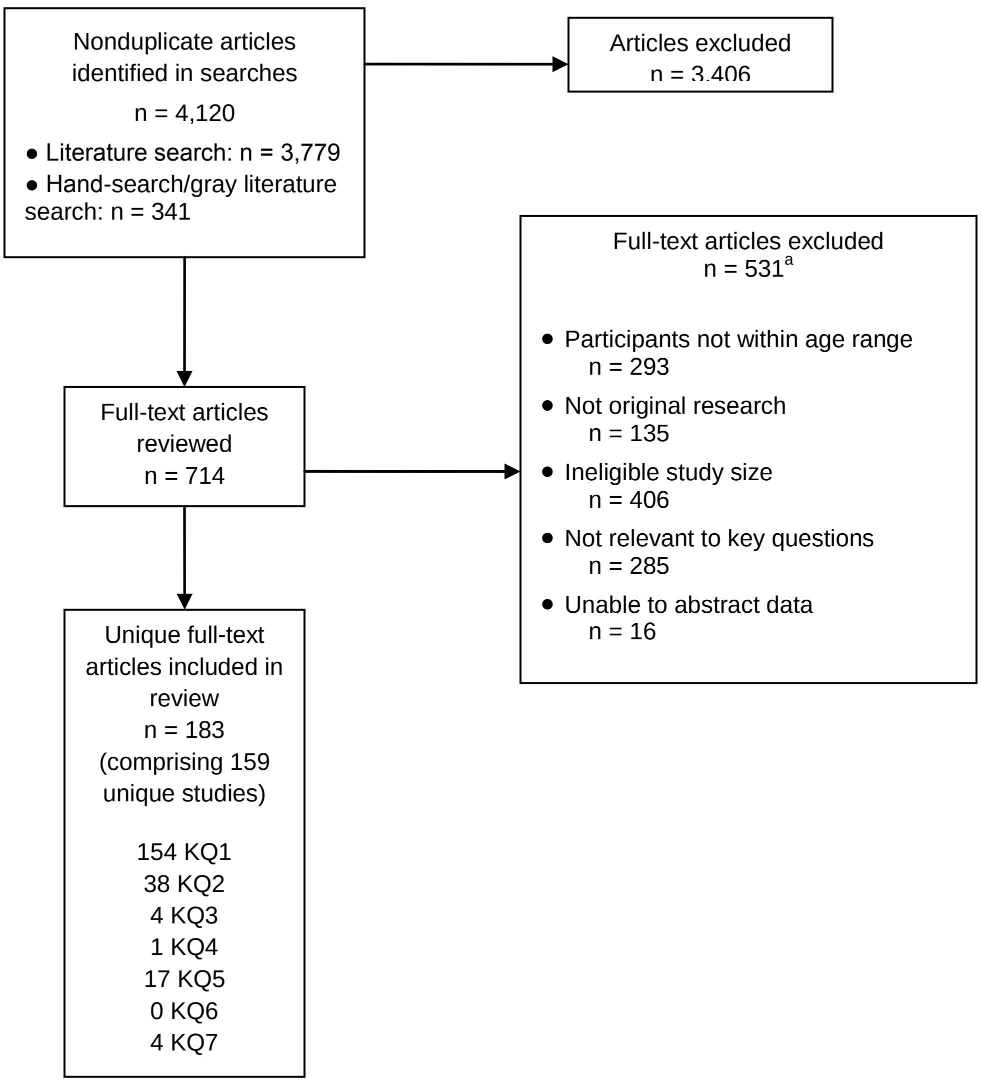
Evidence synthesis. We used summary tables to synthesize studies that included comparison groups and summarized the results qualitatively.

Strength of evidence. The degree of confidence that the observed effect of an intervention is unlikely to change is presented as strength of evidence, and it can be regarded as insufficient, low, moderate, or high. Strength of evidence describes the adequacy of the current research, in quantity and quality, and the degree to which the entire body of current research provides a consistent and precise estimate of effect. We established methods for assessing the strength of evidence based on the Evidence-based Practice Centers Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[8] Details of our strength-of-evidence methods are in Chapter 2 of the full report.

Results

Our searches retrieved 4,120 nonduplicate citations. We included 183 articles, representing 159 unique studies, in the review (Figure B). The full report details reasons for exclusion.

Figure B. Disposition of articles addressing therapies for children with ASDs



[a]The total number of articles in the exclusion categories exceeds the number of articles excluded because most of the articles fit into multiple exclusion categories.
Note: KQ = key question.

KQ1. Outcomes of Therapies for ASDs in Children Ages 2-12

Behavioral interventions. We identified 78 unique behavioral studies.[9-92] Early intensive behavioral and developmental intervention may improve core areas of deficit for individuals with ASDs; however, few randomized controlled trials (RCTs) of sufficient quality have been conducted, no studies directly compare effects of different treatment approaches, and little evidence of practical effectiveness or feasibility exists.

Within this category, studies of UCLA/Lovaas-based interventions report greater improvements in cognitive performance, language skills, and adaptive behavior skills than broadly defined eclectic treatments available in the community.[11,13,19,23,35,36,40] However, strength of evidence is currently low. Further, not all children receiving intensive intervention demonstrate rapid gains, and many children continue to display substantial impairment.[23] Although positive results are reported for the effects of intensive interventions that use a developmental framework, such as the Early Start Denver Model (ESDM),[37] evidence for this type of intervention is currently insufficient because few studies have been published to date.

Less intensive interventions focusing on providing parent training for bolstering social communication skills and managing challenging behaviors have been associated in individual studies with short-term gains in social communication and language use.[17,18,46] The current evidence base for such treatment remains insufficient, with current research lacking consistency in interventions and outcomes assessed.

Although all of the studies of social skills interventions reported some positive results,[47-62] most have not included objective observations of the extent to which improvements in social skills generalize and are maintained within everyday peer interactions. Strength of evidence is insufficient to assess effects of social skills training on core autism outcomes for older children or play- and interaction-based approaches for younger children.

Several studies suggest that interventions based on cognitive behavioral therapy are effective in reducing anxiety symptoms.[79-82] Strength of evidence for these interventions, however, is insufficient pending further replication.

Educational interventions. We identified 15 unique studies of educational interventions meeting our inclusion criteria.[93-108] Most research on the Treatment and Education of Autistic and Communication related handicapped CHildren (TEACCH) program was conducted prior to the date cutoff for our review. Newer studies continue to report improvements among children in motor, eye-hand coordination, and cognitive measures.[94,96] The strength of evidence for TEACCH, as well as broad-based and computer-based educational approaches included in this category,[106-108] to affect any individual outcomes is insufficient because there are too few studies and they are inconsistent in outcomes measured.

Medical and related interventions. We identified 42 unique studies in the medical literature,[109-115,116,117-161] of which 27 were RCTs.[109-120,122-124,126,128,131-133,137-143,145-152,159-161] Although no current medical interventions demonstrate clear benefit for social or communication symptoms, a few medications show benefit for repetitive behaviors or associated symptoms.

The clearest evidence favors the use of medications to address challenging behaviors. The antipsychotics risperidone and aripiprazole each have at least two RCTs demonstrating improvement in a parent-reported measure of challenging behavior.[109-120,122,123] A parent-reported hyperactivity and noncompliance measure also showed significant improvement. In addition, repetitive behavior showed improvement with both risperidone and aripiprazole. Both medications also cause significant side effects, however, including marked weight gain, sedation, and risk of extrapyramidal symptoms (side effects, including muscle stiffness or tremor, that occur in individuals taking antipsychotic medications). These side effects limit use of these drugs to patients with severe impairment or risk of injury.

We rated the strength of evidence as high for the adverse effects of both medications, moderate for the ability of risperidone to affect challenging behaviors, and high for aripiprazole's effects on challenging behaviors.

Allied health. The allied health interventions reviewed here were varied and reported in 17 unique studies.[162-184] The research provided little support for their use. Specifically, all studies of sensory integration and music therapy were of poor quality, and two fair-quality studies of auditory integration showed no improvement associated with treatment.[173,174] Language and communication interventions (Picture Exchange Communication System [PECS] and Responsive Education and Prelinguistic Milieu Training [RPMT]) demonstrated short-term improvement in word acquisition without effect durability, and should be studied further.[162-165] No other allied health interventions had adequate research to assess the strength of evidence.

CAM. Evidence for CAM interventions is insufficient for assessing outcomes.[185-191]

KQ2. Modifiers of Treatment Outcomes

With rare exceptions,163, 164, 192 few studies are designed or powered to identify modifiers of treatment effect. Although we sought studies of treatment modifiers, only one included study actually demonstrated true treatment modifiers based on appropriate study design and statistical analysis.163, 164 One other study192 was designed to examine the role of provider on outcomes but showed no difference, possibly because it was underpowered to do so.

This first study[163] included an analysis of initial characteristics of the children, demonstrating that children who were low in initial object exploration benefited more from RPMT, which explicitly teaches play with objects, while children who were relatively high in initial object exploration demonstrated more benefit from PECS. An additional analysis[164] showed greater increases in generalized turn-taking and initiating joint attention in the RPMT group than in PECS. The increased benefit in joint attention for RPMT was seen only in children who began the study with at least seven acts of joint attention.

One study[192] explicitly sought to examine the impact of provider (parent vs. professional) using similar interventions in an RCT. The study did not show a difference in outcomes for children receiving the UCLA/Lovaas protocol-based intervention in a clinical setting vs. at home from highly trained parents.

Other studies identified potential correlates that warrant further study. Modifiers with potential for further investigation but with currently conflicting data included pretreatment IQ and language skills, and age of initiation of treatment (with earlier age potentially associated with better outcomes). Social responsiveness and imitation skills have been suggested as skills that may correlate with improved treatment response in UCLA/Lovaas treatment,[192] whereas "aloof" subtypes of ASDs may be associated with less robust changes in IQ.[16] Other studies have seen specific improvement in children with PDD-NOS vs. Autistic Disorder diagnoses,[23] which may be indicative of baseline symptom differences. However, many other studies have failed to find a relationship between autism symptoms and treatment response.

KQ3. Early Results in the Treatment Phase That Predict Outcomes

The literature offers almost no information about specific observations of children that might be made early in treatment to predict long-term outcomes. Some evidence suggests that changes in IQ over the first year of either UCLA/Lovaas-based or ESDM intervention predicts, or accounts for, longer term change in IQ.[37,192] However, findings also suggest that although gains in the cognitive domain might be identified primarily within the first year of treatment, changes in adaptive behavior in response to these same interventions may occur over a longer timeframe,[19,37,45,192] if they occur at all.[13]

KQ4. End-of-Treatment Effects That Predict Outcomes

One study specifically addressed end-of-treatment effects to predict longer range outcomes. The feasibility of such studies was established in this language study, which reported outcomes 12 months postintervention.[65,66]

KQ5. Generalization of Treatment Effects

Few studies measured generalization of effects seen in treatment conditions to either different conditions or different locations. Among behavioral studies, those of treatments for commonly associated conditions, such as anxiety, employed outcomes assessment outside the therapeutic environment, with positive results observed. However, in most cases, outcomes are parent reported and not confirmed by direct observation.

For medical studies, data across classes of medications are likely to be transferable outside of the clinic setting, primarily because the outcome measures used in these studies rely on parent report of the subjects' behavior in the home or other settings and are augmented in some studies by teacher report.

KQ6. Drivers of Treatment Effects

No studies were identified to answer this question.

KQ7. Treatment Approaches in Children Under Age 2 at Risk for ASDs

Research on very young children is preliminary, with four studies identified.[15,34,37,42] One good-quality RCT suggested benefit from the use of ESDM in young children,[37] with improvements in adaptive behavior, language, and cognitive outcomes. Diagnostic shifts within the autism spectrum were reported in close to 30 percent of children but were not associated with clinically significant improvements in ADOS severity scores or other measures.

Discussion

Key Findings

In the behavioral literature, some evidence supports early and intensive behavioral and developmental intervention, including intensive approaches (provided >30 hours per week) and comprehensive approaches (addressing numerous areas of functioning). These included a UCLA/Lovaas-focused approach and developmentally focused ESDM approach.[23,37] Both approaches were associated with greater improvements in cognitive performance, language skills, and adaptive behavior skills compared with broadly defined eclectic treatments in subgroups of children, although the strength of evidence (confidence in the estimate) is low pending replication of the available studies.

Not all children receiving such interventions demonstrate rapid gains. Some data suggest that many children continue to display prominent areas of impairment and that subgroups may account for a majority of the change within certain samples.[23] No studies directly compare effects of different treatment approaches (for example, there are no direct comparisons of UCLA/Lovaas and ESDM) and little evidence of practical effectiveness or feasibility beyond research studies exists, so questions remain about whether reported findings would be observed on a larger scale within communities. Furthermore, existing studies have used small samples, different treatment approaches and duration, and different outcome measurements. Nonetheless, improvements occur in some aspects of language, cognitive ability, adaptive behavior, challenging behaviors, and potentially, educational attainment, for some children.

Strength of evidence is insufficient for the effects of social skills training for older children and for play- and interaction-based approaches for younger children. Cognitive behavioral therapy (CBT) for associated conditions such as anxiety also has insufficient strength of evidence supporting positive outcomes.

The strength of evidence is insufficient to provide confidence in observed improvements in cognitive outcomes with educational interventions, including the TEACCH intervention, and there is insufficient evidence for broad-based educational approaches, often based on applied behavior analysis (ABA) principles and computer-based approaches.

A few medications show benefit for repetitive behaviors or associated symptoms, with the clearest evidence favoring risperidone and aripiprazole, both studied in RCTs and showing evidence of improvement in problem and repetitive behavior. Significant side effect profiles, however, make it clear that although these drugs are efficacious, caution is warranted regarding their use in patients without severe impairments or risk of injury.

A few other medical interventions show some promise for future research, including serotonin reuptake inhibitors (SRIs),[128-130] methylphenidate,[131-134,136] omega 3 fatty acids,[154] and melatonin.[153] Others, including secretin,[137-144] are clearly not efficacious and warrant no further study.

Evidence is insufficient at this time to support the use of sensory or auditory integration, insufficient for speech and language interventions, and insufficient for CAM approaches.

Applicability of Evidence

By definition, ASDs are heterogeneous. Characterizing a “typical” child with an ASD is not possible, although certain symptoms are central to the range of children within the autism spectrum. Individual therapies are developed and tested to ameliorate specific symptoms or groups of symptoms, often in a fairly circumscribed subset of children.

Behavioral interventions. Studies of early intensive behavioral and developmental interventions were conducted primarily in preschool and young children (typically children initially ages 2-7 years). Questions remain about how these approaches apply to and benefit younger children (under 2) at risk for ASD. The cognitive, language, and adaptive behavior profiles of participants included in these studies were generally in line with those typically seen in young children with ASD. Participants typically had substantial impairment or delay, but some children had less early cognitive/language impairment.

The range of approaches studied may not always match what is available in practice—that is, either the studies were often conducted in highly controlled environments (e.g., university-supported intervention trials) or the actual methodology was not well described (i.e., approaches lacking treatment manuals). Thus, individuals wishing to infer the potential results of clinical practice based on the available research need to assess carefully the degree to which the study methods matched those available and used in practice.

Most studies of social skills interventions targeted children of elementary school age (6-13 years old). Most also excluded children with IQs below 60. Therefore, evidence on social skills interventions is likely applicable only to older, higher functioning children. Similarly, CBT for commonly associated conditions was targeted toward older children who were higher functioning. The effectiveness of both of these types of interventions in other groups of children with ASDs is currently unknown.

Medical and related interventions. In the medical literature, study participants were generally recruited from non-primary-care populations. Such individuals' parents may be seeking a higher level of care than is the case for the broader population of children with ASDs, based on more severe or acute symptoms, including aggression or other challenging behaviors. Most studies of medical interventions targeted elementary-school-age and older children with autism, with little data on the treatment of younger children. Some studies also expanded their inclusion criteria to include children with Asperger syndrome or PDD-NOS.

Gaps in the Evidence and Methodologic Concerns

Roughly 40 percent of studies in this review failed to use a comparison group. This lack of comparison groups presents substantial challenges for assessing effectiveness at a population level or for conducting comparative effectiveness research.

Studies without a comparison group with at least 10 children with ASDs were included in the review. Single-subject design studies were not excluded on the basis of their design; however, the majority of these studies do not include at least 10 participants and are therefore not represented in the review. Single-subject design studies can be helpful in assessing response to treatment in very short timeframes and under very tightly controlled circumstances, but they typically do not provide information on longer term or functional outcomes. They are useful in serving as demonstration projects, yielding initial evidence that an intervention merits further study, and in the clinical environment, they can be useful in identifying whether a particular approach to treatment is likely to be helpful for a specific child. Our goal was to identify and review the best evidence for assessing the effectiveness of therapies for children with ASDs, with an eye toward utility in the clinical setting and for the larger population of children with ASDs. By definition, "populations" in single-subject design studies are likely to be idiosyncratic and therefore unlikely to provide information that is generalizable.

Even in studies with a comparison group, sample size is frequently insufficient to draw conclusions. Larger multisite trials are needed across all treatment types. A few studies used comparison groups that were inappropriate for observing group differences in treatment effect (e.g., comparing treatment effects in children with autism to the effects of the treatment in typically developing peers or to children with a different developmental disorder). For those studies we could use only the pre-post case series data available in the group with autism, limiting the ability to comment on effectiveness.

We encourage investigators to provide adequate detail as they describe their interventions to allow for replicable research. Ideally, investigators publish the treatment manuals they develop, which are then referenced in later research, but many studies made general references to their use of an underlying approach (e.g., ABA) without specifying the ways in which they used or modified the technique. Lack of detail about the intervention makes it difficult to assess the applicability of individual studies, to synthesize groups of studies, or to replicate studies.

Characterization of the study population was often inadequate, with 125 of 159 studies failing to use or report gold standard diagnostic measures (clinical DSM-IV-based diagnosis plus ADI and/or ADOS). Because ASDs are spectrum disorders, it is difficult to assess the applicability of interventions when the population in which they were studied is poorly defined or described.

We identified more than 100 distinct outcome measures used in this literature base, not accounting for subscales of many. The use of so many and such disparate outcome measures makes it nearly impossible to synthesize the effectiveness of the interventions. We recommend a consistent set of rigorously evaluated outcome measures specific to each intended target of treatment to move comparative effectiveness research forward and to provide a sense of expected outcomes of the interventions. At the same time, the means for assessing outcomes should include increased focus on use of observers masked to the intervention status of the participant. When some outcomes are measured in a masked fashion but others not, evaluators should place more emphasis on those that are masked.

We noted a strong tendency for authors to present data on numerous outcomes without adjusting for multiple comparisons. Investigators also failed to report the outcome that was the primary outcome of a priori interest and on which, presumably, they based sample-size calculations (when these calculations were present). This may suggest the presence of selective reporting. We attempted to identify a primary intended outcome in the papers, but in almost all cases we were unable to do so.

Duration of treatment and followup was generally short. Few studies provided data on long-term outcomes after cessation of treatment. Future studies should extend the followup period and assess the degree to which outcomes are durable. Few studies adequately accounted for concomitant interventions that might confound observed effectiveness. Accounting for concomitant interventions should be standardized in future research.

Areas for Future Research

A critical area for further research is identifying which children are likely to benefit from particular interventions. To date, studies have failed to characterize adequately the subpopulation of children who experience positive response to intervention, although it is clear that positive outcomes are more prominent in some children than in others. One powerfully replicated finding in the available behavioral literature is that not all children receiving early intensive intervention demonstrate robust gains, and many children continue to display prominent areas of impairment. Dramatic improvements are observed in a subset of children, and mild improvements in terms of standardized outcomes are seen in others. This fact may translate into meaningful improvements in quality of life for some children and family members, suggesting that early intensive approaches have significant potential but require further research.

Behavioral interventions by their nature often employ multiple components, and data on whether specific functional components of the interventions drive effectiveness are currently unavailable. Component analyses in this field would be productive for refining intervention approaches and for assessing applicability and generalizability of the results.

Health services research on feasibility and accessibility is currently lacking, and given the growing number of children diagnosed with an autism spectrum disorder, it is needed. A few studies in this literature made preliminary strides in addressing these issues, but studies that specifically measure the role of setting, provider, and other factors would strongly benefit our ability to inform implementation practices. In line with this need, we recommend future consideration of the ways in which the cultural context of the child and family may affect the applicability or effectiveness of specific interventions.

The medical literature lacks properly designed, appropriately powered RCTs of a number of interventions that have been inadequately studied to date. Some of the strongest studies to support the use of medical interventions have been funded by pharmaceutical companies or device manufacturers that profit from the treatment. Certainly, the NIH (National Institutes of Health) has funded some large-scale studies of a few medical interventions, but publicly funded studies of medications for ASDs are few and more are warranted.

Also lacking in the literature are comparisons of medical interventions with behavioral interventions and combinations of the two, despite the fact that most children are undergoing multiple concurrent treatments. Harms data are also typically not reported in nonmedical studies, although potential harms of behavioral and other interventions should not be discounted.

In sum, while some therapies hold promise and warrant further study, substantial needs exist for continuing improvements in methodologic rigor in the field and for larger, potentially multisite studies of existing interventions. New studies should better characterize children, both phenotypically and genotypically, to move toward personalization of treatments for improved outcomes.

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Introduction

Need for Evidence for Treatment of Autism Spectrum Disorders in Children

Autism spectrum disorders (ASDs) are common neurodevelopmental disorders, with an estimated prevalence of one in 110 children in the United States.[1] ASDs have multiple etiologies involving both genetic and environmental risk factors. Among the environmental risk factors that may contribute to ASD risk are advanced parental age[2] and prematurity.[3] Disorders within the autism spectrum include Autistic Disorder, Asperger syndrome, and Pervasive Developmental Disorder, Not Otherwise Specified (PDD-NOS).

Individuals with ASDs have significant impairments in social interaction, behavior, and communication.[4] These impairments include a lack of reciprocal social interaction and joint attention (i.e., the ability of the child to use nonverbal means such as pointing to direct others' attention to something in which the child is interested); dysfunctional or absent communication and language skills; lack of spontaneous or pretend play; intense preoccupation with particular concepts or things; and repetitive behaviors or movements.[5-7] Children with ASDs may also have impaired cognitive skills and sensory perception.[1,4] ASDs are often accompanied by other conditions such as seizure disorders, hyperactivity, and anxiety.[6,7] The expression and severity of symptoms of ASDs differ widely, and treatments include a range of behavioral, psychosocial, educational, medical, and complementary approaches[8-10] that vary by a child's age and developmental status.

The goals of treatment for ASDs focus on improving core deficits in communication, social interactions, or restricted behaviors, as changing these fundamental deficits may help children develop greater functional skills and independence.[6] In addition, comprehensive treatment programs developed in the 1980s target behaviors and development more broadly instead of focusing on a specific behavior of interest.[11] Positive effects seen with these approaches in terms of cognition and language have led to the suggestion that beginning intensive therapy (25 to 30 hours/week) at an earlier age may lead to greater improvements.[11-13]

Treatment is frequently complicated by emergent symptoms such as irritability and other co-morbid conditions that may warrant targeted treatment. There is no cure for ASDs and no global consensus on which intervention strategy is most effective.[13,14] Chronic management is often required to maximize functional independence and quality of life by minimizing the core autism spectrum disorder features, facilitating development and learning, promoting socialization, reducing maladaptive behaviors, and educating and supporting families. Individual goals for treatment vary for different children and may include combinations of medical and related therapies, behavioral therapies, educational therapies, allied health therapies and complementary and alternative medicine (CAM) therapies.

The following sections briefly describe interventions discussed in the literature meeting our criteria for this review. Additional interventions for children with ASDs that did not meet criteria for our review are described in recent systematic and narrative reviews.[8-10,14-20]

Behavioral Interventions

Studies of behavioral interventions are addressed in this review in the broad subcategories of early intensive behavioral and developmental interventions; social skills interventions; focal play-based or interaction-based interventions; interventions focused on associated behaviors; and a small group of other behavioral interventions assessing a variety of targets. Table 1 outlines key features of behavioral interventions addressed in the report.

Early intensive behavioral and developmental interventions. In 1987, Ivar Lovaas published findings[21] on a subgroup of children who demonstrated improvements in cognitive abilities and educational placement in response to intensive intervention based on the principles of applied behavior analysis (ABA). As a result, ASDs were re-conceptualized from largely untreatable disorders,[22] to disorders marked by plasticity and heterogeneity, where there was hope for "recovery" and better outcomes for children receiving appropriate intervention. Subsequent research focused on social communication and behavioral impairments and used both highly structured approaches and natural/developmental approaches that deliver intervention within natural contexts (Floortime, the Social Communication Emotional Regulation Transactional Support model), some of which integrate approaches (Early Start Denver Model [ESDM]).

We adopted a similar approach to the operationalization of this category as Rogers and Vismara[12] in their review of "comprehensive" evidence-based treatments for early ASDs. Interventions in this category all have their basis in or draw from principles of applied behavior analysis (ABA), with differences in methods and setting. ABA is an umbrella term describing principles and techniques used in the assessment, treatment and prevention of challenging behaviors and the promotion of new desired behaviors. The goal of ABA is to teach new skills, promote generalization of these skills, and reduce challenging behaviors with systematic reinforcement. The principles and techniques of ABA existed for decades prior to specific application and study within ASDs.

We include in this category two intensive manualized (i.e., have published treatment manuals to facilitate replication) interventions: the UCLA/Lovaas model and the ESDM. These two interventions have several key differences in their theoretical frameworks and implementation, although they share substantial similarity in the frequent use of high intensity (many hours per week, one-on-one) instruction utilizing ABA techniques. They are described together here because of these similarities. We note, however, that the UCLA/Lovaas method relies heavily on one-on-one therapy sessions during which a trained therapist uses discrete trial teaching with a child to practice target skills, while the ESDM blends ABA principles with developmental and relationship-based approaches for young children.

We review ESDM, which focuses specifically on younger children, under Key Question 7 in Chapter 3 (Results), but we integrate our discussion of UCLA/Lovaas-based approaches and ESDM in Chapter 4 (Discussion) of this report, given the model's similarity in underlying methodology.

The other treatment approaches in this section also incorporate ABA principles, and may be intensive in nature, but often have not been manualized. We have classified these approaches broadly as "UCLA/Lovaas-based" given their similarity in approach to the Lovaas model. A third particular set of interventions included here are those using the principles of ABA to focus on key pivotal behaviors rather than global improvements. These approaches emphasize parent training as a modality for treatment delivery (e.g., Pivotal Response Training, Hanen More than Words, social pragmatic intervention, etc.) and may focus on specific behaviors such as initiating or organizing activity or on core social communication skills. Because they emphasize early training of parents of young children, they are reviewed here.

Interventions intended primarily to be administered in educational settings, or studies for which the educational arm was most clearly categorized are included in the section on educational interventions.

Social skills interventions. Difficulty with social engagement has been reported since the earliest descriptions of ASDs[23] and is the unique and essential aspect of ASDs that distinguishes them from other childhood disorders.[4,24] The social impairment seen in ASDs takes many forms and can vary greatly from one child to the next. Therefore interventions focused on enhancing social behavior and competence in children with ASDs should be targeted with respect to the child's age, developmental level, and peer group. Interventions for very young children may focus on teaching parents how to engage their child and encourage back-and-forth play. At preschool and early childhood levels, interventions may focus on playing with peers, understanding emotions, and learning the basics of turn-taking and initiating and responding to social interactions. In the later elementary years and into adolescence, interventions may focus more on teaching perspective-taking and social problem-solving and understanding peer group social norms. Given that social impairments are a core feature of ASDs, numerous skill-based approaches have tried to address this vulnerability through direct instruction within individual (e.g., Social Stories) or group (e.g., Skillstreaming, Children's Friendship Training) formats. Other approaches aim to foster the development of social skills solely through structured interactions with peers (e.g., Lego therapy).

Play-/interaction-based interventions. These interventions use interactions between children and adults (either parents or researchers) to improve outcomes such as imitation or joint attention skills or the ability of the child to engage in symbolic play. They include teaching parents how to interact differently with their children within daily routines and interactions, often using standard behavior management strategies. They also include foci on generic day-to-day interactions outside of the family (Table 1).

Behavioral interventions focused on associated behaviors. Several behavioral interventions target symptoms like anger and anxiety, which are often present with ASDs (Table 1). CBT is a common treatment for anxiety symptoms in otherwise typically developing children and has more recently been adapted for and applied to children with ASDs,[25-28] particularly children with higher IQs. The approach focuses on teaching cognitive skills and relaxation strategies, helping children recognize anxious feelings, and providing them with behavioral exposures in which to practice coping skills in the face of anxiety-provoking situations. The goal of treatment is to reduce generalized and specific anxiety symptoms over time.[29]

Challenging behaviors, such as noncompliance, tantrums, self-injury, and aggression, are also common, and parent training protocols are used to teach behavior prevention, intervention, and management strategies. Once trained, parents can act as "co-therapists," shaping behavior to reduce negative behaviors in daily life. Parent training interventions also often have secondary targets of improving parental feelings of self-efficacy and decreasing parental stress.

Table 1. Description of behavioral interventions addressed in the report

Intervention	Brief description
Approaches aimed at core symptoms: Early intensive behavioral and developmental approaches	
UCLA/Lovaas-based approaches	• Intervention approach that primarily employs techniques derived from principles of ABA within highly structured contexts. Interventions generally include high intensity (many hours per week) one-on-one instruction with primary emphasis on discrete trial techniques which introduce a stimulus (instruction/cue) to which a child may respond. Responses may be reinforced/rewarded, and the trial of stimulus-potential response-reward is repeated to promote mastery; additional emphasis on incidental teaching. • Programs additionally emphasize incidental teaching and parent training in terms of promoting generalization of skills. • Includes the UCLA/Lovaas model and other ABA-based variants.
Early Start Denver Model and other developmental and relational approaches	• Intervention approaches emphasize learning within naturalistic contexts such as caregiving relationships, play, and daily routines. • Parents are typically included as co-therapists and incidental teaching (involves structuring education in line with a child's ongoing/typical activities; parent training to allow parents to continue training at home and in other settings) is a primary emphasis. • Approaches may often employ techniques derived from principles of applied behavior analysis within such contexts (i.e., ESDM) and/or focus on developing core play and relationship skills (Floortime, Relationship Development Intervention).
Parent training approaches	• Approach relying on training parents to facilitate social and communication development within home and other natural settings. Trainings are typically provided at a low intensity (e.g., once per week or month) over extended periods of time with the idea that parents will use intervention techniques in multiple situations. • Includes approaches such as social-pragmatic intervention and the Hanen More than Words program. • Includes Pivotal Response Training, an approach based on ABA principles focusing on altering gateway/pivotal behaviors considered central to broad areas of functioning and in which improvements would lead to improvements in behaviors; pivotal behaviors include motivation to initiate or and respond to stimuli, self-direction of behavior, and responsiveness to cues/stimuli; typically involves extensive parent/family training components.
Approaches aimed at core symptoms: Social skills approaches	
Social skills training	• Interventions intended to help children interact socially, particularly with their peers. May focus on specific behavioral skills (e.g., conversations, greetings, initiating game play, joint attention), affective understanding (e.g., recognizing emotions in self and others), and social cognition (e.g., theory of mind, which describes the ability to ascribe mental states to oneself and others to understand and forecast behavior; problem-solving; self-regulation). • Vary in focus given a child's developmental context to target areas of relevance to the child (e.g., age, developmental level, and peer group).

Table 1. Description of behavioral interventions addressed in the report (continued)

Intervention	Brief description
Approaches aimed at core symptoms: Play-/Interaction-based approaches	
Joint attention interventions	• Approaches aimed at promoting joint attention (e.g., communication behaviors to share and direct interest in objects/activities in one's environment) abilities in children with ASDs. • Joint attention skills are viewed as potential core precursor skills contributing to long-term language and social development. • May employ ABA principles and parent or peer training.
Symbolic play and play-based interventions	• Approaches aimed at promoting symbolic play (e.g., pretend play, "make believe" activities) abilities in children with ASDs to promote long-term language and social skills development. • May employ ABA principles and parent or peer training. • May employ interactions between children and adults (either parents or researchers) to affect outcomes such as imitation or joint attention skills or the ability of the child to engage in symbolic play. • May include teaching parents how to interact differently with their children within daily routines.
Approaches aimed at commonly associated symptoms / Additional approaches	
Cognitive Behavioral Therapy (CBT)	• Approaches aimed at understanding and restructuring patterns of thought and behavior. • Often used to treat anxiety, mood, eating, substance abuse, and personality disorders. Application of CBT to ASD populations has primarily focused on teaching coping skills, increasing insight/awareness into behaviors, and systematically providing behavioral exposures to reduce symptoms of anxiety and associated distress.
Neurofeedback	• Aims to remediate abnormal brainwave activity associated with disorders such as anxiety, ADHD, and ASDs through training individuals to control brain activity patterns. • Involves the placement of electrodes to monitor brain activity while participants interact with specially designed computer games or other modalities designed to promote attention or other skills.
Sleep interventions	• Aim to improve difficulties associated with sleep including disordered sleep patterns, night waking, and difficulty falling asleep common among children with ASDs. • Behavioral interventions include sleep workshops which may provide training to parents in dealing with difficult sleep behaviors and establishing sleep routines.

ABA=applied behavior analysis; ADHD=Attention Deficit Hyperactivity Disorder; ASDs=autism spectrum disorders; CBT=cognitive behavioral therapy; ESDM=Early Start Denver Model; UCLA=University of California, Los Angeles

Educational Interventions

Most children with ASD receive at least some treatment in an educational setting, beginning with preschool. For children with ASDs, educational interventions often aim at promoting personal independence and social responsibility.[13] Educational interventions have focused both on traditional areas of academic progression/achievement, as well as on addressing social, cognitive, and behavioral issues in classrooms or through specialized instruction. These interventions include the Treatment and Education of Autistic and Communication related handicapped CHildren (TEACCH) program,[30] early intervention center- or classroom-based instruction, and computer-based approaches.

Originally developed in the 1970s at the University of North Carolina at Chapel Hill, TEACCH involves structured teaching and therapeutic techniques that encompass a "whole life" approach. Instruction is based on the idea that individuals on the autism spectrum have difficulty in perception and understanding; the intervention therefore relies heavily on visual supports like a picture schedule and arranging the physical environment to support the individual.

Classroom- and center-based approaches include a blend of teaching strategies that rely on principles and techniques of ABA including reinforcement-based procedures such incidental teaching, discrete trial training, and Pivotal Response Training (Table 2). Other interventions such as TEACCH and language development interventions may also be incorporated in center-based treatment. Computer-based programs use technology to deliver behaviorally-based teaching in areas like language acquisition and reading skills.

Table 2. Description of educational interventions addressed in the report

Intervention	Brief description
Treatment and Education of Autistic and Communication related handicapped CHildren (TEACCH)	• Uses structured teaching to apply structure to the organization of time, space, and sequences of events within the educational environment to promote learning by making activities clearer and easier to perform. • Includes visual supports (e.g., picture schedules) and arranging the physical environment to support individual learning by physically indicating sequences of events and organizing individual tasks to promote developmentally appropriate behaviors.
Broad-based approaches	• Approaches generally based in schools or centers that combine elements of EIBI- and ABA-based interventions. • May also incorporate elements of language development interventions and interventions including TEACCH.
Computer-based approaches	• Approaches which use technology to deliver behaviorally based teaching in areas such as language acquisition and reading skills.

ABA=applied behavior analysis; EIBI=early intensive behavioral intervention; TEACCH= Treatment and Education of Autistic and Communication related handicapped CHildren

Medical and Related Interventions

Interventions in this category are those in which a medication, supplement, or other substance is administered to a child with ASDs. Medical treatments for symptoms of ASDs comprise a variety of pharmacologic agents including antipsychotics, psychostimulants, and serotonin reuptake inhibitors (SRIs) that are generally intended to treat common comorbidities of ASDs. Modalities such as therapeutic diets, supplements, hormonal supplements, immunoglobulin, hyperbaric oxygen, and chelating agents also have been employed to treat ASDs symptoms (Table 3).

Antipsychotics. Antipsychotic medications generally act on the dopamine system, which is involved in regulating emotions, and potentially decrease behavioral outbursts.[31,32] Whereas the older typical antipsychotic drugs act primarily on the dopamine system, newer atypical antipsychotic drugs interact with a variety of brain chemicals, such as serotonin.[33,34] Although these medications were developed to treat psychosis, they have also been studied extensively for the treatment of other disorders, including mood disorders,[35,36] obsessive compulsive disorder,[37] and tic disorders.[38]

Among typical antipsychotics, haloperidol has been used since the 1980s to treat challenging behavior in children with ASDs.[39] More recently, risperidone, an atypical antipsychotic that acts on both dopamine D_2 and serotonin 5-HT_{2A} receptors,[34] was the first medication to receive Food and Drug Administration (FDA) approval for the treatment of irritability in children with ASDs. Aripiprazole, which has a more complex mechanism of action,[34] also recently received FDA approval for irritability in children with ASDs.

Serotonin reuptake inhibitors. Serotonin is associated with mood elevation and reduced anxiety symptoms. SRIs block the serotonin transporter so that increased serotonin stays in the system.[40] SRIs have come into wide use for the treatment of depression and anxiety and are some of the most commonly prescribed medications for children with ASDs.[41-43] SRIs were tested for use in children with ASDs[44,45] after it was noted that 30 percent of this population had elevated blood serotonin.[46] Early RCTs of both comipramine[44,47] and fluvoxamine[48] showed improvements in multiple behaviors. Open label trials of selective SRIs in the 1990s provided further support for the idea that this class may benefit some children with ASDs, but also revealed common side effects including hyperactivity and decreased sleep.[45,49] Most recent clinical trials in children with ASDs have focused on changes in repetitive behaviors with SRIs with longer half-lives, including fluoxetine, and citalopram or escitalopram, one of two component drugs contained in citalopram.[49] Longer half lives can be associated with a more stable blood level over time, reducing susceptibility to the effects of missed doses.

Stimulants and other medications for hyperactivity. Psychostimulants treat hyperactivity and inattention in patients diagnosed with attention deficit hyperactivity disorder (ADHD). Stimulants studied in ASDs include methylphenidate (MPH), amphetamine, and dextroamphetamine (Table 3). All stimulant medications inhibit dopamine uptake from the synapse; amphetamine and dextroamphetamine also cause release of dopamine into the synapse.

Other medications studied for the treatment of ADHD have also been studied for the treatment of hyperactivity in ASDs, including atomoxetine, which inhibits norepinephrine reuptake from the synapse[50-52] Guanfacine, a norepinephrine receptor alpha-2a agonist that was originally used for the treatment of high blood pressure, has also been studied for use in ASDs.[53,54]

Secretin. Secretin is a gastrointestinal polypeptide used to treat peptic ulcers[55,56] and in the evaluation of pancreatic function. Animal studies have suggested that secretin affects the central nervous system.[57,58] Interest in secretin for the treatment of symptoms of ASDs derived from a report of 3 children with ASDs given synthetic intravenous secretin during a routine endoscopy evaluation for gastrointestinal problems.[59] The report noted social, cognitive and communicative gains after the first infusion and after a second infusion given weeks later.

Other medical interventions. Additional studies in the medical literature addressed medical therapies for sleep and gastrointestinal dysfunction as well as the use of hyperbaric oxygen, specialized diets, supplements, and other agents explored to address symptoms of ASDs (Table 3).

Management of sleep issues. Children with ASDs commonly sleep little or fitfully, creating stress for them and their families.[60] Melatonin, a hormone associated with regulating circadian rhythms,[61] and iron supplementation[62] have been studied to improve disordered sleep in children with ASDs.

Management of gastrointestinal symptoms. Gastrointestinal (GI) symptoms may or may not have an increased prevalence in ASDs, with some evidence supporting increased difficulty with constipation but not other GI symptoms. Oral immunoglobulin has been considered for its potential utility in addressing GI symptoms in ASDs.[63,64]

Dietary supplements and restrictive diets for core symptoms of ASDs. A range of dietary supplements with potential neurologic effects show some benefit in other chronic neurological conditions and have been assessed for use in treatment of ASDs (Table 3). Magnesium-vitamin B6 and two amino acid-related compounds, L-carnosine and dimethylglycine, show some potential anticonvulsant activity in observational studies[65-67] and have been tried in ASDs for potential positive behavioral effects. Reduced levels of free polyunsaturated fatty acids (PUFAs) have been reported in a range of neuropsychiatric conditions including ASDs.[68,69] Supplementation with agents containing PUFAs, such as fish oil and evening primrose supplements, have been considered for their possible benefits in ASDs.

Some observational data suggest benefit of a ketogenic diet, a high fat, low carbohydrate diet, in some patients with epilepsy and seizures refractory to standard therapy,[70] and this strategy has also been explored in ASDs.

Other. Amantadine, an antiviral agent,[71] is thought by some to have neurologic effects that may positively affect behavior problems in ASDs. Similarly, the putative cognitive enhancer piracetam has been used in the treatment of dementia[72] and has been considered for potential cognitive benefit in ASDs. Hyperbaric therapy, in which oxygen is administered in special chambers that maintain a higher air pressure, has shown possible effects in other chronic neurologic conditions[73,74] and has also undergone preliminary exploration in ASDs. Cholinesterase inhibitors, such as donepezil hydrochloride and rivastigmine tartrate, inhibit an enzyme that breaks down the neurotransmitter acetylcholine; these drugs have been used to prevent further cognitive decline in Alzheimer's disease[75] and have similarly been studied for possible benefit in ASDs.

Dimercaptosuccinic acid (DMSA), used in chelation therapy, was approved by the FDA to treat lead poisoning,[76] and may have similar activity against other heavy metals such as mercury.[77] While no clear evidence suggests that mercury or ability to remove mercury from the body is involved in ASDs in any way, investigators have evaluated the ability of DMSA to affect ASD symptoms based upon existing off-label use in some children with autism.[78]

Pentoxifylline is typically used to improve blood flow in individuals with peripheral arterial disease and also inhibits the production of tumor necrosis factor, suggested as playing a role in neurological disorders; the drug also acts on the release and uptake of serotonin and dopamine and was suggested for use in autism after improvements in autistic behavior were noted in a child with an ASD receiving the medication for suspected post-traumatic brain damage.[79]

Table 3. Description of medical and related interventions addressed in the report

Intervention	Brief description
Antipsychotics	• Pharmacologic agents including risperidone, aripiprazole, and haloperidol that act on the dopamine system and may also affect other systems, including the serotonin system. • Primarily used to treat psychosis and mood disorders. • Within ASDs, primarily studied for effects on problem/challenging behaviors including irritability, aggression, and self-injurious behavior.

Table 3. Description of medical and related interventions addressed in the report (continued)

Intervention	Brief description
Serotonin Reuptake Inhibitors (SRI)	• Pharmacologic agents including fluoxetine and citalopram that act on the serotonin system. • Blood serotonin levels are elevated in 30% of children with ASDs. • Primarily used to treat depression, anxiety, and obsessive compulsive disorder. • Studied for potential to ameliorate repetitive behavior and challenging behaviors in ASDs.
Stimulants and other medications for hyperactivity	• Pharmacologic agents methylphenidate (MPH), amphetamine, and dextroamphetamine primarily affect the dopamine system. • Guanfacine primarily affects the norepinephrine system. • Primarily used to treat hyperactivity and inattention in patients with ADHD • Studied to treat hyperactivity in ASDs.
Secretin	• Gastrointestinal polypeptide used initially to treat peptic ulcers. • Use in ASDs stems from findings of social and communication gains in an unblinded, uncontrolled cases series of 3 children with ASDs receiving secretin during a routine endoscopic evaluation. • Evaluated in multiple studies for potential effects on language, gastrointestinal symptoms, adaptive behavior, cognitive impairments, and social and fine motor skills in ASDs.
Dietary supplements / restrictive diets	• Pharmacologic agents including melatonin, iron, magnesium-vitamin B6,L-carnosine, PUFA, and dimethylglycine; special diets including the high fat, low carbohydrate ketogenic diet. • Some of these agents have been studied in other chronic neurologic conditions. • Studied in ASDs for potential effects on behavioral symptoms (magnesium-vitamin B6, L-carnosine, dimethylglicine, PUFA, ketogenic diet) and associated comorbidities including sleep difficulties (melatonin, iron).
Other medical interventions	• Pharmacologic agents and interventions including antiviral agents (amantadine); nootropic drugs (piracetam); cholinesterase inhibitors (donepezil hydrochloride, rivastigmine tartrate), hyperbaric oxygen; immunoglobulin; and pentoxifylline. • Chelating agents (DMSA) used in ASDs given potential activity against heavy metals including mercury based on the unproven hypothesis that ASDs may be related to mercury concentrations in the body, although no clear evidence supports this hypothesis. • Some of these agents have been studied in other chronic neurologic conditions. • Studied in ASDs for potential effects on cognition (piracetam, donepezil, rivastigmine), gastrointestinal symptoms (immunoglobulin), and behavior (hyperbaric oxygen, amantadine, pentoxifylline) in ASDs.

ADHD=attention deficit hyperactivity disorder; ASDs=autism spectrum disorders; DMSA=dimercaptosuccinic acid; MPH=methylphenidate; PUFA= polyunsaturated fatty acids

Allied Health Interventions

Several allied health interventions address core symptoms of ASDs as well as associated difficulties and deficits. We broadly divided allied health studies into three categories: those focused on language, sensory or auditory integration techniques including music therapy, and other approaches (including horseback riding and occupational therapy) (Table 4).

Speech and language development. As a core feature of ASDs, communication difficulties are an important target of treatment. Frequently, verbal communication is the target of treatment, but establishing functional nonverbal communication for children who do not speak also can be the primary goal. Two approaches to increasing speech and language were identified: Responsive Education and Prelinguistic Milieu Teaching (RPMT), and the Picture Exchange Communication System (PECS). RPMT is a two-component system aimed at both parents and children. It is play-based, and encourages gestural, non-word vocal, gaze use, and later, word use for intentional communication around play, including for turn-taking, requesting and commenting.[80,81] Parents are taught methods of playing with their children that are thought to facilitate communication, in particular to use linguistic mapping, in which they put into words a child's immediately preceding nonverbal message. Once prelinguistic communication is achieved, Milieu Language Teaching is incorporated, in which prompts are used to encourage verbal imitation and questions are asked to evoke spoken communication.

PECS uses pictures or symbols to teach children to communicate spontaneously.[82] The approach relies on behavioral techniques, especially reinforcement techniques. Providers prompt children to pick up and exchange a symbol/picture for a desired object. The process may include fading those prompts until competency is achieved. PECS can be used while intensive work to increase speech is in progress, and may provide an interim or additional means of communication. PECS relies on immediate positive reinforcement with the child obtaining the desired object upon successfully indicating his desire for it with the corresponding picture.

Sensory and auditory integration and music therapy. Although sensory sensitivity and dysfunction are not core features of ASDs, they are frequently described as challenges for some children with ASDs.[83,84] Sensory Integration (SI) is specialized occupational therapy based on the premise that the brain's response to basic sensory input must be normalized before higher-order processes can be addressed.[85] The approach anticipates that a child who is better able to process, modulate, and integrate sensory information will then be better able to acquire higher-order skills.[16] Auditory integration training (AIT) relates specifically to auditory perception. In AIT, children are repeatedly presented with modulated music according to specific protocols with a therapeutic goal of improving auditory processing, lessening auditory hypersensitivities, and increasing concentration.[86,87] Finally, music therapy is at times employed with children with ASDs, hinging on speculation that children engage more with music than with speech. This treatment method is improvisational and unstructured, and practitioners purport that it can improve both verbal and nonverbal communication skills including joint attention abilities.[88,89]

Additional allied health interventions. A number of additional interventions including other occupational therapy techniques, horseback riding therapy, assistive devices to facilitate reading or motor skills, and movement therapy are also considered allied health approaches and may target difficulties in sensory processing as well as language and adaptive behavior.

Table 4. Description of allied health interventions addressed in the report

Intervention	Brief description
Language/communication	
Picture Exchange Communication System (PECS)	• Approach using pictures or symbols to teach spontaneous communication. • Relies on behavioral techniques through which providers prompt children to pick up and exchange a symbol/picture for a desired object. • May include fading or gradually eliminating those prompts until competency is achieved.
Responsive Education and Prelinguistic Milieu Teaching (RPMT)	• Approach aimed at parents and children incorporating play and encouraging gestural, non-word vocal, gaze use and word use for intentional communication around play, including for turn-taking, requesting and commenting. • Teaches play-based methods thought to facilitate communication to parents. • Uses prompts to encourage verbal imitation and questions to evoke spoken communication.
Sensory/auditory	
Sensory integration	• Occupational therapy approach based on the premise that individuals with ASDs process sensory information differently, often exhibiting atypical responses to sensory input (visual, auditory, etc.). • Posits that a child must be able to process, modulate, and integrate sensory information effectively to facilitate acquisition of higher-order skills. • Approaches employ controlled sensory experiences aimed at encouraging functional responses to sensory stimulation in individuals with ASDs; techniques include weighted vests, swinging, deep pressure touch, and tactile stimulation.
Auditory integration	• Approaches presenting children with modulated sound/music according to specific protocols with a therapeutic goal of improving auditory processing, lessening auditory hypersensitivities, and increasing concentration. • Interventions include Tomatis Sound therapy and auditory integration training.
Music therapy	• Improvisational, unstructured approach hinging on the speculation that children engage more with music than with speech. • Targets verbal and nonverbal communication skills including joint attention.
Other approaches	
Animal-assisted interventions	• Approaches employing animals within a treatment implementation, typically targeting cognitive, social, and psychological domains. • Interventions include therapeutic horseback riding targeting social cognition and animal-assisted occupational therapy focusing on social skills and language use.
Movement therapy	• Approaches premised on stimulating pressure receptors in the body to improve ASDs symptoms. • Includes various techniques including exercise and movement to music.

ASDs=autism spectrum disorders; PECS=Picture Exchange Communication System; RPMT= Responsive Education and Prelinguistic Milieu Teaching

Complementary and Alternative Medicine (CAM) Interventions

Acupuncture is an ancient Chinese medical system based on the balance of energy flows in which imbalance is thought to result in disease (Table 5). Acupuncture therapy aims to manipulate these energies through the insertion of fine needles at highly specific points related to energy flow to specific organs. Like acupuncture, massage therapy is thought to exert effects on the energy field of the body and has been used in ASDs to decrease touch aversion and improve autistic behaviors.[90]

Table 5. Description of CAM interventions addressed in the report

Intervention	Brief description
Massage	• Approaches using therapeutic touch and premised on ameliorating imbalances in the energy field of the body. • Approaches in ASDs include qigong massage and often focus on improving sensory difficulties.
Acupuncture	• Approaches based on manipulating, through the insertion of fine needles into specific energy points, the balance of energy flows to correct imbalances thought to result in disease. • Interventions in ASDs include scalp acupuncture and seven star needle stimulation.

Importance of This Review

While advances have been made in early diagnosis and the promotion of early intervention for ASDs,[5,91,92] few current sources for the comparative effectiveness of treatment interventions exist. Clinicians and families are left to choose among the interventions in part based on what is available to them, what is covered by commercial insurance or Medicaid, or what they can afford out of pocket. Sometimes, a clinical course of action is based on the most common or popular treatments at a given time. Many therapies are not covered by insurance, and a primary reason for insurance denial from private insurers is that no evidence-based resources for this condition exist. Additionally, insurers may find it confusing to distinguish among therapies or to sort out which approaches have an evidence base and which are still experimental.

The delivery and organization of care for ASDs therefore tends to be fragmented, with pieces scattered about in the primary care, school, and specialty clinical settings, making it especially important for families and caregivers to have clear information on effectiveness of treatment components. Treatment outcomes may be highly variable across diagnostic groups and developmental stages and in the presence or absence of co-morbidities. Family context and the child's home and school environment may also alter the effectiveness of treatment. Therapeutic approaches should therefore be tailored to an individual child to the extent possible to optimize effectiveness.[92,93]

Previous reviews of the literature have noted limited quality and consistency in studies assessing ASDs therapies,[9,10,12,94-96] and an umbrella review found methodological weaknesses in systematic reviews of psychosocial interventions.[8] While controlled trials seem to be increasing, much research is observational, generally with small sample sizes, limited followup, and limited discussion of the durability of treatment gains once active therapy ends. As the prevalence of ASDs has increased, the available treatment options have also increased, but evidence overall for many interventions can only be considered preliminary. The need for synthesized research that evaluates the evidence base for various treatments and identifies gaps in the current literature that may drive the research agenda is great.

Scope of This Evidence Report

Evidence reviews of therapeutics seek to identify and systematically summarize objective information about the evidence related to the:

- Effectiveness of specific, well-defined treatments
- Relative benefit of one treatment over another
- Common side effects and serious risks of a treatment
- Whether individual characteristics help predict who will benefit or be harmed

Key Questions and Analytic Framework

Key Questions

We focused this review on treatments for children ages 2-12 with ASDs and children younger than age 2 at risk of a diagnosis of ASD. We have synthesized evidence in the published literature to address these key questions (KQ):

KQ1. Among children ages 2-12 with ASDs, what are the short and long-term effects of available behavioral, educational, family, medical, allied health, or CAM treatment approaches? Specifically,

- **KQ1a.** What are the effects on core symptoms (e.g., social deficits, communication deficits and repetitive behaviors), in the short term (≤6 months)?
- **KQ1b.** What are the effects on commonly associated symptoms (e.g., motor, sensory, medical, mood/anxiety, irritability, and hyperactivity) in the short term (≤6 months)?
- **KQ1c.** What are the longer-term effects (>6 months) on core symptoms (e.g., social deficits, communication deficits and repetitive behaviors)?
- **KQ1d.** What are the longer-term effects (>6 months) on commonly associated symptoms (e.g., motor, sensory, medical, mood/anxiety, irritability, and hyperactivity)?

KQ2. Among children ages 2-12, what are the modifiers of outcome for different treatments or approaches?

- **KQ2a.** Is the effectiveness of the therapies reviewed affected by the frequency, duration, and intensity of the intervention?
- **KQ2b.** Is the effectiveness of the therapies reviewed affected by the training and/or experience of the individual providing the therapy?
- **KQ2c.** What characteristics, if any, of the child modify the effectiveness of the therapies reviewed?
- **KQ2d.** What characteristics, if any, of the family modify the effectiveness of the therapies reviewed?

KQ3. Are there any identifiable changes early in the treatment phase that predict treatment outcomes?

KQ4. What is the evidence that effects measured at the end of the treatment phase predict long-term functional outcomes?

KQ5. What is the evidence that specific intervention effects measured in the treatment context generalize to other contexts (e.g., people, places, materials)?

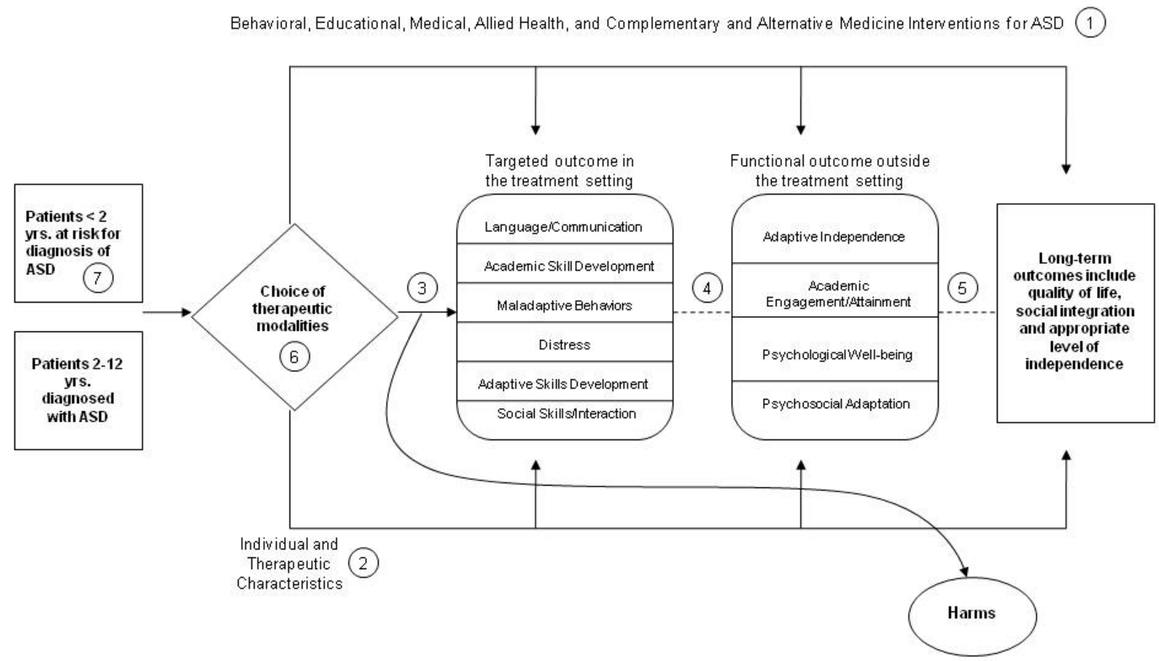
KQ6. What evidence supports specific components of treatment as driving outcomes, either within a single treatment or across treatments?

KQ7. What evidence supports the use of a specific treatment approach in children under the age of two who are at high risk of developing autism based upon behavioral, medical, or genetic risk factors?

Analytic Framework for Therapies for Children With ASDs

The analytic framework in Figure 1 summarizes the process by which families of children with ASDs make and modify treatment choices. Treatment choices are affected by many factors that relate to the care available. Treatment effectiveness may also be affected by factors related to the child (e.g., age, IQ) or the context of care. Ideally, treatment effects are seen both in the short term in clinical changes and in longer term or functional outcomes. Eventual outcomes of interest include adaptive independence appropriate to the abilities of the specific child, psychological well-being, appropriate academic engagement, and psychosocial adaptation.

Figure 1. Analytic framework for therapies for children with ASDs



Organization of This Evidence Report

Chapter 2 describes our methods including our search strategy, inclusion and exclusion criteria, approach to review of abstracts and full publications, and our method for extraction of data into the evidence table and compiling evidence. We also describe the approach to grading of the quality of the literature and to evaluating the strength of the body of evidence.

Chapter 3 presents the results of the evidence report, synthesizing the findings by category of intervention. We report the number and type of studies identified and we differentiate between total numbers of publications and unique studies to bring into focus the number of duplicate publications in this literature in which multiple publications are derived from the same study population. We attempted to emphasize the effect of treatment on the core symptoms and commonly associated co-morbidities of ASDs. We integrate discussion of sub-questions within that for each key question because there was not adequate distinction in the literature to address them separately.

Chapter 4 discusses the results in Chapter 3 and expands on methodologic considerations relevant to each key question. We also outline the current state of the literature and challenges for future research on ASDs.

The report includes a number of appendixes to provide further detail on our methods and the studies assessed. The appendixes are as follows:

- Appendix A. Exact Search Strings and Results
- Appendix B. Sample Data Abstraction Forms
- Appendix C. Evidence Table
- Appendix D. List of Excluded Studies
- Appendix E. List of Peer Reviewers
- Appendix F. Approach to Categorizing Study Designs
- Appendix G. Discussion of Recent Systematic Reviews of Therapies for Children with ASDs
- Appendix H. Quality of the Literature
- Appendix I. Applicability Summary Tables.

A list of abbreviations and acronyms used in the report follows the References section.

Technical Expert Panel (TEP)

We identified technical experts on the topic of ASDs in the fields of developmental disabilities, psychiatry, psychology, occupational therapy and educational research to provide assistance during the project. The TEP contributed to the Agency for Healthcare Research and Quality's (AHRQ) broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of its products. Thus, the TEP was both an additional resource and a sounding board during the project. The TEP included eight members serving as technical or clinical experts, including representatives from our partner organizations (the nominators of the topic), the Medicaid Medical Directors and Autism Speaks. To ensure robust, scientifically relevant work, we called on the TEP to provide reactions to work in progress or possibly overlooked areas of research. TEP members participated in conference calls and discussions through e-mail to:

- Refine the analytic framework and key questions at the beginning of the project;
- Discuss the preliminary assessment of the literature, including inclusion/exclusion criteria;
- Provide input on assessing the quality of the literature.

Because of their extensive knowledge of the literature, including numerous articles authored by TEP members themselves, and their active involvement in professional societies and as practitioners in the field, we also asked TEP members to participate in the external peer review of the draft report.

Uses of This Report

This evidence report addresses the key questions outlined above using methods described in Chapter 2 to conduct a systematic review of published literature. We anticipate that the report will be of value to clinicians who treat children with ASDs, including general pediatricians, developmental and behavioral pediatricians, neurodevelopmentalists, child neurologists, psychologists, psychiatrists and behavioral experts. In addition, this review will be of use to the National Institutes of Health, Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, and the Health Resources and Services Administration–all of which have offices or bureaus devoted to child health issues. This report can bring practitioners up to date about the current state of evidence, and it provides an assessment of the quality of studies that aim to determine the outcomes of therapeutic options for the management of ASDs. It will be of interest to families affected by ASDs and the general public because of the high prevalence of ASDs and the recurring need for families and their health care providers to make the best possible decisions among numerous options. We also anticipate it will be of use to private sector organizations concerned with ASDs, as they work to guide research priorities and educate communities about ASDs.

Researchers can obtain a concise analysis of the current state of knowledge in this field. They will be poised to pursue further investigations that are needed to understand best approaches to therapies for children with ASDs.

Methods

This chapter documents procedures that we used to develop this comparative effectiveness review on the treatment of autism spectrum disorders (ASDs) in children ages 2-12. We first describe our strategy for identifying articles relevant to our key questions, our inclusion/exclusion criteria, and the processes used to abstract relevant information from eligible articles and generate the evidence table. We also discuss our criteria for grading the quality of individual articles and for rating the strength of the evidence as a whole.

Literature Review Methods

Inclusion and Exclusion Criteria

Our inclusion/exclusion criteria were developed in consultation with the Technical Expert Panel (TEP). Criteria are summarized below (Table 6).

Table 6. Inclusion and exclusion criteria

Category	Criteria
Study population	Children ages 2-12 with ASDs or ages 0-2 at risk for diagnosis of an ASD
Publication languages	English only
Admissible evidence (study design and other criteria)	<u>Admissible designs</u> RCTs, prospective and retrospective cohort studies, non randomized controlled trials, case-control studies, and case series <u>Other criteria</u> Original research studies providing sufficient detail regarding methods and results to enable use and aggregation of the data and results Studies must have relevant population & ≥ 10 participants with ASDs for behavioral, educational, CAM, and allied health studies and ≥ 30 participants with ASDs for medical studies Studies must address one or more of the following for ASDs: Treatment modality Predictors of treatment outcomes Generalization of treatment outcomes to other contexts Drivers of treatment outcomes Treatment approaches for children 0-2 at risk for an ASD diagnosis Relevant outcomes must be able to be abstracted from data in the papers

ASDs=autism spectrum disorders; CAM=complementary and alternative medicine; RCT=randomized controlled trial

For this review, the relevant population for key questions (KQ) one through six was children with ASDs (autism, Pervasive Developmental Disorder-Not Otherwise Specified (PDD-NOS), Asperger syndrome) whose mean age plus standard deviation was ≤ 12 years and 11 months. Studies needed to provide adequate information to ensure that participants fell within the target age range. Specifically, we chose to limit the age range to 2–12 because a) diagnosis of ASDs earlier than age 2 is less established and b) adolescents likely have substantially different challenges and would warrant different interventions than children in the preschool, elementary and middle school age groups. We did, however, add one question (KQ7) focusing on children under age 2; children in this age group are not definitively diagnosable, but may be at risk either because they have a sibling with ASDs, or they may be exhibiting signs suggestive of a possible ASD diagnosis.

We excluded studies that included fewer than 10 total participants for studies of behavioral, educational, allied health, or complementary and alternative medicine (CAM) interventions or fewer than 30 total participants for medical studies. We selected these criteria in consultation with our content experts as a minimum threshold for comparing interventions. We believed that given the greater risk associated with the use of medical interventions, it was appropriate to require a greater sample size to accrue adequate data on safety and tolerability, in addition to efficacy. We restricted the review to medical studies with at least 30 participants given that most studies of medical interventions for ASD with fewer than 30 subjects report preliminary results that are replaced by later, larger studies. This restriction did not eliminate specific medical therapies from the review as treatments are typically assessed in larger studies following their preliminary investigation. Moreover these sample size constraints are not uncommon in the systematic review/comparative effectiveness review literature.

We accepted any study designs except individual case reports, and our approach to categorizing study designs is presented in Appendix F. Our interest was in identifying the effectiveness of interventions that target core and commonly associated symptoms of ASDs, compared with other intervention or no interventions.

We note that if a research study used a comparison group that did not contribute to an estimate of the contrast of interest in our review, we included the one arm of the study that was relevant. For example, an intervention study in which the intervention group is children with ASDs and the comparison group is a group of children with Down Syndrome would not provide an estimate of the effect of the intervention for children with ASDs. Rather than exclude this study, we include the group of children with ASDs as a case series.

We recognize that setting a minimum of 10 participants for studies to be included effectively excluded much of the literature on behavioral interventions using single-subject designs. Because there is no separate comparison group in these studies they would be considered case reports (if only one child included) or case series (multiple children) under the rubric of the EPC study designs. Case reports and case series can have rigorous evaluation of pre- and post- measures, as well as strong characterization of the study participants, and case series that included at least 10 children were included in the review.

Single-subject design studies can be helpful in assessing response to treatment in very short timeframes and under very tightly controlled circumstances, but they typically do not provide information on longer term or functional outcomes, nor are they ideal for external validity without multiple replications.[97] They are useful in serving as demonstration projects, yielding initial evidence that an intervention merits further study, and, in the clinical environment, they can be useful in identifying whether a particular approach to treatment is likely to be helpful for a specific child. Our goal was to identify and review the best evidence for assessing the efficacy and effectiveness of therapies for children with ASD, with an eye toward utility in the treatment setting. With the assistance of our technical experts, we selected a minimum sample size of 10 in order to maximize our ability to describe the state of the current literature, while balancing the need to identify studies that could be used to assess treatment effectiveness.

As the team lacked translators for potentially relevant non-English studies, we also excluded studies that were not published in English. In addition, we excluded studies that:

- Did not report information pertinent to the key questions
- Were published prior to the year 2000 (the revision of the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) and widespread implementation of gold standard assessment tools including the Autism Diagnostic Observation Schedule (ADOS) and the Autism Diagnostic Interview–Revised [ADI-R])
- Were not original research

- Did not present aggregated results (i.e., included data for individual participants only) or presented graphical data only.

Literature Search and Retrieval Process

Databases. We employed search strategies provided in Appendix A to retrieve research on the treatment of autism spectrum disorders, including Asperger syndrome and Pervasive Developmental Disorder, Not-Otherwise-Specified. Our primary literature search employed three databases: MEDLINE® via the PubMed interface, PsycINFO (psychology and psychiatry literature), and the Education Resources Information Center (ERIC), searched from 1980 to the present. We also hand-searched the reference lists of all included articles to identify additional studies for review.

Grey literature. The AHRQ Scientific Resource Center also searched for information on the two medications specifically approved for treating irritability in ASDs (risperidone and aripiprazole) in resources including the websites of the US Food and Drug Administration and Health Canada and clinical trials registries such as ClinicalTrials.gov. We gave manufacturers of these medications as well as of hyperbaric oxygen chambers an opportunity to provide additional information.

Search terms. Controlled vocabulary terms served as the foundation of our search in each database, complemented by additional keyword phrases to represent ASDs in the clinical and educational literature. We also employed indexing terms when possible within each of the databases to exclude undesired publication types (e.g., reviews, case reports, news), items from non-peer-reviewed journals, and items published in languages other than English.

Our searches were executed between May 2009 and May 2010. Appendix A provides our search terms and the yield from each database.

Article selection process. Once we identified articles through the electronic database searches, review articles, and bibliographies, we examined abstracts of articles to determine whether studies met our criteria, including the cutoff date of the year 2000. Two reviewers separately evaluated each abstract for inclusion or exclusion, using an Abstract Review Form (Appendix B). If one reviewer concluded that the article could be eligible for the review based on the abstract, we retained it. The group included 3 expert clinicians (WS, ZW, JV), and two senior health services researchers (MM, RJ). Two reviewers assessed the full text of each included article using a standardized form (Appendix B); disagreements between reviewers were resolved by a third-party adjudicator.

Categorization of Interventions

As has been previously noted, ASD intervention categories overlap substantially, and it is difficult to cleanly identify the category into which an intervention should be placed.[14] We considered multiple approaches for organizing the results, and note that no alternative approaches would have changed our overall findings either in terms of outcomes or strength of evidence for any category of intervention.

Behavioral interventions. We defined behavioral interventions to include early intensive behavioral and developmental interventions, social skills interventions, play/interaction-focused interventions, interventions targeting symptoms commonly associated with ASDs such as anxiety, and other general behavioral approaches.

Early intensive behavioral and developmental interventions. We adopted a similar approach to the operationalization of the early intensive behavioral and developmental intervention category as Rogers and Vismara[12] in their review of "comprehensive" evidence-based treatments for early ASDs. Interventions in this category all have their basis in or draw from principles of applied behavior analysis (ABA), with differences in methods and setting. ABA is an umbrella term describing principles and techniques used in the assessment, treatment and prevention of challenging behaviors and the promotion of new desired behaviors. The goal of ABA is to teach new skills, promote generalization of these skills, and reduce challenging behaviors with systematic reinforcement. The principles and techniques of ABA existed for decades prior to specific application and study within ASDs.

We include in this category two intensive manualized (i.e., have published treatment manuals to facilitate replication) interventions: the University of California, Los Angeles (UCLA)/Lovaas model and the Early Start Denver Model (ESDM). These two interventions have several key differences in their theoretical frameworks and implementation, although they share substantial similarity in the frequent use of high intensity (many hours per week, one-on-one) instruction utilizing ABA techniques. They are described together here because of these similarities. We note, however, that the UCLA/Lovaas method relies heavily on one-on-one therapy sessions during which a trained therapist uses discrete trial teaching with a child to practice target skills, while ESDM blends ABA principles with developmental and relationship-based approaches for young children.

The other treatment approaches in this category also incorporate ABA principles, and may be intensive in nature, but often have not been manualized. We have classified these approaches broadly as UCLA/Lovaas-based given their similarity in approach to the Lovaas model. A third particular set of interventions included in this category are those using principles of ABA to focus on key pivotal behaviors rather than global improvements. These approaches emphasize parent training as a modality for treatment delivery (e.g., Pivotal Response Training, Hanen More than Words, social pragmatic intervention, etc.) and may focus on specific behaviors such as initiating or organizing activity or on core social communication skills. Because they emphasize early training of parents of young children, they are reviewed in this category.

Social skills interventions. Social skills interventions focus on facilitating social interactions and may include peer training and social stories.

Play/interaction-focused interventions. These approaches use interactions between children and parents or researchers to affect outcomes such as imitation or joint attention skills or the ability of the child to engage in symbolic play.

Interventions focused on behaviors commonly associated with ASDs. These approaches attempt to ameliorate symptoms such as anger or anxiety, often present in ASDs, using techniques such as Cognitive Behavioral Therapy (CBT) and parent training focused on challenging behaviors.

Additional behavioral interventions. We categorized approaches not cleanly fitting into the behavioral categories above in this group, which includes interventions such as sleep workshops and neurofeedback.

Educational interventions. Educational interventions are those focusing on improving educational and cognitive skills and intended primarily to be administered in educational settings, or studies for which the educational arm was most clearly categorized. These interventions include programs such as the Treatment and Education of Autistic and Communication related handicapped CHildren (TEACCH) model and other treatments implemented primarily in the educational setting. Some of the interventions implemented in educational settings are based on principles of ABA and may be intensive in nature, but none of the educational interventions described in this report used the UCLA/Lovaas or ESDM manualized treatments.

Medical and related interventions. We broadly defined medical and related interventions as those that included the administration of external substances to the body in order to treat symptoms of ASDs; medical interventions represented in the literature included in this review comprised prescription medications, supplements and enzymes, diet therapies, and treatments such as hyperbaric oxygen.

Allied health interventions. Allied health interventions included therapies typically provided by occupational and physical therapists, including auditory and sensory integration, music therapy and language therapies.

Complementary and alternative medicine (CAM) interventions. Approaches in this category addressed in this review include acupuncture and massage.

Literature Synthesis

Development of Evidence Table and Data Abstraction Process

The staff members and clinical experts who conducted this review jointly developed the evidence table, which was used to abstract data from the studies. We designed the table to provide sufficient information to enable readers to understand the studies, including issues of study design, descriptions of the study populations (for applicability), description of the intervention, appropriateness of comparison groups, and baseline and outcome data on constructs of interest. We also abstracted data about harms or adverse effects of therapies, defined by the EPC program as the totality of all possible adverse consequences of an intervention.[98]

The team abstracted several articles into the evidence table and then reconvened as a group to discuss the utility of the table design. We repeated this process through several iterations until we decided that the table included the appropriate categories for gathering the information contained in the articles. All team members shared the task of initially entering information into the evidence table. Another member of the team also reviewed the articles and edited all initial table entries for accuracy, completeness, and consistency. The full research team met regularly during the article abstraction period and discussed global issues related to the data abstraction process. In addition to outcomes related to treatment effectiveness, we abstracted all data available on harms. Harms encompass the full range of specific negative effects, including the narrower definition of adverse events.

The final evidence table is presented in its entirety in Appendix C. Studies are presented in the evidence table chronologically and alphabetically by the last name of the first author within each year. When possible to identify, analyses resulting from the same study were grouped into a single entry. A list of abbreviations and acronyms used in the table appears at the end of this report.

Several reporting conventions for describing studies in the evidence table were adopted that warrant explanation, namely those related to practice setting, intervention setting, and assessments. We developed a brief taxonomy of the most common practice settings to reflect the entity that conducted the research. Practice settings include:

- Academic (comprises academic medical centers and universities)
- Community
- Specialty treatment centers
- Residential centers
- Private practice
- Other (including pharmaceutical companies).

We developed a similar listing for intervention settings to reflect where the intervention was implemented, including home, school, clinic, and residential center. We considered the default setting for drug studies to be the clinic (even if medication was provided by caregivers in the home). Behavioral interventions involving the clinician in both the home and clinic were coded as occurring in both settings.

We captured data on the conduct of assessments in order to inform the evaluation of quality of study conduct and to address questions of applicability of the intervention outcomes data to different populations of children with ASDs; data reported include the assessment conducted (e.g., ADOS), the context and administrator of the assessment (e.g., administered by study psychologist in the clinic), and the timing (pre-intervention and at the six and eight week study visit, etc.).

Assessing Methodological Quality of Individual Studies

We used a components approach to assessing the quality of individual studies, following methods outlined in the EPC Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[99] The individual quality components are described here. Individual quality assessments for each study are reported in Appendix H.

In some instances, it was appropriate to apply specific questions only to one body of literature (e.g., to medical literature) and we note those cases where appropriate. Each domain described below was assessed individually and combined for an overall quality level using the algorithm below. Three levels were possible: good, fair, and poor.

Study design. Ideally, studies should use a comparison group in order to make causal inferences. The comparison group should accurately represent the characteristics of the intervention group in the absence of the intervention. Specifically, factors that are likely to be associated with the intervention selected and with outcomes observed should be evenly distributed between groups, if possible. These factors may include, for example, age, intelligence quotient (IQ), or ASD severity. Four questions were used to assess the study design:

1. Did the study employ a group design (have a comparison group)?
2. Were the groups randomly assigned?
3. If no, was there an appropriate comparison group?
4. If yes, was randomization done correctly?

We considered the following elements in determining the appropriateness of a study's randomization methods: Were random techniques like computer-generated, sequentially numbered opaque envelopes used? Were technically nonrandom techniques, like alternate days of the week used? Was the similarity between groups documented?

Scoring: Studies with a group design were marked as minimally meeting this domain (+).Those that also received an affirmative response for either question three or four exceeded that minimum (++).

Diagnostic approach. We expected studies to accurately characterize participants, and in particular to ensure that study participants purported to be on the autism spectrum had been diagnosed as such using a validated approach. We developed the hierarchy of diagnostic approaches below to capture the method used; Table 7 includes more information about each approach.

1. Was a valid diagnostic approach for ASDs used within the study, or were referred participants diagnosed using a valid approach?
   A. A clinical diagnosis based on the DSM-IV, in addition to the ADI-R and ADOS assessments.
   B. A clinical diagnosis based on the DSM-IV, in addition to either the ADI-R or ADOS assessment.
   C. A combination of a DSM-IV clinical diagnosis with one other assessment tool from Table 8; or the ADOS assessment in combination with one other assessment tool from Table 8.
   D. Either a clinical DSM-IV-based diagnosis alone or the ADOS assessment alone.
   E. Neither a clinical DSM-IV-based diagnosis nor the ADOS assessment

Scoring: We classified diagnostic approaches A and B as gold standard (++), C and D as adequate (+) and E as unacceptable (-).

Table 7. Overview of diagnostic tools used in quality scoring hierarchy

Diagnostic instrument	Overview
Autism Diagnostic Observation Schedule (ADOS)	Standardized, semi-structured observation-based review of social interaction, play, and communication for children and adults with suspected ASDs; consists of four modules appropriate for various language and developmental levels (nonverbal to verbally fluent) and administered directly to the individual by an examiner. Modules provide social/communication situations/activities designed to engage individuals and elicit behaviors of interest. Does not currently provide scores related to restricted/repetitive behaviors so should be supplemented with additional diagnostic information.
Screening Tool for Autism in Two Year Olds (STAT)	Play and observation-based screening instrument designed to differentiate children with autism from children with other developmental disorders once abnormal development has been indicated with an initial screening tool such as the M-CHAT; designed to be used with children between the ages of 24 to 35 months via a play-like interaction between the examiner and child; assesses behaviors related to imitation, play, communication/interaction, and joint attention.

Table 7. Overview of diagnostic tools used in quality scoring hierarchy (continued)

Diagnostic instrument	Overview
Autism Diagnostic Interview-Revised (ADI-R)	Standardized, semi-structured clinical review administered by clinicians to caregivers of children or adults with suspected ASDs; focuses on behaviors in the domains/areas of social interaction, communication and language, and repetitive, restricted, and stereotyped behavior and interests. Scoring is based on the clinician's judgment related to the caregiver's responses regarding a subject's behavior; higher scores indicate problematic behavior in a given domain, and scores align with diagnostic criteria as outlined in the DSM-IV.
Clinical interview based on Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV)	DSM-IV articulates criteria for diagnosis of ASDs comprising impairments in the areas of social interaction; communication; restricted, repetitive, and stereotyped patterns of behavior, interests and activities; and delays in social interaction/communication and symbolic or imaginative play. Clinical judgment of autistic symptomatology based on DSM-IV criteria is considered the gold standard of ASD diagnosis.
Childhood Autism Rating Scale (CARS)	Behavioral observation- or caregiver report-based scale addressing over 10 domains typically affected in autism (e.g., socialization, communication, emotional responsiveness) rated by the examiner on a 1 (age appropriate behavior) to 4 (severely abnormal behavior) scale. Total scores under 30 do not indicate autism, scores of 30-36 reflect mild to moderate autism, and scores between 37 and 60 indicate severe autism; intended to be used in concert with other instruments to diagnose ASDs.
Modified Checklist for Autism in Toddlers (M-CHAT)	Caregiver-reported checklist designed to screen for autism in children between the ages of 16 and 30 months; includes items related to joint attention, social interests, imitation, responding to name.
Social Communication Questionnaire (SCQ)	Caregiver-reported screening questionnaire designed to evaluate communication and social skills/functioning in children with suspected ASDs and determine the need for complete diagnostic evaluation; includes questions related to language and social behaviors--based on the ADI-R.
Social Responsiveness Scale (SRS)	Caregiver- or teacher- reported screening scale designed for use in children between the ages of 4 and 18; generates scores related to cognitive, expressive, receptive, and motivational aspects of social behavior in addition to autistic preoccupations; can be used to distinguish ASDs from other childhood psychiatric disorders.
Autism Spectrum Screening Questionnaire (ASSQ)	Screening instrument designed to be used with children between the ages of 7 to 16 years; can be completed by teachers or caregivers. Addresses the domains of social interaction, communication, and restricted/repetitive behaviors considered to reflect behavioral characteristics of children with ASDs, particularly higher functioning individuals.
Childhood Autism Spectrum Test (CAST)	Caregiver -reported screening tool designed for use in children between the ages of 4 and 11, used particularly with higher functioning children; includes questions related to social skills, language, and repetitive behaviors and interests.

Participant ascertainment. The means by which participants enter the study cohort and are included in the analysis should be clearly described so that the reader can gauge the applicability of the research to other populations, and to identify selection and attrition bias. In this literature, it is important to understand the population in terms of characteristics commonly associated with outcomes such as IQ, language and cognitive ability. We used four questions to assess participant ascertainment, including who was included in the analysis:

1. Was the sample clearly characterized (e.g., information provided to characterize participants in terms of impairments associated with their ASDs, such as cognitive or developmental level)?
2. Were inclusion and exclusion criteria clearly stated?
3. Do the authors report attrition?
4. Were characteristics of the drop-out group evaluated for differences with the participant group as a whole?

Scoring: Studies minimally had to have an affirmative answer for questions one or two of this domain to be adequate (+). Affirmative responses on questions three or four were considered superior (++).

Intervention characteristics. Sufficient detail should be provided on the intervention so that the reader can fully understand the treatment and so that the research is potentially reproducible. This includes information on dosage, formulation, timing, duration, intensity and other qualities of the intervention. Furthermore, for behavioral treatments there should be some assurance that the treatment providers stayed true to the treatment process (fidelity) and for medical treatment, there should be some assurance that participants adhered to their medication or that adherence was accounted for. Furthermore, because other treatments occurring simultaneously with the treatment under study could have substantial impact on outcomes, it is important that authors gather data on treatments being obtained by their participants outside of the study. We used three questions to obtain quality information in this domain, and allowed for the intervention description to be provided in another, referenced paper:

1. Was the intervention fully described?
2. Was treatment fidelity monitored in a systematic way? (for non-medical interventions)
3. Did the authors measure and report adherence to the intended treatment process? (for medical interventions)
4. Did the authors report differences in or hold steady all concomitant interventions?

Scoring: Authors needed to fully describe the intervention for the study to be awarded one point (+), and studies were given an additional point (++) if they also reported on or held steady concomitant interventions and monitored either fidelity or adherence.

Outcomes measurement. The ASD literature reviewed for this report included more than 100 outcome measures. To understand the meaning of the results at hand, readers need to be confident that the measure validly assessed the intended target behavior or symptom. It is also important that authors specify *a priori* what their outcome of primary interest is as the rest of the study, including sample size, should derive from the intent to measure this outcome. Finally, in measuring outcomes, the individual responsible for coding or measuring effect should be blinded to what intervention the participant received. We attempted to use three questions for this domain, but were forced to drop one regarding whether primary outcomes were pre-determined as it was almost uniformly impossible to tell whether authors had a “called shot” or *a priori* primary outcome, or to tell which of several outcomes was the primary one. We were left with two questions:

1. Did outcome measures demonstrate adequate reliability and validity (including inter-observer reliability for behavior observation coding)?
2. Were outcomes coded and assessed by individuals blinded to the intervention status of the participants?

Scoring: To meet the requirement for an adequate score on outcomes measurement (+), studies were required to have an affirmative answer to both questions.

Statistical analysis. Studies could either have appropriate or inappropriate analysis. We used a series of questions to guide the determination:

1. For RCTs, was there an intent-to-treat analysis?
2. For negative studies, was a power calculation provided?
3. For observational studies, were potential confounders and effect measure modifiers captured?
4. For observational studies, were potential confounders and effect measure modifiers handled appropriately?

Confounders are variables that are associated both with the intervention and the outcome and that change the relationship of the intervention to the outcome. These are variables that we would control for in analysis. Effect measure modifiers are variables that we think of as stratifying, in that the relationship between the intervention and outcome is fundamentally different in different strata of the effect modifier. Observational research should include an assessment of potential confounders and modifiers, and if they are observed, analysis should control for or stratify on them. Other considerations included: was the candidate variable selection discussed/noted?, was the model-building approach described? Were any variables unrelated to the studied variables that could have altered the outcome handled appropriately? Were any variables not under study that affected the causal factors handled appropriately? Was the candidate variable selection discussed/noted?

Scoring: Studies needed a yes or not applicable (NA) on each of the analysis questions to receive a point (+) for analysis.

Scores were calculated first by domain and then summed and weighted as described in Table 8 to determine overall study quality (internal validity).

Table 8. Quality scoring algorithm

Definition and scoring algorithm	Rating
Score algorithm for internal validity quality rating	
• 8/10 points, including a ++ on study design and ++ on diagnostic approach	Good quality
• 6/10 points, including at least a + on intervention	Fair quality
• 5/10 points or less	Poor quality

Applicability. Finally, it is important to consider the ability of the outcomes observed to apply both to other populations and to other settings (especially for those therapies that take place within a clinical/treatment setting but are hoped to change behavior overall). Our assessment of applicability took place in three steps. First, we determined the population, intervention, comparator, and setting (PICOS) in each study and developed an overview of these elements for each intervention category (Appendix I). Second, we reviewed potential modifiers of effect of treatment to identify subgroups for which treatments may be effective, and finally, we answered the following three questions:

1. Were outcomes measured in at least one context outside of the treatment setting?
2. Were outcomes measured in natural environments to assess generalization?
3. Considerations: Was an assessment conducted in the home, school, or community settings (i.e., a setting a child typically goes to in an ordinary week)?
4. Were followup measures of outcome conducted to assess maintenance of skills at least 3 months after the end of treatment?

These ratings of applicability do not factor into a study's overall quality score (good, fair, or poor), nor are they part of strength of evidence. Rather they are presented separately and are discussed in Chapter 4.

Strength of Available Evidence

The assessment of the literature is done by considering both the observed effectiveness of interventions and the confidence that we have in the stability of those effects in the face of future research. The degree of confidence that the observed effect of an intervention is unlikely to change is presented as strength of evidence, and it can be regarded as insufficient, low, moderate, or high. Strength of evidence describes the adequacy of the current research, both in terms of quantity and quality, as well as the degree to which the entire body of current research provides a consistent and precise estimate of effect. Interventions that have demonstrated benefit in a small number of studies but have not yet been replicated using the most rigorous study designs will therefore have insufficient or low strength of evidence to describe the body of research. Future research may find that the intervention is either effective or ineffective.

Methods for applying strength of evidence assessments are established in the Evidence-based Practice Centers' Methods Guide for Effectiveness and Comparative Effectiveness Reviews[99] and are based on consideration of four domains: risk of bias, consistency in direction of the effect, directness in measuring intended outcomes, and precision of effect. Strength of evidence is assessed separately for major intervention-outcome pairs. We also required at least 3 fair studies to be available to assign a low strength of evidence rather than considering it to be insufficient. For determining the strength of evidence for effectiveness outcomes, we only assessed the body of literature deriving from studies that included comparison groups. We required at least one good study for moderate strength of evidence and two good studies for high strength of evidence. In addition, to be considered "moderate" or higher, intervention-outcome pairs needed a positive response on two out of the three domains other than risk of bias.

For determining the strength of evidence related to harms, we also considered data from case series. Once we had established the maximum strength of evidence possible based upon these criteria, we assessed the number of studies and range of study designs for a given intervention-outcome pair, and downgraded the rating when the cumulative evidence was not sufficient to justify the higher rating. The possible grades were:

- High: High confidence that the evidence reflects the true effect. Further research is unlikely to change estimates.
- Moderate: Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- Low: Low confidence that the evidence reflects the true effect. Further research is likely to change confidence in the estimate of effect and is also likely to change the estimate.
- Insufficient: Evidence is either unavailable or does not permit a conclusion.

Results

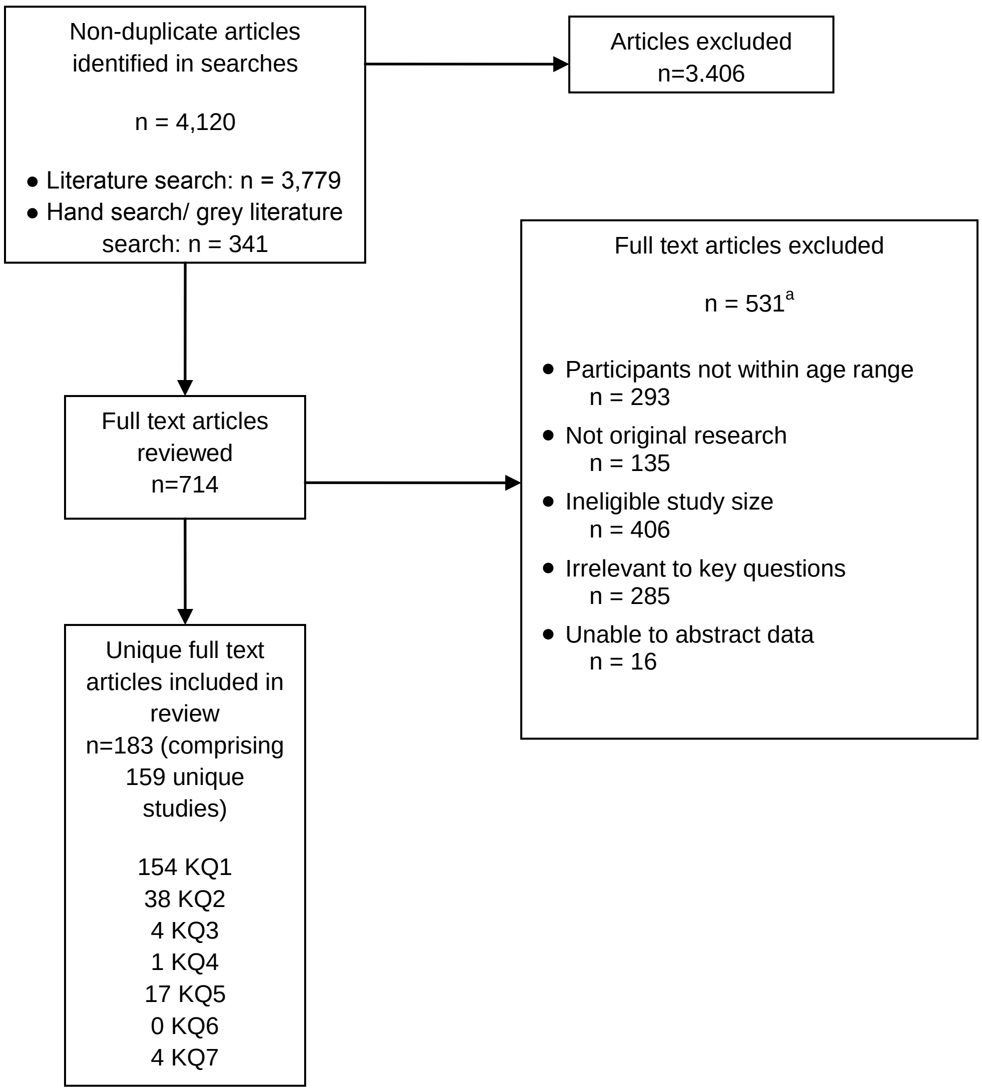
Chapter 3 presents the results of our systematic review. Each category of intervention includes first an overview of the content of the literature as a whole, including the range of study designs used, outcomes assessed and participants included. The summary of the literature provides further discussion and analysis, focusing primarily on those studies that received either a good or fair quality rating. Overview tables document the interventions included, availability of literature by study design, diagnostic approaches, timing of final outcome assessments, geographic location of study populations, and final numbers of participants with autism spectrum disorders (ASDs) for each intervention section (Tables 9, 14, 16, 23, 25).

Studies that received a good or fair quality rating and include a comparison group (randomized controlled trial (RCT), controlled trial, or prospective or retrospective cohort study) also are described in more detailed summary tables in the relevant section of text. For information on studies not included in the summary tables, please see the evidence table in Appendix C; for information on quality scores for each study, see Appendix H.

Article Selection

Of the entire group of 4,120 citations, 714 required full text review (Figure 2). For the full article review, two reviewers read each article and decided whether it met our inclusion criteria, using a Full Text Inclusion/Exclusion form. Of the 714 full text articles reviewed, we retained 183 papers (comprising 159 unique studies) and excluded 531 papers. Reasons for article exclusion are listed in Appendix D.

Figure 2. Disposition of articles addressing therapies for children with ASDs



[a]The total number of articles in the exclusion categories exceeds the number of articles excluded because most of the articles fit into multiple exclusion categories; KQ=key question

KQ1. Effects of Treatment on Core and Commonly Associated Symptoms in Children With ASDs: Behavioral Interventions

A wide range of interventions can be classified as behavioral. For this review, we included studies of early intensive behavioral and developmental interventions, which comprised University of California, Los Angeles (UCLA)/Lovaas-based approaches, the Early Start Denver Model (ESDM), and parent training approaches incorporating principles of Applied Behavior Analysis (ABA) to improve outcomes among young children with ASDs; social skills interventions; focal play-based /interaction-based interventions; behavioral interventions focused on associated behaviors; and a small group of other behavioral interventions assessing other interventions in core/associated areas (e.g., sleep workshops). Table 9 summarizes critical aspects of all studies of behavioral interventions, those addressing key question (KQ) 1 as well as behavioral studies discussed in the KQ2 and KQ7 sections of the report.

Table 9. Overview of behavioral studies[a]

Characteristic	RCTs	nRCTs	Prospective cohort studies	Retrospective cohort studies	Prospective case series	Retrospective case series	Total Literature
	(n=29)	(n=7)	(n=6)	(n=3)	(n=25)	(n=8)	(n=78)
Intervention							
Early intensive behavioral and developmental	6	5	5	2	11	6	35
Social skills	8	0	0	1	7	0	16
Play-/interaction-based	7	0	0	0	4	2	13
Interventions targeting associated behaviors	7	1	1	0	2	0	11
Other	1	1	0	0	1	0	3
Diagnostic approach							
Clinical DSM-IV dx +ADI-R and/or ADOS	5	0	2	0	9	0	16
Combination approaches[b]	15	2	3	0	10	4	34
No DSM-IV or ADOS dx / unspecified	9	5	1	3	6	4	28
Treatment duration							
<1 month	4	0	0	0	2	0	6
>1 to ≤3 months	13	3	1	0	5	0	22
>3 to ≤6 months	5	1	0	0	4	0	10
>6 to ≤12 months	4	1	2	0	9	2	18
>12 months	3	2	3	3	3	5	19
Unknown/not reported	0	0	0	0	2	1	3
Study population							
U.S.	16	3	2	1	17	4	43
Europe	5	4	1	2	3	2	17
Asia	0	0	0	0	0	0	0
Other	8	0	3	0	5	2	18
Total N participants	1,265	215	254	157	860	529	3,065

ADI-R=Autism Diagnostic Interview-Revised; ADOS=Autism Diagnostic Observation Schedule; DSM-IV=Diagnostic and Statistical Manual of Mental Disorders, 4th edition; dx=diagnosis; nRCT=non randomized controlled trial; RCT=randomized controlled trial

[a]This table provides an overview of selected data for all studies categorized as behavioral; not all behavioral studies are addressed in the KQ1 section. Some behavioral studies apply only to KQ2 and KQ7; however these studies are included in this table to provide a comprehensive overview of available behavioral literature. The numbers in the table indicate the number of unique studies with each characteristic.

[b]Clinical DSM-IV dx +other diagnostic tool or ADOS + other diagnostic tool or only clinical DSM-IV dx or only ADOS.

Early Intensive Behavioral and Developmental Interventions

Early intensive behavioral and developmental interventions include interventions based on:

- ABA-based approaches including the UCLA/Lovaas method and variants,
- naturalistic/developmental principles (i.e., ESDM)
- parent/family-based training (e.g., Pivotal Response Training, Hanen More Than Words, and social communication training).

We adopted a similar approach to the operationalization of this category as Rogers and Vismara[12] in their review of "comprehensive" evidence-based treatments for early ASDs. Interventions in this category all have their basis in or draw from principles of applied behavior analysis (ABA), with differences in methods and setting. ABA is an umbrella term describing principles and techniques used in the assessment, treatment and prevention of challenging behaviors and the promotion of new desired behaviors. The goal of ABA is to teach new skills, promote generalization of these skills, and reduce challenging behaviors with systematic reinforcement. The principles and techniques of ABA existed for decades prior to specific application and study within ASDs.

We include in this category two intensive manualized (i.e., have published treatment manuals to facilitate replication) interventions: the UCLA/Lovaas model and the ESDM. These two interventions have several key differences in their theoretical framework and implementation, although they are similar in the use of high intensity (many hours per week, one-on-one) instruction utilizing ABA techniques. The UCLA/Lovaas method relies heavily on one-on-one therapy sessions during which a trained therapist uses discrete trial teaching with a child to practice target skills, while the ESDMblends ABA principles with developmental and relationship-based approaches for young children.

The other treatment approaches in this section also incorporate ABA principles, and may be intensive in nature, but have not been manualized. We have classified these approaches broadly as UCLA/Lovaas-based given their similarity in approach to the Lovaas model. A third set of interventions included here are those using the principles of ABA to focus on key pivotal behaviors rather than global improvements. These approaches emphasize parent training (e.g., Pivotal Response Training, Hanen More than Words, social pragmatic intervention, etc.) and may focus on specific behaviors such as initiating or organizing activity or on core social communication skills. Because they emphasize early training of parents of young children, they are reviewed here.

We review the results of UCLA/Lovaas-based approaches and parent training approaches focused on pivotal behaviors below; we discuss results of the ESDM in the KQ7 section of the report given the question's focus on younger children.

Studies focusing on one specific targeted outcome area (e.g., social skills, maladaptive behavior, mental health comorbidities, play) and intervention studies delivered primarily via educational protocols or allied health providers are reviewed in other sections of this report.

Content of the literature. We identified 34 papers[100-133] from 30 unique study populations that addressed early intensive behavioral and developmental interventions. A majority of the reviewed literature examined specific early intensive behavioral and developmental approaches, with most using variants of the UCLA/Lovaas model or other ABA-based approaches.[101-107,110,111,113-115,118,121,122,124-127,129-133]

Four papers evaluated various parent trainings aimed at social communication skills,[100,108,109,128] two papers examined Pivotal Response Training,[117,120] two studies examined and described eclectic approaches[112,119,123] and one study examined a parent training blending

Pivotal Response Training and other behavioral approaches (Group Intensive Family Training).[116]

Summary of the literature. Of the 34 papers in this section[100-130] comprising 30 unique studies, 11 were fair, and 19 were poor. Outcomes of RCTs and cohort studies rated fair in quality are summarized in Table 10.

Studies of UCLA/Lovaas-based approaches. The one RCT on the UCLA/Lovaas treatment that met inclusion criteria had fair quality.[114] This study compared a clinic-based method to a parent program, and targeted children at about 36 months of age. The study[114] was the first attempted replication of Lovaas' manualized intervention to use random assignment, a standardized assessment battery, and explicit accounting of intervention hours. It included 28 children with a mean intelligence quotient (IQ) of 51 randomized to either an intensive treatment group (UCLA/Lovaas model with an average of 25 hours per week of individual treatment per year with reduced intervention over next 1 to2 years) or a parent-training group (3-9 months of parent training). Gains in IQ were much more tempered than that of Lovaas' original noncontrolled study.[21] Children in the treatment group gained a mean of 15 IQ points in comparison to the relatively stable cognitive functioning of the control group, although average IQ in the treatment group remained in the impaired range. Most of the children who demonstrated large gains in IQ were within the subgroup diagnosed with Pervasive Development Disorder-Not Otherwise Specified (PDD-NOS), whereas children with classically defined Autistic Disorder demonstrated modest improvements.

Two children in the experimental group (vs. one in the control) achieved the "best outcome" or "recovery" status previously defined by Lovaas. No post-treatment group differences were seen in adaptive behavior or challenging behavior. Thus, while replicating improvements in cognitive ability for some children with ASDs within the repeated discrete trial teaching inherent to UCLA/Lovaas method, the study in fact demonstrated a less dramatic impact for the population of children for whom this approach is often recommended (i.e., children with classically defined Autistic Disorder) compared with what was previously reported.

Seven prospective cohort studies and nonrandomized trials were available on UCLA/Lovaas-based methodologies, but none made the same comparisons either in terms of interventions or populations. Hayward and colleagues[126,132] examined the progress of children receiving either intensive clinic directed UCLA/Lovaas-based intervention (n=23; mean age=36 months; 37 hours of weekly treatment) or an intensive parent-managed model (n=23; mean age=34 months; 34 hours of weekly treatment) over the course of one year in the United Kingdom. Group assignment was based solely on geographic location. At follow up, both groups had improved significantly in IQ (16 point gain), nonverbal IQ (10 points), language use/understanding, and most areas of adaptive functioning with the exception of daily living skills but there were no differences between the groups.

Two studies compared intensive center-based treatment to community care. Howard and colleagues[129] studied preschool-aged children receiving intensive behavior analytic treatment (n=29, 1:1 treatment for 25-40 hours per week), intensive "eclectic" intervention (n =16, higher teacher-student ratio intervention for approximately 30 hours per week), and children receiving general intervention in public early intervention programs (n=16, combined methods, small groups, 15 hours per week). Groups were assigned via educational placement teams that specifically included parent input. Controlling for age at diagnosis and combined parental education, children in the intensive behavior analytic group demonstrated significant improvements in all areas assessed at followup, including an average IQ of 89 (41-point improvement over baseline) and a 24-point difference from the combined mean of the other intervention groups.

Significant differences between the eclectic and generic intervention groups were not present at followup. Findings do suggest substantial improvement via an intensive approach for young children with autism; however, important differences in group assignment at baseline, difficulties with systematic measurement overtime, the lack of reported treatment fidelity or adherence characteristics, and the small number of children in the comparison group limits the interpretation of these findings.

These results were echoed in another study[105] of 42 children in which those receiving the Lovaas program had significantly higher IQs (mean=87, gain of 25; mean=73, 14 points) and adaptive behavior skills at outcome, compared with children in undefined community care. Receptive language improvements were observed but were not significant, and expressive language skills and socialization scores on the Vineland Adaptive Behavior Scale (VABS) were not different for the two groups at year 3 outcome. Twelve of the 21 children in the behavioral group had IQs >85 compared with 7 of 21 in the eclectic treatment group at outcome. Likewise, more children in the Lovaas group were in typical schools subsequent to intervention (17 vs. 1); although this specific outcome is potentially attributable to a wide variety of factors including some that might correlate with differences in socioeconomic status and family constellation evident between the groups.

One study[125] of two centers compared an eclectic approach (including the Developmental, Individual-Difference, Relationship-Based/Floortime model, Treatment and Education of Autistic and Communication related handicapped CHildren (TEACCH) and ABA-based approaches) to UCLA/Lovaas-based intervention alone. Hours spent in the intervention were consistent at 8 hours per day, and children were assessed over one year. Significant group differences were noted in terms of both language/communication and reciprocal social interaction domain scores on the Autism Diagnostic Observation Schedule (ADOS), with both groups showing decreases in symptom tallies but more substantial decreases in the ABA group. No significant differences in IQ change were reported. While demonstrating impact on certain ADOS symptom scores, these changes were small, and more recent approaches suggest that calculating an ASD severity score may be a more valuable and sensitive way for measuring changes in ASD symptoms in response to intervention.[134] In a subsequent study on diagnostic stability[124] with unclear sample overlap, most children receiving intervention continued to display scores in the ASDs range on the ADOS (n=53) although some children's classification did shift.

Finally, one study tried to assess the role of intensity of the intervention on outcomes. Reed and colleagues[103] studied the effectiveness of varying intensity of home-based Lovaas-based programs offering primarily one-to-one teaching. High intensity interventions (n=14) were defined as those provided for an average of 30 hours per week. Low intensity interventions (n=13) were provided for on average 13 hours per week. Assignment to the particular intervention modality was based on geographic location, and children in the high intensity group had higher ability and cognitive scores and lower autism severity scores at baseline. Children were assessed 9-10 months after initiation of intervention. Children receiving high intensity intervention demonstrated statistically significant improvements in intellectual and educational functioning from baseline. Children receiving low intensity intervention demonstrated statistically significant changes in educational functioning and nonsignificant improvement in cognitive functioning. The only significant difference between the groups was in improved educational functioning associated with high intensity interventions. No group differences were found in autism severity, cognitive functioning, or adaptive behavior functioning.

Three additional cohort studies[101,106,130] of UCLA/Lovaas-based methodologies provided inconsistent data on the benefit of behavioral approaches, but all three had substantial risk of bias and were thereby rated as poor quality in this report. Nonetheless, they suggest that behavioral approaches may have promise for bolstering aspects of cognitive, language and adaptive functioning in preschool children with ASDs.

Case series of early intervention approaches[104,113,118,119,131] had mixed results, likely in part due to the substantial heterogeneity of interventions examined even within individual studies, little or no control of concomitant interventions, and poor fidelity to any given approach. Outcomes in these studies were more likely to be parent-reported and not based on validated tools.

Several chart reviews and other retrospective analyses have been used to understand treatment patterns and effects.[111,112,115,121-123] Interpretation of findings is most appropriately confined to noting that some children receiving intervention have displayed improvements during intervention in cognitive, adaptive, and autism-specific impairments, that characteristics of starting treatment and baseline abilities are correlated with improvement in some instances, and heterogeneity in terms of improvement is quite common. We do not describe these studies here, but details on all of them are available in the evidence table in Appendix C.

One chart review,[122] however, does provide some evidence for the feasibility of providing intensive behavioral interventions on a larger scale as it reviews data on 322 children served in a large service catchment area. Given the methodological limits including lack of a clearly defined intervention characteristics/protocol, lack of a comparison group, retrospective collection, and lack of key measures for certain children at certain times, the intervention results are limited. However, the study suggests the feasibility of providing intensive intervention to a large group of children.

Studies of intensive parent training approaches. Of the seven studies[100,108,109,116,117,120,128] on parent training, four[100,108,109,120] included comparison groups and had fair[100,108,109] or poor[120] quality. Three were RCTs,[100,108,109] including one pilot study[108] with a report of a later implementation of the intervention including different participants.[100] Drew et al.[109] compared the effects of a home-based, parent-delivered intervention aimed at improving social communication and managing challenging behavior for 12 children with ASDs with a community-based control intervention group of 12 children (mean age 23 months at start of treatment).

Components of the interventions for social communication included developing joint attention, teaching routines, and play activities promoting interaction. Reinforcement techniques, including for alternative behaviors, were used to address challenging behaviors. Training was conducted at home visits (3 hours weekly for 6 weeks), with parents asked to engage in intervention activities for a half to1 hour daily. One year after treatment initiation, the parent training group reported that their children used more words than the community group. There were no group differences on nonverbal intelligence quotient (NVIQ), autism symptom severity, or words/gestures observed during followup assessment. Unexpectedly, the treatment group lost IQ points during the study; whereas the control group demonstrated relatively stable cognitive abilities. This finding is further confounded by a significantly higher IQ present in the treatment group at initiation of the study.

Aldred et al.[108] compared a parent-based intervention focused on advancing social communication skills within interactions (n = 14, median age 51 months) to treatment as usual (n=14, median age 48 months). Parents participated in initial workshops, monthly intervention sessions where videotaped interactions were reviewed, and 6 months of maintenance visits (approximately once every 2 months). Twelve months after baseline, blinded evaluations showed improvements on ADOS scores, with substantial improvement within the social domain, increased expressive vocabulary, as well as improved communication-related behaviors coded during interactions. Language gains were most prominent in younger, lower-functioning children. A lack of standardized measures of developmental performance, including baseline cognitive skills, as well as challenges in understanding and defining "treatment as usual" limit interpretation of the findings.

In a report of a later intervention of this model, 152 children between the ages of 2 and 4 years were randomized to treatment as usual or treatment as usual plus parent training in social communication.[100] Time in "treatment as usual" interventions was similar across groups as were the types of interventions employed. Similar numbers of children in both groups experienced diagnostic shifts from core autism to other diagnoses on the ASDs spectrum as diagnosed on the ADOS-G. Teacher ratings of language and communication after intervention were not significantly different between groups, though ratings of parent-child interactions by independent assessors were positive for children in the social communication group. Parent ratings of language and social communication were also more positive for the social communication group.

Stahmer and Gist[120] examined the effects of an explicit parent education support group with a parent education program focusing on Pivotal Response Training, a treatment program designed to enhance core skill areas in autism using naturalistic interactions. Parents met with the intervention provider weekly for 12 weeks and were taught techniques for presenting clear instructions, following and supplementing child choice, and providing direct/naturalistic reinforcement. Involvement in the 12-week intervention was successful in changing parenting techniques and perceived language gain. However, the lack of randomization, wide variation in children served, the lack of objectively assessed changes in child behavior, and the small number of participating limit the reported results.

Table 10. Outcomes of early intensive behavioral and developmental interventions

Author, year, country Groups, N enrollment/N final Study quality	Age, mean (months) ±SD IQ, mean ± SD	Key outcomes
UCLA/Lovaas-based approaches		
Hayward et al.[126,132] 2009, UK **G1:** Intensive clinic-based UCLA/Lovaas-based intervention, 23/20 **G2:** Intensive parent-managed treatment, 21/19 Quality: Fair	**G1:** 35.7 ± 6.2 **G2:** 34.4 ± 5.7 NR	• No significant group differences at followup. • Improvements in both groups in IQ, non-verbal IQ, language use/understanding, and most areas of adaptive functioning, with the exception of daily living skills.

Table 10. Outcomes of early intensive behavioral and developmental interventions (continued)

Author, year, country Groups, N enrollment/N final Study quality	Age, mean (months) ±SD IQ, mean ± SD	Key outcomes
UCLA/Lovaas-based approaches		
Reed et al.[103] 2007, UK **G1:** High intensity intervention, 14/14 **G1a:** High intensity with focus on Lovaas techniques, 4/4 **G1b:** High intensity with focus on verbal behavior, 5/5 **G1c:** High intensity with focus on CABAS methods, 5/5 **G2:** Low intensity intervention in home-based direct teaching sessions, 13/13 Quality: Fair	**G1:** 42.9 (14.8) **G1a:** 47.5 (13.5) **G1b:** 38.0 (9.9) **G1c:** 44.2 (20.5) **G2**: 40.8 (5.6) NR	• Children in the high intensity group had higher ability and cognitive scores and lower autism severity scores at baseline. • G1: statistically significant improvements in intellectual and educational functioning from baseline. • G2: statistically significant changes in educational functioning. • Group comparisons showed educational functioning improvements for G1 compared with G2. • No group differences were found in autism severity, cognitive functioning, or adaptive behavior functioning.
Zachor et al.[125] 2007, Israel **G1:** UCLA/Lovaas-based intervention, 53/53 **G2:** Eclectic approach, 15/15 Quality: Fair	**G1:** 25.1 ± 3.8 **G2:** 26.3 ± 4.6 NR	• No baseline differences in terms of family characteristics or child functioning. • Significant time by intervention effects noted in ADOS language/communication and reciprocal social interaction domain scores--more substantial decreases in the UCLA/Lovaas group. • Following intervention both groups showed improvements in cognitive and verbal scores and adaptive behavior skills.
Cohen et al.[105] 2006, US **G1:** UCLA/Lovaas-based intervention, 21/21 **G2:** Local services, 21/21 Quality: Fair	**G1:** 30.2 ± 5.8 **G2:** 33.2 ± 3.7 **G1:** 61.6 ± 16.4 **G2:** 59.4 ± 14.7	• Significantly higher IQs and adaptive behavior skills post-treatment in G1. • Receptive language improvements noted at 3 years, but expressive language skills and socialization scores were not different for the two groups. • Twelve of 21 in the behavioral group had IQs >85 compared with 7 of 21 in the eclectic treatment group.
Howard et al.[129] 2005, US **G1:** UCLA/Lovaas-based intervention, 37/29 **G2:** Intensive eclectic therapy **G3:** Non-intensive eclectic therapy **G2+G3:** 41/32 Quality: Fair	At intake: **G1:** 30.86 ± 5.16 **G2:** 37.44 ± 5.68 **G3:** 34.56 ± 6.53 At followup: **G1:** 45.66 ± 6.24 **G2:** 50.69 ± 5.64 **G3:** 49.25 ± 6.81 **G1:** 58.84 ± 18.15 **G2:** 53.69 ± 13.50 **G3:** 59.88 ± 14.85	• G1: significant improvements in all areas assessed at followup, including average IQ of 89 (representing a 41 pt improvement over baseline and a 24 pt improvement over the combined mean of the other intervention groups).

Table 10. Outcomes of early intensive behavioral and developmental interventions (continued)

Author, year, country Groups, N enrollment/N final Study quality	Age, mean (months) ±SD IQ, mean ± SD	Key outcomes
Eikeseth et al.[110,133] 2002, Norway **G1:** UCLA/Lovaas-based intervention, 13/13 **G2:** Eclectic therapy, 12/12 Quality: Fair	**G1:** 66.31 ± 11.31 **G2:** 65 ± 10.95 **G1:** 61.92 ± 11.31 **G2:** 65.17 ± 14.97	• Analysis of change scores demonstrated more improvement for G1 regarding IQ and language. • G2 scores were higher at baseline across most areas of measurement compared with G1.
Smith et al.[114] 2000, US **G1:** UCLA/Lovaas-based intervention, 15/15 **G2:** Parent training from Lovaas manual, 13/13 Quality: Fair	Intake: **G1:** 36.07 ± 6.00 **G2:** 35.77 ± 5.77 Followup: **G1:** 94.07 ± 13.07 **G2:** 92.23 ± 17.24 **G1:** 50.53 ± 11.18 **G2:** 50.69 ± 13.88	• G1 gained mean of 15 IQ pts compared with relatively stable cognitive functioning of controls. • Significant improvement for G1 in visual-spatial skills and expressive language. • IQ scores averaged in impaired range at outcome for G1 and PDD-NOS children appeared to account for majority of change. • No post-treatment group differences seen for adaptive or challenging behavior.
	Parent training	
Aldred et al.[108] 2004, UK **G1:** Parent training in social communication intervention plus community intervention, 14/14 **G2:** Community intervention, 14/14 Quality: Fair	**G1:** median 48 mo **G2:** median 51 mo NR	• G1 showed improvements in ADOS scores, social interaction, expressive language, child communication acts during interaction. • No adaptive behavior differences or differences in parenting stress between groups. • Language gains particularly prominent in younger, lower functioning children.
Drew et al.[109] 2002, UK **G1:** Parent training, 12/12 **G2:** Local/eclectic services, 12/12 Quality: Fair	Intake: **G1:** 21.4 ± 2.7 **G2:** 23.6 ± 3.8 Followup: **G1:** 33.5 ± 2.5 **G2:** 36.2 ± 4.5 **G1:** 88.1 ± 11.2 (NVIQ) **G2:** 23.6 ± 3.8 (NVIQ)	• At 12 mo, G1 had more words and a trend toward understanding more words than G2. • No group differences on NVIQ, autism symptom severity, parental report of stress, or words or gestures produced during followup assessment.

ABA=applied behavior analysis; ADI=Autism Diagnostic Interview; ADOS=Autism Diagnostic Observation Schedule; ASDs=autism spectrum disorders; G=group; IQ=intelligence quotient; mo=month; N=number; NVIQ=nonverbal intelligence quotient; PDD-NOS=Pervasive Development Disorder-Not Otherwise Specified; RBS=Repetitive Behavior Scale; SD=standard deviation; UCLA=University of California, Los Angeles; UK=United Kingdom; VABS=Vineland Adaptive Behavior Scale

Social Skills Interventions

The social interventions reviewed in this section focus primarily on children at elementary-school ages and those functioning at higher cognitive/developmental levels. They use various approaches to address three primary dimensions of social competence: specific behavioral skills (e.g., greetings, initiating game play, joint attention), affective understanding (e.g., recognizing emotions in self and others), and social cognition (e.g., theory of mind, problem-solving, self-regulation).

Content of the literature. We located 16 unique papers addressing social skills interventions. This number includes two sets of papers with possibly overlapping samples evaluating a Skillstreaming intervention[135,136] and a cognitive-behavioral-ecological social skills approach.[137,138] The ages of children studied ranged from 4-16 years old. Twelve studies focused exclusively on higher functioning children or included language and/or cognitive requirements among their eligibility criteria.[135-146] Three studies provided individual treatment to children,[137,145,147] three used a combination of individual and small group formats,[138,146,148] and nine employed a small group format only.[135,136,139-144,149] In addition, five interventions included some form of parent training or involvement as an adjunct to child treatment.[137,139,141,144,146] For the 14 studies with prospective designs, the total amount of training provided ranged from 6.7 hours to 180 hours. Table 10 summarizes additional details.

Among studies of social skills interventions, seven were fair quality and nine were poor.

Summary of the literature. Three RCTs[139,141,146] (Table 11) evaluated social skills interventions targeting high functioning children with ASDs using a format that involved training for both children and their parents. The criteria for determining whether a child was high functioning and therefore eligible to participate varied by study, but at a minimum the child had to have a verbal IQ above 60. Different outcome measures were used across the samples, making direct comparisons difficult.

The Children's Friendship Training[141] program involves children with and without ASDs, and uses didactic instruction on rules of social behavior; modeling, coached behavioral rehearsal, and performance feedback during treatment sessions; rehearsal at home; homework assignments; and coaching by parents during play dates with a peer. Children were randomly assigned to receive Children's Friendship Training either immediately or 12 weeks later (Delayed Treatment Control group). Treatment was conducted in 60-minute small parallel group sessions for parents and children, and lasted 12 weeks.

Immediately following treatment, the Children's Friendship Training group showed significant improvements in social behavior and social cognition compared with the Delayed Treatment Control group. Children in the treatment group also spent less time during the play date engaged in minimally socially interactive activities (such as watching television) compared with the delayed treatment group ($p<0.001$), but did not spend significantly more time in socially interactive activities (e.g., talking). Parents of children in the Children's Friendship Training group reported that their children demonstrated increased self-control when provoked by others relative to the control group ($p<0.05$).

Parent- and teacher-reported reductions in social withdrawal showed nonsignificant changes. Children in the treatment group self-reported decreased loneliness ($p<0.025$) and increased popularity ($p<0.025$) relative to the control group. Three months post-treatment significant improvements were maintained in the treatment group on parent reported hosting of play dates, conflict during play dates, time spent in minimally socially interactive activities, assertion, self-control, and social withdrawal compared with the baseline scores. After treatment, findings from the Delayed Treatment Control group largely replicated those of the Children's Friendship Training group.

Relative to Children's Friendship Training, the Social Adjustment Enhancement Curriculum has a more comprehensive curriculum targeting emotion and facial expression recognition; theory of mind, the ability to ascribe mental states to oneself and others to understand and forecast behavior; perspective taking; executive functioning, which allows for planning and abstract thinking; problem solving; and conversation skills. Eighteen boys between 8 and 12 years old met eligibility criteria.[139]

Participants were matched on age and IQ and randomly assigned to an immediate intervention condition or a wait list condition. Parents and children in the treatment condition received the Social Adjustment Enhancement Curriculum at a clinic for 20 weekly 1.5 hour sessions. Children and parents met separately. Child groups of four or five were structured with a high adult-to-child ratio and followed a consistent schedule each week, using a variety of instructional strategies including in vivo teaching, visual templates, games, and role playing.

Immediately following the intervention participants in Social Adjustment Enhancement Curriculum had higher facial recognition scores post-treatment ($p<0.05$), while the scores of the participants in the wait list control group declined (although not significantly). There was significantly improved executive function skills (covarying Verbal IQ) post-treatment ($p<0.05$) in the intervention group, while the scores of those in the wait-list control declined. However, when the one child with a PDD-NOS diagnosis was excluded from the treatment group these results were no longer significant. Both the control and Social Adjustment Enhancement Curriculum group demonstrated significant improvements on the Faux Pas Stories Task post-treatment ($p<0.001$) but not on the Strange Stories Task. Total social problems reported per time reporting dropped significantly from the first eight weeks of the intervention to the last eight weeks of the intervention ($p<0.05$).

Beaumont and Sofronoff[146] investigated a comprehensive social skills intervention that utilized a computer game as well as child and parent small therapy groups to teach emotion recognition and regulation, problem solving, and social interaction skills. Forty-nine children diagnosed with Asperger syndrome between the ages of 7.5 and 11 years old were randomly assigned to the Junior Detective Training Program or a wait list control. Data suggests that this computerized intervention was beneficial for improving knowledge of emotion management strategies and parent-reported social skills, but not emotion recognition, immediately after treatment over a the waitlist control.

Some of these results were also replicated when the wait-list group underwent treatment in pre-post analyses. Pre- post scores were significantly different on the parent-reported measures of social skills for the intervention group immediately, 6 weeks, and 5 months following the intervention, suggesting maintenance of these treatment effects. However this study had substantial risk of bias and was rated as poor quality in this report. Additional details on this and other studies not fully described in this section are available in the evidence table in Appendix C.

One study attempted to ascertain whether the type of feedback that children received during a social skills intervention affected the outcomes. Skillstreaming[150] is a comprehensive, structured social skills curriculum that employs systematic procedures for teaching specific social behaviors (e.g., listening, sharing, having a conversation, accepting a compliment, responding to teasing), as well as social cognition (using self-control), and affect (e.g., recognizing and expressing feelings, responding to anger). The Skillstreaming curriculum used in the study was adapted to focus on social skills particularly important for children with autism.

Unlike in the previous RCTs reviewed in this section, this intervention did not include a parent training component. Fifty-four children between the ages of 6 and 13 years with high functioning ASDs were randomly assigned to small-group Skillstreaming intervention that used either a response-cost condition (involving immediate performance feedback and rewards based on specific social skills and behaviors) or a noncategorical feedback condition (involving more general feedback and noncontingent rewards). The only difference found between the response cost and noncategorical feedback intervention conditions post-treatment was that interventionists reported significant improvements measures of atypicality, withdrawal, and behavior symptoms in the response cost group relative to the noncategorical feedback group ($p<0.05$).

However, both groups combined made significant improvements after treatment on both parent and interventionist reports of social skills, withdrawal, adaptive skills, and behavior symptoms ($p<0.001$--$p<0.05$). As for facial recognition, participants in neither group made significant improvements on the Diagnostic Analysis of NonVerbal Accuracy. A previous case series to assess Skillstreaming[136] for 21 children between 6 and 13 years old diagnosed with Asperger disorder found similar results: significant improvements in parent reported social skills, adaptability, and atypicality) and on staff reported social skills.

Three RCTs[143,145,149] and a related retrospective cohort study[148] evaluated social skills interventions focused on improving children's ability to socially interact with others while playing. The Quirmbach et al.[145] study evaluated the effectiveness of using Social Stories to teach seven to 14 year old children with ASDs social skills when playing board games. Social Stories[151] are descriptive brief vignettes constructed according to a specific formula that are read to or by individuals with ASDs to convey appropriate behavior expected for a specific situation. Children in one of two social stories groups (standard or directive) showed significant game play skill improvements across the four trials ($p<0.001$) while the children who received the control story did not. Children in the two experimental conditions maintained the results of the intervention a week later.

These results provide preliminary support for the effectiveness of a short, focused intervention on improving the specific targeted skills. However, further research is needed to ascertain whether these results generalize to other people (such as peers) and other settings, whether these results are maintained when the intervention is discontinued (i.e., the child stops reading the Social Story), and whether other Social Stories are successful at improving the skills that they target. Despite authors' predictions that the children who read the directive story would improve their game play skills at a faster rate than the children who read the standard story (because the directive story does not include additional information), there were no significant differences in results between participants receiving the standard vs. directive social stories (both groups showed significant improvements across trials).

In the other studies, direct teaching was associated with greater gains in initiating, responding, and interacting behaviors than an unstructured play group,[149] in 4 to 6 year olds. Results on LEGO therapy were conflicting, with one a retrospective cohort study[148] showing benefit for LEGO therapy over an unspecified "other" intervention on socialization measures, while one RCT[143] had inconsistent results on the benefit of LEGO therapy over a Social Use of Language Program and no intervention. The Lego group improved on measures of social skills when compared with the Social Use of Language Program and control groups; and pre-post scores did not significantly differ on these measures for the Lego group. Both the Lego and Social Use of Language Program groups improved on measures of maladaptive behavior over the no intervention group. The Lego group improved in the duration of social interaction on the playground from pre to post treatment.

Seven additional studies used prospective case series designs to evaluate the effectiveness of social skills interventions.[137,138,140,142,144,147,152] All studies noted improvements in some social behaviors that, depending on the study, included eye contact, emotion recognition, and interaction with peers; outcome measures were generally parent-reported. The studies also lacked control groups so it is difficult to determine whether improvements are treatment-specific.

Table 11. Outcomes of RCTs of social skills behavioral interventions

Author, year, country Groups, N enrollment/N final Study quality	Age, mean years ± SD IQ, mean ± SD	Key outcomes
Quirmbach et al.[145] 2009, US **G1:** Social Stories, standard condition, 15/15 **G2:** Social stories, directive condition, 15/15 **G3:** Control story unrelated to social skills, 15/15 Quality: Fair	**G1:** 9.49 ± 2.09 **G2:** 10.33 ± 2.53 **G3:** 8.85 ± 1.59 **G1:** 86.2 ± 22.8 **G2:**81.00 ± 20.26 **G3:** 79.47 ± 22.68	• G1 & G2 showed significant game play skill improvements across four trials while G3 did not ($p<0.001$). • Game play skills for G1 & G2 maintained a week later.
Lopata et al.[135] 2008, US **G1:** Response-cost; receive feedback based on operationally defined behaviors), 29/29 **G2:** Noncategorical; receive feedback based on no predetermined categories, 25/25 Quality: Fair	**G1:** 9.60 ± 2.12 **G2:** 9.41 ± 2.31 **G1:** 100.87 ± 17.92 **G2:** 97.56 ± 13.62	• Both groups (as a whole) demonstrated significant improvements on parent and interventionist reported social skills post-treatment ($p<0.01$). Group differences were not significant on any of parent reported measures. • Interventionists reported significant improvements on BASC Atypicality and Withdrawal subscales in G1 compared with G2 ($p<0.05$). • Neither group improved significantly on facial expression recognition.
Solomon et al.[139] 2004, US **G1:**Social Adjustment Enhancement Intervention, 9/9 **G2:** Waitlist group, 9/9 **Ga:** Younger participants with higher mean FSIQ **Gb:** Older participants with lower mean FSIQ Quality: Fair	**G1a:** 8.58 **G1b:** 10.83 **G2a:** 8.33 **G2b:** 10.17 **G1a:** 115 **G1b:** 86 **G2a:** 119 **G2b:** 95	• Fewer social problems reported by parents of G1 ($p<0.05$). • G1 recognized more facial expressions post-intervention than G2 ($p=0.003$) (but not more than before treatment). • No group differences evident on theory of mind measures post-intervention. • G1 demonstrated improved executive function skills post-intervention, compared with G2, ($p<0.05$).

Table 11. Outcomes of RCTs of social skills behavioral interventions (continued)

Author, year, country Groups, N enrollment/N final Study quality	Age, mean years ± SD IQ, mean ± SD	Key outcomes
Frankel et al.[141] 2010, US **G1:** Children's Friendship Training, 35/26 **G2:** Delayed Treatment Control group, 33/31 Quality: Fair	**G1:** 8.6 ± 1.27 **G2:** 8.46 ± 1.25 **G1:** 106.9 ± 19.1 **G2:** 100.5 ± 15.7	• Parents of G1 reported that their children hosted significantly more play dates after treatment relative to G2 (p<0.0001), but were not invited to significantly more play dates. • Parents reported that G1 spent less time engaged in minimally socially interactive activities during play dates compared with G2 (p<0.001), but did not spend significantly more time in socially interactive activities (such as talking). • Parents of G1 reported increased self-control in children (p<0.05) when provoked by others. • No changes reported by teachers. • G1 showed significant decreases in loneliness (p<0.025) and increases in popularity (p<0.025) following treatment relative to G2.

BASC=Behavioral Assessment System for Children; FSIQ=full scale intelligence quotient; G=group; N=number; NR=not reported; SD=standard deviation; SULP=Social Use of Language Program; VABS=Vineland Adaptive Behavior Scale

Play-/Interaction-Based Interventions

These interventions focused on children's interactions with either their parents or experimenters and targeted skills including joint attention and play abilities. Most studies were conducted in the context of a play situation, and included children across broad age and developmental ranges.

Content of the literature. We included 15 papers addressing play- or interaction-based interventions[153-167] comprising 13 unique populations. Seven studies were randomized controlled trials,[153-157,161,163-165] including a trial of the Stepping Stones Triple P program with two publications,[153,154] and a trial comparing joint attention and symbolic play interventions with two publications.[155,156] Two additional studies assessed joint attention and symbolic play and likely share overlapping participants with this trial.[157,158] Three RCTs assessed comparable interventions (imitation compared with contingent responsiveness) using similar procedures;[163-165] two of these[163,165] may share participants.

Multiple interventions involved parent training or parent interaction components, including Parent-Child Interaction Therapy,[161] responsive teaching,[166] play-based approaches based on the Floortime model,[160] the Mifne model,[162] the Stepping Stones Triple P program,[153,154] and the Relationship Development Intervention program.[159] Participants ranged in age from 12 months[166] to 12 years[161] across all studies. Duration of therapy in prospective studies ranged from five weeks[156,157] to 12 months.[160,166] Table 10 includes additional study details. Among the 13 unique studies, three were fair quality and 10 were poor.

Summary of the literature. Among the fair quality studies was an RCT evaluating Parent-Child Interaction Therapy,[161] in which parents of children with an ASD were trained to interact with their children using behavior management strategies (Table 12). The Parent-Child Interaction Therapy intervention group consisted of ten children and the wait-list control group included nine; children in both groups were on average 8 years old. Improvements were greater in the intervention group in challenging behavior, behavioral flexibility and atypical behaviors, and hyperactivity, inattention, challenging behaviors, and depression ratings. However changes on each scale fell short of statistical significance in comparison with the control group. A second parent-focused RCT addressed the Stepping Stones Triple P Parenting Program,[153,154] which focuses on managing children's behavior by considering the function of the behavior and uses procedures such as descriptive praise, planned ignoring, skill acquisition, and communication.

Parents of the children in the treatment group reported statistically significant decreases in child challenging behavior on the Eyberg Child Behavior Inventory Intensity and Problem Scales. Wait-list controls eventually received the same treatment, and parents of children in this group also reported statistically significant decreases in child challenging behavior on both Eyberg Child Behavior Inventory scales. At six-month follow up, the treatment group maintained gains on both the Eyberg scales.

The additional studies in this section included three RCTs that compared the effects of imitation and contingent responsiveness.[163-165] Contingently responsive behavior refers to the adult responding to the child's initiations by either commenting back or gesturing within the play context. In the first phase, the child entered the room with an adult present holding a neutral facial expression. During Phase 2, the adult interacted with the child by using either imitation or contingently responsive behavior in response to the child's behavior. The third phase mimicked Phase 1, and the fourth and final phase included a spontaneous play interaction. Each of these four phases was three minutes in duration.

Each of the three RCTs included 20 children randomly assigned to either the imitation group or the contingently responsive group,[163-165] Significantly greater effects were seen in the imitation group compared with the contingent responsiveness groups in all three studies. Improvements included spending more time engaged with both objects and adults,[163] a greater reduction in motor activity,[165] and more social interest.[164]

Two RCTs,[155-157]one of which was fair quality,[155,156] and two case series[158,167]focused on the potential for interventions based on joint attention or symbolic play. Generally speaking, interventions with a joint attention focus did result in improvements in tasks based on joint attention. In the first RCT,[157] all groups improved in coordinated joint looks over time. No differences were found in pointing to a toy or giving a toy to an adult to share in any group. Both Joint Attention and Symbolic Play groups improved in the following areas compared with controls: showing toys to an adult, shared looks between a toy and the child's mother, and symbolic play skills.

Compared with other groups, the Joint Attention group showed more improvement in responding to joint attention over time. With respect to mother-child interactions (generalization) assessing the same outcome areas, the Joint Attention group had significantly greater improvement than the Symbolic Play group in giving and showing a toy. Children in the Joint Attention group engaged in more child-initiated joint engagement than those in the control group. The Symbolic Play group showed significantly greater improvement on the Structured Play Assessment than did the control group for overall mastered level of play. In the second RCT,[157] significantly more children in the Joint Attention group engaged in coordinated looks during the final stimulus presentation (76.5 percent) than in the Symbolic Play group (38.9 percent). Children in the Joint Attention group engaged in significantly longer periods of coordinated looks between the person in the room and the stimulus presentations across the three time periods.

A second RCT155,156 comparing joint attention and symbolic play interventions included 58 children with autism between 3 and 4 years of age. Investigators assessed language development, joint attention and play skills, and mother-child interactions at pre- and post-intervention and 6 and 12 months after the end of the 5 to 6 week intervention. Children in both groups showed significantly greater growth in expressive language, initiation of joint attention, and duration of child-initiated joint attention over time than did participants in the control group (p<.01 to <.05, moderate to large effect sizes). Growth in receptive language was not significantly affected by the intervention from pre-intervention to 12 months post-intervention. Children in the Symbolic Play group also showed significantly more growth in play level than did children in either the Joint Attention (p<.01) or control (p<.001) groups.

In a fair quality case series describing an eight week, 24-session intervention designed to foster joint attention and language skills as well as joint engagement with the mother,167 episodes of distress occurred in an average of 9.4 sessions (range=four to 24 sessions), with children displaying negativity for an average of 20 percent of the time (range=6-52 percent). There were no associations between negativity and children’s mental or chronological age. Both mothers and children showed improvements in behavior regulation over the course of the intervention. Children engaged in behavioral strategies significantly more often during episodes of negativity than in nonnegative episodes (p<.01). The study also reports associations between mothers’ vocal behavior regulation strategies and child-related stress as reported on the Parenting Stress Index; mothers with greater child-related stress used fewer vocal strategies such as vocal comfort and reassurance. Mothers whose children exhibited more externalizing problems (as rated on the Child Behavior Checklist) used more active behavior regulation strategies (e.g., shifting child’s attention away from negative stimulus, hugging child, etc.).

None of the four additional case series that met criteria for inclusion in this section described the same intervention. They described a relationship-focused intervention teaching parents to use responsive teaching strategies to assist their children with acquiring pivotal behaviors,166 the Developmental, Individual-Difference, Relationship-Based/ Floortime model,160 the Relationship Development Intervention,159 and the Mifne treatment model.162All four report positive outcomes that are difficult to interpret absent a comparison group.

Table 12. Outcomes of RCTs assessing play-/interaction-based interventions

Author, year, country Groups, N enrollment/ N final Study quality	Age, mean ± SD (range) IQ, mean ± SD	Key outcomes
Parent-focused interventions		
Solomon et al.[161] 2008, US **G1:** Parent training focused on behavior management and requesting (PCIT), 10/10 **G2:** Wait list, 9/9 Quality: Fair	**G1:** 8.2 yrs ± 1.7 **G2:** 8.1 yrs ± 2.2 NR	• Challenging behaviors decreased in both groups. • Scores declined on BASC Hyperactivity Scale for G1 but not G2. • Score on BASC Adaptability Scale increased significantly for G1. • Parents of G1 children reported significantly less atypicality on the BASC scale.
Kasari et al.[155,156] 2006, US **G1:** Joint attention intervention, 20/20 **G2:** Symbolic play intervention, 21/17 **G3:** Control group, 17/16 Quality: Fair	**G1:** 43.2 ± 7.05 **G2:** 42.67 ± 6.93 **G3:** 41.94 ± 4.93 NR	• Children in the intervention groups showed greater growth in expressive language, initiation of joint attention, and duration of child-initiated joint attention than did control group children (p= <.01, <.05). • Receptive language growth not significantly affected by intervention. • Amount of intervention services received post-intervention was not related to growth in skills at followup 12 months after the ~6 week intervention, except for child-initiated joint attention: children receiving fewer hours of additional services showed greater growth in child-initiated joint attention.

BASC=Behavioral Assessment for Children; G=group; IQ=intelligence quotient; PCIT=Parent-Child Interaction Therapy; N=number; NR=not reported; SD=standard deviation

Behavioral Interventions Focused on Associated Behaviors

Several behavioral interventions target symptoms commonly associated with autism, such as anxiety and anger management. Cognitive behavioral therapy-based (CBT) interventions are particularly common and involve teaching cognitive skills and relaxation strategies, promoting recognition of anxious feelings, and providing children with behavioral exposures in which to utilize their new coping skills in the face of anxiety-provoking stimuli, with an ultimate goal of reducing anxiety symptoms over time.[29]

Parent training protocols, often implemented to help parents deal with challenging behaviors such as noncompliance, tantrums, self-injury, and aggression, attempt to teach parents strategies to curb negative behaviors. Once trained, parents can act as “co-therapists,” shaping behavior toward the goal of reducing challenging behaviors in daily life, where parents by necessity must act as the primary interventionist. Parent training interventions also often have secondary targets of improving parental feelings of self-efficacy and decreasing parental stress.

Many of the studies of behavioral methods used to treat challenging behaviors, such as functional behavior analysis and positive behavior support, included fewer than 10 participants with ASDs and thus were not included in this review.

Content of the literature. We identified 11 studies reported in 12 papers[25,26,168-177] that addressed behavioral interventions focused on symptoms commonly associated with ASDs including anxiety and anger management. Six studies reported on CBT interventions,[25,26,168-171,176] four used parent training techniques,[172,174,175,177] and one used teacher training methods.[173]

While the overlap among studies is somewhat unclear, sets of studies from the same authors and using the same methodology appear to include the same or overlapping samples.[169,176;170,171;174,175] Accounting for this potential overlap, it appears that at least four independent studies of CBT interventions and three independent studies of parent training address anxiety and anger in children with ASDs. All studies examining CBT treatments included children ages seven and older, with means ranging from nine to eleven years of age. In two studies examining CBT treatments, only children with an Asperger diagnosis were included,[169,176] while the Wood et al. RCT enrolled children with an ASD and a comorbid anxiety disorder.[170,171]

Parent training studies included parents of children ranging from age four to twelve with mean ages spanning seven to nine years.[172,174,175,178] In three of four parent training studies, only parents of children with Asperger syndrome were included.[174,175,178] In the teacher training study, children ranged in age from two to fifteen and all had diagnoses of autistic disorder.[173] Table 10 summarizes additional study details. Among all studies, six were fair quality and five were poor.

Summary of the literature. Among the studies assessing CBT approaches, one RCT examined the efficacy of a modified version of the Building Confidence CBT program for treating comorbid anxiety disorders (i.e., separation anxiety disorder, social phobia, or obsessive compulsive disorder) in seven to eleven year-old children with ASDs.[170,171] This was the only RCT in which CBT occurred at the individual level.

The intervention program consisted of sixteen 90-minute weekly sessions conducted by clinical or educational psychologists or trainees in these programs. In the first report from the study,[170,171] anxiety symptoms were assessed by evaluators blind to treatment condition using the Anxiety Disorders Interview Schedule, Clinical Global Impression (CGI)–Improvement Scale, and both parent and child versions of the Multidimensional Anxiety Scale for Children.

On the CGI, 92.9 percent of children in the intervention condition met criteria for positive treatment response, while only 9.1 percent of children in the waitlist control group met the same criteria; on the Anxiety Disorders Interview Schedule, 64.3 percent of children in the intervention group no longer met criteria for any anxiety disorder, whereas only 9.1 percent of children in the waitlist control group lost their anxiety disorder diagnosis at post-test.

Eight of ten children from the intervention group who returned for a three-month followup did not meet criteria for any anxiety disorder at followup. Maintenance of treatment response was also indicated by CGI and Multidimensional Anxiety Scale for Children scores at followup. The second report from the study[171] included 58 percent of participants from the initial report (42 percent new participants), and measured effects of the intervention on autism symptoms using the Social Responsiveness Scale. Significant group differences were observed at outcome in the Social Responsiveness Scale total score as well as the social communication, social motivation, and social awareness subscales, with children in the intervention group showing fewer autism symptoms post-treatment than children in the waitlist control group.

The remainder of CBT-based interventions (Table 13) were conducted in group settings or directed toward parents. Reaven et al.[26] conducted a nonrandomized trial of a 12-week CBT-based group intervention for high-functioning (i.e., IQ above 70) children ages eight to fourteen years (mean = 11.83) with ASDs and comorbid anxiety disorders.

The authors created an original protocol,[27] and treatment involved both children and their parents. Ten children received active treatment in this pilot study, while 23 served as a wait-list control. Anxiety symptoms in children participating in the treatment group decreased over time, while symptoms in the control group did not on the parent (but not child) version of the Kiddie-

Schedule for Affective Disorders and Schizophrenia or on the Screen for Child Anxiety and Related Emotional Disorders.

Chalfant et al.[25] examined children ages eight to thirteen years (mean = 10.8) with ASDs and one or more comorbid anxiety disorder diagnoses including separation anxiety, generalized anxiety, social phobia, specific phobia, and panic disorder confirmed by structured clinical interview using the Anxiety Disorders Interview Schedule. Children were randomly assigned to treatment and waitlist conditions. Treatment involved a 12-session CBT-based group therapy protocol, led by licensed clinical psychologists, with nine weekly two-hour sessions followed by three monthly booster sessions.

The protocol for the study was based on a manualized CBT-based anxiety intervention for children (Cool Kids) with adaptations made to account for the learning style of children with ASDs (e.g., more visual aids and structured worksheets, increased focus on relaxation and exposure, simplification and decreased emphasis on cognitive components of the treatment). Parents of children in the intervention group participated in concurrent parent groups with a manual also adapted from the Cool Kids program.

Measures were collected at baseline and at the completion of intervention (approximately five and a half months later); clinicians administering the pre- and post-intervention measures were the same clinicians who led treatment groups. No group differences were observed on any measure at baseline. However, children in the treatment group improved significantly over time while children on the waitlist did not in the number of anxiety disorder diagnoses present, as well as in the number of anxiety symptoms reported by children on the Children's Automatic Thoughts Scale Internalising Scales, Revised Children's Manifest Anxiety Scale, and Spence Children's Anxiety Scale, by parents in their report on the Spence Children's Anxiety Scale—Parent and the Strengths and Difficulties Questionnaire Emotional and Externalizing Scales, and by teachers using the Strengths and Difficulties Questionnaire Emotional and Externalizing Scales.

Table 13. Studies assessing interventions targeting conditions commonly associated with ASDs

Author, year, country Groups, N enrollment / N final Study quality	Age, mean/yrs ± SD IQ, mean ± SD	Key outcomes
Reaven et al.[26] 2009, US **G1:** Active CBT, 10/10 **G2:** Wait list Note: for children with comorbid anxiety, 23/21 Quality: Fair	**G1+G2:**11.02 ± 1.9 **G1+G2:** 102.65 ± 16.22 NR	• Anxiety symptoms in G1 decreased over time, while symptoms in G2 did not (p=0.01).

Table 13. Studies assessing interventions targeting conditions commonly associated with ASDs (continued)

Author, year, country Groups, N enrollment / N final Study quality	Age, mean/yrs ± SD IQ, mean ± SD	Key outcomes
Wood et al.[170,171] 2009, US **G1:** Building confidence CBT program, 17/17 **G2:** Wait list control, 23/23 **Quality:** Fair	**G1:** 9.18 ±1.42 **G2**: 9.22 ±1.57 NR	• 92.9% of children in the intervention condition met criteria for positive treatment response. • 64.3% of children in G1 no longer met criteria for any anxiety disorder on the ADIS. • MASC scores were significantly lower (i.e., reduction in anxiety) in G1 than in G2 post-test (p<0.0001). • Maintenance of treatment response was indicated by diagnosis and CGI and MASC scores at followup. • Children in the autism group had lower scores than control group children at outcome on the SRS total score as well as the social communication, social motivation, and social awareness subscales.
Sofronoff et al.[168] 2007, Australia **G1:** CBT, 24/24 **G2:** Wait list control, 21/21 Note: for children with Asperger disorder and anger management difficulties **Quality:** Fair	**G1:** 10.79 ± 1.12 **G2:** 10.77 ± 0.87 **G1:** 105.24 ± 22.3 **G2:** 108.7 ± 21.6	• G1 had significant improvement on parent-reported anger inventory between pre- and post-intervention (p<0.0001) and between pre-intervention and.6-wk followup (p<0.001) • Significant improvement on frustration and relationships with authority subscales in G1. • Parents of children in G1 reported fewer instances of anger post-intervention (and at six-wk follow up) than pre-intervention. • Significant between-group differences in reports of anger incidents post-intervention (p<0.02) and at followup (p=0.005). • G1 generated significantly more anger management strategies post-intervention and at six-wk follow up (p<0.01 and p<0.05, respectively) relative to baseline and relative to children in G2 at post-intervention (p<0.01).
Sofronoff et al.[169] 2005, Australia **G1:** Child only CBT, 23/22 **G2:** Wait list, 23/20 **G3:** Child and Parent CBT, 25/24 Note: Children with Asperger disorder and anxiety symptoms **Quality:** Fair	**G1:** 10.56 ± 0.99 **G2:** 10.75 ± 1.04 **G3:** 10.54 ± 1.26 **G1:** 107.5 ± 27.3 **G2:** 101 ± 27.2 **G3:** 105.6 ± 21.2	• Significant differences on the SCAS-P total score observed between the two intervention groups, G3 (p<0.03). • Significant time by group interaction (SWQ) observed (p<0.0001), with significant. improvement in scores between baseline and six-wk followup observed for both G1 and G3 (p<0.001). • G1 and G3 scored better than G2 at followup on the James and the Maths test, and G3 scored better than G1 at followup (p<0.0001).
Aman et al.[177] 2009, US **G1:** Risperidone, 49/40 **G2:** Risperidone + parent training, 75/55 **Quality:** Fair	**G1:** 7.5 ± 2.80 **G2:** 7.38 ± 2.21 NR	• Significant group by time interaction on the HSQ (p<0.006); HSQ scores declined (i.e., decreased severity) in more children in G2. • ABC irritability, stereotypic behaviors, hyperactivity subscales all showed significant group differences over time with less severe symptoms in each of the domains in G2.

ABC=Aberrant Behavior Checklist; ADIS=Anxiety Disorders Interview Schedule; CBT=cognitive behavioral therapy; CGI=Clinical Global impression; CHiAP=Children's Inventory of Anger-Parent report; ECBI=Eyberg Child Behavior Inventory; G=group; HSQ=Home Situations Questionnaire; MASC=Multidimensional Anxiety Scale for Children; NR=not reported;

SCAS-P=Spence Child Anxiety Scale-Parent version; SRS=Social Responsiveness Scale; SD=standard deviation; SWQ=Social Worries Questionnaire

A series of papers examined CBT approaches delivered directly to children and via parent training. CBT provided by graduate students in psychology was assessed in high functioning children with Asperger disorder with comparisons made across two intervention conditions (child-only and parent-plus-child) and waitlist controls.[169,176] Significant improvements in Spence Child Anxiety Scale-Parent scores were observed for both intervention groups on the total score and separation anxiety, obsessive compulsive disorder, social phobia, panic, and generalized anxiety scales; significant improvement on the personal injury scale was observed for the parent-plus-child intervention group. No significant differences were observed from baseline to six-week followup in the waitlist control group.

On the Social Worries Questionnaire, there were significant improvement in scores between baseline and six-week followup observed for both intervention groups, but not for the waitlist control group. Similarly, children in both intervention groups generated more strategies to cope with anxiety at six-week followup than at baseline, while children in the waitlist control group did not. Both intervention groups scored better than the wait-list control group at followup, and children in the parent-plus-child condition scored better than children from the child-only groups at followup. A separate study of the same intervention[168] to examine the impact of CBT-based treatment on anger management difficulties in high-functioning (i.e., average IQ above 100) children ages ten to fourteen years with Asperger syndrome found similarly positive results.

Parent training in using CBT approaches[174,175]for parents of children ages six to twelve years with Asperger syndrome diagnoses includes psychoeducation, comic strip conversations and social stories introduction, and management techniques for externalizing behaviors, rigid behaviors, and anxiety. In studies of this approach, parents who attended a one-day workshop or who participated in six weekly one-hour individual sessions reported fewer challenging behaviors at both one-month post-treatment and three-month followup relative to baseline, while there were no significant differences over time for the waiting list control group.

Parents from both intervention groups also reported significantly fewer challenging behaviors in their children, decreased challenging behavior intensity and improved social skills at both time points. At three-month followup, individual session participants reported significantly lower intensity of challenging behaviors relative to both the waiting list control group and workshop intervention group; the workshop group no longer showed differences from the control group by three-month followup in terms of parental report of child challenging behavior intensity.

The Research Units on Pediatric Psychopharmacology (RUPP) Autism Network first reported on the feasibility of a parent-training program for parents of children with autism spectrum disorders ages 4 to 13 years who were on stable medications for behavior problems.[172] The parent training protocol consisted of 11 required sessions covering topics including prevention strategies, schedules, reinforcement, planned ignoring, compliance training, functional communication training, teaching techniques, and generalization. Two home visits were always conducted, four optional sessions were available, and booster sessions were provided to parents in later weeks; parent training was administered according to a structured curriculum.

Outcome measures related to child functioning included the Home Situations Questionnaire , the Aberrant Behavior Checklist (ABC), the Clinical Global Impressions – Improvement Scale (CGI-I), the VABS, and the Assessment of Basic Language and Learning Skills. Results indicated significant decrease in noncompliance on the Home Situations Questionnaire over the course of parent training intervention. Irritability and Hyperactivity/Noncompliance measured on the ABC showed improvement over time. Fifty-three percent of children were reported as very much improved on the CGI-I, and thirty percent were reported to show minimal improvement. Finally, with regard to adaptive behavior, improvement in daily living skills and increase in adaptive skills were also shown over the course of treatment. The correlation between improved compliance and improved adaptive behavior also strengthened over the course of treatment.

Following the initial feasibility study,[172] Aman et al.[177] conducted an RCT assessing whether risperidone treatment combined with parent training in behavior management was superior to risperidone treatment alone; this study was conducted as part of the RUPP Autism Network. Parents of children ages 4 to 13 years with ASDs and significant tantrums, self-injury, and aggression who were randomly assigned to the combined treatment group received parent training with a behavior therapist according to a RUPP manual. As noted, the manual specified 11 core treatment sessions, three optional sessions, and up to three booster sessions of 60-90 minutes in length.

On average, parents in the combined condition participated in 10.82 sessions. As in the feasibility study, outcome was assessed on the Home Situations Questionnaire and ABC; the Children's Yale-Brown Obsessive Compulsive Scale–PDD version was also administered both pre- and post-intervention. After 24 weeks of treatment, HSQ scores for 71 percent of children assigned to the combined treatment group and 60 percent of children assigned to the medication-only treatment group declined (i.e., decreased severity), which represents a significant difference between groups over time. In addition, the ABC irritability, stereotypic behaviors, and hyperactivity/noncompliance subscales all showed significant group differences over time, with children of parents who received the parent training showing less severe symptoms in each of the domains.

One case series of a teacher training procedure in reducing challenging behaviors (e.g., aggression, noncompliance, off-task behavior)[173] reported a significant reduction in the rate of the target behavior following classroom instruction (45 hours) and practical application, training, and supervision (45 hours) in applied behavior analysis.

Other Behavioral Interventions

Additional behavioral interventions include techniques such as neurofeedback and sleep hygiene education. Neurofeedback, or electroencephalogram (EEG) biofeedback, aims to remediate abnormal brainwave activity associated with disorders such as anxiety, ADHD, and ASDs through training individuals to control brain activity patterns. Neurofeedback involves the placement of electrodes to monitor brain activity while participants interact with specially designed computer games or other modalities designed to promote attention or other skills.[179] Behavioral treatments for sleep problems may attempt to affect the timing of sleep, sleep-wake cycle disorders, or promote efficacious sleep behaviors like bedtime routines and positive reinforcement.[180]

Content of the literature. Three studies[181-183] of additional behavioral interventions met our inclusion criteria. Participant ages ranged from three to fourteen years across the studies, and all three occurred in a clinic setting. Jarusiewicz[181] and Coben et al.[182] used neurofeedback with children directly while the Reed et al. sleep workshops were aimed at parents using a group approach.[183] Table 10 includes additional study details. All three studies in this section were considered poor quality.

Summary of the literature. Jarusiewicz's RCT examined the efficacy of neurofeedback on autistic symptoms as assessed using the parent-rated Autism Treatment Evaluation Checklist as the primary outcome measure.[181] Participants included 40 children ages four to 13 (mean=7) with a previous diagnosis of autism; participants were matched on gender, age, and autism severity, and individuals in each pair were randomly assigned to either neurofeedback or a wait list. Diagnostic and randomization procedures were not described.

Neurofeedback protocols varied depending on a child's autism severity as assessed by the Autism Treatment Evaluation Checklist and parental report of troubling symptoms; children typically received one to three sessions per week. Eight children in the neurofeedback group dropped out of the study due to family considerations or non-ASDs-related illness; the twelve remaining participants completed 20 to 69 neurofeedback sessions (mean=36). Scores on the Autism Treatment Evaluation Checklist improved from eight percent to 56 percent post-neurofeedback training, with an overall average reduction of 26 percent ($p < 0.001$). Scores for control participants improved by three percent overall (ns).

Coben et al.[182] sought to extend Jarusiewicz's findings in a nonrandomized controlled trial of 49 children diagnosed with ASDs; diagnostic techniques were not described. Children in the experimental (n=37) and control (n=12) groups were matched on age, gender, handedness, ASDs severity, and other treatments received. Participants' ages across groups ranged from 3-14 years; the majority (75 percent) of participants in the neurofeedback group were diagnosed with PDD-NOS or autism. Four children in this group had Childhood Disintegrative Disorder. Outcome measures included the Autism Treatment Evaluation Checklist, Gilliam Autism Rating Scale, Gilliam Asperger Disorder Scale, the Personality Inventory for Children, Behavior Rating Inventory of Executive Function as well as parental ratings of the effectiveness of the treatment and a battery of neuropsychological tests to assess attention, visual-perceptual, executive function, and language skills.

Neurofeedback protocols were individualized for each child based on assessment information and initial quantitative electroencephalogram results; treatment consisted of 20 sessions, with sessions occurring twice weekly for an unspecified duration. Eighty-nine percent of parents reported improvement in the neurofeedback group; 83 percent of control group parents reported no change ($z=2.167$, $p=0.000$). Scores on all measures except the Gilliam Autism Rating Scale , improved significantly in the treatment group ($p=0.000$ to 0.006) as did scores on neuropsychological tests. The authors did not correct for multiple testing, however.

Reed at al.[183] employed sleep hygiene workshops targeted at parents and taught by a neurology sleep specialist, pediatrician with an ASDs treatment background, educational psychologist, and nurse educator. Twenty families participated and completed both baseline and followup assessments; the mean age of children in the study was 5.8±2.7 years, and the majority (n=15) had ADOS scores in the autism range. Workshops addressed establishing effective daytime/nighttime routines, minimizing night and early waking, and discussion of techniques to handle individual sleep concerns. Assessments, conducted prior to the initial workshop and approximately one month after the final session assessed sleep changes, repetitive behavior, and parental stress and also included a week of actigraphy measurement of sleep-wake patterns coupled with a parent-maintained sleep diary.

Significant improvements ($P<0.05$) over baseline scores were seen in subscales of measures assessing hyperactivity, sleep disturbance, self-stimulatory, bedtime resistance, sleep onset delay, sleep duration subscales, and restricted behavior. Items related to reduction of stimulating activities before bedtime and the use of bedtime routines also improved. Actigraphy data, available for 12 children, illustrated a decrease in sleep latency in nine children with difficulty initiating sleep ($p=0.039$); among all 12 children, time in bed also significantly improved ($p=0.039$). Parental stress did not change significantly with the workshops.

KQ1. Effects of Treatment on Core and Commonly Associated Symptoms in Children With ASDs: Educational Interventions

Most children with ASDs will receive some treatment in an educational setting. Educational interventions have focused both on traditional areas of academic progression/achievement, but also are often used to address core areas of social, cognitive, and behavioral vulnerability via classroom or specialized instruction. Educational approaches vary in scope from specific intervention techniques attempting to impart change in short periods of time to comprehensive intervention programs aimed at improving many areas of development.

Within the context of this review we examine the available literature focusing on applications of the TEACCH program, broad-based early intervention center- or classroom-based instruction, and computer-based approaches to educational intervention. Table 14 summarizes critical aspects of studies of educational interventions addressing key question KQ1, and Table 15 summarizes key outcomes of studies of good or fair quality.

Table 14. Overview of educational studies[a]

Characteristic	RCTs	nRCTs	Prospective cohort studies	Retrospective cohort studies	Prospective case series	Retrospective case series	Total Literature
	(n=3)	(n=1)	(n=5)	(n=1)	(n=3)	(n=2)	(n=15)
Intervention							
TEACCH	0	0	2	0	2	0	4
Broad-based approaches	1	1	3	1	1	1	8
Computer-based approaches	2	0	0	0	0	1	3
Diagnostic approach							
Clinical DSM-IV dx +ADI-R and/or ADOS	1	0	1	0	0	0	2
Combination approaches[b]	0	0	1	0	3	0	4
No DSM-IV or ADOS dx/ unspecified	2	1	3	1	0	2	9
Treatment duration							
≤1 month	1	0	0	0	0	0	1
>1 to ≤3 months	0	0	0	0	1	0	1
>3 to ≤6 months	0	0	0	0	0	1	1
>6 to ≤12 months	2	1	3	1	2	1	10
>12 months	0	0	2	0	0	0	2
Study population							
U.S.	2	0	0	0	1	1	4
Europe	0	1	4	1	2	1	9
Asia	0	0	1	0	0	0	1
Other	1	0	0	0	0	0	1
Total N participants	100	17	209	33	40	44	443

ADI-R=Autism Diagnostic Interview-Revised; ADOS=Autism Diagnostic Observation Schedule; DSM-IV=Diagnostic and Statistical Manual of Mental Disorders, 4th edition; dx=diagnosis; nRCT=non randomized controlled trial; RCT=randomized controlled trial; TEACCH= Treatment and Education of Autistic and Communication related handicapped CHildren
[a]Numbers in the table indicate the number of unique studies with each characteristic.
[b]Clinical DSM-IV dx +other diagnostic tool or ADOS + other diagnostic tool or only clinical DSM-IV dx or only ADOS.

TEACCH

Originally founded in the 1970s at the University of North Carolina at Chapel Hill, TEACCH involves primarily "structured teaching." Structured teaching refers to applying "structure" to the organization of time, space, and sequences of events within the educational environment to promote learning by making activities clearer and easier to perform. Instruction is based on the idea that individuals on the autism spectrum have specific neuropsychological profiles described by strengths regarding processing visual information (compared with language use/understanding), heighted attention to details, significant variability regarding attention, communication difficulties, difficulties with time, attachment to routines, intense interests and impulses, and marked sensory preferences and aversions.[184]

By applying physical structure, indicating sequences of events, organizing individual tasks, and work/systems within a classroom environment children with autism are thought to engage in more developmentally appropriate behaviors that ultimately promote learning. TEACCH approaches often include a heavy reliance on visual supports (e.g., picture schedule) and arranging the physical environment to support individual learning.

Content of the literature. We identified 15 studies evaluating educational interventions overall (Table 15).[185-200] Four of those studies[185-188] evaluated implementation of iterations of the TEACCH program. Among studies assessing TEACCH, one was good quality, one was fair, and two were poor.

Summary of the literature. Four studies assessed various outcomes associated with implementation of components of the TEACCH curriculum (Table 15). One prospective cohort study[187] evaluated the TEACCH program over 12 months for 18 children involved in a TEACCH classroom, with 16 receiving other types of individualized training (age range, 3-5 years). Evaluations of cognitive/developmental level, nonverbal intelligence, and adaptive behavior, were assessed using the Chinese version of the Psycho Educational Profile, The Merrill-Palmer Scale of Mental Tests, and the Hong Kong-Based Adaptive Behavioral Scales respectively at baseline, six months after initiation of treatment (Posttest 1), and again at 12 months (Posttest 2).

The intervention group demonstrated statistically significant improvement compared with the control group on the Chinese version of the Psycho Educational Profile Developmental Scale in perception, fine motor skills and gross motor skills ($p \leq 0.05$) after controlling for age, IQ, and pretest scores at Posttest 1. However, the control group showed more progress than the intervention group in the daily living domain and the Hong Kong-Based Adaptive Behavioral Scales sum of domains standard score ($p \leq 0.05$). Although significant improvements were see in the intervention group at 12 months for all scales and subscales in the Chinese version of the Psycho Educational Profile, Merrill-Palmer Scale of Mental Tests (total raw scores and mental age), and the Hong Kong-Based Adaptive Behavioral Scales the 12 month data are not provided for the control group.

The second prospective cohort study compared the effects of TEACCH in a residential center (n=11, mean age = 9.66 years), a specific school setting (n=13, mean age = 8.66 years), and included a comparison group in an inclusive mainstream classroom (n=10, mean age 9.09 years)[185] The main components of the TEACCH intervention groups included arranging the environment with visual aids, individualized communication systems, self-care skills training, and daily living skills related intervention. Cognitive/developmental level and adaptive behavior were evaluated for each participant twice with a 3-year interval between evaluations, using the Psycho Educational Profile and the VABS respectively. Both TEACCH groups showed significant improvement on adaptive measures, but the mainstream classroom group did not. The mainstream group improved significantly on the Psycho Educational Profile perception measure only; both TEACCH groups demonstrated cognitive improvements on the Psycho Educational Profile on a variety of additional subscales.

Two case series of TEACCH were identified, one focused on a psycho-educational training program for parents[188] and the other on teachers.[186] Both had poor quality scores on our assessment. Each included 10 children with ASDs. After the parent training, children improved on the Ankara Developmental Screening Inventory in total development score, language-cognitive subscale, social and self-care subscale, fine motor subscale, and gross motor subscale.

The teacher training program was targeted to slightly older children (mean age 10 years), and evaluated effectiveness with a study-designed tool (the Classroom Child Behavioral Symptoms questionnaire), which was completed by their teachers at baseline and post-treatment (nine months later). Scores decreased from a mean pretest score of 106.4 to a post-test score of 100.8, representing a medium range effect size (d = 0.66).

Broad-Based Educational Approaches

Classroom and center-based approaches include a blend of teaching strategies that rely on ABA principles and techniques including reinforcement-based procedures such as incidental teaching, discrete trial training, and pivotal response training. Other interventions, such as TEACCH and language development interventions may also be incorporated in center-based treatment.

Content of the literature. Eight papers evaluated a variety of broad-based educational strategies.[191-199] One study in this category was good, four were fair quality, and three were poor.

Summary of the literature. Several studies have investigated outcomes of children receiving specific or general instruction within early intervention centers or other classroom environment either within a specific curriculum or across multiple types of interventions (e.g., speech therapy, parent education, ABA instruction) (Table 15). A nonrandomized controlled trial[197] compared a developmentally based early intervention (N=12, mean age = 42.6 months) to no treatment (N=5, mean age = 37.7 months). The Scottish Centre for Autism developed an individualized treatment program for preschool aged children with ASDs focusing on social, communicative, play, and adaptive behaviors and included a parent training component focusing on behavior management and teaching new skills. After approximately 11 months of treatment, adaptive behavior scores (VABS for socialization, daily living skills, motor, and composite) improved significantly for the intervention group compared with controls. The intervention group also showed a statistically significant improvement in imitation scores on the Pre-Verbal Communication Schedule, as well as joint attention scores, and social interaction skills measured on the Early Social Communication Scales.

One prospective cohort study compared an early intensive, home-based intervention using discrete trial techniques (and Verbal Behavior) (N=28) to a nursery school-based eclectic intervention (based in autism-specific classrooms) (N=16), which included components of TEACCH, the Picture Exchange Communication System (PECS), and other developmental and behavioral teaching strategies.[195] The early intensive home-based intervention group and the nursery school-based intervention group had a mean age of 38 and 42.5 months, respectively. Nonverbal intelligence, cognitive ability, language skills, academic achievement/aptitude, and adaptive behavior were evaluated twice, with a 23-27 month interval between assessments.

No statistically significant differences were identified between the groups post-intervention on any of the measures, although both groups demonstrated improvement across measurements on average. A majority of the children demonstrating improvement had initial IQs above 70 and all but one were verbal at pre-treatment. Initial IQ and receptive language scores were correlated with progress over time.

Another prospective cohort study described outcomes for 65 children (ages 2.5–4 years at start of treatment) involved in broad-based eclectic teaching interventions and programs, often including reinforcement-based interventions, special nursery placements, speech and language therapy, and parent education programs. The authors compared groups (based on median split) of children receiving either[196] high/low intensity (less than 15.6 hours per week of intervention) intervention whose parents either reported high or low levels of stress. Children were assessed at baseline and then after 9-10 months, including assessments of developmental/cognitive and adaptive behavior. Children receiving more intervention time (high intensity) had greater improvements across all three measures compared with those with less intervention time. Parenting stress did not affect gains with low intensity interventions but reduced the gains made by those in higher time interventions.

A prospective cohort study[192] compared home-based tutor-led ABA teaching interventions (n=12) to two other teaching interventions, one of which was a school-based teaching program borrowing components from TEACCH with 6-8 children in each class (Special Nursery Placement) (n=20), and one (Portage) of which was a home-based, tutor-led program (n=16). The ABA intervention group received 1:1 interaction for two to three hours (including Lovaas, verbal behavior, and Comprehensive Application of Behavior Analysis to Schooling interventions). In the Special Nursery group, the children had several two to three hour sessions per week in a structured classroom (outlined by TEACCH methodology) with 6-8 other student and a teacher. In the portage group, a supervisor visited parents once every one to two weeks to demonstrate how to apply a system developed by a portage supervisor. Sessions were 40 to 60 minutes per day and scheduled when the parent believed the child would be at his or her most receptive. Children were taught new skills through the use of questions and tasks, prompts, and rewards.

The children were evaluated using multiple measures of symptom severity and intellectual functioning. Scores on measures related to intellectual functioning (the Psycho Educational Profile) in the ABA intervention group showed an overall gain of approximately 14 points, the nursery, approximately ten points, and little gain was shown in the portage group (~2 points). Authors documented cognitive, behavioral and adaptive behavioral skill improvements within each intervention group, but did not conduct direct comparisons between groups.

In a similar study comparing a one-to-one home based program (Parents of Autistic Children Training and Support), general special nursery placement, and ASDs-specific nursery placement and including children between 2 and 4 years old, participants in all groups showed marginal decreases in autistic severity and improved in educational functioning relative to baseline scores.[199] Children in the nursery groups also showed improvements in adaptive behavior.

Rickards et al.[194,198] investigated the addition of home-based intervention to a center-based educational program. The center-based program used training techniques like chaining, variety, repetition, sequencing, and a reward system to encourage learning through play, and used communication systems and behavior reinforcement. The home-based program included one of two specialist preschool teachers who visited each family weekly for one to one and a half hours for 12 months to discuss protocols developed at the centers, and develop new goals and strategies.

The home-based program also included parent training and adapting the home environment for the needs of the child. IQ improved by 1.6 points between baseline and Time 2 for the home plus center group and decreased by 4.3 for the center only group (p = .09). Preschool Behavior

Checklist scores decreased by 8.4 for the intervention group and decreased by 1.8 for the control group (p=0.054).

Fifty-four children were assessed 12 months after intervention ceased,[198]with children who had received the center and home based treatment maintaining cognitive gains compared with children receiving center-based intervention only (p=0.007). Behavioral improvements seen in the center+home based intervention group were not maintained a year later. Children from families experiencing greater parent-reported stress saw greater improvements in IQ at the 12-month followup than children from lower-stress families.

Case series[191,193] evaluating the effects of a variety of ABA-based methods used within a teaching context in center-based classrooms were consistent with group design studies, measuring improvements in social and communication behaviors.

Computer-Based Educational Approaches

Computer-based programs use technology to deliver behaviorally-based teaching in areas such as language acquisition and reading skills.

Content of the literature. We identified thee papers evaluating computer-based intervention programs delivered in school settings.[189,190,200] All studies in this section were poor quality.

Summary of the literature. Two randomized controlled trials[189,200] and one prospective case series[190] of computer-based academic interventions were included in this review. One randomized controlled trial compared a computer and teacher-led vocabulary acquisition program using behaviorally based teaching strategies like positive reinforcement,[189] with seven children ages 3 to 6 years in each group. The computer program paralleled the teacher led approach with the addition of features such as color, animation and music. Children recalled more nouns after exposure to the computer, program, (mean=4.43, 74 percent) compared with teacher presentation (mean= 2.43, 41 percent), ($p < .01$) and were more attentive to the computer than to the teacher (mean= 97 percent vs. 67 percent), $p<0.01$.

A randomized trial of the TeachTown: Basics computer aided instruction program included 47 children randomized by classroom to either TeachTown instruction or regular school day instruction. Children in the intervention group received computer-based instruction for approximately 20 minutes a day for three months. Scores on standardized measures were better overall for children in the TeachTown group, but differences were not statistically significant. Some language scores for preschool children (but not those in kindergarten or first grade) in the TeachTown group improved significantly over those of children in the control group (p=.036). The total amount of time spent using the software was also correlated with the total number of lessons mastered.

In the case series on the use of multimedia computer program using voice, animation, video and sign language for increasing literacy and language,[190] children also increased in verbal expressions (p=0.02), seeking help ($p<0.05$) and enjoyment ($p<0.05$) from pre to post intervention.

Table 15. Outcomes of studies assessing educational interventions

Author, year, country Groups, N enrollment/N final Study quality	Age, mean ± SD IQ, mean ± SD	Key outcomes
TEACCH		
Panerai et al.[185] 2009, Italy **G1:** TEACCH in a residential center, 11/11 **G2:** TEACCH at home and at mainstream schools, 13/13 **G3:** Inclusive education in mainstream schools, 10/10 Quality: Good	**G1:** 9.66 yrs ± 2.31 **G2:** 8.66 yrs ± 2.01 **G3:** 9.09 yrs ± 2.07 NR	• Significant difference in PEP-R analysis from baseline to post-intervention (G1, p=0.02, G2, p=0.022, G3: p=ns) and between-groups (G3 vs. G1 vs. G2: p=0.009, G3 vs. G2: p=0.001, G3 vs. G1: p=ns, G2 vs. G1: p=ns). • Significant difference in VABS analysis between outcome vs. baseline (G1: p=0.02, G2: p=0.02, G3: p=ns) but not between-groups (G3 vs. G1 vs. G2: p=n.s, G3 vs. G2: p=n.s, G3 vs. G1: p=ns, G2 vs. G1: p=ns).
Tsang [187] 2007, China **G1:** TEACCH curriculum (Chinese version), 18/18 **G2**: Non-TEACCH classroom setup and teaching, 18/16 (2 at 12-mo followup) Quality: Fair	**G1:** 4.063 yrs ± 0.529 **G2:** 4.050 yrs ± 0.734 NR	• G1 statistically significant improvement compared with G2 for CPEP-R Developmental Scale in perception (p≤0.05), Fine Motor (p≤0.01), and Gross Motor (p≤0.05) subsets (means adjusted after controlling for age, IQ, and pretest scores). • G2 showed more progress than G1 in the Daily living domain (p≤0.001) and the HKBABS sum of domains standard score (p≤0.05) (means adjusted after controlling for age, IQ, and pretest scores). Improvement differences over time in G1 were significant over 12 mo (pre-test, post-test 1, and post-test 2) for all scales and subscales in CPEP-R, Merrill-Palmer Scale of Mental Test (total raw scores and mental age), and the HKBABS (all indicators except overall sum of domain standard score) (range: p<0.05 to p<0.001).
Broad-based educational approaches		
Rickards et al.[194,198] 2007, Australia **G1:** Combined center-based and home based program, 30/30 **G2:** Center based program only, 29/29 Quality: Good	**G1:** 44.6 mo ± 6.1 **G2:** 43.1 mo ± 6.5 **G1:** 60.2 ± 20 **G2:** 60.6 ± 21.8	• IQ improved by 1.6 points between T1 and T2 for G1 and decreased by 4.3 for G2 (p= 0.09). • PBCL scores decreased by 8.4 for G1 and decreased by 1.8 for G2 (p=0.054). • NOTE: also includes children diagnosed with developmental and language delays.

Table 15. Outcomes of studies assessing educational interventions (continued)

Author, year, country Groups, N enrollment/N final Study quality	Age, mean ± SD IQ, mean ± SD	Key outcomes
Reed et al.[192] 2007, UK **G1:** ABA, 12/12 **G2:** Special Nursery based on TEACCH, 20/20 **G3**: Portage (visits to parents), 16/16 Quality: Fair	**G1:** 40 mo SD NR **G2:** 43 mo SD NR **G3:** 38 mo SD NR NR	• Gains in intellectual functioning: G1-overall gain of approximately 14 points, G2- approximately 10 points; little gain for G3 (~2 points). • Statistically significant gains in the sub-domains of the PEP-R for G1 in imitation (p<0.01), perception (p<0.01), gross motor (p<0.01), hand-eye (p<0.05), cognitive (p<0.01), and verbal (p<0.05). • Statistically significant gains in the sub-domains of the PEP-R for G2 in gross motor (p<0.01), cognitive (p<0.01), and verbal (p<0.01). • Statistically significant gains in the sub-domains of the BAS II for G1 in verbal comprehension (p<0.05), picture matching (p<0.01), naming (p<0.01), and early number skills (p<0.01). • Statistically significant gains in the sub-domains of the BAS II for G2 picture matching (p<0.01), naming (p<0.01), and early number skills (p<0.05). • Statistically significant gains in the sub-domains of the BAS II for G3 in picture matching (p<0.01). • In the sub-domains of the VABS for G2 in communication and socialization (p<0.05). • Statistically significant gains in the sub-domains of the VABS for G3 in communication (p<0.05).
Magiati et al.[195] 2007, UK **G1:** Home-based family intervention , 28/28 **G2:** Autism nursery with eclectic approach, 16/16 Quality: Fair	**G1:** 38 mo ± 7.2 **G2:** 42.5 mo ±7.8 **G1:** 83 ± 27.9 G**2:** 65.2 ± 26.9	• No statistically significant differences between the groups post-intervention.

ABA=applied behavior analysis; BASII=British Abilities Scale-2nd edition; BCBA=Board Certified Behavior Analyst; CABAS= Comprehensive Application of Behavior Analysis to Schooling; C-PEPR=Chinese version of the PsychoEducational Profile-Revised; EIBI=early intensive behavioral intervention; HKBABS=Hong Kong Based Adaptive Behavior Scales; IQ=intelligence quotient; M=mean; PBCL=Preschool Behavior Checklist; PEP-R=PsychoEducational Profile-Revised; TEACCH= Treatment and Education of Autistic and Communication related handicapped CHildren

KQ1. Effects of Treatment on Core and Commonly Associated Symptoms in Children With ASDs: Medical Interventions

Medical treatments for symptoms of ASDs comprise a variety of pharmacologic agents including antipsychotics, psychostimulants, and serotonin reuptake inhibitors (SRIs). Modalities such as therapeutic diets, supplements, hormonal supplements, immunoglobulin, hyperbaric oxygen, and chelating agents have been employed to treat ASDs symptoms. We identified a total of 42 studies of medical interventions, of which 27 were RCTs. Table 16 summarizes critical aspects of studies of medical and related interventions addressing KQ1.

Table 16. Overview of studies of medical interventions[a]

Characteristic	RCTs	nRCTs	Prospective cohort studies	Retrospective cohort studies	Prospective case series	Retrospective case series	Total Literature
	(n=27)	(n=0)	(n=0)	(n=0)	(n=9)	(n=6)	(n=42)
Intervention							
Antipsychotics	7	0	0	0	2	0	9
Serotonin Reuptake Inhibitors	2	0	0	0	1	2	5
Stimulants and other medications for hyperactivity	1	0	0	0	0	3	4
Secretin	7	0	0	0	1	0	8
Dietary and other	10	0	0	0	5	1	16
Diagnostic approach							
Clinical DSM-IV dx +ADI-R and/or ADOS	13	0	0	0	1	0	14
Combination approaches[b]	12	0	0	0	7	6	25
No DSM-IV or ADOS dx/ unspecified	2	0	0	0	1	0	3
Treatment duration							
≤1 month	5	0	0	0	1	0	6
>1 to ≤3 months	19	0	0	0	4	0	23
>3 to ≤6 months	3	0	0	0	1	0	4
>6 to ≤12 months	0	0	0	0	3	0	3
>12 months	0	0	0	0	0	4	4
Unknown	0	0	0	0	0	2	2
Study population							
U.S.	19	0	0	0	3	6	28
Europe	0	0	0	0	4	0	4
Asia	1	0	0	0	0	0	1
Other	7	0	0	0	2	0	9
Total N participants	1,623	0	0	0	325	655	2,603

ADI-R=Autism Diagnostic Interview-Revised; ADOS=Autism Diagnostic Observation Schedule; DSM-IV=Diagnostic and Statistical Manual of Mental Disorders, 4th edition; dx=diagnosis; nRCT=non randomized controlled trial; RCT=randomized controlled trial

[a]Numbers in the table indicate the number of unique studies with each characteristic.

[b]Clinical DSM-IV dx +other diagnostic tool or ADOS + other diagnostic tool or only clinical DSM-IV dx or only ADOS.

Antipsychotics

Recent clinical trials in children with ASDs have focused on the efficacy of a number of atypical antipsychotic medications for treating challenging behavior as well as other distressing symptoms. Risperidone was the first medication to receive US Food and Drug Administration (FDA) approval for the treatment of irritability in children ASDs. Aripiprazole also recently received FDA approval for irritability in children (6-17 years old) with autistic disorder.

Content of the literature. We identified 17 papers from nine studies that addressed the use of antipsychotic medications in children with autism spectrum disorders. Five of these studies evaluated the effects of risperidone,[201-207,208,209-214] two of aripiprazole,[215,216] and one of the addition of cyproheptadine to haloperidol.[217] Most participants were recruited from non-primary care populations; table 16 summarizes additional information about these studies.

The risperidone literature base includes four RCTs,[203,206,210-212] all comparing risperidone to placebo. Three of these RCTs were conducted in academic clinic settings using institutional and grant funding.[203,206,212] The pharmaceutical company that owned the patent for risperidone sponsored another RCT.[210,211] One prospective case series[214] reported on associations between adverse events and efficacy of risperidone and eight candidate genes.

The literature base on the effects of aripiprazole in children with ASDs includes two RCTs,[215,216] both conducted by the pharmaceutical company that owned the patent for aripiprazole. Each RCT compared aripiprazole to placebo in multiple study centers including both academic clinics and independent research centers.[215,216]

The literature base on the effects of cyproheptadine added to haloperidol includes one RCT.[217] This study compared haloperidol alone to haloperidol plus cyptoheptadine in an academic clinic setting.

A variety of outcomes are reported in the literature on antipsychotic effects in children with ASDs, but the literature converges on the Aberrant Behavior Checklist-Community Version (ABC-C), a rating scale completed by caregivers of individuals with ASDs. For the purposes of this review, we will emphasize specific domains of behavioral change because most studies with significant differences in overall ratings also showed significant improvements on more specific measures. Potential side effects or harms, including assessment of weight gain, somnolence, and GI symptoms, were also assessed by most of these studies.

The RCTs included a total of 322 participants in treatment arms, and 214 participants in comparison arms. Participants had an average age of 9.0 and 8.7 years, in the treatment and comparison groups, respectively, when excluding one study that did not provide average ages in each arm.[206] Both treatment and comparison groups had more male subjects (83.9 percent and 83.2 percent, respectively). Five of the studies included only participants with a DSM-IV diagnosis of Autistic Disorder;[203,206,215-217] whereas one included subjects with any pervasive development disorder (Autistic Disorder, PDD-NOS or Asperger Disorder).[211] Four of the studies used the ADI-R to corroborate diagnosis;[203,206,215,216] whereas one study used the Childhood Autism Rating Scale[211]and another study used DSM-IV criteria only.[217] Only three RCTs provided IQ data on subjects, with the majority of subjects with IQs in the intellectual disability range.[203,206,211]

Among the studies of antipsychotics, three were good quality, four were fair, and two were poor.

Summary of the Literature

Risperidone. Of the four RCTs of risperidone, two targeted challenging behavior as the primary outcome (Table 17).[206,211] The first study[201,202,204-209] was sponsored by the National Institute of Mental Health as part of the RUPP Autism Network. The second study was sponsored by the manufacturer of risperidone.[211]

These studies included a total of 89 subjects in risperidone arms and 91 subjects in placebo arms. Both studies used a graduated dose titration design over eight weeks, with an average risperidone dose ranging from 1.5-1.8 mg per day, with one study using primarily once daily dosing[211] and the other using twice daily dosing.[201,202,204-209] In these two studies, baseline ratings of irritability were similar across risperidone (ABC-C-Irritability 18.9-26.2) and placebo (ABC-

C-Irritability 21.2-25.5) arms. Decreases in ABC-C Irritability were significantly greater for the risperidone arms in both studies, which saw improvements of 12.1-14.9, compared with the placebo arms, which saw improvements of 3.6-6.5.

Similar improvements for a second measure of challenging behavior, the ABC-C Hyperactivity subscale, which indexes noncompliance as well as hyperactivity, were also seen in both trials. Baseline ratings of hyperactivity were similar, with decreases significantly greater for risperidone compared with placebo (14.8-14.9, in comparison to 4.7-7.4). The RUPP study also reported a number of other outcomes that may correlate with challenging behavior, including the Ritvo-Freeman Real Life Rating Scale Affectual Reactions subscale, which includes abrupt changes in mood, temper tantrums, and crying, the VABS Maladaptive Behavior Domain, and quantitative ratings of parent-rated target symptoms, each of which showed significant improvements in the risperidone group.[204,207]

Secondary outcomes in the two RCTs of risperidone included measures of repetitive behavior. Both studies included the ABC-C Stereotypy Subscale, which showed greater response in the risperidone arm. Baseline ratings of stereotypy were similar across risperidone and placebo arms. Decreases in ABC-C-Stereotypy were significantly greater for risperidone in one RCT (4.8 vs. 1.7)[206] but would not have been significant after correction for multiple testing in the other RCT (4.3 vs. 2.4).[211] One study[204,206] also used the Children's Yale-Brown Obsessive Compulsive Scale-PDD version to assess repetitive behavior, finding no baseline differences between the groups but a significantly greater decrease in the risperidone compared with placebo arms (3.9 vs. 1.0). A number of other outcomes were measured in these studies, but none outside of challenging behavior and repetitive behavior would have yielded statistically significant findings once corrected for multiple comparisons.

Two additional RCTs were identified that did not provide specific numerical ratings on either challenging behavior or repetitive behavior.[203,212] One of these was an eight-week drug discontinuation RCT with risperidone and placebo arms[203] after positive response during four months of open label risperidone treatment following the RUPP risperidone RCT.[206] This publication did not provide quantitative outcome data but instead indexed "relapse" using a composite measure of ABC-C-Irritability and clinician ratings of CGI-I,[203] finding significantly less "relapse" in the risperidone arm (two of 16 subjects) in comparison to the placebo arm (10 of 16 subjects).

The last RCT was a six-month RCT with risperidone and placebo arms that used a variety of general rating scales to assess response and provided quantitative outcome data on only some of these scales,[212] with the primary outcome measures being parent ratings on the Childhood Autism Rating Scale and clinician ratings on the Children's Global Assessment Scale. The study only reports Childhood Autism Rating Scale median ratings for those participants with at least a 20 percent response.[212] Average ratings on the Children's Global Assessment Scale were similar in the risperidone (29.8) and placebo (32.7) arms with more improvement in the risperidone (11.1) than placebo (2.5) arms.

All of the risperidone RCTs also provided data on adverse events or side effects (Table 19). All studies reported on weight gain,[202,203,206,210-212] which was greater in the risperidone arms (2.7-2.8 kg) than in the placebo arms (0.8-1.7 kg), with a statistically significant difference reported in two of the studies.[202,206,210,211] Three of the RCTs[202,203,206,210,211] provided data on other adverse events in both the risperidone and placebo arms. Somnolence or drowsiness was the most common adverse event in two of these studies, occurring in 53 of 89 subjects in risperidone arms and nine of 91 subjects in placebo arms.[202,206,210,211] These studies also reported that this somnolence improved over time.[202,206,210,211] Both these studies also reported more extrapyramidal symptoms, including tremor, dyskinesia, and rigidity, in the risperidone arm in comparison with the placebo arm, but these events were categorized and summed differently between the two studies and did not clearly show a statistically significant difference between treatment arms.[202,206,210,211]

The RUPP study[206] also reported a greater rise in prolactin levels in the risperidone arm (27.7 ng/mL) compared with the placebo arm (0.8 ng/mL);[209] although it did not report clinical events such as gynecomastia or galactorrhea that could be related to elevated prolactin levels.[203,206] The RUPP study specifically assessed cognitive function in a subset of subjects and found no worsening and some evidence of improvement on risperidone that would not be statistically significant after correction for multiple testing.[201,206]

Table 17. Outcomes of RCTs of antipsychotic medications for challenging and repetitive behaviors

Author, year, country Groups, N enrollment / N final Study quality	Mean age, years ± SD	Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores[a], mean ± SD
RUPP[203] 2005, US **G1**:risperidone, 16/16 **G2**:placebo, 16/16 Quality: Fair	NR, subset of subjects from RUPP 2002	NR, subset of subjects from RUPP 2002	Overall, ABC-C-Irritability: 27.6 ± 6.1 Overall, ABC-C-Hyperactivity/ Noncompliance: 34.4 ± 8.7 Relapse: 2 consecutive weeks of 25% increase on ABC-C-Irritability and CGI-I of “much worse” or “very much worse”	Relapse: **G1:** 2/16 (12.5%) **G2:** 10/16 (62.5%) p=0.01
Shea, et al.[210,211] 2004, Canada **G1:** risperidone, 41/39 **G2:** placebo, 39/38 Quality: Fair	**G1:** 7.6 ± 2.3 **G2:** 7.3 ± 2.3	**G1:** ≥85:3 71-84:6 50-70:12 35-49:10 **G2:** ≥85:11 71-84:4 50-70:8 35-49:12	ABC-C-Irritability: **G1:** 18.9 ± 8.8 **G2:** 21.2 ± 9.7 ABC-C-Hyperactivity/ Noncompliance: **G1:** 27.3 ± 9.7 **G2:** 30.9 ± 8.8 ABC-Stereotypic behavior: **G1:** 7.9 ± 5.0 **G2:** 8.1 ± 5.6	Change in: ABC-C-Irritability: **G1:** -12.1 ± 5.8 **G2:** -6.5 ± 8.4 p ≤ 0.001 ABC-C-Hyperactivity/ Noncompliance: **G1:** -14.9 ± 6.7 **G2:** 7.4 ± 9.7 p ≤ 0.001 ABC-Stereotypic behavior: **G1:** -4.3 ± 3.8 **G2:** -2.4 ± 4.0 p ≤ 0.05

Table 17. Outcomes of RCTs of antipsychotic medications for challenging and repetitive behaviors (continued)

Author, year, country Groups, N enrollment / N final Study quality	Mean age, years ± SD	Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores[a], mean ± SD
RUPP[201,202,204-209] 2002, US **G1**:risperidone, 49/49 **G2**:placebo, 52/52 Quality: Good	Overall 8.8 ± 2.7	Overall, N(%) ≥Avg: 3 (7) Borderline: 8 (17) Mild or moderate retardation: 20 (43) Severe retardation: 15 (33)	ABC-C-Irritability: **G1:** 26.2 ± 7.9 **G2:** 25.5 ± 6.6 ABC-C-Hyperactivity/ Noncompliance: **G1:** 31.8 ± 9.6 **G2:** 32.3 ± 8.5 ABC-Stereotypic behavior: **G1:**10.6 ± 4.9 **G2:** 9.0 ± 4.4 CYBOCS: **G1:** 15.51 ± 2.73 **G2:** 15.18 ± 3.88	ABC-C-Irritability: **G1:** 11.3 ± 7.4 **G2:** 21.9 ± 9.5 p<0.001 ABC-C-Hyperactivity/ Noncompliance: **G1:** 17.0 ± 9.7 **G2:** 27.6 ± 10.6 p<0.001 ABC-Stereotypic behavior: **G1:** 5.8 ± 4.6 **G2**: 7.3 ± 4.8 p<0.001 CYBOCS: **G1:** 11.65 ± 4.02 **G2:** 14.21 ± 4.81 p<0.005
Marcus et al.[215] 2009, US **G1**: aripiprazole 5 mg, 53/44 **G2**:aripiprazole 10 mg, 59/49 **G3**:aripiprazole 15, 54/47 **G4**:placebo, 52/38 Quality: Good	**G1:** 9 ± 2.8 **G2:** 10±3.2 **G3:** 9.5±3.1 **G4:** 10.2±3.1	NR	ABC-C-Irritability: **G1:** 28.6 ± 7.6 **G2:** 28.2 ± 7.4 **G3**: 28.9 ± 6.4 **G4:** 28 ± 6.9 ABC-C-Hyperactivity/ Noncompliance: **G1:** 33.1 ± 1.4 **G2:** 33.7 ± 1.3 **G3:** 32.2 ± 1.4 **G4:** 31.0 ± 1.4 ABC-C-Stereotypic: **G1:** 11.4 ± 0.8 **G2:** 11.6 ± 0.8 **G3:** 11.6 ± 0.8 **G4:** 10.7 ± 0.8 CYBOCS: **G1:** 13.9 ± 0.6 **G2**: 13.5 ± 0.5 **G3:** 14.1 ± 0.5 **G4:** 13.7 ± 0.6	Change in: ABC-Irritability **G1**:-12.4 **G2:** -13.2 **G3:** -14.4**G4:** -8.4 **G1 v G4:** p=0.032 **G2 v G4:** p=0.008 **G3 v G4:** p=0.001 ABC-C-Hyperactivity/ Noncompliance: **G1:** -14.0 ± 1.6 **G2:** -13.3 ± 1.5 **G3:** -16.3 ± 1.6 **G4:** -7.7 ± 1.7 **G1 v G4:** p≤0.005 **G2 v G4:** p≤0.05 **G3 v G4:** p≤0.001 ABC-C-Stereotypic **G1:** -4.5 ± 0.68 **G2:** -4.2 ± 0.63 **G3:** -4.5 ± 0.66 **G4:** -1.8 ± 0.69 **G1 v G4:** p≤0.005 **G2 v G4:** p≤0.05 **G3 v G4:** p≤0.005 CYBOCS: **G1:** -2.6 ± 0.5 **G2:** -2.4 ± 0.4 **G3:** -3.2 ± 0.5 **G4:** -1.7 ± 0.5 G1 v G4:p NS G2 v G4: p NS G3 v G4:p≤ 0.05

Table 17. Outcomes of RCTs of antipsychotic medications for challenging and repetitive behaviors (continued)

Author, year, country Groups, N enrollment / N final Study quality	Mean age, years ± SD	Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores[a], mean ± SD
Owen et al.[216] 2009, US **G1**: aripiprazole, 47/39 **G2**: placebo, 51/36 Quality: Good	**G1:** 9.7 ± 3.2 **G2:** 8.8 ± 2.6	NR	ABC-C-Irritability: **G1:** 29.6 ± 6.4 **G2:** 30.2 ± 6.5 ABC-C-Hyperactivity/ Noncompliance: **G1:** 34.1 **G2:** 34.7 ABC-C-Stereotypic: **G1:** 11.9 **G2:** 10.7 CYBOCS: **G1:** 12.8 **G2:** 13.7	Change in: ABC-Irritability (change): **G1:** -12.9 **G2:** -5.0 P< 0.001 ABC-C-Hyperactivity/ Noncompliance (change): **G1:** -12.7 **G2:** -2.8 P< 0.001 ABC-C-Stereotypic (change): **G1:** -4.8 **G2:** -2.0 p< 0.001 CYBOCS (change): **G1:** -3.8 **G2:** -0.8 p< 0.001 CYBOCS (change): **G1:** -3.8 **G2:** -0.8 p< 0.001

[a]Decrease in scores on outcome measures indicates improvement in behavior assessed. ABC-C=Aberrant Behavior Checklist-Community Version; CGI-I=Clinical Global Impression-Irritability; CYBOCS=Children's Yale-Brown Obsessive Compulsive Scale; NR=not reported; RUPP=Research Units on Pediatric Psychopharmacology

Case series data, including that from the risperidone arm and open label extension of the RUPP RCT,[203] indicated results consistent with the risperidone arms of the RCTs.[177,203,206,208,214]

Aripiprazole. We identified two eight-week randomized, controlled trials of aripiprazole in children with ASDs (Table 17).[215,216] The manufacturer of aripiprazole sponsored both studies. The primary outcome for these studies was challenging behavior indexed by the ABC-C Irritability subscale. These studies included a total of 213 subjects in aripiprazole arms and 103 subjects in placebo arms within the intent to treat analyses.

One study used a fixed dose design with one placebo arm and three arms corresponding to 5, 10, and 15 mg per day of aripiprazole,[215] with all subjects beginning at two mg per day with forced titration weekly to the next dose until they reached their goal dose. The other study used a dose titration schedule with weekly progression from 2 mg to 5 mg, 10 mg, and 15 mg per day following clinical judgment.[216] In these two studies, baseline ratings of irritability were similar across aripiprazole (ABC-C-I 28.2-29.6) and placebo (ABC-C-Irritability 28.0-30.8) arms. Decreases in ABC-C Irritability were significantly greater for the aripiprazole arms in both studies, with improvements of 12.4-14.4, in comparison to the placebo arms, with improvements of 5.0-8.4. The trial with differing set doses of aripiprazole demonstrated increasing response with increasing dose.[215] Overall, the results of the trial that used titration following clinical judgment were more pronounced.[216]

Additional assessments of challenging behavior were also performed in these two aripiprazole RCTs. Similar improvements for a second measure of challenging behavior, the ABC-C Hyperactivity subscale, which indexes noncompliance as well as hyperactivity, were also seen across both trials. Baseline ratings of hyperactivity were similar across aripiprazole and placebo arms. Decreases in ABC-C-Hyperactivity were significantly greater for aripiprazole in which improvements of 12.7-16.3 were seen, in comparison to the placebo arms, with improvements of 2.8-7.7. The ABC-C Inappropriate Speech subscale also showed significant improvement in one study216 with a supportive trend in the other.[215]

Secondary outcomes in the two major RCTs of aripiprazole included measures of repetitive behavior.218 Both studies included the ABC-C Stereotypy Subscale, which showed significantly greater response in the aripiprazole arms. Baseline ratings of stereotypy were similar across aripiprazole and placebo arms. Decreases in ABC-C-Stereotypy were greater for aripiprazole, with improvements of 4.2-4.8, in comparison to placebo arms, with improvements of 1.8-2.0. Both studies also used the Children's Yale-Brown Obsessive Compulsive Scale-PDD version to assess repetitive behavior, finding no baseline differences between the groups but a greater decrease in the aripiprazole compared with placebo arms (2.4-3.8 vs. 0.8-1.7). A number of other outcomes were measured in these two studies, but none outside of challenging behavior and repetitive behavior yielded statistically significant findings once corrected for multiple comparisons.

The two aripiprazole RCTs also provided data on harms (Table 19). Both studies reported on weight gain,215, 216 which was greater in the aripiprazole arms (1.3-2.0 kg) than in the placebo arms (0.3-0.8 kg), with a statistically significant difference reported in both of the studies.[215,216] Somnolence and sedation were the most common adverse events in both of these studies, occurring in 66 of 210 subjects in aripiprazole arms and eight of 101 subjects in placebo arms.[215,216] Both studies also reported more extrapyramidal symptoms, including tremor, dyskinesia, and rigidity, occurring in 44 of 210 subjects in the aripiprazole arms in comparison with ten of 210 subjects in the placebo arms.[215,216] Both studies found a statistically significant decrease in prolactin levels in the aripiprazole arms in contrast with the placebo arms.[215,216]

Cyproheptadine plus haloperidol. One eight-week RCT compared addition of cyproheptadine versus placebo to haloperidol.[217] Each arm contained 20 subjects.[217] The medication doses were titrated up from some starting point to cyproheptadine 0.05 mg/kg/day and haloperidol 0.2 mg/kg/day, but no details are provided. Two general outcome measures were used, the ABC-C and the Childhood Autism Rating Scale. Each measure was apparently translated into Farsi, although no details were provided on validation of the translated versions, nor is it clear whether parents completed paper and pencil versions of these measures or were interviewed. Baseline scores on measures were only presented in graphs.

The ABC-C scores shown are markedly lower than the total ABC-C scores obtained at baseline in other medication trials,[206,211,215,216] suggesting that a subscale may have been administered; although this is not stated.[217] The response to placebo plus haloperidol was smaller[217] than the response found in previous haloperidol trials.[39,219] The improvement in ABC-C score in the cyproheptadine plus haloperidol arm was larger (10.9) than the improvement in the placebo plus haloperidol arm (3.7).[217] Similarly, the improvement in Childhood Autism Rating Scale score was greater in the cyproheptadine plus haloperidol arm (1.85) than in the placebo plus haloperidol arm (0.37).

Serotonin Reuptake Inhibitors

SRIs have come into wide use for the treatment of depression and anxiety and are some of the most commonly prescribed medications for children with ASDs.[41-43] Most recent clinical trials in children with ASDs have focused on their potential to decrease repetitive behaviors.[49]

Content of the literature. We identified five studies that addressed the use of serotonin reuptake inhibitor medications in children with autism spectrum disorders; table 17 includes additional details. Two of these studies evaluate the effects of fluoxetine,[220,221] one of citalopram,[222] one of escitalopram,[223] and one of a variety of SRIs.[224]

The literature base on the effects of fluoxetine in children with ASDs included one retrospective case series[221] and one randomized, controlled, cross-over trial of fluoxetine compared with placebo. Both of these studies were conducted in academic clinic settings using institutional or grant funding.[220] The single study on the effects of citalopram in children with ASDs was a randomized, controlled trial conducted in multiple academic centers using institutional and grant funding.[222] The single study on the effects of escitalopram in children with ASDs was a prospective case series[223] that analyzed outcome by serotonin transporter genotype, and is therefore discussed in detail in the Modifiers of Treatment Effectiveness (KQ 2) section of the report. One retrospective case series[224] reported on a number of SRIs.

The two RCTs included a total of 112 participants in treatment arms, and 115 participants in comparison arms. Participants had an average age of 8.8 and 9.1, in the treatment and comparison groups, respectively.[220,222] Both treatment and comparison groups had more male subjects (83.7 percent and 81.7 percent, respectively). Both of the studies included subjects with any pervasive development disorder (Autistic Disorder, PDD-NOS, or Asperger Disorder) and used either the ADI-R[222] or the ADI-R and the ADOS for corroboration.[220]

One of the RCTs had a minority of subjects with intellectual disability,[222] and the other had an average IQ in the intellectual disability range.[220] The three case series included 276 subjects with any diagnosis of PDD.[221,223,224] One study used ADI-R to corroborate DSM-IV diagnosis,[223] one used CARS plus ADOS,[221] and one used DSM-IV only.[224] Among the case series subjects, the average age was 6.9 years old and 87.1 percent were male. Only one case series provided IQ measures on subjects[223] and had average verbal and nonverbal IQ in the borderline to low average range (76 and 86, respectively). Among all studies of SRIs, one was good quality, two were fair, and two were poor.

Summary of the literature. We review citalopram and escitalopram together because escitalopram is the active component (enantiomer) of citalopram. One 12-week randomized, controlled trial of citalopram was identified.[222] This trial focused on repetitive behavior outcomes with a number of secondary outcomes also measured.

The entry criteria for the study were a PDD diagnosis corroborated by both ADI-R and ADOS, moderate illness severity on the CGI-Severity and significant repetitive behavior on the Children's Yale-Brown Obsessive Compulsive Scale-PDD version.[222] It had 73 subjects in the citalopram arm and 76 in the placebo arm.[222] Subjects were begun on 2.5 mg of citalopram daily with weekly increases of 2.5 mg per day for the first five to six weeks as clinically indicated, followed by weekly increases of up to five mg per day thereafter, up to a maximum dose of 20 mg per day.[222] This dose is lower than the equivalent daily dose of SRIs used in obsessive compulsive disorder in previous studies,[225,226] but it is similar to dosing used in an earlier case series in autism.[227]

No significant difference between citalopram and placebo arms was seen in measures of repetitive behavior, with similar baseline scores on the Children's Yale-Brown Obsessive Compulsive Scale-PDD version (15.1 vs. 15.0) and similar improvements (2.0 vs. 1.9) in each arm. The other measures of repetitive behavior, including the Repetitive Behavior Scale-Revised, also showed similar baseline scores and similar improvements in each arm with no evidence for an effect of citalopram (Table 18).[222] The CGI-Improvement similarly showed no significant difference between the citalopram and the placebo arm. On the other hand, the primary measure of challenging behavior reported in this trial, the ABC-C Irritability subscale, showed an advantage for citalopram.

The baseline ratings were not statistically different between the citalopram and placebo arms (13.2 and 11.2, respectively), but more improvement was seen for citalopram (3.2) than for placebo (0.9).[222] Adverse effects in this study included a marked increase in what were termed "activation" symptoms, including increased energy, hyperactivity, inattention, disinhibition, and decreased sleep in the citalopram arm in comparison to the placebo arm.[222] Diarrhea and dry or itchy skin were also more common in the citalopram arm.[222]

Table 18. Outcomes of studies of SRIs for the treatment of repetitive and challenging behaviors in ASDs

Author, year, country Study quality	Groups, N enrollment/N final	Mean age, years ± SD	Mean IQ ± SD	Outcome measure/Baseline scores, mean ± SD	Outcome measure/Post-treatment scores[a], mean ± SD
King et al.[222] 2009, US Quality: Good	**G1**:citalopram hydrobromide, 73/60 **G2**:placebo, 76/63	**G1**: 9.1 ± 3.2 **G2**: 9.6 ± 3.1	**G1**: >70, N (%): 43(61.4) **G2**: >70, N (%): 43(60.6)	CYBOCS-PDD: **G1**:15.1 ± 1.8 **G2**: 15 ± 2.1	CYBOCS-PDD: **G1**: 13.1 ± 3.7 **G2**: 13.1 ± 3.2
Hollander et al.[220] 2005, US Quality: Fair	**G1a**:placebo /fluoxetine, placebo segment 45(total)/20	7.35 SD - NR	68.1 ± 26.7	CYBOCS: Wk 0: 13.5 ± 2.9	CYBOCS: Wk 8: 13.0 ± 3.2
	G1b:placebo/ fluoxetine, fluoxetine segment 45(total)/20	7.35	68.1 ± 26.7	CYBOCS: Wk 12: 12.9 ± 3.5	CYBOCS: Wk 20: 11.8 ± 3.2 P<0.05 for repeated measures cross-over comparison of G1b to G1a and G2a to G2b
	G2a:fluoxetine/placebo, fluoxetine segment 45(total)/19	9.1±3.7	59.2 ± 29.1	CYBOCS: Wk 0: 12.8 ± 2.6	CYBOCS: Wk 8: 11.6 ± 3.8 P>0.05 for parallel group comparison of G2a to G1a
	G2a:fluoxetine/placebo, placebo segment 45(total)/19	9.1±3.7	59.2 ± 29.1	CYBOCS: Wk 12: 12.2 ± 3.5	CYBOCS: Wk 20: 12.4 ± 2.4

[a]Decrease in scores on outcome measure indicates improvement in behavior assessed. ABC-C=Aberrant Behavior Checklist-Community Version; CYBOCS=Children's Yale-Brown Obsessive Compulsive Scale; CYBOCS-PDD=Children's Yale-Brown Obsessive Compulsive Scale-Pervasive Development Disorders

One prospective case series of escitalopram was identified.[223] This ten-week study sought to identify pharmacogenetic modifiers of treatment response in the challenging behavior domain as measured by the ABC-C-Irritability. Fifty-eight subjects with a PDD corroborated by ADI-R and a minimum ABC-C-I score of 12 underwent a forced dose titration of escitalopram from 2.5 mg daily increasing weekly to 5 mg, 10 mg, 15 mg, and 20 mg, essentially twice the dose equivalent of citalopram given that escitalopram is the active component of racemic citalopram. Pre-designated dose-limiting side effects included sleep disruption and an increase in ABC-C Irritability or Hyperactivity subscales of ten points over the previous week. Average daily doses of escitalopram were 10.8-12.4 mg and did not differ across genotype groups, which reflects the fact that most subjects in all genotype groups could not tolerate the maximum dose. Unfortunately, the data are presented in figures only, and raw values cannot be inferred. It is evident, however, that the ABC-C-Irritability for all subjects was 20 or greater at baseline and that improvements were about ten points for three of the four genotype groups.[223] Adverse effects were not directly assessed in this study.

One randomized, controlled crossover trial of fluoxetine was identified with two eight-week treatment periods separated by a four-week washout period.[220] Thirty-nine subjects with a PDD corroborated with ADI-R and ADOS were included in the final analysis with no minimum required score on a repetitive behavior scale. Five additional subjects were randomized but not included in the analysis for various reasons. Of the randomized subjects, 19 received fluoxetine followed by placebo and 20 received placebo followed by fluoxetine. During each phase of the study, subjects began the first week at 2.5 mg per day of fluoxetine or placebo, followed as clinically indicated by weekly upward titration to 0.3 mg/kg for week 2, 0.5 mg/kg/day for week 3, and 0.8 mg/kg/day for weeks four to eight. During the first eight-week treatment period of the study, subjects randomized to fluoxetine first had baseline Children's Yale-Brown Obsessive Compulsive Scale scores of 12.8 and those to placebo first had baseline scores of 13.5.

Subjects in the first fluoxetine group showed an improvement of 1.2, and those in the first placebo arm showed an improvement of 0.5. These differences were not statistically significant when considered alone. In the second eight-week treatment period, subjects randomized to fluoxetine second had baseline Children's Yale-Brown Obsessive Compulsive Scale scores of 12.8 and those to placebo second had baseline scores of 12.2. Subjects in the second fluoxetine arm showed an improvement of 1.2, and those in the second placebo arm showed a worsening of 0.1. When analyzed together with the first treatment period in a repeated measures design, the Children's Yale-Brown Obsessive Compulsive Scale change in the fluoxetine arms was significantly greater than the change in the placebo arms. No adverse events were significantly more frequent in the fluoxetine group; although more subjects on fluoxetine had their dose reduced due to agitation.[220] The two chart reviews of SRIs [221,224] reported in the literature were of poor quality and included general outcome measures that are difficult to compare with the RCT data.

Table 19. Harms frequently reported in studies of medical interventions[a]

Range % subjects with adverse event (number of studies)	Placebo	Risperidone	Aripiprazole	SRIs	Psycho-stimulants
Abdominal pain	1.5-18 (5)	1.6-20 (4)	4.2 (1)	1.1-17.8 (2)	12.0 (1)
Constipation	2.6-12 (2)	3.2-31.5 (5)	NR	3.4 (1)	NR
Diarrhea	6.1-22 (5)	1.6-33.1 (3)	8.5 (1)	4.5-26.0 (3)	4.6 (1)
Appetite changes/weight gain	3.0-25 (6)	7.9-89.5 (7)	12.1-14.9 (2)	3.4-24.7 (3)	24.2 (1)
Nausea/vomiting	3.0- 24 (6)	4.8-42.7 (4)	13.3-14.9 (2)	19.2 (1)	NR
Fatigue	0-27 (6)	1.6-75 (4)	15.2-21.3 (2)	13.7-17.9 (2)	6.1 (1)
Insomnia	1.5-47.2 (5)	4.8-37.9 (4)	6.4 (1)	12.4-38.4 (3)	18.2 (1)
Somnolence/sedation/ drowsiness	3.9-12 (4)	3.2-72.5 (7)	17.0-23.6 (2)	NR	NR
Urinary symptoms	2.0-29 (4)	3.2-38.7 (4)	2.4-6.4 (2)	10.3 (1)	NR
Rash or other skin changes	2.0-14 (3)	4.8-29.0 (3)	2.4 (1)	28.7 (1)	NR
Headache	0-16.0 (6)	3.2-34.7 (4)	6.4-7.9 (2)	1.1-20.5 (2)	6.0 (1)
Fever/pyrexia	0-17.9 (3)	4.8-21.0 (3)	8.5-9.1 (2)	NR	NR
Cold/flu/respiratory infection/cough/nasal congestion	3.9-39 (5)	6.3-79.8 (5)	6.4-9.7 (2)	42.5 (1)	NR
Cardiac changes	0-6.1 (3)	12-14.5 (3)	NR	NR	4.6 (1)
Extrapyramidal symptoms	0-12.8 (5)	1.6-27.5 (6)	10.3-14.9 (2)	1.1 (1)	NR
Mood changes (irritability, outbursts, agitation)	3.0-44.0 (4)	1.6 (1)	NR	24.7-46.2 (3)	13.6 (1)
Anxiety/nervousness	3.0-33.3 (4)	4.8-29.0 (4)	NR	1.1-15.9 (3)	8.0 (1)
Self injury or suicide ideation	2.8-6.0 (2)	NR	2.1 (1)	NR	6.0 (1)
Withdrawal from study due to adverse event	2.5-9.2 (4)	1.6-22.6 (4)	10.2-10.6 (2)	12.3-19.0 (2)	18.1 (1)

[a]Includes interventions for which there was more than one study; NR=not reported, SRI=serotonin reuptake inhibitor

Stimulants and Other Medications To Treat Hyperactivity

Psychostimulants treat hyperactivity and inattention in patients diagnosed with attention deficit hyperactivity disorder (ADHD) and include agents such as methylphenidate (MPH), amphetamine, and dextroamphetamine. Other medications studied for the treatment of ADHD have also been studied for the treatment of hyperactivity in ASDs.[50-54]

Content of the literature. We identified six publications[228-233] from four studies that addressed stimulant and other medications to treat hyperactivity; table 17 summarizes study information.

Most participants were recruited from centers in the RUPP network.[228-230] Studies assessed the use of MPH in children with PDD-NOS and hyperactivity;[228-230] psychostimulants;[231,233] and guanfacine to target hyperactivity, inattention, and impulsivity in children with PDD.[232] Among all studies of these medications, one was good quality and three were poor.

Summary of the literature. The RUPP Autism Network's double-blind cross-over trial[228-230] of MPH included 72 children with autism, PDD-NOS or Asperger disorder who received a one-day placebo followed by two days at each of three (low, medium, high) test doses of MPH; doses ranged from 7.5 mg/day to 50.0 mg/day. Subjects tolerating MPH (n=66) moved on to a 4 week, double-blind crossover phase. Subjects with a positive response in the double blind phase (n=34) completed an eight week open label continuation phase at their best dose. The primary outcome measure was hyperactivity as assessed by the ABC-C teacher-rated hyperactivity subscale; secondary measures included the ABC-C parent-rated hyperactivity subscale. Blinded clinicians also assessed participants using the CGI-Irritability scale; this subscale and the ABC parent and teacher rated hyperactivity subscales were combined to assess response.

In the double-blind crossover phase, all MPH doses demonstrated effects that were statistically superior to placebo, and effect sizes favored the medium dose for parent ratings and high dose for teacher ratings. Parent-rated lethargy/ social withdrawal significantly worsened during the high dose of MPH compared with placebo. Significant improvement in parent-rated stereotypy and inappropriate speech were seen at the medium dose of MPH compared with placebo. Hyperactivity/impulsivity also improved more with the medium and high MPH doses than at the low dose (Table 20).

Significantly more joint attention behaviors as measured on the Joint Attention from the Early Social Communication Scales in the intervention group were reported both with the best MPH dose and with the low dose compared with placebo. There was improved self-regulation, as assessed in a "competing demands" task in low dose as well as in medium dose MPH compared with placebo. A significant increase in neutral affect was also found for the medium and high dose, which could be either beneficial, in the case of children with a labile mood, or damaging, in the case of children with flattened affect due to a medication side effect. Irritability was the most frequent reason for discontinuation (18 percent) of treatment.

Table 20. Outcomes of studies of stimulants for the treatment of hyperactivity in ASDs

Author, year, country Groups, N enrollment / N final Study quality	Mean age, years ± SD	Mean IQ ± SD	Outcome measure/ Baseline scores, mean ± SD	Outcome measure/Post-treatment scores[a], mean ± SD
RUPP,[228] Posey et al.[229]& Jahromi et al.[230] 2005, 2007, & 2009, US Total N=66 **G1:** low dose MPH (n=45) **G2:** medium dose MPH (n=52) **G3**: high dose MPH (n=33) **G4**: optimal dose MPH (n=58) **G5:** placebo (n=46) Quality: Good	7.5 ± 2.2	Slosson IQ: 62.6 ± 32.9	Teacher ABC-Hyperactivity: 30.9 ± 7.9	**G1:** 22.9 ± 12.8, p=0.03 **G2:** 23.6 ± 12.5, p=0.008 **G3:** 20.3 ± 11.9, p=0.002 **G4:** 20.1 ± 12.4, p<0.001 **G5:** 26.0 ± 11.7

[a]Decrease in scores indicates improvement in outcome assessed. ABC=Aberrant Behavior Checklist; IQ=intelligence quotient; MPH=methylphenidate; RUPP=Research Units on Pediatric Psychopharmacology

Three chart reviews assessed guanfacine and psychostimulant use in children with ASDs, all of which were poor in quality and provided conflicting results on the effectiveness of stimulants for hyperactivity in children with ASDs.[231-233]. The three chart reviews had a longer duration of followup visits: 7 days to 4.8 years,[232] 1 day to10 years,[233] 4 ± 3.9 years,[231] while the RCT followed patients for 8 weeks.[228-230]

Secretin

Interest in secretin for the treatment of ASDs symptoms stemmed from an unblinded, uncontrolled cases series of three children that reported social, cognitive and communicative gains in recipients after the first infusion and after a second infusion given weeks later.[59] Multiple studies conducted after the initial case series have evaluated secretin's utility in treating autistic symptoms, employing single or multiple doses of synthetic human or porcine secretin.

Content of the literature. We identified eight publications[234-241] addressing secretin use in eight unique populations; table 17 summarizes additional study information. Among studies of secretin, two were good quality, five were fair, and one was poor.

Summary of the literature. Of the eight studies evaluating the impact of secretin in the treatment of ASDs, one[238] was a repeated dose intervention study. Two studies used synthetic human secretin,[234,235] three used porcine secretin,[237,239,240] and one biologic secretin.[236] All were randomized controlled trials except one open label trial of secretin (type unknown) with a prospective case series study design;[241] all of the studies evaluated only short-term outcomes with followup periods ranging from 3 to 12 weeks.

No studies showed significantly greater improvements in measures of language, cognition or autistic symptoms when compared with placebo; in those studies that demonstrated improvement over time, they did so equally in both intervention and placebo groups. There also was no benefit by type of secretin (porcine or synthetic).

Dietary and Other Medical Interventions

Additional studies in the medical literature addressed the use of dietary interventions (including special diets) as well as medical therapies for sleep and gastrointestinal dysfunction, hyperbaric oxygen, and other agents.

Content of the literature-dietary interventions. We identified eight studies conducted in the clinic setting that addressed the use of various oral dietary supplements to treat ASDs in children, including ages ranging from one to 18 years; interventions included iron,[242] magnesium-vitamin B6,[243] melatonin,[244] ketogenic diet,[245] and fish oil and evening primrose oil.[246] Two studies focused on amino acid derivatives, including L-carnosine[247] and N,N dimethylglycine,[248] and one on a digestive enzyme supplement.[249]

Studies measured a wide range of outcomes, with little overlap in instruments utilized among the studies. Most studies analyzed outcomes after 18 days to 3 months;[242,246-249]one study assessed outcomes after 6 months,[245] one study after a mean of eight months,[243]and one examined data at a mean of 1.8 years of followup.[244] Five studies reported adverse events.[242,245,248-250] Table 17 includes additional study information.

Summary of the literature-dietary interventions. Two RCTs explored dietary supplementation with amino acid derivatives in ASDs. The 8-week RCT of daily L-carnosine supplementation was conducted at a specialty clinic and included 31 children ages three to twelve years with ASDs.[247] Significant changes on the CGI at 2 weeks compared with 6 weeks were observed in the L-carnosine group; significant effects on receptive vocabulary and GARS scores were also observed before vs. after treatment in this group. However, no significant changes were observed between groups in the Gilliam Autism Rating Scale measure of ASDs severity, Receptive and Expressive Picture Vocabulary scores, or parent-rated CGI measure of overall improvement. Adverse effects in the L-carnosine group included sporadic hyperactivity and were alleviated by dose reduction.

The 4-week randomized controlled trial of daily N,N-dimethylglycine treatment was conducted at an academic clinic and included 37 children with ASDs ages three to eleven years.[248] The dimethylglycine group did not improve more than the placebo group on any behavioral measure (VABS, ABC-C). There was no significant effect on neurologic examination of motor skills, muscle tone, or coordination. Adverse effects in the dimethylglycine group were similar to placebo.

A six month, double blind, crossover RCT of a digestive enzyme supplement (Peptizyde) which combines the enzymes peptidase, protease 4.5, and papain, included 43 children between the ages of 3 and 8 years (mean= 69.4 months).[249] Most participants (84 percent) were diagnosed with autistic disorder. Participants were randomized to either enzyme for three months followed, after a one-week washout period, by placebo (n=21) or placebo for three months (one-week washout period) followed by enzyme (n=22). Sixteen participants (10 in the enzyme/placebo group and 6 in placebo/enzyme) dropped out of the study for reasons including a parent-perceived increase in negative behavior and child refusal to eat food with contents of enzyme capsules added. In intention to treat analyses, investigators reported significant differences between enzyme and placebo only on a measure of food selectivity, which was not sustained over the study period. Investigators noted no serious adverse effects though four children withdrew from the study because of behavioral deterioration perceived by parents. The authors also assessed potential effects of alternative therapies, multivitamins, prescription medications, and special diets on the effects of Peptizyde but found no changes.[249] Table 21 summarizes the results of studies of good or fair quality.

Table 21. Outcomes of RCTs of dietary supplements for the treatment of ASDs

Author, year, country Groups, N enrollment/N final Study quality	Mean age, years ± SD	Mean IQ ± SD	Key outcomes
Munasinghe et al.[249] 2010, Australia **G1:** enzyme/placebo 21/11 **G2:** placebo/enzyme 22/16 Quality: Fair	**G1:** 68.57 ± 21.28 months **G2:** 70.14 ± 23.66 months	NR	• No clinically significant changes noted between enzyme and placebo. • 27/43 children completed study. Four children withdrew from study because of negative behavioral changes perceived by parents; 5 because of difficulties with enzyme capsule administration; 7 because of other reasons/lost to followup.
Chez et al.[247] 2002, US **G1**: L-carnosine, 14/14 **G2:** placebo, 17/17 Quality: Fair	**G1**: 7.71 ± 2.41 **G2:** 7.14 ± 2.05	NR	• Significant difference at baseline in communication subscale of the GARS, with worse scores in G1 (p=0.02). • Pre-post changes on some measures present in the intervention group only, but the authors did not compare the differences across groups.
Kern et al.[248] 2001, US **G1:**dimethyl-glycine, 39(total)/18 **G2**:placebo, 39(total)/19 Quality: Fair	Overall 3-11 (mean & SD NR)	NR	• No significant differences on any outcomes assessed were observed between N,N-dimethylglycine and placebo arms.

ASDs=autism spectrum disorders; GARS=Gilliam Autism Rating Scale; G=group; IQ=intelligence quotient; NR=not reported; RCT-randomized controlled trial; SD=standard deviation

The remainder of the studies were case series of poor quality, in which modest effects were observed in improving sleep with iron supplementation[242] and melatonin,[244] and for affecting general autism symptoms with magnesium and vitamin B6[243] and a combination of fish oil and evening primrose oil.[246] Modest improvements were seen in some children with a ketogenic diet, but drop out was high.[245]

Content of the literature-other interventions. We identified eight papers from seven studies conducted in the clinic setting that examined various other medical therapies for treatment of ASDs in children, including ages ranging from two to 19 years; interventions included amantadine,[251] piracetam or pentoxifylline added to a risperidone regimen,[252,253] hyperbaric therapy,[254] oral human immunoglobulin,[64]and dimercaptosuccinic acid (DMSA).[250,255] Two studies focused on cholinesterase antagonists, including rivastigmine tartrate[256] and donezepil hydrochloride.[257]

These studies typically examined outcomes after three to 12 weeks of therapy.[64,251-254,256,257] Seven studies reported on adverse events.[64,251-255,257] Table 16 summarizes additional study details. Among all studies of dietary and other interventions, two were good quality, seven were fair, and seven were poor.

Summary of the literature-other interventions. The RCT of amantadine,[251] conducted at six academic clinics in the US and UK and including 39 children, showed no effect of daily amantadine over four weeks on parent-rated ABC-C behavior scores and clinician-rated CGI rating of overall improvement (Table 22). However, children in the amantadine arm improved significantly more than those receiving placebo in clinician-rated ABC-C subscales for hyperactivity and inappropriate speech. There were no differences in harms, and no serious complications.

Table 22. Outcomes of RCTs of other medical interventions for the treatment of ASDs

Author, year, country Groups, N enrollment/N final Study quality	Mean age, years ± SD	Mean IQ ± SD	Key outcomes
Akhondzadeh et al.[253] 2010, Iran **G1:** risperidone+pentox-ifylline, 20/20 **G2:** risperidone+placebo, 20/20 Quality: Fair	**G1:** 8.05 ± 2.01 **G2:** 7.37 ± 2.41	NR	• Significant improvements on the lethargy/social withdrawal, stereotypic behavior, hyperactivity/noncompliance, and inappropriate speech ABC-C subscales for the risperidone+pentoxifylline group (P ≤ 0.0001). • Scores on the Extrapyramidal Symptoms. Rating Scale and frequency of side effects did not differ between groups. • Harms in either group included gastrointestinal symptoms, restlessness, drowsiness, weight gain/increased appetite, and fatigue.
Handen et al.[64] 2009, US **G1a**: IGOH, 32/27 **G1b:** IGOH, 31/23 **G1c:** IGOH, 31/24 **G2:** placebo, 31/26 Quality: Good	**G1a:** 7.4 ± 3.1 **G1b:** 8 ± 4.1 **G1c:** 7.6 ± 3.5 **G1d:** 6.2 ± 3.3	NR	• No significant difference between groups in the primary endpoint, overall clinical response to treatment based on MGIS (140 mg/day, p=0.39; 420 mg/day, p=0.19; 840 mg/day, p=0.44). • No significant benefit of all active treatments combined compared with placebo (p=0.22).
Rossignol et al.[254] 2009, US **G1:** hyperbaric oxygen, 33/30 **G2:** pressurized room air, 29/26 Quality: Good	**G1:** 4.97 ± 1.29 **G2:** 4.86 ± 1.13	NR	• Significant improvements on ABC total score (p=0.0118); in the treatment group only, indicating improvements in challenging behaviors. • Significant improvements on the ATEC sensory/cognitive awareness subscale in the treatment group compared with the control group.
Chez et al.[257] 2003, US **G1:** DH, 23/17 **G2:** placebo, 20/17 Quality: Fair	**G1:** 6.8 **G2:** 6.9	NR	• Speech and language (EOWPVT & ROWPVT) improved in the treatment group relative to baseline scores but not when compared with the placebo group.

Table 22. Outcomes of RCTs of other medical interventions for the treatment of ASDs (continued)

Author, year, country Groups, N enrollment/N final Study quality	Mean age, years ± SD	Mean IQ ± SD	Key outcomes
King et al.[251] 2001, US **G1:** amantadine, 43(total)/19 **G2:** placebo, 43(total)/20 Quality: Fair	**G1:** 7 (SD NR, range=5-11) **G2:** 7 (range=5-15)	Overall= >35	• Proportion of responders (reduction of at least 25% in subscale scores for ABC-C-irritability &/or hyperactivity) in treatment group (9, 47%) was higher than in the placebo group (7, 37%), but was not statistically significant (p=0.511).

ABC=Aberrant Behavior Checklist; ATEC=Autism Treatment Evaluation Checklist; DH=donepezil hydrochloride; EOWPVT=Gardner's Expressive One Word Picture Vocabulary Test; IGOH=oral human immunoglobulin; MGIS=Modified Global Impression Scale; ROWPVT=Gardner's Receptive One Word Picture Vocabulary Test; SD=standard deviation

Risperidone plus piracetem was associated with more improvement on the ABC-C than risperidone alone in one RCT of 40 children ages 3–11, with similar incidence of extrapyramidal symptoms, and other adverse events.[252]

A 10-week RCT of pentoxifylline added to risperidone compared with placebo plus risperidone included 40 children between the ages of 4 and 12 years.[253] Scores on the ABC-C lethargy/social withdrawal, stereotypic behavior, hyperactivity/noncompliance, and inappropriate speech subscales were significantly better for the pentoxifylline group compared with placebo ($P \leq 0.0001$). Scores on the Extrapyramidal Symptoms Rating Scale and frequency of side effects did not differ between groups. Adverse events reported in either group included GI symptoms, restlessness, drowsiness, weight gain/increased appetite, and fatigue.

In one RCT at 12 US centers, oral human immunoglobulin showed no effect on gastrointestinal symptoms, ABC-C scores or clinical rated global impression scores, and there was a significant effect in favor of placebo on the parent-rated global impression scores.[64]

Hyperbaric therapy was also studied in one RCT and showed some benefit. The study was conducted at six US clinics and included 62 children ages 2-7 years with ASDs.[254] Participants were randomized to 40 hourly sessions over 4 weeks of either hyperbaric therapy (room pressure 1.3 atmospheres (atm); 24 percent oxygen) or slightly pressurized room air (1.03 atm; 21percent oxygen). Both groups had significant improvement in clinician-rated CGI after treatment as compared with baseline; however, while eighty percent of children in the hyperbaric group improved on this outcome, only 38 percent of control participants improved.

The investigators reported no significant difference in ABC-C or parent-rated CGI between groups at outcome. There were significant changes in Autism Treatment Evaluation Scale total scores and some subscales for both groups compared with baseline; significant between-group differences in the amount of change were observed on the sensory/cognitive awareness subscale only. No episodes of seizure or barotrauma occurred during the sessions; other adverse events were rare and included two skin-related events, worsening of asthma, and GI symptoms.

Two studies explored the use of cholinesterase inhibitors in ASDs, both conducted at a specialty clinic. The study of donepezil hydrochloride included 43 children ages 2-10 years with ASDs.[257] Children were randomized to six weeks of donepezil or placebo, followed by a six-week open label continuation. Both groups showed significant improvements on the Childhood Autism Rating Scale measure, but there were no between group differences. Nine children withdrew after the first six weeks; six of these children were in the donepezil group when blinding was broken and two of these discontinued due to gastrointestinal problems, while six discontinued due to increased irritability and associated behavioral issues.

One poor study each was identified for rivastigmine tartrate therapy[256] and daily oral DMSA.[250,255] In a 2-week open label study of rivastigmine tartrate therapy scores at 12 weeks were significantly improved on the Childhood Autism Rating Scale, expressive picture vocabulary, and the Comprehensive Psychopathological Rating Scale measure of oppositional, hyperactive, and inattention-related behaviors; no significant effects were observed on receptive picture vocabulary at 12 weeks. The randomized controlled trial of DMSA demonstrated no advantage of DMSA over placebo.

KQ1. Effects of Treatment on Core and Commonly Associated Symptoms in Children With ASDs: Allied Health Interventions

Among allied health disciplines, several intervention approaches have been developed to address core symptoms of autism and associated difficulties and deficits. We broadly divided allied health studies meeting our inclusion criteria into those focused on language, those employing sensory or auditory integration techniques including music therapy, and those addressing techniques such as horseback riding and occupational therapy. Table 23 summarizes aspects of studies of allied health interventions addressing KQ1.

Table 23. Overview of allied health studies[a]

Characteristic	RCTs	nRCTs	Prospective cohort studies	Retrospective cohort studies	Prospective case series	Retrospective case series	Total Literature
Intervention	(n=7)	(n=2)	(n=0)	(n=0)	(n=8)	(n=0)	(n=17)
Language therapy	2	1	0	0	1	0	4
Sensory	1	0	0	0	1	0	2
Auditory/music therapy	3	0	0	0	0	0	3
Other	1	1	0	0	6	0	8
Diagnostic approach							
Clinical DSM-IV dx +ADI-R and/or ADOS	2	0	0	0	0	0	2
Combination approaches[b]	5	0	0	0	2	0	7
No DSM-IV or ADOS dx/ unspecified	0	2	0	0	6	0	8
Treatment duration							
≤1 month	1	1	0	0	3	0	5
>1 to ≤3 months	3	1	0	0	2	0	6
>3 to ≤6 months	2	0	0	0	1	0	3
>6 to ≤12 months	0	0	0	0	1	0	1
>12 months	1	0	0	0	0	0	1
Unknown/not reported	0	0	0	0	1	0	1
Study population							
U.S.	3	1	0	0	2	0	6
Europe	3	1	0	0	3	0	7
Asia	1	0	0	0	3	0	4
Other	0	0	0	0	0	0	0
Total N participants	211	105	0	0	202	0	518

ADI-R=Autism Diagnostic Interview-Revised; ADOS=Autism Diagnostic Observation Schedule; DSM-IV=Diagnostic and Statistical Manual of Mental Disorders, 4th edition; dx=diagnosis; nRCT=non randomized controlled trial; RCT=randomized controlled trial

[a]Numbers in the table indicate the number of unique studies with each characteristic.

[b]Clinical DSM-IV dx +other diagnostic tool or ADOS + other diagnostic tool or only clinical DSM-IV dx or only ADOS.

Language Interventions

Two approaches to increasing speech and language were identified in the included studies: the Picture Exchange Communication System (PECS) and Responsive Education and Prelinguistic Milieu Teaching (RPMT). We have clustered these two approaches for the purposes of the report, and because in the one study that compared different approaches, these were the two comparative conditions.

Content of the literature. Our search identified eight publications focused on speech and language interventions,[258-265] representing four distinct study populations. Two of the studies were RCTs; one was described in four papers,[258-261] and one in a single study.[263] Three of the four studies referred to a protocol, and one measured treatment fidelity. No two studies used exactly the same outcome measure, making it difficult to summarize across studies. Each is therefore described separately below, and Table 23 provides an overview of study information. Among the four unique studies, one was good quality and three were poor.

Summary of the literature. Four analyses from one randomized trial[258-261] comparing RPMT to PECS in the United States met our criteria and were included. The 36 preschoolers included in the study had a confirmed diagnosis of Autistic Disorder or PDD-NOS, were between 18 and 60 months of age, and were nonverbal or had low verbal status (fewer than 20 different words used cumulatively during three communication samples). Most (86 percent) of the participants were male, and most (69 percent) were white. Although the mean chronologic age of the children was 33.6 months (range from 21 to 54 months), the mean mental age in the nonverbal children was 18.6 months and in the verbal children was 11.9 months, based on Mullen Scales of Early Learning. Diagnosis of autism was confirmed with the ADOS for all children. Nineteen children were randomized to receive PECS and 17 to receive RPMT.

During the six-month treatment phase, children attended three 20-minute therapy sessions per week, with parents offered up to 15 hours of training. Outcomes were measured at the end of treatment and 6 months after treatment completion in the context of a 15-minute free play session in which the interaction style, toys, examiner and location were all different from those in which the intervention was conducted. Treatment fidelity was assessed monthly, interrater reliability was assessed on at least 20 percent of data points, and coded data were double entered to ensure accuracy.

At Time 2, the PECS group had significantly higher frequency of non-imitative spoken communication at Time 2 than the RPMT group, and higher numbers of different non-imitative words. No overall significant between group differences were observed at Time 3, indicating that the treatment effects did not maintain at six months after the end of treatment. This study included an analysis of initial characteristics of the children, demonstrating that children who were low in initial object exploration benefitted more from RPMT, which explicitly teaches play with objects; while children who were relatively high in initial object exploration demonstrated more benefit from PECS.

These results were maintained at 6 months. An additional analysis based on this study[260] showed greater increases in generalized turn-taking and initiating joint attention in the RPMT group than in PECS. The increased benefit for RPMT in join attention was only seen, however, in children who began the study with at least some initiation of joint attention. Specifically, children most likely to benefit from RPMT in increasing joint attention had demonstrated at least seven acts of joint attention in the pre-intervention assessment. RPMT was also superior in this analysis in increasing object exchange turns.

The second RCT[263] in this literature was a pragmatic trial focused on the effect of providing expert training in PECS to teachers in specialist schools, under the assumption that although more than half of autism-specific schools in the UK claim to use PECS system, few teachers have been adequately trained to provide it. This study aimed to explore the potential effects of intensive training of teachers on child outcomes in spontaneous communication and speech; thus randomization occurred at the classroom level in three groups – immediate treatment group, delayed treatment group, and no treatment group. Teachers in the delayed treatment group received intensive training 2 terms after the immediate treatment group.

The 83 children included in the study were between the ages of 4 and 11 and had little or no functional language; most (75) met ADOS-Generic criteria for Autistic Disorder, and nine met criteria for another ASD. Treatment and assessment of language and nonverbal developmental quotient (nonverbal mental age equivalent/chronological age X 100) took place in schools with children videotaped and language outcomes codes by non-masked assessors. Videotaping took place during snack sessions, selected because they are time limited and structured to include requesting and other social communication.

The use of PECS in treatment classrooms was substantially increased immediately after training, with children in the PECS training classrooms having 3.90 times (95 percent CI: 1.75–8.68) the odds of being in a higher PECS use category than those whose teachers received no PECS training. The effect, however, was not maintained, and by Time 3, the immediate treatment group children were no more likely to be in a higher PECS rate category than untreated children (OR 1.10; 95 percent CI: 0.46–2.62).

The third trial available on language intervention was also on PECS and was a nonrandomized controlled trial, with selection into or out of treatment based on a geographical limit. This study was reported in two papers.[262,265] Intervention was provided to 24 children whose special education classrooms were within 50 miles of the researchers; while a comparison group was selected from special education classrooms outside the 50-mile limit. Children were between 3 and 7 years old, with a diagnosis of Autistic Disorder. Diagnosis was clinically based, and not independently confirmed by the investigators. Children in the study were to have received no PECS training prior to the research.

Children in the intervention group received a total of 15 hours of PECS teaching during various classroom activities over 4 to 5 weeks. The research team designed the instrument by which they assessed communicative interactions. They did not validate the instrument. The investigators followed the Bondy and Frost guidance[82] for using PECS in the classroom, but at Phase III randomly assigned children to either the approach specified in the PECS manual, or a modified PECS teaching procedure.[265]

Observation occurred 6 weeks prior to commencement of PECS intervention, 1 week prior to intervention and during the week immediately following completion of the 15 hours of PECS. The authors contended that the differences observed between the first and second observation periods (during which no intervention took place) would provide a measure of rate of maturation that could be used to differentiate maturation from treatment effects after the intervention phase; however, no evidence that this approach is valid was provided in the paper.

No differences were observed on child-initiated communication either between the two pre-intervention measurement periods or between the two groups immediately prior to intervention. After intervention, however, the children in the PECS manual group had a significant increase in initiations, while the children in the control group had no increase, and the frequency of child to adult initiations was higher overall in the PECS manual group. Total adult-to-child initiations with the opportunity for child response showed an opposite response, with no significant increase in the PECS manual group, but a significant increase in the control group.

Because the study only measured outcomes immediately after intervention in the classroom setting (at 6 weeks), it is impossible to determine whether the outcomes have any durability or to assess the effects outside of the classroom. Furthermore, although reliability of the observations was reported to be high (89.78 percent agreement), it was measured in only 56 percent of observation sessions, and the observers were not blinded to intervention status.

Sensory- and Auditory-Focused Interventions

Sensory integration, a specialized occupational therapy model based on the premise that the brain's response to basic sensory input must be normalized before higher-order processes can be addressed,[85] typically involves one-on-one, child-directed treatment with a trained occupational therapist and a focus on somatosensory and vestibular systems. Ultimately, it is hypothesized that if a child is better able to process, modulate, and integrate sensory information, he will then be better able to acquire higher-order skills.[16]

Auditory integration training (AIT) relates more specifically to sensory differences in the auditory realm. AIT involves repeatedly presenting children with modulated music according to specific protocols with a therapeutic goal of improving auditory processing, lessening auditory hypersensitivities, and increasing concentration.[87] Finally, music therapy is at times employed with children with ASDs, hinging on speculation that children engage more with music. This treatment method is improvisational and unstructured in nature, and practitioners purport that it can improve both verbal and nonverbal communication skills including joint attention abilities, thereby improving core symptoms of autism.[88,89]

Content of the literature. We identified two studies[266-268] that addressed sensory integration interventions, including a prospective case series with two publications presenting nearly identical results[267,268] conducted in South Korea. Both were completed in a clinic setting and included children ages 6 years[267,268] and older.[266] All children in both studies met criteria for autism (i.e., none had diagnoses of PDD-NOS or Asperger Disorder). Both studies used outcome assessments developed within the project and focused on sensory and motor functioning. Both sensory studies were poor quality.

Two papers assessed auditory integration interventions[269,270] and targeted children between 3 and 7 years old[270] and 7 to 13 years old.[269] Both studies were conducted through a clinic associated with an academic institution and enrolled children with diagnoses of autism across a broad range of cognitive functioning levels. Table 24 provides additional study details.

We identified two papers from a single crossover RCT that compared music and play therapy interventions.[89,271] The study included children ages 3 to 5 years meeting DSM-IV criteria for autism and meeting criteria on the Childhood Autism Rating Scale; some were also administered the ADOS to confirm diagnosis. Among studies of auditory integration and music therapy, two were fair quality and one was poor.

Summary of the literature. Two studies examining sensory integration training met our inclusion criteria (Table 25).[266-268] An RCT from Fazlioglu and colleagues[266] examined the effects of a sensory integration protocol on low-functioning children with autism ages 7 to 11 years who had not previously received sensory integration therapy. The intervention program used in this study was based on “The Sensory Diet” and included a prescribed schedule of somatosensory stimulation activities targeting 13 behaviors across sensory modalities and motor skills development and conducted in a specially arranged sensory room. Results indicated that the difference between treatment and control groups was significant at outcome, but not at baseline, with children receiving sensory integration intervention showing significantly fewer sensory problems at followup than children in the control group.

In contrast to Fazlioglu’s more traditional play-based, child-directed sensory integration intervention, Jung et al.[267,268] used a virtual reality – tangible interaction system sensory integration training protocol in 12 five- and 6-year-old children with autism The sensory integration components comprised less than a third of the intervention described, and no outcome measures were reported related to sensory integration activities.

To study auditory integration intervention (Table 24), Corbett et al.[270] used a double-blind, placebo-controlled crossover design on the effects of Tomatis Sound Therapy on language skills in children with autistic disorder, ages 3 to 7 years who had not previously had auditory stimulation treatments. In the treatment condition, children listened to music passed through an electronic ear for attenuation and modulation for two hours per day in accordance with the Tomatis Method protocol. The protocol was divided into four blocks, each lasting 3 weeks. In the placebo condition, children listened to commercially produced music in the same blocked schedule. No improvements in receptive or expressive language were related to treatment conditions, as the increase in scores over time (i.e., pre-first condition, midpoint, post-second condition) was not different between groups (i.e., Treatment/Placebo and Placebo/Treatment).

Mudford and colleagues studied AIT in children with autism ages 5 to 13 years (mean age= 9.4);[269] all children had significant language delays and low adaptive behavior levels. No significant benefit of AIT was found (Table 24).

Table 24. Outcomes of RCTs of auditory/music interventions for the treatment of ASDs

Author, Year, Country Groups, N enrollment/ N final Study quality	Age, mean years ± SD	IQ, mean ± SD	Key outcomes
Corbett et al.[270] 2008, US **G1:** Tomatis Sound Therapy followed by placebo in four three-wk blocks, 6/6 **G2:** placebo followed by Tomatis Sound Therapy in four three-wk blocks, 5/5 Quality: Fair	**G1:** 5.25 (range: 3.5-7.42) G2: **5.93 (range: 4-7.17)**	66.8 (combined)	• Results indicated no improvements in receptive or expressive language related to treatment.
Mudford et al.[269] 2000, UK **G1:** AIT followed by control **G2:** control followed by AIT Total N at enrollment: 21 Final N: **G1**: 7 **G2**: 9 Quality: Fair	9.42 yrs ± 29 mo	6/21 untestable; 15/21 mean=56	• No significant benefit of auditory integration found; greater reduction in challenging behavior and hyperactivity following control relative to treatment condition.

AIT=auditory integration therapy; IQ=intelligence quotient; N=number; NR=not reported; SD=standard deviation; SI=sensory integration

One study investigated the effects of music therapy in children ages 3 to 5 years (mean = 51.2 months) with autism in comparison to the effects of play-based sessions on joint attention behaviors with results reported in two papers.[89,271] A crossover design was used such that all children completed both music and play interventions, with treatment order randomly assigned. Sessions in both conditions were divided into 15 minutes of undirected child-led activities, followed by 15 minutes of directed activities according to a semi-flexible treatment manual developed for the study. There were no significant between group differences on the Pervasive Development Disorder Behavior Inventory, though both groups improved with time. Results from the Early Social Communication Scales, reflecting growth in joint attention skills, suggested that music therapy was significantly more effective than play sessions. Change scores pre- to post-music therapy were significantly greater than change scores pre- to post-play sessions.

In the second paper,[89] treatment sessions were coded for emotional and motivational responsiveness (i.e., joy, emotional synchronicity, initiation of engagement) toward attunement promoted by the therapist and for responsiveness (i.e., social invitation and interpersonal demands) toward the therapist's initiation of interaction during joint attention episodes within selected four-minute segments of four treatment sessions. More joy, emotional synchronicity, and initiation of engagement were observed during music therapy than play sessions. In addition, children had significantly more compliant behavior and significantly fewer episodes of no response behaviors in the music therapy condition.

Additional Allied Health Interventions

A number of studies addressing interventions such as animal-assisted therapies and assistive tools met our review criteria.

Content of the literature. We found eight studies[272-279] addressing additional allied health interventions. Two papers report similar interventions and participants recruited from similar locations and may include overlapping participants.[275,277] Treatment duration ranged from 47 days[278] to 21 weeks,[279] and participants ages ranged from 3 to 18 years.[273] Table 23 provides additional study details. All studies in this section were considered poor.

Summary of the literature. Bass and colleagues conducted a randomized controlled trial investigating the potential benefits of therapeutic horseback riding sessions in 34 children with ASDs assigned to either a horseback riding group (n=19, mean age 6.95 yrs ±1.67) or wait-listed group (n=15, mean age 7.73 yrs±1.65).[276] Children in the riding group attended sessions of 1 hour per week over 12 weeks. Scores on four of the five Sensory Profile subscales (sensory seeking, inattention/distractibility, sensory sensitivity, and sedentary), along with the overall Sensory Profile mean score, showed a significant between-group difference. The overall Social Responsiveness Scale score and social motivation subscale also showed a significant between-group difference.

A nonrandomized controlled trial investigated the effect of movement therapy on behavior among children with ASDs.[274] Children were recruited from specialized schools and underwent 30-minute movement training sessions twice a week for 2 months. Behavior was recorded during the first and last meetings for 6 one-minute periods, in 10-second sample units. Eight behaviors were assessed: stereotypical behaviors, wandering, responding to touch negatively, on-task passive, on-task active, eye contact, social relatedness towards the teacher, and resisting the teacher. Of these, four exhibited significant changes: a decrease in wandering, responding to touch negatively, resisting the teacher, and an increase in on-task passive behavior.

Two prospective case series focused on the effect of incorporating colored overlays to assess effects on reading in children with ASDs.[275,277] In the initial study,[277] participants attended one session with researchers and performed reads of 30 seconds and 1 minute. Children with autism read significantly more words per minute with than without colored overlays. Seventy-nine percent of children with ASDs showed improvement in reading with colored overlays.[277] In a later study,[275] Ludlow and colleagues conducted three individual tests to assess the therapeutic benefits of colored overlays when reading; results showed more words read using overlays and slightly better performance on a picture matching task using overlays.

One prospective case series aimed at identifying the effect of therapeutic sessions incorporating animal interaction among children with ASDs.[272] Therapy sessions focused on facilitating sensory integration, language use, sensory skills, and motor skills, with each participant attending at least two sessions of each type over 15 weeks. Results indicated that participants engaged in significantly greater use of language and social interaction in the therapy sessions incorporating animal interaction than in the standard occupational therapy sessions. In another series, Carmody and colleagues examined the effect of eyeglasses with specialized prism lenses.[273] Children were recruited from a child development center, and each child was assessed for 20 to 30 minutes by a single interviewer, with trials of 60 to 90 seconds without glasses and with each of the lens orientations. Participants showed a significant improvement in a ball catching when wearing lenses (64 percent compared with 20 percent without lenses).

A 21-week study included 16 boys with ASDs and assessed the effects of a water exercise program on social skills.[279] Participants had either Asperger syndrome (n=8) or high functioning/mild autism (n=8) and showed decreases in antisocial behavior following the swimming program. Finally, Laud and colleagues conducted a prospective case series that included a systematic feeding program and oral motor therapy aimed at improving feeding behaviors among children with ASDs.[278] Participants underwent 3 hours of behavioral training and 1 hour of oral therapy at least 5 days per week. Behavioral training consisted of systematic meal sessions with individualized behavior protocols while the oral training was conducted by an occupational therapist or speech pathologist to determine skill and safety while eating. Significant changes from admission to discharge were found in the following areas: increases in acceptance and grams consumed, increase in refusal behavior, and a decrease in negative vocalizations.

KQ1. Effects of Treatment on Core and Commonly Associated Symptoms in Children With ASDs: Complementary and Alternative Medicine (CAM)

CAM Interventions

As noted, studies of CAM interventions meeting our criteria addressed acupuncture and massage, including qigong massage. Table 25 summarizes critical aspects of studies of CAM interventions addressing KQ1.

Content of the literature. We found seven studies[280-286] of CAM interventions meeting our inclusion criteria; two studies[282,283] likely contain overlapping participants. Interventions occurred in the clinic[280,282,283,286] and home,[282-284] and studies addressed massage,[284-286] qigong massage,[282,283] and acupuncture.[280,281] Treatment duration ranged from 1[284] to 9 months,[280] and participants' ages ranged from 3 to 10 years. Among the seven CAM studies, two were fair quality and five were poor.

Table 25. Overview of CAM studies[a]

Characteristic	RCTs	nRCTs	Prospective cohort studies	Retrospective cohort studies	Prospective case series	Retrospective case series	Total Literature
Intervention	(n=6)	(n=0)	(n=0)	(n=0)	(n=1)	(n=0)	(n=7)
Massage	4	0	0	0	1	0	5
Acupuncture	2	0	0	0	0	0	2
Diagnostic approach							
Clinical DSM-IV dx +ADI-R and/or ADOS	1	0	0	0	0	0	1
Combination approaches[b]	2	0	0	0	0	0	2
No DSM-IV or ADOS dx/ unspecified	3	0	0	0	1	0	4
Treatment duration							
≤1 month	0	0	0	0	0	0	0
>1 to ≤3 months	3	0	0	0	0	0	3
>3 to ≤6 months	1	0	0	0	1	0	2
>6 to ≤12 months	2	0	0	0	0	0	2
>12 months	0	0	0	0	0	0	0
Study population							
U.S.	3	0	0	0	1	0	4
Other	3	0	0	0	0	0	3
Total N participants	164	0	0	0	26	0	190

ADI-R=Autism Diagnostic Interview-Revised; ADOS=Autism Diagnostic Observation Schedule; DSM-IV=Diagnostic and Statistical Manual of Mental Disorders, 4th edition; dx=diagnosis; nRCT=non randomized controlled trial; RCT=randomized controlled trial

[a]Numbers in the table indicate the number of unique studies with each characteristic.

[b]Clinical DSM-IV dx +other diagnostic tool or ADOS + other diagnostic tool or only clinical DSM-IV dx or only ADOS.

Summary of the literature. Studies assessing massage focused primarily on sensory impairments; a series of studies from Silva et al. assessed qigong massage using similar approaches and potentially including overlapping participants, though the exact overlap is unclear. A 2007 RCT[283] extended a 2005 case series (not included in the present review) of 8 children with ASDs; the RCT[283] included 15 participants with autism diagnosed according to DSM-IV criteria (mean age at first assessment=4 years, 10 months). Children were stratified into three cognitive groups according to Batelle Development Inventory scores and randomly assigned to treatment or control within each group. Massage treatment for the eight intervention group participants consisted of 11 different qigong massage movements. A trained practitioner delivered massage twice a week in the clinic for two 5-week periods separated by 5 weeks of no practitioner-delivered therapy. Parents were trained to provide massage at least once daily during the 5 week practitioner-delivered and interval periods; parents were also tested to ensure accurate administration of massage. The seven control children received special education, and four were concurrently receiving speech therapy.

Total Sensory Profile scores improved in the massage group by an average of 5.4 points, with an average worsening in control group of 2.7 points ($p<0.01$); average improvement in daily living skills was 9.8 months compared with 0.9 months in the untreated group ($p<0.02$) and 10.0 months compared with 4.7 months in control participants ($p<0.04$). No significant differences between groups were seen in VABS language and motor development scores or on the Autism

Behavior Checklist. Children with bowel or sleep difficulties in the treatment group improved according to parent report.

A 2008 case series assessed whether individuals completing an 80 hour training program could deliver qigong massage yielding positive adaptive behavior and sensory outcomes.[282] The qigong sensory training curriculum for trainers included didactic and experiential instruction; during the 5 month intervention, each of the 18 trainers worked with two families with a supervisor present for several sessions to assess treatment fidelity; several treatment sessions were also videotaped to inform training efforts. Participants showed gains in sensory and adaptive behavior, and most trainers were considered to have mastered the training program.

A later multisite RCT assessing a similar qigong methodology modified for application in early intervention programs[285] included 46 children between the ages of 3 and 6 and evaluated participants in both the home and preschool settings. Children were randomized to either Qigong Sensory Training, comprising 10 hours of practitioner-delivered therapy in addition to daily parent-delivered massage. Practitioners, including some early intervention personnel, received training and weekly supervision during the intervention period. Six therapy sessions were also videotaped over the course of the project to assess treatment fidelity. Assessments were conducted prior to the intervention, after the final massage session, and 5 months after the final session (parent-report) to evaluate maintenance of effects.

The Qigong group (n=25, mean age=65.2 ± 20.7 months) and wait list control group (n=21, mean age=53.3 ± 18.7 months) differed significantly in parent-rated Pervasive Developmental Disorder Behavior Inventory Social/Communication and Autism composite scores ($p<0.05$) as well as teacher-rated Sensory scores ($p<0.01$) at baseline. Scores from pre- to post-treatment for the Qigong group improved significantly on all measures ($p<0.00$); only change scores on the teacher-rated Pervasive Developmental Disorder Behavior Inventory maladaptive behavior subscale reached significance for the control group ($p<0.01$). Parent-rated data illustrated a significant overall treatment effect on outcomes and in adjusted comparisons on the Sense and Systems Checklist and Pervasive Developmental Disorder Behavior Inventory sensory, maladaptive behavior, social/communication, and autism domains; effect sizes (partial η^2) were considered to be large. Treatment effect for teacher rated data was also significant overall, and adjusted comparisons found significant effects (moderate effect size) for the Pervasive Developmental Disorder Behavior Inventory social/communication composite and the Autism Behavior Checklist. Descriptive data collected 5 months after the final massage session in 19 participants available for followup showed significant differences in all scores on parent-rated measures at all three assessment times.

In an RCT of Thai traditional massage, 60 autistic children between the ages of 3 and 10 were randomized to receive 8 weeks (16 total sessions) of either sensory integration therapy (n=30, mean age 4.48) or sensory integration therapy plus massage (n=30, mean age=4.84).[286] The same occupational therapist conducted sensory integration sessions, which were individualized for each child but followed established principles. One masseuse delivered all massage sessions following a standard protocol. Both groups saw improvements in behavior with significant differences between groups from baseline to week 8 noted in parental report of conduct problems ($p=0.03$).

In a one-month study of pre-bedtime, parent-delivered massage,[284] twenty children with autism (mean age ± SD=5.2 ± 1.8, range 3-6 years) as diagnosed according to the DSM III-Revised criteria were randomly assigned to nightly massage or reading attention control groups. Assessments, conducted on the first and last days of the study, included subscales of the Conners

Teacher and Parent Scales, behavioral observations in the classroom and playground by blinded research associates, and parent-maintained sleep diaries. Teachers' blinded ratings on the Conners Scale showed greater improvement for children in the massage group on the Emotional Index and the DSM-IV criteria for inattentiveness ($p<0.05$). Parent ratings were significant for these subscales as well as the ADHD and restless-impulsive behavior indices ($p<0.05$). Observation ratings across the playground and classroom illustrated a decrease in stereotypical behaviors and increase in on-task behaviors in the massage group. Poor sleep behaviors also exhibited greater declines among the massage group according to parent report.

Two studies meeting our criteria addressed acupuncture. An RCT conducted in Egypt[280] assessed the effects of scalp acupuncture and language therapy compared with language therapy alone on elements of attention, receptive and expressive semantics and syntax, phonology, and pragmatics. Children included in the 9 month study were between the ages of 4 and 7, were diagnosed with autism and delayed language development, and had Childhood Autism Rating Scale scores ≥30. Children randomized to language therapy plus acupuncture (n=10) received language therapy twice a week and scalp acupuncture twice a week for 2 months, followed by a 2 week rest period for the 9 months of the study. Children randomized to language therapy alone (n=10) received treatment twice a week for the 9 month study; further detail on the content of language sessions was not reported. The Arabic Language Test was used to measure outcomes.

The acupuncture and language therapy group showed significant pre-post gains in attention ($p=0.001$) and receptive ($p=0.001$) and expressive semantics ($p=0.021$). Children receiving language therapy only improved in attention, cognition, and receptive semantics from pre- to post-treatment, but the magnitude of improvement is not reported. Outcomes between groups were significant for attention ($p=0.008$) and receptive semantics ($p=0.034$).

A 6 week RCT of the seven star needle acupuncture technique[281] similarly assessed changes in language function as well as social and stereotyped behaviors. The acupuncture technique uses a specially designed dermatoneural hammer housing seven needles in the shape of a star. Thirty-two children with ASDs (diagnosis not specified) included in the study were randomized to treatment (five 5-10 minute daily sessions per week for 6 weeks) or a wait list control group. Assessments were conducted before and after the 6 week study period and included a Parent Rating Questionnaire designed for the study and evaluating language, social, and motor functioning and stereotyped behaviors. EEG data, assessed by a rater blinded to treatment status, measured changes in neural processing.

Children in the treatment (n=16, mean age=6.85±1.76, mean IQ=84.06 ± 15.75) and control (n=16, mean age=6.89 ± 1.77, mean IQ=86.82 ± 19.91) groups were matched in age and IQ as measured by the Test of Nonverbal Intelligence. Parents of children in the treatment group reported significantly greater overall improvement than parents of control group children as well as greater improvement in language, especially related to sentence length and speech clarity and frequency. Social interaction, including gains in eye contact and facial expression, was also significantly improved for the treatment as compared with the control group. Changes in EEG data, which were available for 9 control and 7 treatment group children, suggested that the brain's information processing functions were affected by the seven star treatment.

KQ2. Modifiers of Treatment Outcomes

Understanding the degree to which child characteristics (i.e., specific ASDs related difficulties and skills), treatment factors (e.g., type, duration, intensity), and systems (e.g., family, community) influence response to treatments could improve targeting of treatments to the appropriate children and circumstances. However, with rare exceptions,[259,260,287] few studies are designed or powered to allow analysis of heterogeneous effects in order to identify true modifiers of treatment effect. Although we sought studies of treatment modifiers, only one included study [259,260]actually demonstrated true treatment modifiers based upon appropriate study design and statistical analysis. One other study [287] was designed to examine the role of provider on outcomes, but showed no difference, possibly because it was underpowered to do so.

This first study[259] included an analysis of initial characteristics of the children demonstrating that children who were low in initial object exploration benefitted more from RPMT, which explicitly teaches play with objects, while children who were relatively high in initial object exploration demonstrated more benefit from PECS. These results were maintained at 6 months. An additional analysis based on this study[260] showed greater increases in generalized turn taking and initiating joint attention in the RPMT group than in PECS. The increased benefit for RPMT in join attention was only seen, however, in children who began the study with at least some initiation of joint attention. Specifically, children most likely to benefit from RPMT in increasing joint attention had demonstrated at least seven acts of joint attention in the pre-intervention assessment. RPMT was also superior in this analysis in increasing object exchange turns.

One study[287]explicitly sought to examine the impact of provider choice (parent versus professional) using similar interventions in an RCT. The study did not show a difference in outcomes for children receiving UCLA/Lovaas protocol-based intervention in a clinical setting versus at home from highly trained parents. both clinic and parent groups received over 30 hours of intervention weekly and no group differences related to IQ, language, adaptive behavior, or other outcomes were seen. Children in both groups demonstrated substantial gains in a number of areas. Nonetheless, the results do provide further evidence of response to treatments anchored in the UCLA/Lovaas method, with some children demonstrating rapid acquisitions of new skills and change in IQ. Other studies not specifically designed to examine modifiers have also compared parent to clinic-based interventions [126,132,288] and demonstrated equivalent group change when delivered in the same intensity.

Other studies in this section are those in which potential correlates were identified that may act as true moderators, but not in the context of studies designed and powered to identify modifiers. These potential moderators should be assessed in properly designed and powered studies for this purpose.

Behavioral Interventions

Frequency, duration, and intensity. Apart from the studies described above, a number of potential correlates of treatment effect are observed in the existing literature and should be studied further. The most commonly noted characteristics as potential correlates of effectiveness in the study of behavioral interventions are treatment intensity and approach (e.g., parent-led versus clinician-led) as well as baseline measures of child characteristics, including IQ, language and verbal skills and severity of the autistic disorder.

Vismara and colleagues[178] found equivalent results across training (distance vs. in person) modalities for providers of ESDM treatment. When examining characteristics of UCLA/Lovaas-based intervention, Luiselli et al. found that months of treatment was significantly related to language gain, but numbers of hours per week and total hours of treatment were not.[121] Intensity of supervision within UCLA/Lovaas-based treatment has also been demonstrated to be positively correlated with change in cognitive in cognitive abilities, although not other skills domains, within one treatment study.[126,132]

Because of the potentially increased efficiency and desirability of having parents provide intervention to their children in their own homes, several studies have reported on varying approaches to preparing parents to provide behavioral therapies. Sofronoff et al.[174,175] conducted a parent training intervention with parents of children ages six to twelve years with Asperger syndrome diagnoses. Parents either (a) participated in a one-day workshop, (b) attended six weekly 1-hour individual sessions conducted by master's or doctoral students in psychology, or (c) were placed in a waitlist control group. Components of the intervention were the same in both treatment groups and involved psychoeducation, comic strip conversations and social stories introduction, and management techniques for externalizing behaviors, rigid behaviors, and anxiety. Parents from both intervention groups reported significantly better social skills in their children than did parents in the waitlist control group at both 1-month post-treatment and 3-month followup; at 3-month followup, parents from the individual session group reported marginally better social skills for their children than did parents from the workshop group, suggesting little modification of effect by intensity (one day vs. weekly training).

Finally, in a case series assessing an intervention intended to improve either joint attention or symbolic play skills, a teacher-led approach was compared with one in which the child took the lead and found positive effects associated with the teacher leadership.[158]

Child characteristics. Several characteristics of the child have been assessed to determine whether there were identifiable variables associated with positive outcomes in intensive behavioral interventions.

Cognitive abilities/IQ. The most commonly reported characteristic investigated relates to pretreatment cognitive abilities/IQ. Several investigations have noted that pretreatment IQ and language predicts IQ at followup within the context of UCLA/Lovaas-based methodologies.[101,104,115,124,287] However, other studies have suggested having a lower IQ at initiation of treatment is related to increased change in IQ over time[127] or and change in response to intervention[102,126,132] within this same methodology. In contrast to UCLA/Lovaas-based methodologies, parent training interventions for teaching early social communication skills demonstrate that children with lower language levels and/or lower IQ at baseline may actually benefit more from this intervention.[108,109] Some data from Pivotal Response Training studies suggest that less impaired children do better in response to offered parent training.[117]

Language/communication skills. Baseline language/communication skills may also correlate with treatment success, with studies generally suggesting a benefit for communication skills, including changes in ASDs classification associated with baseline language skills in an ABA-based approach.102, 124 In one RCT155, 156 comparing the use of targeted joint attention intervention to development of symbolic play skills, children with initially higher levels of expressive language showed greater growth in expressive language from pre-intervention to 12 months post-intervention. Among children with lower expressive language initially, those in the joint attention group showed significantly greater improvements in expressive language. In addition, joint attention initiations, responding to joint attention, the duration of child-initiated joint attention, average highest level of play, total number of symbolic play types, and initial receptive language age all predicted greater gains at 6 and 12 months post intervention.

Similarly, social skills studies have found verbal skills, either verbal comprehension (using the Verbal Comprehension Index) or expressive communication skills to be associated with social skills at outcome. Children with higher verbal comprehension scores who participated in the Social Story intervention[145] made larger gains in the evaluated game play skills, while children with extremely low verbal comprehension scores did not. Social Stories, an intervention program that relies heavily on the child understanding information presented in a written format, may not be as effective for children with low verbal comprehension abilities. In another study[139] pre-treatment communication skills, as measured by VABS Communication domain and Verbal IQ, were associated with social skills at outcome (VABS Socialization) in both a Lego treatment group and the treatment as usual control group (but more so in the Lego group).

Autism symptom severity. Some evidence indicates that specific constellations of symptoms related to ASDs may be important in understanding response to treatment. Social responsiveness and imitation skills have been suggested as skills that may predict improved treatment response in UCLA/Lovaas-based approaches,[287] whereas "aloof" subtypes of ASDs have been suggested to be associated with less robust changes in IQ,[107] and lower baseline symptom tallies have also been demonstrated to be related to specific gains.[104] Other studies have seen specific improvement with UCLA/Lovaas-based intervention for children with PDD-NOS vs. Autistic Disorder diagnoses,[114] which may be indicative of baseline symptom differences. However, many other studies have failed to find a relationship between autism symptoms and treatment response.

Two social skills studies[139,148] looked at the diagnosis of participants (PDD-NOS vs. high functioning autism vs. Asperger syndrome for one study, autistic disorder vs. Asperger/PDD-NOS for the other) as a potential modifier of treatment effects and failed to find any significant direct effects. However in the study evaluating the social adjustment enhancement curriculum,[139] the results on a measure of theory of mind were no longer significant when the one participant with PDD-NOS was excluded.

Age at identification/initiation of treatment. Some evidence suggests that children initiating treatment at earlier ages may benefit more from UCLA/Lovaas-based intervention;[115,129] however, other explicit comparisons have not found this same relationship for UCLA/Lovaas-based approaches[121] and age at initiation of treatment may in fact be confounded by type of treatment initiated.[129]

Neurobiological and genetic variation. Only one of the included and reviewed studies examined the relations between potential underlying neurobiological markers/variation and this study simply indexed head circumference as a measurement within design[102] and this did not appear to be related to outcome.

Family characteristics. Although family characteristics were rarely reported in the behavioral literature, in one study of a parent-directed play interaction, change in child behavior was not significantly predicted by whether parents perceived their child having a causal role in their own behavior or the parent having a causal role in their child's behavior,[154,161] but parent positive affect, measured through behavioral coding was positively related to parental reports of child adaptive behavior and negatively related to parental reports of child challenging behaviors.

Educational Interventions

Child characteristics. In educational interventions, baseline IQ and receptive language predicted rate of progress in one study.[195] In a comparison of a home-based intervention plus center-based (intervention) to a center-based only (control) educational intervention,[194,198] no girls in the intervention group improved in IQ or on the Preschool Behavior Checklist. In the control group, one girl improved in IQ, and 2 improved on the Preschool Behavior Checklist. Improvement in IQ in the intervention group was higher with low socioeconomic status, younger age, and high family stress. Improvement in Preschool Behavior Checklist scores was associated with younger age in the intervention group. This study also considered the potential effect of family stress and non-English speaking in the home and found no effect on outcomes.

Family characteristics. One study measured parental stress and its association with outcomes in four different teaching interventions (reinforcement-based interventions, special nursery, speech and language therapy, and parent education programs),[196] and found that parenting stress was not associated with gains seen in interventions that required less total time but reduced the gains made by those interventions that required more total time. Moreover, evidence suggests that at lower levels of parenting stress, higher time intensity interventions are more effective than lower time intensity interventions. For the lower parenting stress group, higher time intensity interventions significantly improved intellectual functioning and educational functioning but not adaptive functioning as measured by the VABS.

Medical Interventions

No modifiers of treatment outcome were identified in studies of antipsychotic medications in ASDs, though one case series of risperidone use[205] reported a correlation between weight gain in the first month and final weight gain. We were, however, able to identify papers that included modifier data for stimulants and SRIs. None assessed measures of frequency, duration or intensity of treatment specifically; nor did they assess training experience of the investigator or clinician providing care.

Child and family characteristics. Some characteristics of the family and child were found to be useful in predicting treatment success, including a history of psychiatric diagnoses in the family, early verbal skills in the child,[224] and, potentially, genotype for predicting lack of treatment response or adverse reactions.[214,223] Several studies of stimulant use highlighted differences in effectiveness by diagnosis type[228-230,232,233] finding that children with Asperger syndrome were typically more responsive to psychostimulant treatment than those with autistic disorder. The presence of co-morbid intellectual disability was associated with lower treatment response in one study.[232]Two studies sought to examine differences in treatment response by gender and found none.[231,232] Details are provided below.

One open-ended study of fluoxetine treatment in 129 children assessed response qualitatively. Subjects with an average age of 4.5 years were diagnosed with a PDD by DSM-IV criteria corroborated by Childhood Autism Rating Scale and ADOS and were then treated with fluoxetine as felt to be clinically indicated, with up to 72 months of treatment. They analyzed potential predictors of good/excellent response, including family history and subject characteristics. When comparing to subjects with fair/poor response, they found an increased rate of family history of affective disorder (major depressive disorder and bipolar disorder) and "unusual intellectual achievement" in those subjects with a good/excellent response. Subjects with good/excellent response also showed an increased rate of verbal language before starting fluoxetine. Finally, subjects with a good/excellent response were more likely to have hyperlexia, an early or precocious interest in letters or numbers. They did not find a significant relationship between history of regression and response to fluoxetine. They also did not find a relationship between dose of fluoxetine and likelihood of response.

One additional retrospective case series described response to various serotonin reuptake inhibitors, primarily sertraline, citalopram, paroxetine, and fluvoxamine in 89 children and adolescents with ASDs by DSM-IV criteria.[224] The CGI-Improvement was used to gauge medication response, with 40 subjects rated as at least "much improved." Family history of ASDs was significantly associated with positive treatment response. Other possible moderators showed no association with response, including family history of depression or anxiety, subject diagnosis, concurrent medications, specific SRI prescribed, and indication for SRI initiation, whether for anxiety, repetitive behavior, aggression, or depression.

In the double-blind cross-over trial of MPH in 66 children with PDDs,[228-230] authors found no effect of age, IQ, weight, or diagnosis on teacher- or parent-rated hyperactivity subscale scores / Swanson Nolan and Pelham-Fourth edition rating scale (SNAP-IV) / Children's Yale-Brown Obsessive Compulsive Scale-PDD scores. Children with Asperger syndrome/PDD-NOS (n=19) showed a trend of being more likely to be classified as responders to both placebo and MPH than those with autism. Response to each dose of MPH was significantly superior to placebo in the autism subgroup but not for the Asperger / PDD-NOS subgroup.

Similarly, Posey et al., in their retrospective review of 80 children with PDDs treated with guanfacine,[232] found that subjects with PDD-NOS and Asperger syndrome showed a greater rate of global response than those with autistic disorder. Those without intellectual disability showed a higher rate of global response to guanfacine (37.5 percent) than those with co-morbid intellectual disability (17.9 percent). They also identified that the responders were less aggressive at baseline by the CGI severity item. Finally, Stigler et al., in their study on the effectiveness of psychostimulants in 195 children with PDDs, found that children with Asperger disorder were found to be more likely to respond to treatment than those with autistic disorder or PDD-NOS. Those children on concomitant medication were also found to be more likely to respond to treatment; the study did not find any association between stimulant type, gender or IQ and response to treatment.[233]

Of particular interest currently in the study of medical treatment of autism is the possibility of genetic modifiers that might be used to target treatment choices. One prospective ten-week case series of escitalopram sought to identify pharmacogenetic modifiers of treatment response in the challenging behavior domain as measured by the ABC-C-Irritability.[223] Fifty-eight subjects with ASDs corroborated by ADI-R and a minimum ABC-C-Irritability score of 12 underwent a forced dose titration of escitalopram from 2.5 mg daily increasing weekly to 5 mg, 10 mg, 15 mg, and 20 mg, essentially twice the dose equivalent of citalopram given that escitalopram is the active component of racemic citalopram. Pre-designated dose-limiting side effects included sleep disruption and an increase in ABC-C Irritability or Hyperactivity subscales of 10 points over the previous week.

Subjects were also genotyped at several polymorphisms in the serotonin transporter gene. Average daily doses of escitalopram were 10.8-12.4 mg and did not differ across genotype groups, which reflects the fact that most subjects in all genotype groups could not tolerate the maximum dose. One genotype group, designated *a priori* as the low-expression genotype group, showed diminished response to escitalopram,[223] with a particularly striking difference in a subgroup of the low-expression genotype based upon previous association with platelet serotonin uptake measures.[289] The low-expression genotype group also had verbal and nonverbal IQ scores that were 25 to 26 points lower than the other subjects; although this was not described as a statistically significant difference. Genotype groups also differed with respect to percentage of Caucasian subjects, with the high-expression genotype group only containing Caucasian subjects; although the pattern of results was reported to be the same in a Caucasian-only analysis.

In other medical studies, children treated with DMSA[250,255] had greater improvement in core and associated ASDs symptoms if they were older than age 5. Children with lower initial ADOS scores (below the 50th percentile) also had greater improvements than were seen among children with initially higher scores. It is unclear whether either of these modifiers is significant in the context of a trial with no overall difference in response between DMSA and placebo. In one study of a ketogenic diet,[245] the two patients with the greatest improvement were those whose baseline condition was classified as mild using CARS scores, and those with severe autistic behavior showed substantially less improvement. In a study assessing omega 3 fatty acid use, a negative correlation between docosahexaenoic acid level and CARS before treatment was observed in nonresponders. Finally, attempts to identify subgroups of children for whom oral immunoglobulin was successful in treating GI symptoms and associated autism symptoms found no effect of age, regression onset of symptoms, or predominant bowel type.[64]The treatment was uniformly ineffective.

CAM Interventions

One CAM study[285] noted correlations between changes in scores on sensory measures after qigong massage therapy and positive behavioral changes.

KQ3. Early Results in the Treatment Phase That Predict Outcomes

Early Identifiable Changes Predicting Response/Outcome

Information about early response to treatment, or lack thereof, can be essential to guiding treatment selection, implementation, and modification. The reviewed literature offers almost no information about what specific changes predict long-terms outcome and response. Some evidence indicates that early response to both UCLA/Lovaas-based approaches and ESDM intervention in terms of changes in IQ over the first year of treatment predicts, or accounts for, longer-term change in IQ.[287,290] However, findings also suggest that while gains in the cognitive domain might be accounted for primarily within the first year of treatment, changes in adaptive behavior in response to these same interventions may occur over a longer time frame[110,133,287,290] if they occur at all.[105]

KQ4. End of Treatment Effects That Predict Outcomes

One study meeting our criteria addressed whether outcomes measured at the end of treatment could predict longer term functional outcomes. An RCT comparing joint attention and symbolic play interventions[155,156] included 58 children with autism between 3 and 4 years of age. Investigators assessed language development, joint attention and play skills, and mother-child interactions at pre- and post-intervention and 6 and 12 months after the end of the 5 to 6 week intervention. Children in the symbolic play and joint attention groups showed significantly greater growth expressive language over time than did participants in the control group ($p<.01$, moderate to large effect sizes). Growth in receptive language was not significantly affected by the intervention from pre-intervention to 12 months post-intervention.

Children in the both the joint attention and symbolic play groups showed significantly more growth in initiation of joint attention and duration of child-initiated joint attention than did the control group ($p<.01$ to $<.05$). Children in the symbolic play group also showed significantly more growth in play level than did children in either the joint attention ($p<.01$) or control ($p<.001$) groups.

The investigators also assessed differences in the amount (total hours) of intervention services (speech and overall) children in the three groups received post-intervention, with children in the control group receiving significantly more hours of overall services than either the joint attention or symbolic play groups ($p<.05$ and $<.01$, respectively); differences in hours of speech interventions received were not significant. Only the duration of child-initiated joint attention episodes was related to hours of intervention received post-treatment, with children with fewer hours of overall services showing greater growth in child-initiated joint attention episodes.[155] Hours of speech interventions received did not affect growth in skills.

KQ5. Generalization of Treatment Effects

Parents and clinicians wish to know whether outcomes observed in the treatment setting are likely to also be found in other settings and are thus generalizable. To try to assess generalizability, we recorded the degree to which studies collected outcomes data in multiple settings when it would be appropriate. For example, we noted when studies occurring in the clinical setting also collected data in the home or school. We also noted the period of time for which studies collected data.

For some areas of intervention, outcomes are primarily measured outside of the setting in which the treatment takes place. This includes, for example, behavioral interventions for associated conditions like anxiety, in which treatment occurs in therapy sessions. For these interventions, outcomes are usually measured using parent, self, and/or teacher report at home, at school and in the community. Studies of these behavioral interventions do, in fact, report positive outcomes in children’s natural settings to mirror what is seen in the treatment setting; however, these outcomes are generally identified with parent report rather than the preferred direct observation. Few behavioral interventions continue to monitor children in their studies and so maintenance of the results over time is largely unknown.

In a number of studies of social skills interventions[154-155,162-163], parents reported positive outcomes outside of the treatment session, but parents were not blinded to intervention status. Participants in cognitive-behavioral-ecological[137,138] and Lego therapy[143] were shown to have improved social skills outside of the intervention settings. Although the parents of children involved in Children’s Friendship Training[141] reported significant changes in child social behavior at home immediately following the intervention (as well as 3 months later), teachers did not report any changes in the children’s behavior at school. On the other hand, teachers of children involved in a social competency and social skills training program[140] reported improvements in student behavior at school.

One study attempted to assess the ability of children to apply new skills across changing intervention conditions. Participants in Social Stories[145] were able to generalize the social skills they learned while playing with one set of board games to a different set of board games. However these “generalization” trials were conducted by the same experimenter in the same room as the other assessments, so it is not clear whether the targeted social skills would generalize to more naturalistic settings with peers.

In medical studies, although the treatment is prescribed in a clinical setting, it is generally administered at home, and one would expect effects of medications to be observed in terms of behavior in the home and other settings. However, medical studies may be good sources of information on the duration of perceived effects. Unfortunately, other than case series data for risperidone[177,203,204,206,213] demonstrating continued effects and side effects beyond six months. few data are available on longer term outcomes of medical treatment.

Two of the case series studies of SRIs are based upon durations of treatment longer than 6 months, but the general and sometimes qualitative ratings of change in these studies are difficult to compare with the results of the RCTs to understand if medication responses reported in RCTs are likely to be durable.[221,224]

KQ6. Drivers of Treatment Effects

No studies were identified to answer this key question.

KQ7. Treatment Approaches for Children Under Age Two at Risk for Diagnosis of ASDs

This section presents the results of our literature search and findings regarding the use of treatment approaches in younger children who are at high risk of developing autism based upon behavioral, medical, or genetic risk factors. Studies located typically included participants whose mean age exceeded 24 months; however, the studies address interventions which can be used with children under age 2. The average age for diagnosis of ASDs in the US is not until at least age 3, but a reliable diagnosis may be possible as early as age 2.[291-293] Research suggesting that early intervention can improve outcomes has compelled investigators to consider intervening in very young children.[115]

We identified four papers[178,290,294,295] with unique study populations addressing treatment approaches for very young children. Three studies were conducted in the US[178,290,294] and one in the UK.[295] Two of the studies were prospective case series,[178,294] one was a nonrandomized controlled trial,[295] and one was a randomized controlled trial.[290] Table 26 summarizes outcomes for studies considered to be fair or good quality and employing comparison groups.

The RCT[290] and nonrandomized trial[295] were completed in a clinic setting with instruction to continue with parents at home. All children in the RCT met DSM-IV criteria as well as criteria on ADOS and Toddler Diagnostic Interview for diagnosis confirmation; the mean age of participants in the treatment and control groups was 23 months. The nonrandomized trial[295] employed parent training techniques to teach social communication skills and included children with a mean age of 38 months in the intervention group and 34 months in the control group.

One of the case series describes an evaluation of techniques to train personnel to provide ESDM-based therapy and included children with a mean age of 33 months.[178]The second case series[294] was completed in the home and classroom and focused on social-communication and language outcomes; children assessed in the study were between 18 and 36 months. Among studies in this section, 1 was considered good quality, 1 fair quality, and 2 were considered poor.

The Dawson et al.[290] randomized controlled trial evaluated the effectiveness of the ESDM for young children with ASDs. ESDM, a comprehensive, manualized intervention that blends ABA with developmental and relational approaches, was designed to be used with children as young as 12 months, delivered in the home, and to utilize parents as well as trained therapists.

After 2 years of intensive intervention (31 hours of intervention per week, 15 from a therapist and 16 from parents) children receiving ESDM treatment displayed significantly larger gains in IQ (when compared with a community sample receiving 18 hours of individual and group intervention). Children in the experimental group also demonstrated significantly larger gains in terms of adaptive behavior skills (i.e., all areas except socialization) than controls. The authors also reported greater diagnostic shifts (i.e., from Autistic Disorder to PDD-NOS for seven (29.2 percent) children in the ESDM group and for one (4.8 percent) child in the community services group; two (8.3 percent) children in the ESDM group and five (23.8 percent) children in the community services group experienced a diagnosis change from PDD-NOS to ASDs); however, these shifts were not matched with clinically significant improvements in terms of ADOS severity scores nor measurements of restricted and repetitive behaviors (i.e., RBS scores).

While no replication of this study has been conducted, the model had been subject to an early effectiveness trial[178] wherein the research team compared distance learning vs. live instruction for community-based therapists implementing intervention and training parents. Results suggest that both modalities of learning were effective in teaching therapists to implement and train parents, with significant child gains over time and across modalities; however, results also suggested that implementation with fidelity required specific and explicit supervision. Thus, while promising in terms of treatment efficacy and extension to a younger population of children with ASDs, training demands for broad implementation appear substantial. Further, the average age for enrollment was very close to 2 years of age. As such, concerns about how this model would apply to children closer to 1 year of age remain.

In another evaluation of an early intervention approach, parents of 51 preschool-aged children suspected of ASDs (mean age, intervention group = 38 months, mean age, control group = 34 months) participated in the Hanen More than Words program, as created by the Hanen Center either immediately (n = 26) or after a delay (n = 25).[295] The program focused on weekly group instruction in enhancing interactions and facilitating communication. In addition to 20 hours of group intervention, parents received individual in-home feedback on three occasions. Operationalization of “suspected ASDs” was identification of language delay and some aspect of concern about social behavior by a pediatrician and/or a speech and language therapist.

Ultimately, this resulted in inclusion of children within intervention and control groups without ASDs, with the authors grouping PDD-NOS and other developmental concerns under a category of “non-core autism.” After the intervention period, reported language use was substantially higher for the intervention group, with both the core autism and non-core autism children demonstrating improvements. Parent use of taught strategies was also higher in the intervention group than in the comparison group but only for the children with core autism. No group differences were found for ADOS scores or behavior issues.

Notably, more children in the intervention group had ASDs, and the intervention group also received more “substantial intervention” outside of the treatment context. Thus, while demonstrating potential benefit for parent training in social communication for young children with ASDs, the unique impact of this program for specific children remains unclear.

Wetherby and colleagues’[294] prospective case series served as a preliminary study for the Early Social Interaction Project, which emphasizes a parent-implemented individualized curriculum in a natural environment. The authors found significant within-group differences from pre- to post-test for 11 of the 13 social-communication measures on the Communication and Symbolic Behavior Scales Developmental Profile in the Early Social Interaction group (n=17). The post-Early Social Interaction group performed significantly better than the third-year contrast group (n=18) on three measures of social signals, rate of communicating, three measures of communicative functions, and understanding.

The third-year contrast group performed significantly better than the pre-Early Social Interaction group on all three measures of communicative means and on actions to others in play, but there were no significant differences on the three measures of social signals, rate of communicating, the three measures of communicative functions, understanding, and inventory of actions. The percentage of children who were verbal was 5.9 percent in the pre- Early Social Interaction group, 76.5 percent in the post- Early Social Interaction group, and 55.6 percent in the third-year contrast group.

These findings suggest that the Early Social Interaction project has a positive impact on ASDs symptoms, but because the groups were unable to be compared at pretest, we cannot conclude whether the benefits were due to Early Social Interaction or to normal maturation. Another limitation in the authors' methodology is the lack of documentation of parental implementation in the home, given that the parents' involvement is a significant factor in the effectiveness of Early Social Interaction treatment.

Table 26. Outcomes of interventions for children at risk for diagnosis of ASDs

Author, year, country Groups, N enrollment/N final Study quality	Age, mean (mo) ± SD Diagnostic category, N (%)	Key outcomes
Dawson et al.[290] 2010, US **G1:** ESDM, 24/24 **G2:** Community-based interventions, 24/21 Quality: Good	**G1+G2**: Intake: 38 Followup: 52 Autism: 39 (75) PDD-NOS: 9 (17)	**1 yr outcomes:** • Significantly greater improvement in IQ for ESDM (154 vs. 22 pts) than community-based. • No adaptive behavior differences. **2 yr outcomes:** • Significantly more improvement in ESDM group vs. community-based on IQ; receptive language, and expressive language. • Adaptive behavior improvements in both groups (all domains except socialization); significantly greater improvements in ESDM group. • No change in ADOS severity scores or repetitive behavior. • Diagnostic shift toward milder diagnosis (PDD-NOS) greater for ESDM group.
McConachie et al.[295] 2005, UK **G1**: More than Words (MW), 26/26 **G1a**: MW, participants with autism dx, 17/17 **G1b**: MW, participants with PDD-NOS or other childhood developmental disorder, 9/9 **G2**: Wait list control, 21/21 **G2a**: Wait list control, participants with autism dx, 12/12 **G2b**: Wait list control: participants with PDD-NOS or other childhood developmental disorder, 13/13 Quality: Fair	**G1**: 38.12 (6.54) **G2**: 34.96 (6.68) **G1**: Autism: 17 (65) NCA: 9 (35) **G2**: Autism: 12 (48) NCA: 13 (52)	• Reported language use was substantially higher for G2 with both the core autism (on average 50 words) and NCA groups demonstrating improvements. • No group differences were found for ADOS scores or behavior issues.

ADOS=Autism Diagnostic Observation Schedule, dx=diagnosis; ESDM=Early Start Denver Model, G=group; IQ=intelligence quotient; mo=months; MW=More than Words; NCA=non core autism

Discussion

In this chapter, we summarize our findings about therapies for children with autism spectrum disorders (ASDs). We provide an overview of the state of the literature by intervention type, detail the strength of evidence for the impact of each major intervention on relevant outcomes, and describe major issues and gaps in the current body of evidence.

The organization of interventions into categories followed in this report is one of many possible approaches, none of which is uniformly accepted in the field. In developing a comparative effectiveness review for the Effective Healthcare Program, our primary intent is to provide information to end users making treatment choices, rather than to academic researchers who might choose to organize the report differently, for example by underlying philosophy or approach. Therefore, in selecting the categories of interventions reflected here, we attempted to incorporate both treatment approach and treatment setting, as these two elements would be considered in a treatment decision. This consideration means that some categorical divisions of similar approaches are reviewed in different sections. For example, studies employing early intensive intervention approaches are included in the early intensive behavioral and developmental studies section and in the educational section. We considered whether alternate organizations would have changed our conclusions in any area and determined that neither our assessment of the literature nor our strength of the evidence determinations would have changed.

Our summary begins with results of the literature search on behavioral interventions, which we have organized into five major categories: early intensive behavioral and developmental approaches; social skills training; play and interaction-based interventions; behavioral interventions for associated conditions; and additional interventions. We subsequently review educational interventions, which we defined as those interventions intended primarily to be administered in educational settings, or studies for which the educational arm was most clearly categorized. This section includes TEACCH (Treatment and Education of Autistic and Communication related handicapped CHildren) and other treatments implemented primarily in the educational setting. Some of the interventions implemented in educational settings are based on principles of ABA and may be intensive in nature, but none of these interventions used the UCLA/Lovaas or Early Start denver Model (ESDM) manualized (i.e., have published treatment manuals to facilitate replication) treatments.

Finally, we discuss medical and related interventions, allied health interventions, and then remaining complementary and alternative medicine (CAM) interventions not fitting the above categories.

The assessment of the literature is done by considering both the observed effectiveness of interventions and the confidence that we have in the stability of those effects in the face of future research. The degree of confidence that the observed effect of an intervention is unlikely to change is presented as strength of evidence, and can be insufficient, low, moderate or high. Strength of evidence describes the adequacy of the current research, both quantity and quality, and whether the entire body of current research provides a consistent and precise estimate of effect. Interventions that have shown significant benefit in a small number of studies but have not yet been replicated using rigorous study designs will have insufficient or low strength of evidence, despite potentially offering clinically important benefits. Future research may find that the intervention is either effective or ineffective.

Methods for applying strength of evidence assessments are established in the Evidence-based Practice Centers' Methods Guide for Effectiveness and Comparative Effectiveness Reviews[99] and are based on consideration of four domains: risk of bias, consistency in direction of the effect, directness in measuring intended outcomes, and precision of effect. For determining the strength of evidence for effectiveness outcomes, we only assessed the body of literature deriving from studies that included comparison groups. We required at least 3 fair studies to be available to assign a low strength of evidence rather than considering it to be insufficient. We required at least one good study for moderate strength of evidence and two good studies for high strength of evidence. In addition, to be considered "moderate" or higher, intervention-outcome pairs needed a positive response on two out of the three domains other than risk of bias. For determining the strength of evidence related to harms, we also considered data from case series.

Once we established the maximum strength of evidence possible based upon these criteria, we assessed the number of studies and range of study designs for a given intervention-outcome pair, and downgraded the strength of evidence rating when the cumulative evidence was not sufficient to justify the higher rating. As could be expected in a field that is testing a broad array of interventions, most intervention-outcome pairs had insufficient strength of evidence to establish confidence in the stability of observed effects.

Tables 27 through 35 provide summaries of results, including strength of evidence, for each category of intervention (behavioral, educational, medical, allied health, and CAM). Table 36 documents the strength of evidence for each domain of the major intervention-outcome combinations for which the strength of evidence was not insufficient. Table 37 presents those interventions-outcomes pairs for which the strength of evidence is insufficient.

Outcomes and Strength of Evidence of Therapies

Effectiveness of Behavioral Interventions

Categories of behavioral intervention studies included early intensive behavioral and developmental intervention studies, social skills approaches, play- and interaction-based approaches, interventions focused on commonly associated conditions, and studies of additional behavioral interventions. Tables 27 through 31 summarize effectiveness findings for studies of behavioral approaches.

Early intensive behavioral and developmental interventions. We adopted a similar approach to the operationalization of this category as Rogers and Vismara[12] in their review of "comprehensive" evidence-based treatments for early ASDs. Interventions in this category have their basis in or draw from principles of applied behavior analysis (ABA), with differences in methods and setting. ABA is an umbrella term describing principles and techniques used in the assessment, treatment and prevention of challenging behaviors and the promotion of new desired behaviors. The goal of ABA is to teach new skills, promote generalization of these skills, and reduce challenging behaviors with systematic reinforcement. The principles and techniques of ABA existed for decades prior to specific application and study within ASDs.

We first discuss two intensive manualized interventions: the UCLA/Lovaas model and the ESDM. These two interventions have several key differences in their theoretical frameworks and implementation, but are similar in the frequent use of high intensity (many hours per week, one-on-one) instruction utilizing ABA techniques. They are described together here because of these similarities. The UCLA/Lovaas method relies heavily on one-on-one therapy sessions during which a trained therapist uses discrete trial teaching with a child to practice target skills, while the Early Start Denver Model (ESDM) blends ABA principles with developmental and relationship-based approaches for young children.

The other treatment approaches in this section also incorporate ABA principles, and may be intensive in nature, but often have not been manualized. We have classified these approaches broadly as UCLA/Lovaas-based given their similarity in approach to the Lovaas model. A third set of interventions included here use the principles of ABA to focus on key pivotal behaviors rather than global improvements. These approaches emphasize parent training (e.g., Pivotal Response Training, Hanen More than Words, social pragmatic intervention, etc.) and may focus on specific behaviors such as initiating or organizing activity or on core social communication skills. Because they emphasize early training of parents of young children, they are reviewed here.

Summary. We located 38 papers[100-133,178,290,294,295] comprising 34 unique studies addressing early intensive behavioral and developmental interventions. Individual studies using UCLA/Lovaas-based interventions or ESDM report improvements in outcomes for some preschool and early school-aged children. Improvements are most often seen in cognitive abilities and educational attainment, and less consistently in adaptive, social, and challenging behaviors. Of note, however, even children who have meaningful improvement in specific areas (most commonly in cognitive skills) often continue to have substantial impairment in adaptive, social, and behavioral functioning. This sustained level of impairment, along with a lack of longer-term outcomes data, makes it difficult to assess whether treatment-related changes can modify long-term functional and developmentally appropriate adaptive independence.

To date, studies have failed to characterize adequately the subpopulation of children who experience positive response to intervention, although it is clear that positive outcomes are more prominent in some children but not others. One powerfully replicated finding is that not all children receiving early intensive intervention demonstrate robust gains, and many children continue to display prominent areas of impairment. Nonetheless, dramatic improvements are observed in a subset of children and even small improvements in standardized outcomes may translate into meaningful improvements in quality of life. Early intensive behavioral and developmental approaches have significant potential, yet require further research.

Unfortunately, there have been to date very few well-controlled trials and those conducted have used small samples; different treatment approaches (i.e., developmental to intensive behavioral); intensity (12 hours over 3 months vs. 30 hours over 1 week); and duration (weeks to years); varied inclusion and baseline assessment criteria; children of varying ages (intake age ranging from 18 months to 7 years); and different outcome measurements over different periods of time (weeks to years).

Observational and noncontrolled studies also have reported improvement for children receiving early intensive treatments when compared with eclectic treatments. Positive outcomes have been most common when early intensive behavioral and developmental interventions are systematically delivered by expert providers, including well-supervised and trained parents, over fairly lengthy intervals of time (> 1 year). A challenge to interpreting the observational literature, however, is that although authors assert that they used early intensive behavioral and developmental interventions, many of the studies are inadequately described, fail to include fidelity and treatment adherence measurements and procedures, and may in fact be delivering very different interventions. As a result, the body of observational literature categorized in this report as “early intensive behavioral” is so disparate that conclusions cannot easily be drawn.

Few studies directly comparing the effects of different treatment approaches are available (for example, direct comparison of UCLA/Lovaas and ESDM), and few data on practical effectiveness or feasibility beyond research studies exist, so questions remain about whether reported findings would be observed on a larger scale within communities. Similarly, no studies in this category reported harms of intervention.

Less intensive interventions to provide parent training for bolstering social communication skills and managing challenging behaviors may be useful for younger children with ASDs, particularly to improve social communication, language use, and potentially symptom severity and family functioning.[108,109,120,295] However, while parent training programs can modify parenting behaviors during interactions, data are limited about their contribution to specific child improvements in the short- and long-term beyond simple language gains for some children.

Table 27. Summary of results of studies of early intensive behavioral and developmental approaches

Intervention	Study design/Quality	Study results and overall strength of evidence
UCLA/Lovaas-based interventions	1 RCT / 1 fair[114] 3 Nonrandomized trials / 3 fair,[103,110,126] 5 Prospective cohorts / 3 fair,[105,125,129] 2 poor[101,124] 2 Retrospective cohorts / 2 poor[106,130] 6 Prospective case series[102,104,107,112,115,119] 6 Retrospective case series[111,113,118,121,122,127,131]	• Young children receiving high intensity interventions (>30 hours a week for 1-3 years by well trained therapists) display improvements in areas of cognitive, language, adaptive functioning. • Subgroups of children display a positive response to this intervention, but the subgroup with a positive response is not well characterized. • Strength of evidence for UCLA/Lovaas-based intervention in affecting language, cognitive, educational, and adaptive outcomes and ASD symptom severity is low.

Table 27. Summary of results of studies of early intensive behavioral and developmental approaches (continued)

Intervention	Study design/Quality	Study results and overall strength of evidence
Early Start Denver Model	1 RCT/1 good[290] 1 Prospective case series[178]	• Improvements in cognitive, language, and adaptive behavior skills are seen over 2 years in one RCT of ESDM intervention for young children with ASDs. • ESDM findings are not yet replicated and it is unclear how core ASDs symptoms change in response to treatment. • Strength of evidence for ESDM-based intervention in affecting cognitive, language, and adaptive outcomes currently is insufficient.
Intensive parent training	3 RCTs / 3 fair[100,108,109] 1 Nonrandomized controlled trial / 1 poor[120] 3 Prospective case series[116,117,128]	• Some indication of short-term improvements in language, social, and adaptive skills for children whose parents receive training in these areas but studies vary in interventions and outcomes studied. • Data do not yet demonstrate long-term functional improvements across domains for any specific form of training. • Strength of evidence for changing core ASDs deficit areas is insufficient as studies vary in interventions and outcomes reported.

ASDs=autism spectrum disorders; ESDM=Early Start Denver Model; RCT=randomized controlled trial; UCLA=University of California, Los Angeles

Strength of evidence. In general, there are too few studies of either UCLA/Lovaas-based approaches, ESDM, or intensive parent training approaches to assert that observed estimates of effect for either approach are unlikely to change with future research. With a relatively larger (albeit still inadequate) body of literature, the UCLA/Lovaas studies report positive shifts in language, adaptive, cognitive and educational outcomes, but our confidence (strength of evidence) in that effect is low, based on the need for additional, confirmatory research (Table 27). With only one RCT, we can only judge the literature on ESDM to be insufficient; although results in this one study were positive and the study warrants replication. On balance, however, the combined research on UCLA/Lovaas and ESDM suggests a benefit of early intensive approaches for some children that should continue to be studied. The evidence for parent training interventions was insufficient; the few available studies used interventions that varied from study to study. Furthermore, outcomes assessed in these studies were frequently short-term, indirect (intermediate) measures.

Social Skills Training

Summary. We located 16 papers addressing interventions targeting social skills.[135-149,152] Although all of the studies of social skills interventions reported some encouraging results, most have not included objective observations of the extent to which social skills improvements are maintained within everyday peer interactions. In addition, the current research focuses almost exclusively on children considered high functioning based on IQ and language skills, excluding the majority of children diagnosed with an ASD. The quality of the studies was poor to fair, although some results may suggest benefit for a subgroup of particularly high functioning children. No two studies evaluated the same intervention, making it impossible to know whether observed results are likely to be consistently observed. No studies reported harms of intervention.

Strength of evidence. The strength of evidence for the effect of social skills interventions on social outcomes is insufficient (Table 28). Of 8 RCTs, four were fair in quality and none was good. All studies did demonstrate benefit on at least one outcome measure but a lack of consistency in the interventions or outcome measures makes it impossible to assess consistency or precision. Most studies relied on report of intermediate outcomes.

Table 28. Summary of results of social skills interventions

Intervention	Study design/Quality	Study results and overall strength of evidence
Group-format	6 RCTs / 3 fair[135,139,141], 3 poor[143,146,149] 1 Retrospective cohort / 1 poor[148] 5 Prospective case series[136,138,140,142,144]	• High functioning children with ASDs improved on various social outcomes in individual studies, however the specific social skills in which benefits were observed and reported (such as emotion recognition, theory of mind, and observed peer interactions) varied depending on the study. • Strength of evidence on social outcomes is insufficient given variations in the interventions and outcomes assessed.
Individual-format	2 RCTs / 1 fair,[145] 1 poor[152] 2 Prospective case series[137,147]	• Improvements were seen in targeted social skills for treated participants but interventions and outcomes varied substantially across studies. • Strength of evidence for social outcomes is insufficient given variations in the interventions assessed.

ASDs=autism spectrum disorders; RCT=randomized controlled trial

Play- and Interaction-Based Interventions

Summary. Fifteen papers (13 unique study populations) assessed play-/interaction-based approaches.[153-167] Parent training in play-based interventions shows some promise for reducing challenging behavior and encouraging early social communication skills (e.g., joint attention and symbolic play). Joint attention and symbolic play interventions also promoted expressive language growth.[155,156] No studies reported harms of intervention.

Strength of evidence. Although there were at least two RCTs available for most categories of play interventions (parent-focused, relationship-based, imitation, joint attention and symbolic play), none was of good quality and the diversity of specific interventions and outcomes prohibits drawing conclusions about specific approaches (Table 29).

Table 29. Summary of results of studies of play-/interaction-based interventions

Intervention	Study design/ Quality	Study results and overall strength of evidence
Parent-focused therapies	2 RCTs / 1 fair,[161] 1 poor[153,154]	• Problem behavior declined for the treated group in both studies. • Adaptive behavior skills increased for the treated group in one RCT. • Parent reports indicated that the treated group appeared more typical following intervention in one study. • Strength of evidence for effectiveness in affecting challenging behavior is insufficient.
Imitation	3 RCTs / 3 poor[163-165]	• Children in imitation treatment groups showed more interaction with adults compared with those in contingent response groups in all three studies. • Strength of evidence for the effect on social behavior is insufficient.
Joint attention and symbolic play	2 RCTs / 1 fair[155,156], 1 poor[157] 2 Prospective case series[158,167]	• Joint attention and symbolic play were both effective in improving responsive joint attention or expressive language in the short and long term in one RCT. • Greater improvement in outcomes predicated on increased joint attention in the joint attention groups in one RCT. • Mother-mediated joint attention intervention yielded increases in joint engagement in one study. • Strength of evidence for effectiveness of joint attention intervention in affecting joint attention outcomes is insufficient.
Relationship-focused interventions	2 Prospective case series[160,166] 2 Retrospective case series [159,162]	• Positive behavioral outcomes noted in all series, but no comparison groups. • Insufficient evidence to determine effectiveness.

RCT=randomized controlled trial

Behavioral Interventions for Commonly Associated Conditions

Summary. We identified 11 studies reported in 12 papers [25,26,168-177] that addressed behavioral interventions focused on symptoms commonly associated with ASDs. Most studies of behavioral interventions to address commonly associated conditions are limited to high-functioning children (based on IQ) with ASDs who are at least school age. These studies evaluated behavioral treatments for commonly occurring comorbid symptoms in ASDs, including anxiety, anger management difficulties, and challenging behaviors. All report promising results, with caveats concerning study quality.

Interventions included cognitive behavioral therapy in individual and group formats, parent training, and teacher training to address target symptoms. Cognitive behavioral therapy (CBT)-based treatments varied across studies and were generally adapted from existing manuals to be more amenable for use in children with ASDs. Several studies suggested that CBT-based interventions were effective in reducing anxiety symptoms.[26,170,171]

This category of intervention also included various parent training approaches to decrease challenging behaviors. Results of two studies combining parent training with risperidone treatment suggested that adding parent training to medication increased adaptive behavior and decreased noncompliance and irritability/aggression in children with ASDs.[172,177] Another set of parent training studies suggested that training parents improved both the frequency and intensity of a child's challenging behaviors.[174,175]

While individual studies of CBT and parent training for decreasing comorbid anxiety, anger management, and externalizing symptoms reported positive results, results should be interpreted cautiously. The small number of studies overall use disparate intervention approaches and different outcome measures. Additionally, in some of these studies, parents were involved in delivering the interventions and completed the majority of questionnaires to assess symptoms before and after treatment. No studies reported harms of intervention.

Strength of evidence. Current strength of evidence for CBT- based, parent-training, and teacher-training interventions on comorbid symptoms is insufficient. Consistent positive findings of improvement in anxiety, anger, and challenging behavior levels are offset by variation among the interventions and outcomes assessed (Table 30).

Table 30. Summary of results of studies targeting behaviors commonly associated with ASDs

Intervention	Study design/ Quality	Study results and strength of evidence
CBT for anxiety	4 RCTs / 2 fair,[169-171] 2 poor[25,176] 1 Nonrandomized trial / 1 fair[26]	• Decrease in anxiety symptoms in treated groups in individual studies. • Participants meeting criteria for anxiety disorders decreased in one study. • Improvement in social skills in treated children. • Strength of evidence for a positive effect on comorbid symptoms was insufficient based on variation in the interventions assessed.
CBT for anger management	1 RCT / 1 fair[168]	• Reduction in parent-reported instances of anger in the treated group of one RCT. • Strength of evidence for a positive effect on comorbid symptoms was insufficient, based on only on RCT of fair quality.
Parent and teacher training focused on commonly associated behaviors	1 RCT / 1 fair[177] 2 prospective cohorts / 2 poor[174,175] 2 prospective case series[172,173]	• Less severe challenging behaviors were observed in children taking risperidone whose parents participated in parent training in one RCT • Parent training in individual sessions was more effective than in a workshop setting in one study. • Strength of evidence for a positive effect on comorbid symptoms was insufficient, based on variation in the interventions and outcomes assessed.

CBT=cognitive behavioral therapy; RCT=randomized controlled trial

Additional Behavioral Interventions

Summary. Three studies[181-183] of additional behavioral interventions (neurofeedback, sleep workshops) met our inclusion criteria. These intervention studies were limited by small sample sizes, short-term followup and largely parent-reported outcomes. No studies reported harms of intervention.

Strength of evidence. With few studies of additional behavioral interventions, all of poor quality, there is insufficient evidence to evaluate the relative effect of other behavioral interventions on targeted outcomes including ASDs symptom severity, problem behaviors, and sleep concerns (Table 31).

Table 31. Summary of results of studies of other behavioral interventions

Intervention	Study design/ Quality	Study results and overall strength of evidence
Neurofeedback	2 RCTs / 2 poor[181,182]	• Insufficient strength of the evidence based on few, poor studies.
Sleep workshops	1 Prospective case series [183]	• Insufficient strength of the evidence.

ASDs=autism spectrum disorders; RCT=randomized controlled trial

Effectiveness of Educational Interventions

Studies of educational interventions. Interventions intended primarily to be administered in educational settings, or studies for which the educational arm was most clearly categorized, were included in this category. This included studies of the Treatment and Education of Autistic and Communication related handicapped CHildren (TEACCH) program, computer-based educational intervention studies, as well as studies implemented in educational settings based on principles of ABA that were intensive in nature (broad-based studies).

This third group of studies is included in this section because they were implemented in an educational setting and they did not utilize a specific treatment manual (e.g., UCLA/Lovaas, ESDM) . We note that these studies make use of intensive behavioral approaches as comparators. They are included here because the educational arms of the studies are more clearly characterized than the ABA arms. Our conclusions would not have changed had these studies been included in the early intensive behavioral and developmental section of the report.

Summary. The TEACCH program has historically been the most widely studied educational intervention, but the majority of research on it took place prior to the date cutoff for our review. Thus, only four studies met our criteria for inclusion.[185-188] This newer research continues to report some improvements in motor and cognitive measures.

Among the studies of broad-based interventions evaluating the setting and the type of instructional strategy, one study[195] found that children in both a home-based early intensive behavioral intervention and an autism-based nursery program improved at similar rates, and that child characteristics including IQ and receptive language at baseline were strong predictors of progress. An additional study[192] suggested that home-based ABA teaching interventions were more effective than those in a school-based intervention borrowing from TEACCH, and a home-based portage program, in which parents were provided training to conduct the intervention at home. Few studies of computer-based interventions met our criteria, and those that did employed varied approaches. No studies of educational interventions included here reported harms.

Strength of evidence. The strength of evidence for positive outcomes observed for educational interventions on all outcomes measured (cognitive, socialization, communication) was insufficient based on too few studies measuring the same outcomes (Table 32).

Table 32. Summary of results of educational interventions

Intervention	Study design/ Quality	Study results and overall strength of evidence
TEACCH	2 Prospective cohorts / 1 good,[185] 1 fair[187] 2 Prospective case series [186,188]	• In prospective cohorts, all treated groups improved in gross motor skills and cognitive performance. • Inconclusive outcomes for fine motor skills, perception, daily living skills, imitation, and socialization. • Strength of evidence for effect on cognitive outcomes is insufficient, based upon too few studies.
Broad-based approaches	1 RCT / 1 fair[194,198] 1 Nonrandomized trial / 1 poor[197] 3 Prospective cohorts / 3 fair[192,195,196] 1 Prospective case series[193] 1 Retrospective cohort/ 1 fair[199] 1 Retrospective case series [191]	• Combination of home- and center-based program compared with a center-based program alone improved IQ and behavior in one study. • ABA and a nursery program showed higher gains compared with the portage program in educational functioning and adaptive behavior in one study. • Special nursery placement, both ASD-specific and general specialized nursery, was associated with greater gains in adaptive behavior in one study. • Strength of evidence for effect on communication and social skills is insufficient because studies differed in interventions and outcomes assessed, and were of too low quality.
Computer-based approaches	2 RCT / 2 poor[189,200] 1 Prospective case series [190]	• Insufficient strength of the evidence for the effects of computer-based programs on language skills because studies differed in the interventions assessed and were poor quality.

ABA=applied behavior analysis; IQ=intelligence quotient; RCT=randomized controlled trial; TEACCH= Treatment and Education of Autistic and Communication related handicapped CHildren

Effectiveness of Medical and Related Interventions

Medical and Related Interventions

Summary. Although no current medical interventions demonstrate clear benefit for social or communication symptoms in ASDs, a few medications show benefit for repetitive behaviors or associated symptoms. Given that many children with ASDs are currently treated with medical interventions,[41-43] strikingly little evidence exists to support clear benefit for most medical interventions, especially in the realm of interventions such as restrictive diets and supplements.

We located 17 papers from nine studies addressing antipsychotic medications;[201-207,208,209-217] five studies addressing serotonin reuptake inhibitors (SRIs);[220-224] six publications[228-233] from four studies evaluating stimulants and other medications for hyperactivity; eight studies addressing secretin;[234-241]and 17 papers (16 unique studies) addressing dietary and other medical interventions.[64,242-257]

The clearest evidence favors the use of medications to address challenging behaviors (Table 33). Risperidone and aripiprazole are the two best-studied medications in ASDs, with the corresponding pharmaceutical companies funding at least one RCT for each. Each medication now has at least two RCTs demonstrating improvement in a parent-reported measure of challenging behavior that includes emotional distress, aggression, and self-injury. A parent-reported hyperactivity and noncompliance measure also showed significant improvement. Although it was not the primary target behavior addressed in these studies, repetitive behavior also showed improvement with both risperidone and aripiprazole. Both medications also cause significant side effects, including marked weight gain, sedation, and risk of extrapyramidal symptoms. When considered in aggregate, risperidone and aripiprazole are efficacious but are associated with significant side effects that limit their use to patients with severe impairment or risk of injury (Table 33).

Table 33. Summary of results of medical studies

Intervention	Study design/Quality	Study results and overall strength of evidence
Antipsychotics		
Risperidone vs. placebo	4 RCT / 1 good,[201,202,204-209] 3 fair[203,210-212] 2 prospective case series[213,214]	• Improvements in challenging behavior and repetitive behavior. • Adverse effects, including weight gain, sedation and extrapyramidal effects. • Strength of evidence for reducing challenging behavior and repetitive behavior is moderate. • Strength of evidence for adverse events is high based on RCTs and case series; common side effects include weight gain, sedation, and extra-pyramidal effects.
Aripiprazole vs.placebo	2 RCT / 2 good[215,216]	• Improvements in challenging behavior and repetitive behavior. • Adverse effects, including weight gain, sedation and extrapyramidal side effects. • Strength of evidence for reducing challenging behavior and repetitive behavior is high. • Strength of evidence for adverse events is high; common side effects include weight gain, sedation, and extra-pyramidal effects.
Cyproheptadine added to haloperidol vs. haloperidol and placebo	1 RCT / 1 fair[217]	• Behavioral improvement reported but without indicating specific domains in one study. • Strength of evidence for reducing challenging behavior and repetitive behavior is insufficient.
Fluoxetine vs. placebo	1 RCT / 1 fair[220] 1 Retrospective case series [221]	• Greater change in repetitive behavior with fluoxetine compared with placebo. • Strength of evidence for SRIs to decrease repetitive behavior is insufficient. • Strength of evidence for adverse events is insufficient with only one RCT of fair quality.
Citalopram vs. placebo	1 RCT / 1 good[222] 1 Prospective case series [223]	• No significant difference between the groups on repetitive behavior in one study. • Significant but clinically small reduction in challenging behavior in the treatment group compared with placebo. • Genotype effect on improvement in challenging behavior. • Strength of evidence for effect of SRIs to reduce repetitive behavior is insufficient. • Strength of evidence for adverse events is insufficient.
Various SRIs (including sertraline,citalopram, paroxetine, fluvoxamine)	1 Retrospective case series[224]	• 40/89 subjects ranked as “much improved.” • Strength of evidence for effect of SRIs to reduce repetitive behavior is insufficient. • Strength of evidence for adverse events is low when SRIs are considered as a class.

Table 33. Summary of results of medical studies (continued)

Intervention	Study design/Quality	Study results and overall strength of evidence
Stimulants and other medications to treat hyperactivity		
Stimulants	1 RCT / 1 good[228-230] 2 Retrospective case series[231,233]	• Improvement in hyperactivity and non-compliance in one study. • Adverse events, including increases in challenging behavior and loss of appetite. • Strength of evidence for effectiveness in affecting hyperactivity is insufficient. • Strength of evidence around adverse events is also insufficient.
Guanfacine	1 Retrospective case series [232]	• Symptom improvement observed for hyperactivity, inattention, insomnia, and tics. • Strength of evidence for effectiveness on hyperactivity and inattention is insufficient.
Secretin		
Secretin vs. placebo	7 RCTs / 2 good,[237,238] 5 fair[234-236,239,240] 1 Prospective case series [241]	• No studies showed significantly greater improvements in the secretin group; • No difference for porcine or synthetic secretin. • Strength of evidence is high for lack of effectiveness in affecting language, cognition, behavior, communication, autism symptom severity, and socialization.
Dietary interventions		
Dietary interventions and supplements	1 RCT/ 1 fair[249] 4 Prospective case series[242,243,245,246]	• Some studies showed improvements with iron supplementation, magnesium and vitamins, fish oil, evening primrose oil and ketogenic diet. • Some lessening of food selectivity behaviors in study of dietary enzyme supplementation. • Few studies had comparison groups and most were poor. • Insufficient evidence to determine effectiveness.
Other interventions		
Various medical Interventions	9 RCTs / 2 good,[64,254] 6 fair,[247,248,251-253,257] 1 poor[250,255] 1 Prospective case series[256] 1 Retrospective case series [244]	• Early promise for omega 3 fatty acids, melatonin, L-carnosine, and piracetam. • 85% of parents reported decrease in or resolution of sleep problems with melatonin; problems returned in some children. • One good RCT of hyperbaric oxygen showed benefit on general ratings and social and challenging behaviors. • Fair RCT of pentoxifylline added to risperidone compared with risperidone+ placebo showed significant improvements in irritability, lethargy/social withdrawal, stereotypic behavior, hyperactivity, and inappropriate speech for the pentoxifylline group. • No effect for cholinesterase inhibitors (donepezil) on language or behavior. • Amantadine, oral immunoglobulin, and the chelating agent DMSA showed no benefit in single RCTs. • Insufficient evidence to determine strength of the evidence for any one of the various medical interventions. • Insufficient evidence in any one category.

DMSA=dimercaptosuccinic acid; RCT=randomized controlled trial; SRI=serotonin reuptake inhibitor

Secretin has been exhaustively studied in multiple RCTs with clear evidence that it lacks benefit in ASDs. Amantadine, N-dimethylglycine, oral immunoglobulin, and the chelating agent dimercaptosuccinic acid (DMSA) showed no benefit in single RCTs. Methylphenidate improved hyperactivity in the ASDs population in an RCT, and a followup analysis suggested possible improvements in a measure of social communication. An RCT of hyperbaric oxygen treatment showed benefit on general ratings of improvement. The SRI fluoxetine showed benefit for repetitive behavior in a single cross-over RCT; although this effect was driven by only one arm of the study.[220] An RCT of the SRI citalopram[222] showed no benefit for repetitive behavior but possible improvement in irritability/problem behavior.

Strength of evidence. We rated the strength of evidence for the effect of atypical antipsychotic medications on challenging behavior and repetitive behavior to be moderate for risperidone and high for aripiprazole (Table 33). There were a total of six RCTs in this area, three of which had good quality and the other three fair. They produced consistent and precise estimates of effect. Strength of evidence around adverse events is high for both aripiprazole and risperidone, based on RCTs and case series. Common side effects included weight gain, sedation and extra-pyramidal effects.

It is clear from existing research that secretin is not effective in affecting language, cognition, behavior, communication, autism symptom severity, and socialization skills, and the strength of evidence for this lack of effectiveness is high. With seven RCTs with fair to good quality scores and one case series contributing to this evidence base, future studies are unlikely to change the estimate of effect for this treatment.

With only one good quality RCT available, and an additional RCT of fair quality, we consider the strength of evidence for the ability of SRIs to reduce repetitive behavior to be insufficient. SRIs were also studied for their effect on irritability/problem behavior, but the one good RCT on SRIs did not focus primarily on this outcome. The direction of the effect was inconsistent given that worsening of behavior can be an adverse effect of the treatment, and we assessed the strength of evidence for this relationship to be insufficient. Evidence of adverse effects with SRIs (decreased sleep and increased energy) had insufficient strength of evidence (two RCTs, one of which was good) with variability in how the outcomes were measured. The strength of evidence for the effects of both stimulants and guanfacine on hyperactivity was insufficient. Evidence was also insufficient for assessing the strength of evidence of varied medical and dietary interventions including hyperbaric oxygen, ketogenic diet, omega 3 fatty acids, and cholinesterase inhibitors (Table 33).

Effectiveness of Allied Health Interventions

Language and Speech

Summary. Our search identified eight publications focused on speech and language interventions (Picture Exchange Communication System [PECS] and Responsive Education and Prelinguistic Milieu Teaching [RPMT]),[258-265] representing four distinct study populations. Both interventions were effective at increasing the number of words used by children early after intervention (up to 3 months) but neither showed maintenance of improvements over the longer term. No studies reported harms of intervention.

While ultimate benefit of these reviewed speech and language interventions in terms of advancing core language skills over time is limited given the existing research, an emerging strength of this reviewed literature has been direct comparison of specific intervention techniques (e.g., PECS vs. RPMT) as well as appropriate analysis of the factors that moderate treatment impact. Specifically, this emerging literature has demonstrated in preliminary fashion that certain children respond to certain interventions differently based on their clinical profile.[258-261] Such a study demonstrates that this underlying assumption of differential response to treatment is a reality for some children with autism related to language intervention.

Strength of evidence. Data from studies in this review were insufficient at this time to rate the strength of evidence for language-focused interventions.

Sensory and Auditory Integration

Summary. We located seven papers,[89,266-271] comprising five unique studies addressing sensory or auditory integration. One study reported harms of intervention.[269]

Strength of evidence. Data from studies in this review were insufficient to rate the strength of evidence related to sensory and auditory integration training for improving language skills, challenging behaviors, or cognitive ability in low functioning children with autism (Table 34). While earlier studies (reviewed in Baranek, 2002[16]) suggested some positive outcomes associated with auditory integration, newer, well-designed studies described here contradict older findings in showing no improvements in the treatment groups.

Table 34. Summary of results of allied health studies

Intervention	Study design/ Quality	Study results and overall strength of evidence
Language and speech interventions		
PECS, RPMT	2 RCTs / 1 good,[258-261] 1 poor[263] 1 Nonrandomized controlled trial / 1 poor[262,265] 1 Prospective case series[264]	• Mixed results for language acquisition. • Observed increases in language have not been maintained long-term or after treatment discontinuation. • Children most likely to benefit from RPMT in increasing joint attention had demonstrated at least 7 acts of joint attention in the pre-intervention assessment. • Strength of evidence for language interventions (PECS and RPMT) is insufficient.
Sensory/auditory interventions		
Sensory integration interventions	1 RCT / 1 poor[266] 1 Prospective case series[267,268]	• Some improvements in sensory problems in treatment groups; however, poor quality studies limit conclusions. • Strength of evidence for effect is insufficient.
Auditory integration interventions	2 RCTs / 2 fair[269,270]	• Receptive or expressive language, cognitive skills, problem or adaptive behaviors did not improve significantly in the treatment groups. • Insufficient evidence to determine effects on language, adaptive behavior, and challenging behaviors.
Music and play therapy interventions	1 RCT / 1 poor[89,271]	• Insufficient evidence to determine effects on social skills outcomes.
Other allied health interventions		
Varied allied health interventions	1 RCT / 1 poor[276] 1 Nonrandomized controlled trial / 1 poor[274] 6 Prospective case series[272,273,275,277-279]	• Small, short-term studies of disparate interventions. • Insufficient evidence to determine effectiveness for any outcome.

PECS=Picture Exchange Communication System; RCT=randomized controlled trial; RPMT= Responsive Education and Prelinguistic Milieu Training

Allied Health Additional Studies

Summary. We found eight studies[272-279] addressing disparate additional allied health interventions. No studies reported harms of intervention.

Strength of evidence. Insufficient evidence is available to assess these interventions, including animal-assisted occupational therapy, prism lenses, and systematic feeding training.
In sum, there have been few studies in the past decade examining the effectiveness of allied health interventions with sufficient sample size to consider closely (Table 34), although these approaches are often pursued by parents of children with autism. It will be important for future research to prioritize studying these treatments using rigorous methodologies to clarify whether (or for what outcomes) these treatments may be effective.

Effectiveness of CAM Interventions

Complementary and Alternative Medicine (CAM)

Summary. Much of the CAM research (seven studies[280-286]) meeting our inclusion criteria is preliminary (Table 35). Brief trials of massage therapy[284,286] suggest a potential role for massage in promoting sleep and behavioral improvement in children with ASDs. Pilot studies of acupuncture provided insufficient evidence based on small sample sizes and treatment duration.[280,281] Studies included here did not report harms of intervention.

Table 35. Summary of results of CAM studies

Intervention	Study design/ Quality	Study results and overall strength of evidence
Massage	4 RCTs / 1fair,[283] 3 poor[284-286] 1 Prospective case series[282]	• Some improvements in sensory, adaptive behaviors, social skills, and language measures. • Short-term, small studies (mean 25 participants/study), largely employing parent reported outcome measures. • Insufficient evidence to determine effectiveness.
Acupuncture	2 RCTs / 1 fair,[280] 1 poor[281]	• Small effects on language measured with unvalidated tools. • Adverse effects not addressed. • Insufficient evidence to determine effectiveness.

RCT=randomized controlled trial

Strength of evidence. We found very few studies of complementary and alternative medicine, so evidence in this area also is insufficient to evaluate effects on outcomes assessed including sleep, language, social skills, sensory difficulties, and adaptive behavior (Table 35).

Assessment of Domains for Strength of Evidence

Table 36 illustrates assessments for each domain (risk of bias, consistency, directness, and precision) pertaining to strength of evidence for each of the major intervention-outcome combinations in this review that received a strength of evidence rating of low or high. As noted in the Evidence-based Practice Centers' Methods Guide for Effectiveness and Comparative Effectiveness Reviews,[99] risk of bias reflects issues in study design and conduct that could result in biased estimates of effect. Consistency reflects similarity of effect sizes seen across studies. Consistency cannot be assessed when only one study is available. Directness is a reflection of the relationship between the intervention and the ultimate health outcome of interest. Precision is an assessment of certainty around the effect observed.

Table 36. Intervention, strength of evidence domains, and strength of evidence for key outcomes

Intervention	Domains pertaining to Strength of Evidence (SOE): Risk of Bias	Consistency	Directness	Precision	SOE
Adaptive behavior					
Behavioral, UCLA/Lovaas	Medium	Consistent	Direct	Imprecise	Low
Adverse events/harms					
Medical, Antipsychotics (Aripiprazole)	Low	Consistent	Direct	Precise	High
Medical, Antipsychotics (Risperidone)	Low	Consistent	Direct	Precise	High
ASDs symptom severity					
Behavioral, UCLA/Lovaas	Medium	Inconsistent	Direct	Precise	Low
Medical, Secretin	Low	Consistent	Direct	Precise	High (lack of effectiveness)
Challenging behavior					
Medical, Antipsychotics (Aripiprazole)	Low	Consistent	Direct	Precise	High
Medical, Antipsychotics (Risperidone)	Low	Consistent	Direct	Precise	Moderate
IQ/cognitive					
Behavioral, UCLA/Lovaas	Medium	Consistent	Direct	Precise	Low
Medical, Secretin	Low	Consistent	Direct	Precise	High (lack of effectiveness)
Language/communication					
Behavioral, UCLA/Lovaas	Medium	Consistent	Direct	Precise	Low
Medical, Secretin	Low	Consistent	Direct	Precise	High (lack of effectiveness)
Repetitive behavior					
Medical, Antipsychotics (Aripiprazole)	Low	Consistent	Direct	Precise	High
Medical, Antipsychotics (Risperidone)	Low	Consistent	Direct	Precise	Moderate
Social skills/social behaviors					
Medical, Secretin	Low	Consistent	Direct	Precise	High (lack of effectiveness)

ASDs=Autism Spectrum Disorders; SOE=strength of evidence; SRIs-selective serotonin reuptake inhibitors; UCLA=University of California, Los Angeles

Most intervention-outcome combinations have insufficient strength of evidence at this time, often because studies were either too diverse in interventions and outcomes studied to summarize, or because the field is early in its development (Table 37).

Table 37. Interventions/outcomes with insufficient strength of evidence by outcomes assessed

Intervention	Adaptive behavior	Adverse events/ harms	Anger	Anxiety	ASDs symptom severity	Challenging behavior	Hyperactivity/ inattention	IQ/cognitive	Joint attention	Language/ communication	Motor/sensory	Repetitive behavior	Sleep	Social skills/ social behaviors
Allied health, Auditory integration	✓					✓		✓		✓				
Allied health, Music therapy														✓
Allied health, PECS/RPMT										✓				
Allied health, Sensory integration											✓			
Allied health, Other	✓									✓	✓			✓
Behavioral, CBT (commonly associated conditions)			✓	✓						✓				
Behavioral, ESDM	✓				✓			✓		✓				
Behavioral, Imitation (play-/interaction-based)														✓
Behavioral, Joint attention/symbolic play (play-/interaction-based)									✓					
Behavioral, Other—Neurofeedback					✓									
Behavioral, Other—Sleep						✓						✓	✓	
Behavioral, Parent & teacher training (commonly associated conditions)			✓	✓		✓								
Behavioral, Parent training (early intensive behavioral)										✓		✓		✓

Table 37. Interventions/outcomes with insufficient strength of evidence by outcomes assessed (continued)

Intervention	Adaptive behavior	Adverse events/ harms	Anger	Anxiety	ASDs symptom severity	Challenging behavior	Hyperactivity/ inattention	IQ/cognitive	Joint attention	Language/ communication	Motor/sensory	Repetitive behavior	Sleep	Social skills/ social behaviors
Behavioral, Parent training (early intensive behavioral)										✓		✓		✓
Behavioral, Parent-focused (play-/interaction-based)						✓								
Behavioral, Relationship-focused (play-/interaction-based)														✓
Behavioral, Social skills														✓
CAM, Acupuncture										✓				✓
CAM, Massage	✓										✓		✓	
Educational, Broad-based								✓		✓				✓
Educational, Computer-based										✓				
Educational, TEACCH								✓		✓				
Medical, Antipsychotics (Cyproheptadine+Haloperidol)						✓						✓		
Medical, Dietary & other					✓	✓				✓			✓	
Medical, Guanfacine		✓					✓							
Medical, SRIs (all)		✓				✓						✓		
Medical, Stimulants		✓					✓							

CAM=complementary and alternative medicine; CBT=cognitive behavioral therapy; ESDM=Early Start Denver Model; PECS=Picture Exchange Communication System; RPMT= Responsive Education and Prelinguistic Milieu Teaching SRI=serotonin reuptake inhibitor; TEACCH=Treatment and Education of Autistic and Communication related handicapped CHildren

KQ2. Modifiers of Treatment Outcomes

Understanding the degree to which child characteristics (i.e., specific ASDs related difficulties and skills), treatment factors (e.g., type, duration, intensity), and systems (e.g., family, community) influence response to treatments could improve targeting of treatments to the appropriate children and circumstances. However, with rare exceptions,[259,260,287] few studies are designed or powered to allow analysis of heterogeneous effects. Although we sought studies of treatment modifiers, only one included study[259,260]actually demonstrated true treatment modifiers based upon appropriate study design and statistical analysis. One other study[287] was designed to examine the role of provider on outcomes, but showed no difference, possibly because it was underpowered to do so.

This first study[259] included an analysis of initial characteristics of the children demonstrating that children who were low in initial object exploration benefitted more from RPMT, which explicitly teaches play with objects, while children who were relatively high in initial object exploration demonstrated more benefit from PECS. These results were maintained at 6 months. An additional analysis based on this study[260] showed greater increases in generalized turn taking and initiating joint attention in the RPMT group than in PECS. The increased benefit for RPMT in join attention was only seen, however, in children who began the study with at least some initiation of joint attention. Specifically, children most likely to benefit from RPMT in increasing joint attention had demonstrated at least seven acts of joint attention in the pre-intervention assessment. RPMT was also superior in this analysis in increasing object exchange turns.

One study[287]explicitly sought to examine the impact of provider choice (parent versus professional) using similar interventions in an RCT. The study did not show a difference in outcomes for children receiving UCLA/Lovaas protocol-based intervention in a clinical setting versus at home from highly trained parents. Both clinic and parent groups received over 30 hours of intervention weekly and no group differences related to IQ, language, adaptive behavior, or other outcomes were seen. Children in both groups demonstrated substantial gains in a number of areas. Nonetheless, the results do provide further evidence of response to treatments anchored in the UCLA/Lovaas method, with some children demonstrating rapid acquisitions of new skills and change in IQ. Other studies not specifically designed to examine modifiers have also compared parent to clinic-based interventions[126,132,288] and demonstrated equivalent group change when delivered in the same intensity.

Other studies in this section are those in which potential correlates were identified that may be moderators, but have not been studied as such. These potential moderators should be assessed in properly designed and powered studies for this purpose.

In terms of correlates with positive outcomes, several investigations have noted that pretreatment IQ and language predicts IQ at followup in early intensive behavioral and developmental studies.[101,104,115,124,287] However, other studies have suggested having a lower IQ at initiation of treatment is related to increased change in IQ over time [127] or failed to find a relationship between IQ and change in response to intervention.[102,126,132] IQ and verbal ability also predict treatment outcomes in educational interventions. Baseline language/communication skills may also correlate with treatment success, with studies generally suggesting a benefit for communication skills, including changes in ASDs classification associated with baseline language skills in an UCLA/Lovaas-based approach.[102,124] Similarly, social skills studies have found verbal skills, either verbal comprehension (using the Verbal Comprehension Index) or expressive communication skills to be associated with greater improvements in social skills.

Data on the degree to which earlier age of treatment initiation is associated with better outcomes with early intensive behavioral and developmental intervention is conflicting. Studies suggesting a preference for early intervention may be confounded by characteristics of treatment.[129]

Finally, some studies suggest that specific constellations of symptoms related to ASDs may be important in understanding response to treatment. Social responsiveness and imitation skills have been suggested as skills that may predict improved treatment response in UCLA/Lovaas treatment,[287] whereas "aloof" subtypes of ASDs have been suggested to be associated with less robust changes in IQ,[107] and lower baseline symptom tallies have also been related to specific gains.[104] Other studies have seen specific improvement in early intensive intervention for children with PDD-NOS vs. Autistic Disorder diagnoses,[114] which may be indicative of baseline symptom differences. However, many other studies have failed to find a relationship between autism symptoms and treatment response.

In the medical literature, some characteristics of the family and child were found to be associated with treatment success, including a history of psychiatric diagnoses in the family and early verbal skills in the child correlating with treatment response to fluoxetine in a case series.[224] One pharmacogenetic study assessed variation in the serotonin transporter gene for predicting lack of treatment response to escitalopram; although replication will be required to confirm the initial findings.[223] Several studies of stimulant use highlighted differences in effectiveness by diagnosis type[228-230,232,233] finding that children with Asperger syndrome were typically more responsive to psychostimulant treatment than those with autistic disorder. The presence of co-morbid intellectual disability was associated with lower response to psychostimulant treatment in one study.[232]

KQ3. Early Results in the Treatment Phase That Predict Outcomes

Information about early response to treatment, or lack thereof, could guide treatment selection, implementation, and modification. The reviewed literature offers almost no information about what specific observations of children might be made early in treatment to predict long-term outcome and response. Some evidence suggests that changes in IQ over the first year of treatment with UCLA/Lovaas-based approaches and ESDM predicts, or accounts for, longer-term change in IQ.[287,290] However, findings also suggest that while gains in the cognitive domain might be accounted for primarily within the first year of treatment, changes in adaptive behavior in response to these same interventions may occur over a longer time frame[110,133,287,290] if they occur at all.[105]

KQ4. End of Treatment Effects That Predict Outcomes

Few studies assess end of treatment effects that may predict outcomes; however, this type of research is feasible as exemplified in one study which assessed language development and joint attention and play skills in 3 to 4 year old children with ASDs.[155,156] Children in the symbolic play and joint attention intervention groups showed significantly greater growth in expressive language, initiation of joint attention, and duration of child-initiated joint attention over time than did participants in the control group ($p<.01$ to $<.05$, moderate to large effect sizes). Growth in receptive language was not significantly affected by the intervention from pre-intervention to 12 months post-intervention. Children in the symbolic play group also showed significantly more growth in play level than did children in either the joint attention ($p<.01$) or control ($p<.001$) groups.

The investigators also assessed differences in the amount (total hours) of intervention services (speech and overall) children in the three groups received post-intervention, with children in the control group receiving significantly more hours of overall services than either the joint attention or symbolic play groups ($p<.05$ and $<.01$, respectively); differences in hours of speech interventions received were not significant. Only the duration of child-initiated joint attention episodes was related to hours of intervention received post-treatment, with children with fewer hours of overall services showing greater growth in child-initiated joint attention episodes.[155] Hours of speech interventions received did not affect growth in skills.

KQ5. Generalization of Treatment Effects

Few studies included in this review explicitly measured generalization of effects seen in treatment conditions to either different conditions or locations. The majority of studies in the behavioral interventions targeting associated conditions did not measure outcomes in the treatment context (i.e., within therapy sessions or groups). Outcomes were primarily assessed using parent, self, and/or teacher report of targeted symptoms (e.g., anxiety, externalizing behaviors) at home, at school, and in the community, suggesting that those interventions conducted in a clinical setting for which measured outcomes were positive may generalize in the sense that they achieve outcomes in the daily context/life of the child. On the other hand, in most cases, these outcomes are parent reported and not confirmed with direct observation. Behavioral intervention studies rarely measured outcomes beyond the intervention period, and therefore, we cannot assume that effects are maintained over time.

In medical studies, although the treatment is prescribed in a clinical setting, it is generally administered at home, and one would expect effects of medications to be observed in terms of behavior in the home and other settings. However, medical studies may be good sources of information on the duration of perceived effects. Unfortunately, other than case series data for risperidone[177,203,204,206,213] demonstrating continued effects and side effects beyond six months. Few data are available on longer term outcomes of medical treatment.

KQ6. Drivers of Treatment Effects

We identified no studies answering this question.

KQ7. Treatment Approaches in Children Under Age Two at Risk for ASDs

Research on very young children is preliminary but promising, with only four studies identified in our review.[178,290,294,295] One was a good quality RCT[290] that suggested benefit for the use of ESDM in young children with improvements in adaptive behavior, language, and cognitive outcomes. Diagnostic shifts were also seen in close to 30 percent of children (but still on the autism spectrum). The observed diagnostic shifts, however, were not associated with clinically significant improvements in terms of ADOS severity scores or other measures. Developing interventions directed to toddlers that take into account the diagnostic uncertainty at this age is a critical need. Therefore, we considered the strength of evidence in this area currently insufficient, pending additional data.

Quality Considerations

To better understand methodological challenges in the autism literature, we calculated the distribution of quality scores for the medical and behavioral (including educational studies). Medical studies had a higher threshold for subject number (30) to be included in the review in comparison to behavioral studies (10). This may have resulted in a different pattern of study types in the two literatures. Studies in other intervention categories were too few in number to examine in this way.

Just over half (58 percent behavioral; 64 percent medical) did employ a group design (i.e., included a comparison group); of the studies with comparison groups, 64 percent of behavioral and 100 percent of medical studies were randomized. Although almost all (87 percent behavioral; 100 percent medical) adequately described their intervention by our criteria, few (32 percent behavioral; 38 percent medical) provided any measure of fidelity or adherence. Only 22 percent of behavioral studies reported differences in or held steady concomitant interventions that might have served as confounders of the observed effect. Sixty seven percent of medical studies did so. Outcome measures were almost always considered valid (94 percent behavioral; 93 percent medical); 26 percent of behavioral studies reported outcomes coded by individuals blinded to the intervention status, compared with 64 percent of medical studies.

Of particular note in the quality assessment is lack of adequate characterization of participant populations. Twenty-one percent of behavioral studies and only 33 percent of medical studies reported using a combination of clinical Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition (DSM-IV) with the ADOS and/or Autism Diagnostic Interview-Revised (ADI-R) to diagnose or confirm diagnoses of ASDs. More than 35 percent of behavioral studies either did not use or did not report use of the DSM-IV or ADOS. Analytic approaches were problematic with 56 percent of behavioral and 67 percent of medical studies conducting using appropriate statistical approaches. Quality scores for each study in this report are presented in Appendix H.

Applicability

By definition, autism spectrum disorders are heterogeneous. Characterizing a “typical“ child with an ASD is not possible, although certain symptoms are central to the range of children within the autism spectrum. Individual therapies are developed and tested to ameliorate specific symptoms or groups of symptoms, often in a fairly circumscribed subset of children. Ideally, research on therapies for ASD should target children most likely to benefit from a particular focus; thus details on the population, intervention, comparator, outcomes, and setting (PICOS) for each intervention category are provided in Appendix I to support translation of our findings and assessment of the applicability of each for differing circumstances and children.

Furthermore, although interim, clinically based improvement is important, longer term functional outcomes are the goal for autism interventions. In terms of followup for assessing durability of effects, most studies report on outcomes collected immediately post-treatment or within 3 months of treatment (76 percent of studies in the behavioral literature, 86 percent in the medical literature). Additional research is needed on the degree to which changes observed during treatment translate to functional outcomes over time should treatment be discontinued.

Behavioral interventions. Studies of early intensive behavioral and developmental interventions were conducted primarily in preschool and young children (i.e., typically children initially ages 2-7) and as such questions remain about how these approaches apply to and benefit younger children with (≤ 2) at-risk for ASD. The cognitive, language, and adaptive behavior profiles of participants included in these studies were generally in line with those seen in the community (i.e., typically marked by substantial impairment/delay, but with some children with more intact early cognitive/language profiles).

The range of approaches studied may not always match what is available in practice. That is, the studies were often either conducted in highly controlled environments (e.g., university supported intervention trials) or the methodology was not well-described (i.e., non-manualized approaches). Thus, individuals wishing to infer the potential results of clinical practice based on the available research need to assess carefully the degree to which the study methods matched those available and used in practice. Two of the primary intensive behavioral intervention programs (UCLA/Lovaas and ESDM) publish and/or employ manuals for intervention, but implementing them requires sophisticated training and oversight that will continue to make translation to common practice difficult.

Studies of parent training interventions for preschool children, often emphasizing principles of ABA, aligned with current practice and the target populations that are typically referred for these services. Training programs often included components to improve social communication skills such as joint attention, play-based interactions, and pragmatic language approaches; interventions were conducted for approximately 1-4 hours/week with parents asked to introduce learned techniques within natural settings. Several programs offer manualized versions of training that can be adopted in other settings with appropriate training.

Most studies of social skills interventions targeted elementary school aged children (between 6 and 13 years old). Only one study targeted younger children (4 to 6 years old); although such interventions may be important in this younger age group. Most also excluded children with IQs below 60 and 6 of the studies specifically targeted children with high functioning ASD or who were diagnosed with Asperger disorder only. Therefore, evidence on social skills interventions is likely applicable to older, higher functioning children only. Similarly, CBT for commonly associated conditions was targeted toward older children who were high-functioning, some with Asperger disorder only, or excluded those with intellectual disabilities. The effectiveness of both of these types of interventions in other groups of children with ASD is currently unknown.

Studies of play-based interventions were generally conducted in clinic settings with children whose ages ranged from 3 to 12 years. Further research is needed to assess the utility of these approaches outside of the clinic.

Medical and related interventions. In the medical literature, study participants were generally recruited from non-primary care populations. As such, families of these children may be seeking a higher level of care than those of the broader population of children with ASDs based upon more severe or acute symptoms, including aggression or other challenging behaviors. Most studies of medical interventions targeted elementary school aged and older children with autism, with little data on the treatment of younger children. Some studies also expanded their inclusion criteria to include children with Asperger syndrome or PDD-NOS.

For some medications, age could be an important modifier of treatment, which should be considered in future studies. As one example, SRIs were reported to be helpful for repetitive behaviors in adults in a previous RCT, but more recent data in children shows less clear evidence for benefit.

In addition to the limitations of the actual populations studied, some characteristics of the family and child were found to be correlated with treatment success within individual studies as noted in the discussion on modifiers. Most of these correlates are difficult to interpret in the absence of studies that directly assess modifiers. Further research will be necessary to evaluate whether family history, cognitive profile,[224] or diagnosis within the autism spectrum could be a modifier.

Review of Systematic Reviews

Because we limited our review to studies published after the year 2000, we reviewed existing systematic review literature so as not to lose important information published previously. Our findings in the current review concur with findings in the previously available reviews in that some evidence supports effectiveness of early intervention approaches and interventions such as CBT.

Most of the reviews generally concluded that the evidence base for early intensive behavioral and developmental intervention is inadequate, noting variability in treatment and intervention, limited followup, lack of comparative studies, need for replication, and unclear inclusion and exclusion criteria.[12,296,297] Meta-analyses from Reichow[298] and Eldevik,[299] reported more positive results, noting strong evidence for intensive ABA-based intervention effects in some children.[298,299] Eldevik's meta analysis of nine studies found an average large effect size for IQ change (1.103, 95 percent CI [CI=.871, 1.335]) and medium effect size for change on the VABS composite score (.660, 95 percent CI [CI=.41, .90]). The meta-analysis from Reichow and Wolery,[298] including studies exclusively based on Lovaas' treatment manuals or replicating the UCLA/Lovaas model and computing mean effect size based on change in the Lovaas group only, also reported a large effect size of .69 for IQ change and mean difference effect sizes suggesting greater gains for children receiving Lovaas-based intervention compared with those receiving minimal behavioral intervention, usual treatment, or eclectic treatment. Additionally, it is a subtle but important weakness concerning the review that evaluations of pre-post change as units of analysis are not sufficient for estimating treatment effects. More specifically, changes observed during the treatment phase may not be entirely accounted for as change because of a treatment.

Each of these reviews also notes significant concerns about the included studies, such as limited accounting for the effects of maturity, lack of equivalent groups, uncertain treatment fidelity, and small sample sizes. Several authors also noted the need for studies comparing intensive behavioral approaches to other approaches that have been similarly empirically tested.

Across all the reviews, areas noted for improvement in the literature included the need for more RCTs, though investigators acknowledge the difficulty of conducting RCTs with interventions of such complexity and ethical issues of withholding treatment for comparison purposes. Additional areas for improvement noted in reviews included the need for larger sample sizes; longer followup to allow for evaluation of the durability of effects; greater treatment fidelity; improved reporting of methodological and participant characteristics; and greater consistency in treatment approaches and outcomes measurement.

In terms of the quality of the reviews themselves, we assessed the reviews to be of generally good quality, though some elements of reporting were inconsistent across reviews. For example, few reviews[12,17,296,300] explicitly reported author conflicts of interest, though, for example, investigators in one meta-analysis were authors of papers included in the analysis. Use of an *a priori* design was not always clearly stated though generally implied, and we considered review designs *a priori* if the review appeared to employ a standardized approach. Similarly, methods for reviewing abstracts and the full papers of studies were not always clearly described (e.g., use of dual reviewers), and six out of 10 reviews provided a complete (ample enough to likely permit replication) description of search terminology.[17,296,297,300-302] Appendix G presents more information on our assessment of recent reviews.

Future Research

State of the Literature

Research on treatment approaches for autism has emerged primarily in the past two decades, and we focused our review on the last decade. Like any young research field, the body of evidence on therapies to treat core and concomitant symptoms of autism is characterized by a predominance of small studies with no comparison groups, a smaller set of nonrandomized cohort studies, and a very small set of RCTs. Only 13 of 159 of the studies were rated as good, although we see a clear evolution in the field toward greater rigor. Within our review, studies of medical interventions were more likely to be rated of higher quality. Several factors could account for this, including the higher minimum sample size that we set for medical interventions.

We felt that the higher risk involved in a child with an ASD taking a medication, pursuing a restricted diet, or participating in another medical intervention warranted a more rigorous standard for studies supporting possible benefit.

Gaps in Areas of Research

Several treatment approaches show promise in early research, but remain understudied in rigorous designs. In the behavioral literature, these include early intensive behavioral and developmental interventions[103,105,114,126,132,133,287,303] (e.g., UCLA/Lovaas model and variants), the ESDM approach,[290], and parent training approaches (e.g., Pivotal Response Training, More than Words,[295] Early Social Interaction[294]). In the medical literature, these include SRIs,[222-224] methylphenidate,[228-231,233] omega 3 fatty acids,[246] and melatonin.[244]

A critical area for further research is understanding which children are likely to benefit from particular interventions. To date, studies have failed to adequately characterize the subpopulation of children who experience positive response, although positive outcomes are most prominent in some children but not others. One powerfully replicated finding is that not all children receiving early intensive intervention demonstrate robust gains, and many children continue to display prominent areas of impairment. Dramatic improvements are observed in a subset of children and mild improvements in terms of standardized outcomes may translate into meaningful improvements in quality of life. Early intensive behavioral and developmental approaches therefore have significant potential, yet require further research.

Data on modifiers of effectiveness is an important area for future study, and preliminary data suggest that some interventions, including intensive behavioral interventions, are likely to be most effective when targeted to yet undefined subgroups of children. Early research suggests child characteristics, such as baseline cognitive, language, and adaptive skill, correlate with treatment outcome; however, such correlational data provides limited information in making predictions of what treatments will work best for individual children. Additionally, the emergence of biomarkers and susceptibility genes may allow researchers to focus on additional characteristics beyond symptom profile that might be useful in personalizing treatment approaches, but research in this area is just emerging.

Behavioral interventions are by their nature often multi-component, and data on whether specific functional components of the interventions drive effectiveness are currently unavailable. Component analyses in this field would be productive to refine intervention approaches and assess applicability and generalizability of the results.

Along those lines, we found few studies providing specific evidence of the generalization of interventions (the maintenance of effects when factors such as the setting, individual providing the intervention, or situational factors are changed). It is essential for families of children with autism to understand the degree to which intervention effects observed during treatment are likely to translate to functional behavior changes in their child at home or in school.

Further, as proposed treatments methods often rely heavily upon parents as coordinating influences and/or primary interventionists, examination of the characteristics of families that modify treatment appears another area for potential examination.

In the social skills literature, we identified several studies[139,140,144,146,147,149] that were the first report of the particular intervention. These approaches are candidates for replication. Most focused on group interventions and more consideration of the potential for family-oriented or individual intervention is warranted. This literature overall focuses almost entirely on high functioning children with ASDs, and it would be helpful to consider whether social skill interventions have potential for a broader range of individuals. There was also a tendency in this area to focus on intermediate outcomes (e.g., recognition of facial expressions) with little information on whether these translate to longer term functional outcomes.

Because the treatment process for ASD is typically intensive, questions of feasibility and accessibility are germane, but understudied. A few studies in this literature made preliminary strides in addressing these issues, but studies that specifically measure the role of setting, provider and other factors would benefit our ability to inform implementation. We also recommend future consideration of the ways in which the cultural context of the child and family may affect applicability or effectiveness of specific interventions.

Almost no studies in the behavioral, educational, allied health or CAM literature reported harms. While adverse effects may appear less likely with some of these types of interventions, assessment of potential harms is warranted.

The medical literature lacks properly designed, appropriately powered randomized, controlled trials of a number of interventions that have been inadequately studied to date. Some of the strongest studies to support the use of medical interventions have been funded by pharmaceutical companies or device manufacturers that profit from the treatment. Certainly, the National Institutes of Health has funded some large-scale studies of a few medical interventions, but publicly funded studies of medications for ASDs are few and more are warranted.

Importantly, the marked improvements in challenging behaviors seen with risperidone and aripiprazole support the study of other atypical antipsychotic medications that do not cause as much weight gain or liability to metabolic disorders. Additionally, medications for hyperactivity and inattention symptoms deserve further scrutiny in autism. Dosing information remains inadequate in the stimulant literature and is particularly important for balancing positive outcomes with potential harms. The data on serotonin reuptake inhibitors are scattered and contradictory, with a particular need to consider modifiers such as age (childhood versus adult, see Posey et al.[304] and pharmacogenetics.[223] The largest published trial of an SRI, citalopram, found no effect at all on repetitive or compulsive behavior but found a possible effect on challenging behavior (ABC-C-Irritability) that warrants follow up in a study with challenging behavior as a focus.[222] A number of other medical interventions are worthy of further study, including hyperbaric oxygen,[254] which was studied in a single RCT by providers with a conflict of interest.

In addition to the need for further study of interventions with some existing research, the need for research on medical interventions with no existing research is tremendous.[305] Clinicians who employ medical interventions without an existing research base should publish case series data to allow researchers to evaluate which treatments are worth studying in RCTs. Given that behavioral interventions are the mainstays of autism treatment, studies examining the effects of coupling medical and behavioral interventions are crucial to match the typical experience of most children with ASDs. Emerging data in other areas, including anxiety and mood disorders, suggest that medications and behavioral treatments may act in synergy to produce benefit, including studies on SRIs and cognitive-behavioral therapy,[306-308] as well as recent studies on the use of cognitive enhancers to potentiate cognitive behavioral therapy.[309]

Finally, this literature lacks comparisons of medical interventions with behavioral interventions and combinations of the two, despite the fact that most children are undergoing multiple concurrent treatments. This approach has proven crucial in studies of obsessive compulsive disorder, depression, and anxiety,[306-308] but only two studies of adequate size have considered combination treatment with risperidone and behavioral treatment, and these studies lacked an arm that considered behavioral treatment alone, in addition to lacking a placebo control.

Methodologic Issues

A high proportion of studies in this review (36 percent) fail to use a comparison group, and while substantial strides have been made in the analysis of single-subject designs, these are not ideal for assessing effectiveness at a population level, nor are they appropriate for comparative effectiveness research. They are, however, used frequently in the behavioral literature, and so we address our decisions regarding them here. Because there is no separate comparison group in these studies they would be considered case reports (if only one child included) or case series (multiple children) under the rubric of the EPC study designs. Case reports and case series can have rigorous evaluation of pre- and post- measures, as well as strong characterization of the study participants.

Studies using this design that included at least 10 children were included in the review. Studies of this type can be helpful in assessing response to treatment in very short time frames and under very tightly controlled circumstances, but they typically do not provide information on longer term or functional outcomes. They are useful in serving as demonstration projects, yielding initial evidence that an intervention merits further study, and, in the clinical environment, they can be useful in identifying whether a particular approach to treatment is likely to be helpful for a specific child. Our goal was to identify and review the best evidence for assessing the efficacy and effectiveness of therapies for children with ASD, with an eye toward their utility in the clinical setting, and for the larger population of children with ASD. By definition, “populations“ in single-subject design studies are likely to be idiosyncratic and therefore not to provide information that is generalizable.

Nonetheless, even in studies with a comparison group, sample size is frequently insufficient to draw conclusions, and larger, multisite trials are needed across all treatment types. Furthermore, the choice of comparison groups in the studies that employed a group design was uneven. A number of studies used comparison groups that were inappropriate for observing group differences in treatment effect (e.g., comparing treatment in children with autism to the effects of the treatment in typically developing peers or to children with a different developmental disorder), and for those studies we could only use the pre-post case series data available in the group with autism, limiting the ability to comment on effectiveness.

We encourage investigators to provide adequate detail as they describe their interventions to allow for replicable research. In ideal circumstances, investigators publish and reference treatment manuals, but many studies made general references to their use of an underlying approach (e.g., ABA) without specifying the ways in which they used the technique or modifications they made to the original, published use of it. Lack of detail about the intervention makes it difficult to assess the applicability of individual studies, to synthesize groups of studies or to replicate studies.

Characterization of the study population was often inadequate, with 125 of 159 studies failing to use or report “gold standard“ diagnostic measures (clinical DSM-IV-based diagnosis plus ADI-R and/or ADOS) for the participants. Because ASDs are spectrum disorders, it is difficult to assess the applicability of interventions when the population in which they were studied is poorly defined or described. Authors often do not consider diagnostic criteria in selecting participants for their studies; nor do they fully describe the children who do participate. We recommend that investigators fully describe participants in their study, both diagnostically and otherwise. In addition, because the myriad causes of ASDs are unknown, even children with the same diagnosis may have distinct genetic or other “causes“ that could affect treatment effectiveness. Ideally, future research will better characterize participants genotypically and phenotypically.

We identified more than 100 distinct outcome measures used in this literature base, not accounting for subscales. The use of so many and such disparate outcome measures makes it nearly impossible to synthesize the effectiveness of the interventions, and we recommend a consistent set of rigorously evaluated outcome measures specific to each intended target of treatment to move comparative effectiveness research forward and to provide a sense of expected outcomes of the interventions. At the same time, the means for assessing outcomes should include increased focus on use of observers or reporters masked to the intervention status of the participant, and where some outcomes are measured in a masked fashion but others not, more emphasis should be placed on those that are.

In addition, many studies use changes in measures of IQ as outcomes, on the basis that IQ deficits are a powerfully impairing co-occurring index of ASD impairment and are therefore an important outcome, particularly in combination with social communication measures. However, IQ assessment for young children with ASDs is challenging as it is dependent not only on nonverbal cognition and receptive and expressive language, but also on a child’s ability to focus in an academic setting and to interact with the person administering the exam. Measures of IQ thus may not be the optimal tool for effectively measuring changes related to core ASD symptoms.

There also was a strong tendency for authors to present data on numerous outcomes without adjusting for multiple comparisons, and to fail to report the outcome that was the primary outcome of *a priori* interest and on which sample size calculations were based (when they were present). This may suggest a level of selective reporting bias in which results are published on a select group of outcomes that show the most effect. We attempted, but were unable, to identify a clear primary intended outcome in almost all of the papers.

Duration of treatment and follow up was generally short, with few studies providing data on long-term outcomes after cessation of treatment. Future studies should extend the follow up period and assess the degree to which outcomes are durable. Few studies adequately accounted for concomitant interventions that might confound observed effectiveness and this should be standardized in future research.

Conclusions

The literature regarding therapies for children with autism spectrum disorders is of highly variable quality and in most specific areas limited and inconclusive. A few conclusions can be drawn, however.

In the behavioral literature, some evidence supports early and intensive behavioral and developmental intervention, including two randomized studies of intensive (i.e., interventions provided >30 hours per week) and comprehensive (i.e., addressing numerous areas of functioning) approaches. These included one UCLA/Lovaas focused approach and one developmentally focused ESDM approach.[114,290] Both approaches demonstrated greater improvements in cognitive performance, language skills, and adaptive behavior skills when compared with broadly defined eclectic treatments in subgroups of children, although the strength of evidence (confidence in the estimate) is low pending replication of the available studies.

Not all children receiving such interventions demonstrate rapid gains, with some data suggesting that many children continue to display prominent areas of impairment[114] and that subgroups may account for a majority of change within certain samples. It seems likely based on preliminary evidence that subgroups of children are more amenable to many of the interventions available. These could potentially include groups defined by initial IQ, language and verbal skills as well as severity of ASDs, but there may also be underlying skill differences that may better account for variability. Current evidence is insufficient, however, to adequately identify and target children most likely to benefit from specific interventions.

No studies directly compare effects of different treatment approaches (for example, there are no direct comparisons of UCLA/Lovaas and ESDM) and there is little evidence of practical effectiveness or feasibility beyond research studies, so questions remain about whether reported findings would be observed on a larger scale within communities. Furthermore, the studies conducted have used small samples, drastically different treatment approaches and duration and different outcome measurements. Nonetheless, improvements occur in some aspects of language, cognitive ability, adaptive behavior, challenging behaviors and potentially improved educational attainment for some children.

While some previous reports[13,296,297] have suggested that it may be unethical to conduct randomized studies of early intensive interventions in the presence of evidence of benefit, the low strength of this evidence suggests that more rigorous trials or well conducted prospective cohort studies are needed.

Strength of evidence is insufficient for the effects of social skills training for older children and for play and interaction based approaches for younger children. Cognitive behavioral therapy for associated conditions such as anxiety also has insufficient strength of evidence supporting positive outcomes.

There is insufficient strength of evidence for improvements in cognitive outcomes with educational interventions, including the TEACCH intervention, and insufficient strength of evidence for broad-based approaches often based on ABA principles.

A few medications show benefit for repetitive behaviors or associated symptoms, with the clearest evidence favoring risperidone and aripiprazole, both studied in RCTs and showing evidence of improvement in problem and repetitive behavior. Significant side effects, however, make it clear that although these drugs are efficacious, caution is warranted regarding their use in patients without severe impairments or risk of injury.

A few other medical interventions show some promise for future research, including SRIs,[222-224] methylphenidate,[228-231,233] omega 3 fatty acids,[246] and melatonin.[244] Others are clearly not efficacious and warrant no further study, including secretin.

Evidence was insufficient at this time to support the use of sensory or auditory integration, insufficient for speech and language interventions, and insufficient for complementary and alternative medicine approaches.

Importantly, the literature lacks comparisons of medical interventions with behavioral interventions and combinations of the two, despite the fact that most children are undergoing multiple concurrent treatments. This approach has proven crucial in studies of obsessive compulsive disorder, depression, and anxiety,[306-308] but few studies of adequate size have considered combination treatment with risperidone and behavioral treatment,[172,177] and these studies lacked an arm that considered behavioral treatment alone, in addition to lacking a placebo control.

In sum, some therapies for ASD do hold promise and warrant further study. Continuing improvements in methodologic rigor are needed, as are larger, potentially multisite, studies of existing interventions in which children are well characterized, both phenotypically and genotypically.

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Acronyms/Abbreviations

ABA	Applied Behavior Analysis
ABC	Aberrant Behavior Checklist
ABC-C	Aberrant Behavior Checklist-Community
ADHD	Attention Deficit Hyperactivity Disorder
ADI	Autism Diagnostic Interview
ADI-R	Autism Diagnostic Interview-Revised
ADIS	Anxiety Disorders Interview Schedule
ADOS	Autism Diagnostic Observation Schedule
ADOS-G	Autism Diagnostic Observation Schedule-Generic
AHRQ	Agency for Healthcare Research and Quality
AIT	Auditory Integration Training
ASDs	Autism Spectrum Disorders
ASSQ	Autism Spectrum Screening Questionnaire
ATEC	Autism Treatment Evaluation Checklist
Atm	Atmospheres
BAS II	British Abilities Scales-Second Edition
BASC	Behavior Assessment System for Children
CABAS	Comprehensive Application of Behavior Analysis to Schooling
CAM	Complementary and Alternative Medicine
CARS	Childhood Autism Rating Scale
CAST	Childhood Asperger Syndrome Test
CBT	Cognitive Behavioral Therapy
CGI	Clinical Global Impression Scale
CGI-I	Clinical Global Impression-Improvement
CHAT	Checklist of Autism in Toddlers
Cont	Continued
CPEP-R	Chinese Version of the PEP-R
CYBOCS	Child Yale Brown Obsessive Compulsive Scale
CYBOCS-PDD	Children's Yale-Brown Obsessive Compulsive Scales-Pervasive Developmental Disorders
DH	Donepezil hydrochloride
DMSA	Dimercaptosuccinic Acid
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition
DTT	Discrete Trial Training
dx	Diagnosis
EEG	Electroencephalogram
EIBI	Early Intensive Behavioral Intervention
EOWPVT	Expressive One-Word Picture Vocabulary Test
EOWPVT-R	Expressive One-Word Picture Vocabulary Test-Revised
EPC	Evidence-based Practice Center
ERIC	Education Resources Information Center
ESDM	Early Start Denver Model
FSIQ	Full Scale Intelligence Quotient

GARS	Gilliam Autism Rating Scale
GI	Gastrointestinal
HKBABS	Hong Kong Based Adaptive Behavioral Scales
HSQ	Home Situations Questionnaire
IGOH	Oral Human Immunoglobulin
IQ	Intelligence Quotient
kg	kilograms
MASC	Multidimensional Anxiety Scale for Children
mg	milligrams
mg/kg/day	milligrams per kilogram per day
MGIS	Modified Global Impression Scale
MPH	Methylphenidate
n, N	number
NCA	Non Core Autism (PDD-NOS or other early childhood developmental disorder such as specific language disorder)
NR	Not reported
nRCT	Non randomized controlled trial
NS, ns	Not (statistically) Significant
NVIQ	Non-Verbal IQ
P	P value
PCIT	Parent Child Interaction Therapy
PDD	Pervasive Developmental Disorder
PDD-NOS	Pervasive Developmental Disorder-Not Otherwise Specified
PECS	Picture Exchange Communication System
PEP-R	Psycho-educational Profile-Revised
PUFA, PUFAs	Polyunsaturated Fatty Acid
RCT	Randomized Controlled Trial
ROWPVT	Receptive One-Word Picture Vocabulary Test
RPMT	Responsive Education and Prelinguistic Milieu Teaching
RUPP	Research Units on Pediatric Psychopharmacology
SCAS-P	Spence Children's Anxiety Scale
SCQ	Social Communication Questionnaire
SD	Standard Deviation
SRIs	Serotonin Reuptake Inhibitors
SRS	Social Responsiveness Scale
STAT	Screening Tool for Autism in Two-Year-Olds
SULP	Social Use of Language Programme
SWQ	Social Worries Questionnaire
TEACCH	Treatment and Education of Autistic and Communication related handicapped CHildren
TEP	Technical Expert Panel
UCLA	University of California, Los Angeles
UK	United Kingdom
VABS	Vineland Adaptive Behavior Scale

Appendix A. Exact Search Strings and Results

Table A1. PubMed search strategies (all searches last updated May 10, 2010)

Search terms		Search results
#1	Autistic[tiab] OR autism[tiab] OR autistic disorder[mh] OR asperger syndrome[mh] OR child development disorders, pervasive[mh:noexp] OR asperger[tiab] OR asperger's[tiab] OR aspergers[tiab] OR pervasive development[tiab] OR pervasive developmental[tiab] OR pdd[tiab]	17,936
#2	therapy[sh] OR therapeutics[mh] OR teaching[mh] OR psychotherapy[mh] OR treatment outcome[mh]	5,713,136
#3	#1 AND #2 AND eng[la] AND humans[mh]	4,712
#4	#3 AND newspaper article[pt]	1
#5	#3 AND letter[pt]	264
#6	#3 AND comment[pt]	158
#7	#3 AND case reports[pt]	811
#8	#3 AND review[pt]	854
#9	#3 AND practice guideline[pt]	6
#10	#3 AND news[pt]	48
#11	#3 AND editorial[pt]	73
#12	#3 AND historical article[pt]	27
#13	#3 AND meta-analysis[pt]	26
#14	#3 AND legal cases[pt]	6
#15	#3 AND published erratum[pt]	1
#16	#3 AND congresses[pt]	8
#17	#3 NOT (#4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16)	2,723*

Key: [mh] Medical Subject Heading; [mh] Medical Subject Heading, not exploded; [tiab] title/abstract word; [pt] publication type; [sh] subheading

***Note:** numbers do not tally as some articles are excluded in more than one category; 12 articles were case reports, comments, and letters; 73 were case reports and letters; 51 were case reports and reviews; 12 were meta-analyses and reviews; 15 were comments and editorials; 1 was a comment, editorial, and review; 95 were comments and letters; 3 were comments and reviews; 2 were reviews and practice guidelines; 1 was an editorial and practice guideline; 8 were historical articles and reviews; 2 were case reports and historical articles; 2 were case reports and editorials; 1 was a case report and meta-analysis; 1 was a case report and a legal case; 3 were editorials and reviews; 1 congresses and case reports.

Table A2. PsycINFO search strategies (CSA interface)

Search terms		Search results
#1	DE=("pervasive developmental disorders" or "aspergers syndrome" or "autism")	16,454
#2	DE=("treatment" or "adjunctive treatment" or "aftercare" or "alternative medicine" or "acupuncture" or "aromatherapy" or "faith healing" or "folk medicine" or "behavior modification" or "behavior therapy" or "aversion therapy" or "covert sensitization" or "conversion therapy" or "dialectical behavior therapy" or "exposure therapy" or "implosive therapy" or "systematic desensitization therapy" or "reciprocal inhibition therapy" or "response cost" or "biofeedback training" or "classroom behavior modification" or "contingency management" or "token economy programs" or "fading conditioning" or "omission training" or "overcorrection" or "self management" or "self instructional training" or "time out" or "bibliotherapy" or "cognitive techniques" or "cognitive restructuring" or "cognitive therapy" or "self instructional training" or "computer assisted therapy" or "creative arts therapy" or "art therapy" or "dance therapy" or "music therapy" or "poetry therapy" or "recreation therapy" or "crisis intervention services" or "hot line services" or "suicide prevention centers" or "cross cultural treatment" or "cross cultural counseling" or "disease management" or "health care services" or "continuum of care" or "long term care" or "mental health services" or "community mental health services" or "palliative care" or "primary health care" or "interdisciplinary treatment approach" or "involuntary treatment" or "medical treatment general" or "gene therapy" or "milieu therapy" or "movement therapy" or "multimodal treatment approach" or "online therapy" or "outpatient treatment" or "outpatient commitment" or "partial hospitalization" or "personal therapy" or "physical treatment methods" or "acupuncture" or "artificial respiration" or "deep brain stimulation" or "drug therapy" or "hormone therapy" or "narcoanalysis" or "sleep treatment" or "polypharmacy" or "vitamin therapy" or "electrosleep treatment" or "gene therapy" or "phototherapy" or "psychosurgery" or "thalamotomy" or "radiation therapy" or "shock therapy" or "electroconvulsive shock therapy" or "insulin shock therapy" or "surgery" or "brain stimulation" or "brain self stimulation" or "chemical brain stimulation" or "electrical brain stimulation" or "spreading depression" or "transcranial magnetic stimulation" or "preventive medicine" or "psychotherapeutic techniques" or "animal assisted therapy" or "autogenic training" or "cotherapy" or "dream analysis" or "guided imagery" or "mirroring" or "morita therapy" or "motivational interviewing" or "mutual storytelling technique" or "paradoxical techniques" or "psychodrama" or "psychotherapy" or "adlerian psychotherapy" or "adolescent psychotherapy" or "analytical psychotherapy" or "autogenic training" or "behavior therapy" or "aversion therapy" or "covert sensitization" or "conversion therapy" or "dialectical behavior therapy" or "exposure therapy" or "implosive therapy" or "systematic desensitization therapy" or "reciprocal inhibition therapy" or "response cost" or "brief psychotherapy" or "child psychotherapy" or "play therapy" or "client centered therapy" or "cognitive behavior therapy" or "acceptance and commitment therapy" or "eclectic psychotherapy" or "emotion focused therapy" or "existential therapy" or "experiential psychotherapy" or "expressive psychotherapy" or "eye movement desensitization therapy" or "feminist therapy" or "geriatric psychotherapy" or "gestalt therapy" or "group psychotherapy" or "encounter group therapy" or "marathon group therapy" or "therapeutic community" or "guided imagery" or "humanistic psychotherapy" or "hypnotherapy" or "age regression hypnotic" or "individual psychotherapy" or "insight therapy" or "integrative psychotherapy" or "interpersonal psychotherapy" or "logotherapy" or "narrative therapy" or "persuasion therapy" or "primal therapy" or "psychoanalysis" or "dream analysis" or "self analysis" or "psychodrama" or "psychodynamic psychotherapy" or "psychotherapeutic counseling" or "family therapy" or "conjoint therapy" or "rational emotive behavior therapy" or "reality therapy" or "relationship therapy" or "solution focused therapy" or "supportive psychotherapy" or "transactional analysis" or "rehabilitation" or "cognitive	465,812

Table A2. PsycINFO search strategies (CSA interface) (continued)

Search terms		Search results
	rehabilitation" or "criminal rehabilitation" or "drug rehabilitation" or "alcohol rehabilitation" or "alcoholics anonymous" or "detoxification" or "neuropsychological rehabilitation" or "occupational therapy" or "physical therapy" or "psychosocial rehabilitation" or "therapeutic social clubs" or "vocational rehabilitation" or "supported employment" or "vocational evaluation" or "work adjustment training" or "relaxation therapy" or "progressive relaxation therapy" or "sex therapy" or "social casework" or "social group work" or "sociotherapy" or "speech therapy" or "treatment guidelines" or "self help techniques" or "self management" or "self instructional training" or "therapeutic social clubs" or "medicinal herbs and plants" or "hypericum perforatum" or "dietary supplements" or "diets" or "nutrition" or "vitamins" or "ascorbic acid" or "choline" or "lecithin" or "folic acid" or "nicotinamide" or "nicotinic acid")	
#3	#1 AND #2 and PT=(journal article) and (ME=(empirical study) or ME=(field study) or ME=(followup study) or ME=(longitudinal study) or ME=(prospective study) or ME=(qualitative study) or ME=(quantitative study) or ME=(retrospective study) or ME=(treatment outcome/clinical trial)), limited to English language and peer-reviewed journals and human population	1,373

Key: DE subject descriptor; PT publication type; ME methodology; AE age group

Table A3. ERIC search strategies (CSA interface)

Search terms		Search results
#1	("pervasive developmental disorders") or autism or ("asperger syndrome")	6,308
#2	(DE=("therapy" or "educational therapy" or "group therapy" or "hearing therapy" or "music therapy" or "occupational therapy" or "physical therapy" or "psychotherapy" or "milieu therapy" or "relaxation training" or "speech therapy" or "therapeutic recreation" or "play therapy" or "art therapy" or "bibliotherapy" or "drug therapy" or "intervention" or "crisis intervention" or "early intervention" or "individualized family service plans" or "prereferral intervention" or "outcomes of treatment" or "rehabilitation" or "special education" or "adapted physical education" or "therapeutic environment" or "Dietetics" or "Food" or "Nutrition") OR KW=("therapy" or "therapeutic" or "therapeutics" or "intervention" or "interventions" or "psychotherapy" or "psychotherapeutics"))	98,472
#3	#1 and #2, limited to peer reviewed journals, English only	770

Key: DE subject descriptor, KW keyword

Appendix B. Sample Data Abstraction Forms

Therapies for Children with Autism Systematic Evidence Review
Abstract Review Form

First Author, Year: __________________ Reference ID #: __________ Abstractor Initials: ___ ___ ___

Primary Inclusion/Exclusion Criteria			
1. Includes participants diagnosed with ASD (Autism, Aspergers, PDD-NOS) OR age 2 and under at risk for diagnosis of ASD a. __participants are ages 2-12 b. __participants are under age 2 and identified as at risk for diagnosis of ASD	Yes	No	Cannot Determine
2. Original research (exclude editorials, commentaries, letters, reviews, etc.)	Yes	No	Cannot Determine
3. Eligible study size (≥ 10) **N=**____	Yes	No	Cannot Determine
4. Addresses: a. __treatment modality (**circle applicable**: medical, behavioral, educational, comprehensive, allied health, CAM) intended to modify core symptoms of ASD in individual diagnosed/at risk b. __short or long term outcomes of treatment intended to modify core symptoms/co-morbidities of ASD in individual diagnosed/at risk. **Mark applicable**: __social skills __communication/language __repetitive/compulsive behavior __problem behavior (**circle applicable**: aggression; self-injury; defiance/non-compliance; property destruction; irritability) __adaptive behavior (life skills/ADL/feeding behaviors) __commonly occurring co-morbidities (**circle applicable**: sleep; hyperactivity; depression/anxiety/mood) __medical (**circle applicable**: GI distress; seizures; autoimmune/allergy) __fine/gross motor skills __sensory __educational/cognitive/academic attainment __other: ___________________________ c. __harms/adverse effects associated with treatment intended to modify core symptoms of ASD in individual diagnosed/at risk	Yes **(must address 4a and 4b or 4a and 4c for “yes”)**	No	Cannot Determine

Retain for: _____BACKGROUND/DISCUSSION _____REVIEW OF REFERENCES _____Other____

COMMENTS:

Therapies for Children with Autism Systematic Evidence Review
Full Text Review Form

First Author, Year: __________________ Reference ID #: __________ Abstractor Initials: ___ ___ ___

1. Includes participants **ages 2-12 diagnosed with ASD** (Autism, Aspergers, PDD-NOS) OR **0-2 at risk** a. If study includes participants >12yrs, record mean age+SD:_____. Circle **Yes** if mean age+SD ≤ 12.	Yes	No
2. Original research (exclude editorials, commentaries, letters, reviews, etc.)	Yes	No
3. Eligible study size (circle **Yes** if N ≥ 10 **TOTAL** age 2-12 with ASD or at risk OR with mean age+SD ≤ 12) a. if No, record N:____	Yes	No
4. Does the study address one or more of the following questions (check applicable KQ below):	Yes	No

__KQ1: Among children ages 2-12 with ASD, what are the short and long-term effects of available behavioral, educational, family, medical, allied health, or CAM treatment approaches?

Treatment studied (circle applicable: medical, educational, allied health, CAM, behavioral)
SPECIFY INTERVENTION______________________________

- __KQ1a: What are the effects on core symptoms (e.g. social deficits, communication deficits and repetitive behaviors), in the short term (≤6 months)?
- __KQ1b: What are the effects on commonly associated symptoms (e.g. motor, sensory, medical, mood/anxiety, irritability, IQ/cognition, and hyperactivity) in the short term (≤6 months)?
- __KQ1c: What are the longer-term effects (>6 mos) on core symptoms (e.g. social deficits, communication deficits and repetitive behaviors)?
- __KQ1d: What are the longer-term effects (>6 mos) on commonly associated symptoms (e.g. motor, sensory, medical, mood/anxiety, irritability, IQ/cognition, and hyperactivity)?

__KQ2: Among children ages 2-12, what are the modifiers of outcome for different treatments or approaches?

- __KQ2a: Is the effectiveness of the therapies reviewed affected by the frequency, duration, and intensity of the intervention?
- __KQ2b: Is the effectiveness of the therapies reviewed affected by the training and/or experience of the individual providing the therapy?
- __KQ2c: What characteristics, if any, of the child modify the effectiveness of the therapies reviewed?
- __KQ2d: What characteristics, if any, of the family modify the effectiveness of the therapies reviewed?

__KQ3: Are there any identifiable changes early in the treatment phase that predict treatment outcomes?

__KQ4: What is the evidence that effects measured at the end of the treatment phase predict long term functional outcomes?

__KQ5: What is the evidence that specific intervention effects measured in the treatment context generalize to other contexts (e.g., people, places, materials)?

__KQ6: What evidence supports specific components of treatment as driving outcomes, either within a single treatment or across treatments?

__KQ7: What evidence supports the use of a specific treatment approach in children under the age of 2 who are at high risk of developing autism based upon behavioral, medical, or genetic risk factors?

5. Study published in English	Yes	No

EXCLUDE IF AN ITEM IN A GRAY BOX IS SELECTED

6. Review the reference list (included papers only) and list author name/year for EPC to verify if included in database: ____
____
____
____

7. If excluded, retain for ____Background/Discussion ___Other: _______________________________

Comments:

Therapies for Children with ASD Systematic Evidence Review
Relevance Review Form for Previous Systematic Reviews (2008-09)

First Author, Year: ______________________ Reference ID #: __________ Reviewer Initials: ___ ___

PICOTS	Comments
Includes appropriate **population**?	
Addresses target **interventions**?	
Includes studies with **comparators** (treatment approach to no treatment, placebo, or comparative interventions/combinations of interventions)?	
Addresses target **outcomes** (including adverse effects/harms)?	
Addresses target **timing**?	
Includes studies in target **setting**?	
Study types specified? (circle applicable: RCT, controlled trials, observational studies (retrospective/prospective cohort studies, case-control, case series), individual case studies, other: ________________________________)	
Includes studies with appropriate N of subjects? (specify N: _______)	
Other	
Includes studies in English only?	
When was the literature search conducted (specify timeframe:________________)	
Recommendation:	

Therapies for Children with ASD Systematic Evidence Review
Quality Review Form for Previous Systematic Reviews (2008-09)

First Author, Year: ______________________ Reference ID #: __________ Abstractor Initials: ___ __

1. Was the search strategy appropriate (relevant terminology, comprehensive approach, etc.)?	Yes	No	N/A or Not Specified
2. Were the databases searched appropriate?	Yes	No	N/A or Not Specified
3. Were other search measures (circle applicable: handsearch, reference list search, contacting experts) specified?	Yes	No	N/A or Not Specified
4. Was grey literature included (dissertations, unpublished reports, etc.)?	Yes	No	N/A or Not Specified
5. Does the review provide an a priori design (e.g. procedures established in advance)?	Yes	No	N/A or Not Specified
6. Was there dual review study selection and data abstraction (e.g., 2 reviewers assessed each study for inclusion/exclusion and data extraction)?	Yes	No	N/A or Not Specified
7. Was a list of included and excluded articles provided?	Yes	No	N/A or Not Specified
8. Were characteristics of included studies provided?	Yes	No	N/A or Not Specified
9. Was the scientific quality of included studies rated and documented?	Yes	No	N/A or Not Specified
10. Was the scientific quality of included studies used appropriately to formulate conclusions?	Yes	No	N/A or Not Specified
11. Were methods used to combine findings of studies appropriate?	Yes	No	N/A or Not Specified
12. Was the likelihood of publication bias assessed?	Yes	No	N/A or Not Specified
13. Was authors' conflict of interest stated?	Yes	No	N/A or Not Specified

Comments:

Appendix C. Evidence Tables

Tables are sorted by year, then last name of first author.

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Akhondzadeh et al. 2010 **Country:** Iran **Practice setting:** Academic **Intervention setting:** outpatient clinic **Enrollment period:** April 2007–April 2009 **Funding:** Tehran University of Medical Sciences **Author industry relationship disclosures:** NR **Design:** RCT (Double-blind, parallel group)	**Intervention:** Pentoxifylline + risperidone or placebo + risperidone for 10 weeks Risperidone titration: • up to 2 mg/day in children weighing between 10 -40 kg (0.5 mg starting dosage with 0.5 mg increments in weekly dosage for first 3 weeks) • 3 mg/day for children >40 kg Pentoxiphylline titration: • 400 mg/day increase for children weighing between 10-40 kg (200 mg starting dose with 100 mg increments every 2 days) • 600 mg (300mg starting dose with 100 mg increments every 2 days) for children >40 kg. Placebo: • matched for shape, size, color and taste **Assessments:** Aberrant Behavior Checklist-Community (ABC-C), Extrapyramidal Symptoms Rating Scale (ESRS) **Groups:** **G1:** pentoxifylline + risperidone **G2:** placebo + risperidone **Co-interventions held stable during treatment:** NR (no psychosocial therapies during trial)	**Inclusion criteria:** • Between 4 and 12 years of age • Met DSM-IV-TR criteria for Autistic Disorder • Outpatients from a specialty clinic for children at a psychiatric teaching hospital **Exclusion criteria:** • concomitant schizophrenia or psychotic disorders • history of drug or alcohol abuse • history of tardive dyskinesia • received neuroleptics or other psychotropic drug 6 months prior to recruitment • significant active medical problem • severe or profound mental retardation precluding definitive diagnosis of autism **Age, mean/yrs ± SD (range):** **G1:** 8.05 ± 2.01 (4-11) **G2:** 7.37 ± 2.41 (4-12) **Mental age:** NR **Gender:** M, n (%): **G1:** 15 (75) **G2:** 14 (70) F, n (%): **G1:** 5 (25) **G2:** 6 (30) **Race/ethnicity:** NR **SES:** NR **Diagnostic approach:** Referral and confirmed In study by child psychiatrist	**Social skills:** ABC-C Lethargy/Social Withdrawal, mean ± SD: **G1:** 18.27 ± 2.97 **G2:** 17.29 ± 3.23 **Communication/ language:** ABC-C Inappropriate Speech, mean ± SD: **G1:** 5.13 ± 0.83 **G2:** 4.94 ± 0.92 **Repetitive behavior:** ABC-C Stereotypic Behavior, mean ± SD: **G1:** 8.01 ± 1.30 **G2:** 7.72 ± 1.44 **Problem behavior:** ABC-C Hyperactivity/noncompliance, mean ± SD: **G1:**16.03 ± 2.60 **G2:**15.44 ± 2.88 ABC-C Irritability, mean ± SD: **G1:** 16.67 ± 2.71 **G2:** 16.06 ± 3.00	**Social skills:** ABC-C Lethargy/Social Withdrawal, mean ± SD: **G1:** Week 10: 8.03 ± 3.64 **G2:** Week 10: 13.05 ± 1.93 G1 and G2 significantly different based on groups x time interaction (*P* ≤ 0.0001) **Communication/ language:** ABC-C Inappropriate Speech, mean ± SD: **G1:** Week 10: 2.08 ± 0.94 **G2:** Week 10: 3.73 ± 0.55 G1 and G2 significantly different based on groups x time interaction (*P* ≤ 0.0001)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Akhondzadeh et al. 2010 (continued)	**Frequency of contact during study:** every 2 weeks for 10 weeks **Concomitant therapies, n (%):** **NR N at enrollment:** **G1:** 20 **G2:** 20 **N at follow-up:** **G1:** 20 **G2:** 20	Diagnostic tool/method: DSM-IV-TR score ≥6, clinical judgment, behavioral observation and semistructured interview with parent **Diagnostic category, n (%):** Autism: 40 (100) **Other characteristics:** Weight/kg, mean ± SD (range): **G1:** 27.90 ± 6.07 (20-41) < 30 kg: 17(85) > 30 kg: 3(15) **G2:** 26.75 ± 6.85 (15-39) < 30 kg: 17(85) > 30 kg: 3(15) History of previous medications, n (%): **G1:** Risperidone: 12 (6) Haloperidol: 2 (1) **G2:** Risperidone: 13 (65) Haloperidol: 3 (15)		**Repetitive behavior:** ABC-C Stereotypic Behavior, mean ± SD: **G1:** Week 10: 3.57 ± 1.61 **G2:** Week 10: 5.59 ± 0.82 G1 and G2 significantly different based on groups x time interaction (*P* ≤ 0.0001) **Problem behavior:** ABC-C Hyperactivity/Noncompliance, mean ± SD: **G1:** Week 10: 8.92 ± 4.05 **G2:** Week 10: 12.59 ± 1.86 G1 and G2 significantly different based on groups x time interaction (*P* ≤ 0.0001) ABC-C Irritability, mean ± SD: **G1:** Week 10: 7.14 ± 3.23 **G2:** Week 10: 11.65 ± 1.72 G1 and G2 significantly different based on groups-by-time interaction (*P* ≤ 0.0001)
Akhondzadeh et al. 2010 (continued)				**Extrapyramidal Symptoms Rating Scale, n (%):** **G1:** 7 (35) **G2:** 8(40)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				No significant difference found between groups. **Harms, n (%):** Constipation: **G1:** 3 (15) **G2:** 2 (10) *P* = 1.00 Restlessness: **G1:** 2 (10) **G2:** 2 (NR) *P* = 1.00 Day time drowsiness: **G1:** 6 (30) **G2:** 4 (20) *P* = 0.71 Gassing: **G1:** 3 (15) **G2:** 1 (5) *P* = 0.34 Increased appetite: **G1:** 8 (40) **G2:** 5 (25) *P* = 0.50 Weight gain: **G1:** 8 (40) **G2:** 7 (35) *P* = 1.00 Dry mouth: **G1:** 2 (10) **G2:** 3 (15) *P* = 1.00 Fatigue: **G1:** 3 (15) **G2:** 5 (25) *P* = 0.69 Loss of appetite: **G1:** 1 (5) **G2:** 3 (15) *P* = 0.60
Akhondzadeh et al. 2010 (continued)				No statistically significant difference found between groups **Modifiers** NR

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Author: Dawson et al., 2010 **Country:** US **Practice setting:** Academic **Intervention setting:** Home **Enrollment period:** NR **Funding:** NIH **Author industry relationship disclosures:** 2 of 8 Early Start Denver Model for Young Children with Autism (royalties) **Design:** RCT	**Intervention:** Early Start Denver Model: 20 hrs/week of ESDM, parent training, parent delivery for ≥ 5 hrs/week of ESDM, community services chosen by parents Assess-and-monitor: Families given resource manuals, intervention recommendations, and referrals for intervention at baseline and 2 follow-up assessments Duration: 2 years Frequency: 2 hour sessions, twice per day, 5 days/week **Assessments:** ADI-R; ADOS; MSEL (fine motor, visual reception, expressive language and receptive language scales); VABS; RBS Yearly assessments conducted by University of Washington examiners blind to group status for both groups (G1 & G2) and by community providers (G2) **Groups:** **G1:** Early Start Denver Model **G2:** assess-and-monitor **Provider:** • Bachelor's level therapists supervised by PhD level clinician with consultation from Clinical psychologist Speech-language pathologist Developmental behavioral pediatrician Occupational therapist **Measure of treatment fidelity reported:** Yes	**Inclusion criteria:** • Age < 30 months at intake • Met criteria for autistic disorder on the Toddler Autism Diagnostic Interview • Met ADOS criteria for autism or ASD • Clinical diagnosis based on DSM-IV criteria using all available information • Resides within 30 minutes of the University of Washington • Willingness to participate in ≥ 2 year intervention **Exclusion criteria:** • Neurodevelopmental disorder of known etiology (such as fragile x syndrome) • Significant sensory or motor impairment • Major physical problems such as a chronic serious health condition • Seizures at time of entry • Use of psychoactive medications • History of a serious head injury and/or neurologic disease • Alcohol or drug exposure during the prenatal period • Ratio IQ below 35 as measured by mean age equivalence score/ chronological age on the visual reception and fine motor subscales of the MSEL **Age, months ± SD:** **G1:** 23.9 ± 4.0 **G2:** 23.1 ± 3.9 **G1/G2:** *P* = 0.490 **Mental age:** NR **Gender, male-to-female ratio:** 3.5:1	**Overall ratings:** ADOS severity score, mean ± SD: **G1:** 7.2 ± 1.7 **G2:** 6.9 ± 1.7 **G1/G2:** *P* = 0.557 **Social skills:** VABS socialization score, mean ± SD: **G1:** 73.8 ± 7.7 **G2:** 72.4 ± 9.4 **G1/G2:** *P* = 0.594 **IQ or Early Learning Composite Score:** MSEL scale score, mean ± SD: Early-learning composite: **G1:** 61.0 ± 9.2 **G2:** 59.4 ± 8.6 **G1/G2:** *P* = 0.530 Receptive language: **G1:** 21.1 ± 4.7 **G2:** 21.2 ± 3.8 **G1/G2:** *P* = 0.920 Expressive language: **G1:** 24.5 ± 7.2 **G2:** 26.0 ± 8.6 **G1/G2:** *P* = 0.492 Visual reception: **G1:** 33.2 ± 11.0 **G2:** 30.8 ± 8.9 **G1/G2:** *P* = 0.406 VABS communication score, mean ± SD: **G1:** 68.4 ± 7.6 **G2:** 69.6 ± 7.3 **G1/G2:** *P* = 0.577 **Repetitive Behavior:** RBS total score, mean ± SD: **G1:** 15.2 ± 10.8 **G2:** 21.5 ± 19.2 **G1/G2:** *P* = 0.171	**Overall ratings:** ADOS severity score, 2 years, mean ± SD: **G1:** 7.0 ± 1.9 **G2:** 7.3 ± 1.8 **G1/G2:** *P* = 0.422 Diagnostic category, 2 years, n: Autism: **G1:** 16 **G2:** 20 PDD-NOS: **G1:** 8 **G2:** 1 **Social skills:** VABS socialization score, 2 years, mean ± SD: **G1:** 69.2 ± 11.6 **G2:** 63.1 ± 9.3 **G1/G2:** *P* = 0.263 **IQ or Early Learning Composite Score:** MSEL scale score, 2 years, mean ± SD: Early-learning composite: **G1:** 78.6 ± 24.2 **G2:** 66.3 ± 15.3 **G1/G2:** *P* = 0.044 Receptive language: **G1:** 40.0 ± 16.3 **G2:** 31.5 ± 10.6 **G1/G2:** *P* = 0.048 Expressive language: **G1:** 36.6 ± 13.6 **G2:** 30.0 ± 9.2 **G1/G2:** *P* = 0.033 Visual reception: **G1:** 41.0 ± 17.9 **G2:** 34.5 ± 13.0 **G1/G2:** *P* = 0.433
Dawson et al., 2010 (continued)	**Co-interventions held stable during treatment:** Yes **Concomitant therapies:**	**Race/ethnicity, %:** Asian: 12.5 White: 72.9 Latino: 12.5	**Adaptive behavior:** VABS adaptive behavior composite score, mean ± SD:	**Communication/language:** VABS communication score,

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	NR **N at enrollment:** **G1:** 24 **G2:** 24 **N at follow-up (%):** Year one: **G1:** 24 (100) **G2:** 23 (96) Year two: **G1:** 24 (100) **G2:** 21 (88)	Multiracial: 14.6 **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral and confirmed in study **Diagnostic tool/method:** Toddler Autism Diagnostic Interview, ADOS, DSM-IV **Diagnostic category, n:** Autism: **G1:** 21 **G2:** 18 PDD-NOS: **G1:** 3 **G2:** 6 **Other characteristics:** NR	**G1:** 69.5 ± 5.7 **G2:** 69.9 ± 7.3 **G1/G2:** *P* = 0.844 VABS daily living skills score, mean ± SD: **G1:** 87.3 ± 11.4 **G2:** 86.8 ± 10.0 **G1/G2:** *P* = 0.381 **Motor skills:** MSEL fine motor score, mean ± SD: **G1:** 33.9 ± 11.9 **G2:** 30.6 ± 10.7 **G1/G2:** *P* = 0.318 VABS motor skills score, mean ± SD: **G1:** 70.9 ± 6.2 **G2:** 72.5 ± 6.5 **G1/G2:** *P* = 0.862	2 years, mean ± SD: **G1:** 82.1 ± 21.8 **G2:** 69.4 ± 15.8 **G1/G2:** *P* = 0.015 **Repetitive behavior:** RBS total score, 2 years, mean ± SD: **G1:** 16.7 ± 13.1 **G2:** 22.0 ± 16.3 **G1/G2:** *P* = 0.545 **Adaptive behavior:** VABS adaptive behavior composite score, 2 years, mean ± SD: **G1:** 68.7 ± 15.9 **G2:** 59.1 ± 8.8 **G1/G2:** *P* = 0.011 VABS daily living skills score, 2 years, mean ± SD: **G1:** 64.7 ± 12.4 **G2:** 58.0 ± 8.1 **G1/G2:** *P* = 0.013 **Motor skills:** MSEL fine motor score, 2 years, mean ± SD: **G1:** 33.5 ± 12.2 **G2:** 28.5 ± 9.5 **G1/G2:** *P* = 0.503 VABS motor skills score, 2 years, mean ± SD: **G1:** 77.4 ± 19.8 **G2:** 64.1 ± 12.3 **G1/G2:** *P* = 0.009
Dawson et al., 2010 (continued)				**Harms:** NR **Modifiers:** NR
Author: Frankel et al., 2010 **Country:** US **Practice setting:** Academic **Intervention**	**Intervention:** Children's Friendship Training: children were integrated into classes being conducted by the UCLA Children's Friendship Program, with no more than 4 children with ASD admitted to any	**Inclusion criteria:** • Satisfied ADOS-G and ADI-R criteria for ASD • Currently attending a 2^{nd} through 5^{th} grade regular classroom for most of the school day without a "shadow" or other closely supervising adult	**Social skills:** Loneliness scale score, mean ± SD: **G1:** 34.3 ± 12.3 **G2:** 37.8 ± 14.3 (n=32) Loneliness scale score, follow-up group, mean ± SD:	**Social Skills:** Loneliness scale score, mean ± SD: **G1:** 31.4 ± 8.5 **G2:** 38.9 ± 13.3 (n=32) **G1/G2:** *P* < 0.025 Loneliness scale

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
setting: School and home **Enrollment period:** September 2003 to March 2008 **Funding:** NIH **Author industry relationship disclosures:** NR **Design:** Case series	class (class size was usually 10). Each training class was composed of children separated by no more than one grade level. Study children were not identified in any way to other class participants. Treatment consisted of 12 weekly sessions, each 60 minutes in length. Children and their parents were seen concurrently in separate locations (except for the finalization of the child's homework assignment). Each child session (except the first and last) was composed of four segments: • Children reported the results of their home-work assignment (10 minutes) • Didactic presentation and brief, coached behavioral rehearsal between two children (20 minutes) • Coached play in which children practiced newly learned skills (25 minutes) • Parents and children were reunited and finalized homework contracts. Number of sessions attended, mean ± SD: **G1:** 11.3 ± 0.8 **G2:** 10.7 ± 1.9	• Not currently prescribed any psychotropic medication • Verbal IQ > 60 • Able to switch topics in conversation when the other person was interested in talking about something else • Had adequate knowledge of rules in playing at least two common age-appropriate board games • Knowledge of rules to play common school yard games • Absence of a thought disorder • Free of clinical seizure disorder, gross neuro-logic disease, or other medical disorders **Exclusion criteria:** • See inclusion criteria **Age, months ± SD:** **G1:** 103.2 ± 15.2 **G2:** 101.5 ± 15.0 **Mental age:** WISC-III Verbal IQ, mean ± SD: **G1:** 106.9 ± 19.1 **G2:** 100.5 ± 15.7 **Gender, n (%):** Male: **G1:** 30 (85.7) **G2:** 28 (84.8)	**G1:** 36.3 ± 12.2 PHS popularity score, mean ± SD: **G1:** 7.2 ± 3.0 **G2:** 6.8 ± 3.00 PHS popularity score, follow-up group, mean ± SD: **G1:** 6.9 ± 3.0 Quality of Play Questionnaire score, mean ± SD: Host: **G1:** 2.4 ± 2.2 **G2:** 1.8 ± 2.3 (n=29) Guest: **G1:** 1.3 ± 1.6 **G2:** 1.1 ± 2.0 (n=29) Conflict: **G1:** 4.8 ± 4.2 **G2:** 5.1 ± 5.2 (n=27) Engage: **G1:** 4.2 ± 2.2 **G2:** 4.3 ± 2.1 (n=27) Disengage: **G1:** 5.2 ± 2.5 **G2:** 5.2 ± 2.2 (n=27) Quality of Play Questionnaire score, follow-up group, mean ± SD: Host: **G1:** 2.0 ± 2.1 Guest: **G1:** 1.4 ± 1.7 Conflict: **G1:** 4.3 ± 3.3	score, follow-up group, mean ± SD: Post-treatment: **G1:** 31.6 ± 8.1 12 weeks: **G1:** 33.0 ± 13.7 **G1/BL:** *P* = NS **G1/PT:** *P* = NS PHS popularity score, mean ± SD: **G1:** 8.0 ± 2.8 **G2:** 6.4 ± 2.9 **G1/G2:** *P* < 0.025 PHS popularity score, follow-up group, mean ± SD: Post-treatment: **G1:** 7.9 ± 2.7 12 weeks: **G1:** 7.4 ± 2.8 **G1/BL:** *P* = NS **G1/PT:** *P* = NS Quality of Play Questionnaire score, mean ± SD: Host: **G1:** 3.7 ± 1.7 **G2:** 1.4 ± 2.0 (n=29) **G1/G2:** *P* < 0.0001
Frankel et al., 2010 (continued)	Homework required social contacts with children who were not class members **Assessments:** Children/parents in the intervention group completed outcome measures at baseline (just prior to receiving the intervention), the last night of the intervention, and at 12 week follow-up; waitlist controls completed outcome measures at baseline, 12 weeks later just prior to starting the	Female: **G1:** 5 (14.3) **G2:** 5 (15.2) **Race/ethnicity, n (%):** White: 45 (66.2) Asian: 10 (14.7) African American: 7 (10.3) Hispanic: 4 (5.9) Pacific Islander: 1 (1.4) Native American: 1 (1.4) **SES:** Hollingshead index, mean ± SD: **G1:** 44.6 ± 10.6 **G2:** 50.6 ± 11.8 (n=32) Household income: NR	Engage: **G1:** 3.8 ± 2.1 Disengage: **G1:** 5.2 ± 2.3 SSRS score, mean ± SD: Assertion: **G1:** 9.5 ± 2.8 **G2:** 9.4 ± 3.4 Self-control: **G1:** 10.2 ± 3.4 **G2:** 9.0 ± 3.9 Externalizing: **G1:** 4.5 ± 2.6 **G2:** 5.4 ± 2.3 Internalizing:	Guest: **G1:** 2.0 ± 2.5 **G2:** 1.2 ± 1.5 (n=29) **G1/G2:** *P* = NS Conflict: **G1:** 1.9 ± 2.8 **G2:** 3.3 ± 3.2 (n=29) **G1/G2:** *P* = 0.069 Engage: **G1:** 4.7 ± 2.2 **G2:** 4.3 ± 1.7 (n=29) **G1/G2:** *P* = NS Disengage:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	intervention, and the last night of the intervention. Children and parents completed assessment measures in the presence of the research team, while teachers were mailed assessment measures at each of the testing periods. Child outcome measures: Loneliness Scale, PHS; parent measures: Quality of Play Questionnaire, SSRS; teacher measures: PEI; at baseline, WISC-III; VABS survey form; Socioeconomic Status **Groups:** **G1:** children's friendship training intervention **G2:** children's friendship training after 12 weeks; delayed treatment control **Provider:** • Psychologist • L.C.S.W. • Undergraduate psychology students **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR	**Diagnostic approach:** In Study **Diagnostic tool/method:** ADOS-G and ADI-R; High Functioning ASSQ **Diagnostic category, n:** Autism: 68 PDD-NOS: 0 Aspergers: 0 **Other characteristics, n (%):** Completely mainstreamed: 61 (89.7) Special education classes (but included in a main-streamed recess and mainstream classroom for part of the school day): 6 (8.8) Mainstream classroom with special help for 1-2 hours a day: 1 (1.5) Grade, mean ± SD: **G1:** 3.2 ± 1.0 **G2:** 3.4 ± 1.2	**G1:** 7.0 ± 1.7 **G2:** 7.2 ± 3.2 SSRS score, follow-up group, mean ± SD: Assertion: **G1:** 9.7 ± 2.8 Self control: **G1:** 9.8 ± 3.5 Externalizing: **G1:** 4.5 ± 2.4 Internalizing: **G1:** 7.1 ± 1.6 PEI score, mean ± SD: Withdrawal: **G1:** 4.0 ± 2.1 (n=31) **G2:** 3.8 ± 2.1 (n=28) Aggression: **G1:** 1.3 ± 1.7 (n=31) **G2:** 1.4 ± 1.8 (n=28) PEI score, follow-up group, mean ± SD: Withdrawal: **G1:** 4.2 ± 2.2 Aggression: **G1:** 1.5 ± 1.8 High functioning ASSQ, mean ± SD: **G1:** 22.4 ± 7.3 **G2:** 22.0 ± 9.3	**G1:** 2.3 ± 1.7 **G2:** 4.8 ± 2.1 (n=29) **G1/G2:** $P <$ 0.0001 Quality of Play Questionnaire score, follow-up group, mean ± SD: Post-treatment: Host: **G1:** 4.0 ± 1.6 Guest: **G1:** 1.8 ± 2.6 Conflict: **G1:** 1.8 ± 3.0 Engage: **G1:** 4.5 ± 2.2 Disengage: **G1:** 2.1 ± 1.6 12 weeks: Host: **G1:** 3.1 ± 2.9 **G1/BL:** P = NS **G1/PT:** $P < 0.05$ Guest: **G1:** 1.9 ± 1.5 **G1/BL:** P = NS **G1/PT:** P = NS Conflict: **G1:** 2.0 ± 2.6 **G1/BL:** P = NS **G1/PT:** $P <$ 0.0005
Frankel et al., 2010 (continued)	**N at enrollment:*** **G1:** 35 **G2:** 33 **N at follow-up:** **G1:** 26 **G2:** 31		VABS score, mean ± SD: Communication: **G1:** 84.3 ± 20.5 (n=34) **G2:** 79.8 ± 15.3 Daily living: **G1:** 67.0 ± 18.2 (n=34) **G2:** 62.4 ± 15.7 Socialization: **G1:** 66.3 ± 10.8 (n=34) **G2:** 66.1 ± 10.8 Composite: **G1:** 68.1 ± 16.4 (n=34) **G2:** 64.4 ± 11.0	Engage: **G1:** 4.2 ± 2.0 **G1/BL:** P = NS **G1/PT:** P = NS Disengage: **G1:** 4.1 ± 2.2 **G1/BL:** $P <$ 0.0001 **G1/PT:** $P <$ 0.025SSRS score, mean ± SD: Assertion: **G1:** 11.8 ± 3.2 **G2:** 10.5 ± 3.2 **G1/G2:** $P = 0.054$ Self-control : **G1:** 12.2 ± 2.9 **G2:** 10.1 ± 3.7

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G1/G2: $P < 0.05$ Externalizing: **G1:** 3.8 ± 2.1 **G2:** 5.2 ± 2.3 **G1/G2:** $P = 0.062$ Internalizing: **G1:** 6.4 ± 2.1 **G2:** 7.3 ± 2.5 **G1/G2:** $P = 0.058$ SSRS score, follow-up group, mean ± SD: Post-treatment: Assertion: **G1:** 11.7 ± 2.8 Self Control: **G1:** 12.0 ± 2.8 Externalizing: **G1:** 3.8 ± 2.0 Internalizing: **G1:** 6.2 ± 1.7 12 weeks: Assertion: **G1:** 12.0 ± 3.5 **G1/BL:** P = NS **G1/PT:** $P < 0.0001$ Self Control: **G1:** 11.8 ± 3.8 **G1/BL:** P = NS **G1/PT:** $P < 0.005$
Frankel et al., 2010 (continued)				Externalizing: **G1:** 3.8 ± 2.5 **G1/BL:** P = NS **G1/PT:** P = NS Internalizing: **G1:** 6.0 ± 2.5 **G1/BL:** P = NS **G1/PT:** $P < 0.025$PEI score, mean ± SD: Withdrawal: **G1:** 3.6 ± 2.4 (n=31) **G2:** 3.7 ± 2.1 (n=28) **G1/G2:** P = NS Aggression: **G1:** 1.0 ± 1.3 (n=31) **G2:** 1.4 ± 2.0 (n=28) **G1/G2:** P = NS PEI score, follow-up group, mean ± SD: Post-treatment:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				Withdrawal: **G1:** 3.5 ± 2.5 Aggression: **G1:** 1.3 ± 1.3 12 weeks: Withdrawal: **G1:** 3.6 ± 2.8 **G1/BL:** *P* = NS **G1/PT:** *P* = NS Aggression: **G1:** 1.6 ± 1.7 **G1/BL:** *P* = NS **G1/PT:** *P* = NS **Harms:** NR **Modifiers:** NR

Comments: * Initially, 40 children were assigned to G1 and 36 were assigned to G2 but 5 in G1 and 3 in G2 did not complete 12 week assessments and are not included in baseline data.

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Author: Golan et al. 2010 **Country:** US (NY), Israel, UK **Practice setting:** Academic Medical Center **Intervention setting:** Home **Enrollment period:** NR **Funding:** NIHR CLAHRC and the NHS Foundation Trust **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** "The Transporters," a children's animation series on DVD with eight vehicle characters moving according to rule-based motion • intended to improve understanding and recognition of emotions in 3-8 yr old ASD children • 15 five-minute episodes, focusing on a specific emotion or mental state (happy, sad, angry, afraid, disgusted, surprised, excited, tired, unfriendly, kind, sorry, proud, jealous, joking and ashamed) • includes quizzes related to each episode • parents given a guide to the DVD and encouraged to help child to internalize and apply learned material to other situations Exposure to DVD or standard school curriculum over a period of 4 weeks, participants tested before (Time 1) and after (Time 2)	**Inclusion criteria:** • Met Autism Development Index – Revised (ADI-R) and Children's Autism Spectrum Test (CAST) criteria for autism spectrum disorder **Exclusion criteria:** • For typical control group only - no history of learning difficulties, neurological, or psychiatric disorders, or close relations with ASD **Age, mean/yrs ± SD (range):** **G1:** 5.6 ± 1.0 (4–7) **G2:** 6.2 ± 1.0 (4–8) **G3:** 5.4 ± 1.1 (4–7) **Mental age:** NR **Gender:** M, n (%): **G1:** 15 **G2:** 15 **G3:** 12 F, n (%): **G1:** 5 **G2:** 4 **G3:** 6 **Race/ethnicity:** NR **SES:** NR	**Overall ratings:** CAST, mean ± SD (range)**:** **G1:** 24.0 ± 6.2 (15–33) **G2:** 24.1 ± 5.4 (17–33) **G3:** 6.3 ± 3.2 (2–12) **Communication/ language:** Verbal ability, mean ± SD (range)**:** **G1:** 98.3 ± 10.7 (76–116) **G2:** 99.4 ± 7.9 (86–111) **G3:** 103.3 ± 7.8 (89–115) Emotional Vocabulary, mean ± SD: (max = 16) **G1:** 8.25 ± 2.81 **G2:** 9.17 ± 3.62 **G3:** 12.50 ± 2.26 Situation-Expression Matching tasks (SEM) Levels 1-3, mean ± SD: SEM-Level 1: (max = 16) **G1:** 8.65 ± 2.54 **G2:** 9.67 ± 2.57 **G3:** 11.94 ± 1.73	**Communication/ language:** Emotional Vocabulary, score, mean ± SD: (max = 16) **G1:** 12.50 ± 3.09 **G2:** 9.11 ± 3.45 **G3:** 13.06 ± 2.49 Group: *P* < 0.01 Time: *P* < 0.001 Group x time: *P* < 0.001 Situation-Expression Matching tasks (SEM) Levels 1-3, mean ± SD: SEM-Level 1: (max = 16) **G1:** 13.00 ± 2.45 **G2:** 8.94 ± 2.34 **G3:** 12.39 ± 2.09 Group: *P* < 0.01 Time: *P* < 0.001 Group x time: *P* < 0.001 SEM-Level 2: (max = 16) **G1:** 13.45 ± 2.35 **G2:** 9.22 ± 2.69 **G3:** 12.94 ± 1.59 Group: *P* < 0.001 Time: *P* < 0.001

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	intervention **Assessments:** ADI-R, Children's Autism Spectrum Test (CAST), British Picture Vocabulary Scale (BPVS), emotional vocabulary, situation-facial expression matching (SEM) task Emotion recognition tasks were conducted on computer using PowerPoint beginning with Level 1 with 16 questions at each level	**Diagnostic approach:** In Study & Referral Diagnostic tool/method: In-Study: ADI-R & CAST for G1; CAST for G2; CAST for G3 Referral: G1 & G2 diagnosed in specialist centers using American Psychiatric Association established criteria	SEM-Level 2: (max = 16) **G1:** 9.80 ± 2.91 **G2:** 9.33 ± 2.91 **G3:** 12.72 ± 2.30 SEM-Level 3: (max = 16) **G1:** 9.85 ± 2.43 **G2:** 9.67 ± 2.77 **G3:** 13.00 ± 2.28	Group x time: *P* < 0.001 SEM-Level 3: (max = 16) **G1:** 13.30 ± 2.27 **G2:** 9.61 ± 2.83 **G3:** 12.89 ± 1.78 Group: *P* < 0.001 Time: *P* < 0.001 Group x time: *P* < 0.001 G1 improved significantly from Time 1 to Time 2 on all four tasks (*P* < 0.001)
Golan et al. 2010 (continued)	**Groups:** **G1:** ASD children given Transporters DVD intervention, at least 3 episodes per day for 4 weeks **G2:** ASD children with no intervention (standard school curriculum) **G3:** typically developing controls with no intervention **Provider:** Parental supervision during DVD viewing session **Treatment manual followed:** NR **Defined protocol followed:** yes **Measure of treatment fidelity reported:** yes **Co-interventions held stable during treatment:** NR **Concomitant therapies, n (%):** NR **N at enrollment:** **G1:** 20 **G2:** 19 **G3:** 18 **N at follow-up:**	**Diagnostic category, n (%):** Autism: **G1:** 20 (51) **G2:** 19 (49) **G3:** 0 **Other characteristics:** Days between assessments, mean ± SD (range) **G1:** 28.8 ± 3.3 (24–38) **G2:** 28.2 ± 3.8 (22–37) **G3:** 27.8 ± 1.4 (25–31)		**Harms:** NR **Modifiers:** Positive correlation between verbal ability and improvement on the Level 2 SEM in G1 (r = 0.58, *P* < 0.01); positive correlation between verbal ability and improvement on the Emotional Vocabulary task in G3 (r = 0.57, *P* < 0.02). No other significant correlations between age, verbal ability, time between two assessment meetings and improvement scores for each task.

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	G1: 20 **G2:** 18 **G3:** 18			
Author: Green et al. 2010 **Country:** UK (London, Manchester and Newcastle) **Practice setting:** Specialty treatment center **Intervention setting:** Clinic, home **Enrollment period:** September 2006 through February 2008 **Funding:** University of Manchester, Medical Research Council; UK Department for Children, Schools and Families; UK Department of Health **Design:** RCT See related study Aldred et al. 2004	**Intervention:** Parent-mediated communication-focused (Preschool Autism Communication Trial [PACT]) intervention or treatment as usual at three specialist centers After an initial orientation meeting, families attended biweekly 2-hr clinic sessions for 6 mos followed by monthly booster sessions for 6 mos (total=18). Between sessions, families were also asked to do 30 min of daily home practice. Families in both groups of the trial continued with treatment as usual. Follow-up at 13 mos. **Assessments:** ADOS, PLS, MCDI, CSBS-DP, & VABS **Groups:** **G1:** Preschool Autism Communication Trial (PACT) and treatment as usual **G2:** Treatment as usual **Provider:** • Speech and language therapists **Treatment manual followed:** Yes **Defined protocol followed:** Yes **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** NR	**Inclusion criteria:** • Met criteria for core autism according to ADOS-G and ADI-R • Age 2 yrs to 4 yrs and 11 mos **Exclusion criteria:** • Twin with autism • Non-verbal age ≤12 mos on the Mullen Early Learning Scales • Epilepsy requiring medication • Severe hearing or visual impairment in a parent or the child • Parent with a severe psychiatric disorder requiring treatment **Age, mean months (range):** **G1:** 45 (26–60) **G2:** 45 (24–60) **Mental age, mean months ± SD:** Mullen non-verbal IQ age equivalent: **G1:** 27.0 ± 10.0 **G2:** 25.3 ± 9.5 **Gender: n (%):** M: **G1:** 71 (92) **G2:** 67 (89) F: **G1:** 6 (8) **G2:** 8 (11) **Parents' race/ethnicity, n (%):** White**:** **G1:** 46 (60) **G2:** 41 (55) 1 white, 1 non-white: **G1:** 5 (6) **G2:** 9 (12) Non-white: **G1:** 26 (34) **G2:** 25 (33)	**ADOS-G total social-communication algorithm score, mean ± SD:** **G1:** 19.6 ± 4.2 **G2:** 19.3 ± 4.0 **ADOS-G social domain, mean ± SD:** **G1:** 10.7 ± 2.2 **G2:** 10.7 ± 2.1 **ADOS-G communication domain, mean ± SD:** **G1:** 8.9 ± 2.5 **G2:** 8.6 ± 2.5 **ADOS-G repetitive behavior domain, mean ± SD:** **G1:** 3.7 ± 1.5 **G2:** 3.7 ± 1.4 **Preschool Language Scales (PLS) receptive raw scores, mean ± SD:** **G1:** 15.6 ± 9.8 **G2:** 15.0 ± 9.7 **PLS expressive raw scores, mean ± SD:** **G1:** 15.0 ± 8.1 **G2:** 15.1 ± 7.9 **Parent-child interaction: parental synchrony, mean % ± SD:** **G1:** 31.8 ± 14.8 **G2:** 31.3 ± 14.6 **Parent-child interaction: child initiations, mean % ± SD:** **G1:** 23.0 ± 17.4	**Change in ADOS-G diagnosis to autism spectrum disorder, n (%):** **G1:** 22 (30) **G2:** 17 (24) **Change in ADOS-G diagnosis to non-spectrum, n (%):** **G1:** 4 (5) **G2:** 5 (7) Analysis adjusted for initial ADOS-G category, age group, and center: nonsignificant effect of treatment on any clinician-or teacher-rated outcomes **Social skills: ADOS-G, total social-communication algorithm score, mean ± SD:** **G1:** 15.7 ± 6.0 **G2:** 16.5 ± 5.7 **Change from baseline, mean ± SD:** **G1:** -3.9 ± 4.7 **G2:** -2.9 ± 3.9 **ADOS-G social domain, mean ± SD:** **G1:** 9.2 ± 3.0 **G2:** 9.8 ± 2.9 **Change from baseline, mean ± SD:** **G1:** -1.5 ± 2.8 **G2:** -0.9 ± 2.5

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
			G2: 24.4 ± 18.5	
Green et al. 2010 (continued)	**Concomitant therapies, n (%):** Contact time with other treatment professionals, mean hours ± SD: **G1:** 9.5 ± 16.3 **G2:** 9.8 ± 12.9 Group-based autism psychoeducation, n (%): **G1:** 28 (38) **G2:** 34 (49) Communication-focused interventions, n (%): **G1:** 27 (36) **G2:** 23 (33) Early intensive behavioral intervention, n: **G1:** 1 **G2:** 0 Son-Rise therapy, n: **G1:** 1 **G2:** 0 Portage, n: **G1:** 10 **G2:** 10 Special educational needs setting, n (%): **G1:** 30 (41) **G2:** 24 (34) Education setting with specific provisions for ASD, n (%): **G1:** 8 (11) **G2:** 10 (14) Speech & language therapy: Mean hrs ± SD: **G1:** 9.5 ± 16.3 /case **G2:** 9.8 ± 12.9 /case **N at enrollment:** **G1:** 77 **G2:** 75 **N at follow-up:** **G1:** 74 **G2:** 72	**SES:** Education (one parent with qualifications after age 16 years), n (%): **G1:** 65 (84) **G2:** 47 (63) Household income: NR **SES** (dichotomized as at least one parent in professional or administrative occupation versus all others), n (%): **G1:** 51 (66) **G2:** 44 (59) **Diagnostic approach:** In Study **Diagnostic tool/method**: • Social and communication domains of the ADOS-G • Two of three domains of the ADI-R **Diagnostic category, n (%):** Core autism: 152 (100) Other characteristics: **NR**	**Parent-child interaction: shared attention time, mean % ± SD:** **G1:** 65.3 ± 22.0 **G2:** 67.0 ± 21.9 **ADI-R, mean (range):** Reciprocal social interaction: **G1:** 17.9 (9–25) **G2:** 18.2 (8–26) Restricted, repetitive, and stereotyped patterns: **G1:** 5.2 (0–10) **G2:** 5.6 (0–10) Non-verbal communication: **G1:** 10.7 (3–14) **G2:** 11.0 (3–14) Verbal communication: **G1** (n=22)**:** 15.7 (9–21) **G2** (n=25)**:** 15.7 (10–23) **ADOS-G, mean (range):** Module 1 (at most single words) (G1: n=60; G2: n=57) Communication: **G1:** 6.3 (4–8) **G2:** 6.1 (4–8) Reciprocal social interaction: **G1:** 10.9 (7–14) **G2:** 10.8 (7–14) Module 2 (phrase speech) (G1: n=17; G2: n=18) Communication: **G1:** 6.6 (5–9) **G2:** 6.7 (5–9)	**Parent-child interaction: parental synchrony, mean % ± SD:** **G1:** 51.3 ± 19.6 **G2:** 32.6 ± 14.0 **Change from baseline, mean % ± SD:** **G1:** 19.5 ± 21.3 **G2:** 1.4 ± 15.3 **Parent-child interaction: child initiations, mean % ± SD:** **G1:** 34.9 ± 19.7 **G2:** 26.0 ± 17.5 **Change from baseline, mean % ± SD:** **G1:** 11.9 ± 25.6 **G2:** 1.6 ± 21.4 **Parent-child interaction: shared attention time, mean % ± SD:** **G1:** 64.0 ± 25.7 **G2**: 55.6 ± 25.7 **Change from baseline, mean % (SD):** **G1:** -1.4 ± 23.7 **G2:** -11.4 ± 28.4 Analysis adjusted for center, age group, sex, verbal ability, nonverbal ability, socioeconomic status, and education qualifications were 2.28 (95% CI 0.17 – 4.39) for CSBS-DP social composite scores;
Green et al. 2010 (continued)			Reciprocal social interaction: **G1:** 9.1 (6–12)	**Communication/ language: ADOS-G**

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
			G2: 9.7 (6–14) Module 1 and 2 restricted and repetitive behavior: **G1:** 3.7 (0–6) **G2:** 3.7 (1–6) **Parent-rated Communication and Symbolic Behavior Scales Development Profile (CSBS-DP), mean ± SD:** **G1:** 29.5 ± 7.1 **G2:** 28.3 ± 8.8 **Parent-rated MacArthur Communicative Development Inventory (MCDI), mean ± SD:** **Receptive raw score:** **G1:** 159.5 ± 114.4 **G2:** 162.0 ± 122.4 **Expressive raw score:** **G1:** 93.5 ± 114.8 **G2:** 111.1 ± 128.6	**communication domain, mean (SD):** **G1:** 6.6 (3.3) **G2:** 6.7 (3.2) **Change from baseline, mean (SD):** **G1:** -2.3 (2.6) **G2:** -1.9 (2.4) **PLS receptive raw scores, mean (SD)** **G1:** 21.5 (13.0) **G2:** 20.3 (12.8) **Change from baseline, mean (SD):** **G1:** 6.0 (6.7) **G2:** 5.3 (5.9) **PLS expressive raw scores** **G1:** 20.0 (11.2) **G2:** 20.0 (11.3) **Change from baseline, mean (SD):** **G1:** 5.1 (5.6) **G2:** 4.9 (5.2) **Parent-rated CSBS-DP, mean (SD):** **G1:** 34.0 (8.2) **G2:** 30.8 (8.3) **Change from baseline, mean (SD):** **G1:** 4.6 (7.0) **G2:** 2.5 (6.0) **Parent-rated MCDI receptive raw score, mean (SD):** **G1:** 233.7 (129.6) **G2:** 209.0 (131.3) **Change from baseline, mean (SD):** **G1:** 74.2 (66.9) **G2:** 47.0 (68.2)
Green et al. 2010 (continued)				**Parent-rated MCDI expressive raw score, mean**

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				mean (SD): **G1;** 171.9 (150.7) **G2:** 163.8 (144.3) **Change from baseline, mean (SD):** **G1:** 78.5 (89.3) **G2:** 51.8 (73.2) Analysis adjusted for center, age group, sex, verbal ability, nonverbal ability, socioeconomic status, and education qualifications were 30.28 (95% CI 6.90-53.68) for MCDI receptive scores; analysis of MCDI expressive scores nonsignificant **Teacher-rated Vineland communication score, mean (SD):** **G1:** 64.3 (17.7) **G2:** 67.7 (17.5) **Repetitive behavior:** **ADOS-G repetitive behavior domain, mean (SD):** **G1:** 3.0 (1.7) **G2:** 3.5 (1.6) **Change from baseline, mean (SD):** **G1:** -0.7 (1.9) **G2:** -0.2 (1.6) **Problem behavior:** NR
Green et al. 2010 (continued)				**Adaptive behavior:** **Teacher-rated**

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				Vineland Adaptive behavior composite, mean (SD): **G1:** 60.3 (15.2) **G2:** 62.8 (14.8) **Commonly occurring co-morbidities:** NR **Medical:** NR **Motor skills:** NR **Sensory:** NR **Educational/ cognitive/ academic attainment:** NR **Harms** NR **Modifiers** No effect of age, baseline autism severity, non-verbal ability or SES on intervention effect Significant treatment by Center interactions for Parental synchrony (*P* = 0.005), child initiations (*P* = 0.06). Smallest treatment differences noted in Manchester.
Author: Munasinghe et al. 2010 **Country:** Australia	**Intervention:** Proteolytic enzyme supplement (Peptizyde) Sequence 1: supplement for 3 months, then 1 week	**Inclusion criteria:** • aged 3-8 years • resident in the Perth metropolitan area • must meet DSM-IV criteria for Autistic	NR	**Social skills:** GBRS, therapist engagement score, mean ± SD: **G1a+G2b:** 4.59 ±

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Practice setting: Academic medical center **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Randomized, double-blind, placebo-controlled cross-over trial	wash-out period, followed by placebo for 3 months; Sequence 2: placebo for 3 months, then 1 week washout period, followed by supplement for 3 months; Treatment: ½ to 1 capsule with the largest meal of the day, increasing over several days to 2 capsules with each meal. Maximum dosage: ≤9 capsules per day. Placebo: rice bran 235 mg, beet root fiber 125 mg per capsule Unused capsule returned to pharmacists and documented **Assessments:** Global Behaviour Rating Scale (GBRS), Additional Rating Scale (ARS), Language Development Survey (LDS), Therapist Rating Scale **Groups:** **G1:** proteolytic enzyme supplement /placebo **G1a:** supplement phase **G1b:** placebo phase **G2:** placebo/proteolytic enzyme supplement **G2a:** placebo phase **G2b:** supplement phase **Co-interventions held stable during treatment:** Any behavioral or medical therapy begun ≥ 3 months prior to study was continued without interruption	Disorder or Pervasive Developmental Disorder, Not Otherwise Specified • parent must agree to avoid starting any other alternative therapies for the child during the study **Exclusion criteria:** • significant hearing or vision loss • co-morbid neurological disorders including phenylketonuria, tuberous sclerosis, neurofibromatosis, other identifiable metabolic disorders, genetic abnormalities or intractable seizure disorders, • any new medical/surgical intervention in the next 6 months or within a week of a scheduled surgery • history of allergy to *Aspergillus* enzyme proteins or papaya or any known allergy to fungal proteins • active stomach or duodenal ulcers or severe bowel inflammation (blood in stool), celiac disease • history of hemophilia or other bleeding disorders **Age, mean/mos ± SD (range):** **G1:** 68.57 ± 21.28 (34–101) **G2:** 70.14 ± 23.66 (36–104) **Mental age:** NR		0.96 **G1b+G2a:** 4.43 ± 0.55 *P* = 0.49 Generalized estimating equation (GEE) comparison of treatment to placebo: *P* = 0.91 **Communication/ language:** LDS Vocabulary score, percentile ± SD: **G1a+G2b:** 56.95 ± 28.6 **G1b+G2a:** 55.59 ± 28.6 *P* = 0.17 GEE comparison of treatment to placebo: *P* = 0.09 LDS Sentence length score, percentile ± SD: **G1a+G2b:** 62.38 ± 26.2 **G1b+G2a:** 63.91 ± 24.9 *P* = 0.55 GEE comparison of treatment to placebo: *P* = 0.42 **Problem behavior:** GBRS, Parent behavior score, mean ± SD: **G1a+G2b:** 4.29 ± 0.79 **G1b+G2a:** 4.11 ± 0.73 *P* = 0.38 GEE comparison of treatment to placebo: *P* = 0.28
Munasinghe et al. 2010 (continued)	**Frequency of contact during study:** Monthly **Concomitant therapies, %:** Alternative therapy(kinesiology,	**Gender:** M, %: **G1:** 86 **G2:** 82 F, %: **G1:** 14 **G2:** 18		**Commonly occurring co-morbidities:** ARS, Food variety score, mean ± SD: **G1a+G2b:** 4.42 ±

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	herbal and homeopathic products): **G1:** 33 **G2:** 27 Prescription medication (methylphenidate, clonidine, sodium valproate, risperidone, trimeprazine tartrate, dexchlorpheniramine, inhaled cromolyn, salbutamol, fluticasone proprionate, topical corticosteroids, laxatives): **G1:** 43 **G2:** 45 Special diet (gluten and casein free, gluten free, organic foods only, egg-free and low sugar): **G1:** 10 **G2:** 27 Multivitamins: **G1:** 14 **G2:** 14 **N at enrollment:** **G1:** 21 **G2:** 22 **N at follow-up:** **G1:** 11 **G2:** 16	**Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral Diagnostic tool/method: DSM IV **Diagnostic category, %:** Autism: **G1:** 90 **G2:** 86 PDD-NOS: **G1:** 10 **G2:** 14 Other characteristics: **NR**		0.62 **G1b+G2a:** 4.06 ± 0.45 *P* = 0.02 GEE comparison of treatment to placebo: *P* = 0.02 ARS, Gastrointestinal symptoms score, mean ± SD: **G1a+G2b:** 4.01 ± 0.68 **G1b+G2a:** 3.87 ± 0.36 *P* = 0.34 GEE comparison of treatment to placebo: *P* = 0.41 Sleep quality score, mean ± SD: **G1a+G2b:** 3.95 ± 0.75 **G1b+G2a:** 3.87 ± 0.56 *P* = 0.61 GEE comparison of treatment to placebo: *P* = 0.74 **Harms** No serious effects reported ; 2 children withdrawn by parents due to increased irritability, aggression, inattentiveness (1 on treatment, 1 on placebo); problems persisted after treatment discontinuation
Munasinghe et al. 2010 (continued)				2 children withdrawn from study due to irritability and difficulty engaging in the classroom (authors note changing family

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				and school environment issues on follow-up) **Modifiers** No significant effect of Use of alternative therapies, multivitamins, prescription medication or special diets on enzyme effect size in GEE model
Author: Owley et al., 2010 **Country:** US **Practice setting:** Academic clinic **Intervention setting:** Academic medical center **Enrollment period:** NR **Funding:** NIH, Autism Speaks **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** 10-week open label study of escitalopram based on genotype group, with participants seen at clinic at study start (baseline), week 4, and week 10. Forced titration with weekly increasing doses of escitalopram (2.5, 5, 10, 15, 20mg) unless specific criteria for downward titration due to side effects were met. **Assessments:** ABC-C completed weekly by parents/caregivers **Groups:** **G1:** all participants **G1a**: Low expression of serotonin transporter polymorphism promoter region (5-HTTPLR) genotypic variation (9 S/S) **G1b:** Intermediate expression (1 L_G/L_G, 2 S/L_G, 2 L_A/L_G, 24 S/L) **G1c**: High expression (19 L_A/L_A) **Co-interventions held stable during treatment:** NR **Frequency of contact during study:**	**Inclusion criteria:** • Diagnosis of an ASD • Minimum score of 12 on the ABC-CV **Exclusion criteria:** • Parental sleep diaries during pre-medication baseline week indicating a range in time of awakening greater than 2 hours over 7 days • Concomitant serious medical or psychiatric conditions, including seizures • Study personnel unable to obtain blood sample due to child's restlessness (n=1) • Dropout (n=1) **Age, mean months ± SD (range):** **G1:** 117 ± 31 (54-204) **G1a:** 124 ± 22 (98–164) **G1b:** 121 ± 34 (82–204) **G1c:** 106 ± 28 (54–160) Mental age: NR Gender, n (%): **G1:** M: 48 (83) F: 10 (17) **G1a:** M: 8 (89) F: 1 (11) **G1b:** M: 25 (86)	**ADI-R, mean ± SD (range):** **G1:** Social interaction: 23 ± 5 (11-30) Communication, verbal: 17 ± 4 (7-26) Communication, non-verbal: 13 ± 2 (10-15) Repetitive behavior: 6 ± 3 (1-15) Abnormality of development: 4 ± 1 (1-5) **G1a:** Social interaction: 24 ± 4 (18-29) Communication, verbal: 18 ± 5 (11-26) Communication, non-verbal: 13 ± 1 (13-14) Repetitive behavior: 6 ± 2 (2-9) Abnormality of development: 4 ± 1 (2-5) **G1b:** Social interaction: 24 ± 4 (14-30) Communication, verbal: 17 ± 4 (10-23) Communication, non-verbal: 12 ± 2 (10-15) Repetitive behavior: 7 ± 3 (2-12)	**Problem behavior**: Final data on ABC Irritability subscale scores only represented graphically. **Harms** NR **Modifiers** Final dose did not differ significantly between genotype groups. Age and weight were not significantly correlated with final dose in the whole group or in the genotype expression subgroups.

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	NR **Concomitant therapies**: Participants ceased psychoactive medication use 1 month prior to study; participants previously on fluoxetine stopped medication 6 weeks prior to study. **N at enrollment**: **G1:** 58* **G1a**: 9 **G1b**: 29 **G1c**: 19	F: 4 (14) **G1c:** M: 14 (74) F: 5 (26)	Abnormality of development: 4 ± 1 (0-5) **G1c:** Social interaction: 23 ± 5 (11-30) Communication, verbal: 17 ± 4 (7-26) Communication, non-verbal: 13 ± 2 (10-15) Repetitive behavior: 6 ± 3 (1-15)	
Owley et al., 2010 (continued)	**N at follow-up**: **G1:** 45 **G1a**: NR **G1b**: NR **G1c**: NR *1 participant with rare genotype excluded from subgroup analyses	**Race/ethnicity, n (%):** **G1:** African American: 6 (10) Asian: 2 (3) Caucasian: 48 (83) Hispanic: 2 (3) **G1a:** African-American: 1 (11) Asian: 1 (11) Caucasian: 7 (78) Hispanic: 0 **G1b:** African-American: 5 (17) Asian: 1 (3) Caucasian: 21 (72) Hispanic: 2 (7) **G1c:** African-American: 0 Asian: 0 Caucasian: 19 (100) Hispanic: 0 **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study: ADI-R, ADOS **Diagnostic tool/method**: ADI-R, Autism Diagnostic Observation Schedule, cognitive testing, psychiatric evaluation **Diagnostic category** (best estimate diagnosis), n (%): **G1:** Autistic disorder: 35 (60) PDD-NOS: 17 (29) Asperger's: 6 (10)	Abnormality of development: 4 ± 1 (1-5) **ADOS, mean±SD (range):** **G1:** Social interaction: 9 ± 3 (4-14) Communication: 5 ± 2 (2-10) Communication+ social: 15 ± 4 (7-23) Play: 2 ± 1 (0-4) Stereotyped behavior/interests: 3 ± 2 (0-6) **G1a:** Social interaction: 9 ± 3 (4-14) Communication: 5 ± 2 (3-8) Communication+ social: 15 ± 5 (7-22) Play: 2 ± 1 (0-4) Stereotyped behavior/interests: 3 ± 2 (0-6) **G1b:** Social interaction: 10 ± 3 (4-14) Communication: 5 ± 2 (2-10) Communication+ social: 15 ± 5 (7-23) Play: 2 ± 1 (0-4) Stereotyped behavior/interests: 3 ± 2 (0-6) **G1c:** Social interaction: 9	

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
		G1a: Autistic disorder: 6 (67) PDD-NOS: 1 (11) Asperger's: 2 (22) **G1b:** Autistic disorder: 20 (69) PDD-NOS: 7 (24) Asperger's: 2 (7) **G1c:** Autistic disorder: 8 (42) PDD-NOS: 9 (47) Asperger's: 2 (11)	± 3 (4-14) Communication: 5 ± 2 (2-10) Communication+ social: 15 ± 4 (7-23) Play: 2 ± 1 (0-4) Stereotyped behavior/interests: 3 ± 2 (0-6)	
Owley et al., 2010 (continued)		**Other characteristics:** NR	**Non-verbal IQ, mean ± SD (range):** **G1:** 86 ± 34 (21-146) **G1a**: 63 ± 34 (21-103) **G1b**: 91 ± 33 (25-140) **G1c**: 86 ± 34 (21-146) **Verbal IQ, mean ± SD (range)::** **G1:** 76 ± 35 (11-141) **G1a**: 60 ± 36 (11-114) **G1b**: 75 ± 34 (14-141) **G1c**: 76 ± 35 (11-141) **ABC Irritability scale score, mean ± SD (range)::** **G1:** 21 ± 6 (12-37) **G1a**: 21 ± 5 (14-30) **G1b**: 20 ± 6 (12-33) **G1c**: 21 ± 6 (12-37) **ABC Hyperactivity scale score, mean ± SD (range)::** **G1:** 25 ± 11 (4-45) **G1a**: 22 ± 8 (10-36) **G1b**: 27 ± 10 (7-45) **G1c**: 25 ± 11 (4-45)	
Author: Pan 2010 **Country:** Taiwan **Practice setting:**	**Intervention:** Water exercise swimming program (WESP), 10 weeks, 20 sessions (two sessions/week, 90 minutes each) for improvement of aquatic and social skills	**Inclusion criteria:** • Diagnosis of mild ASD or Asperger syndrome • Age 6- 9 years • Able to follow instructions • Parental commitment to allow participation	**Social skills:** SSBS-2, mean ± SD: Peer relations: **G1a:** 41.50 ± 4.17 **G1b:** 43.00 ± 4.57 Social competence	**T2:** after 10 weeks of WESP or regular/treatment/ activity **T3:** after an additional 10 weeks

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
University **Intervention setting:** School **Enrollment period:** NR **Funding:** Grant from National Science Council, Taiwan **Design:** Prospective case series	Duration: 21 weeks, with 10 weeks WESP, 10 weeks control, and 1 week transition **Assessments:** School Social Behavior Scales (SSBS-2) completed by classroom teacher Baseline (T1), after 10 weeks (T2) and after 20 weeks (T3). Classroom teachers were blinded to children's treatment conditions. HAAR checklist used to assess aquatic skills **Groups:** **G1a:** WESP for first 10 weeks followed by 10 weeks regular treatment/activity **G1b:** regular treatment/activity for first 10 weeks then WESP for second 10 weeks **Provider:** • 4 research assistants completed WESP training course prior to study and served as swimming instructors **Treatment manual followed:** Yes **Defined protocol followed:** Yes **Measure of treatment fidelity reported:** No	without changing current therapy or activity **Exclusion criteria:** • Intellectual disability **Age, mean/yrs ± SD (range):** **G1a:** 7.27 ± 1.25 (5.58-9.75) **G1b:** 2 7.20 ± 0.89 (6.08-8.58) **Mental age, mean/yrs (range):** NR **Gender, n (%):** M: 16 (100) F: 0 (0) **Race/ethnicity, n (%):** Asian: 16 (100) **SES:** Maternal education: NR Household income: NR All described as residing in urban setting with two-parent household **Diagnostic approach:** Referral (diagnosis by medical and psychological assessment by physicians in the public hospitals) Diagnostic tool/method: DSM-IV **Diagnostic category, n (%):** Mild or high-functioning autism: 8 (50) Aspergers: 8 (50)	total: **G1a:** 42.67 ± 3.02 **G1b:** 43.38 ± 4.31 **Adaptive behavior:** SSBS-2, mean ± SD: Self-management/compliance: **G1a:** 44.13 ± 2.17 **G1b:** 44.38 ± 3.74 **Educational/ cognitive/ academic attainment:** SSBS-2, mean ± SD: Academic behavior, mean: **G1a:** 45.88 ± 2.30 **G1b:** 45.25 ± 6.30 **Problem behavior:** SSBS-2, mean ± SD: Hostile/irritable, mean: **G1a:** 60.38 ± 5.24 **G1b:** 60.75 ± 6.20 Antisocial/ aggressive, mean: **G1a:** 52.00 ± 3.30 **G1b:** 56.00 ± 7.60 Defiant/disruptive: **G1a:** 59.50 ± 5.15 **G1b:** 58.63 ± 7.41 Antisocial behavior total: **G1a:** 58.00 ± 4.17 **G1b:** 59.38 ± 6.93	**Adaptive behavior:** T2: SBSS-2, mean ± SD: Self-management/compliance: **G1a:** 47.13 ± 4.88 **G1b:** 45.13 ± 4.32 T3: SBSS-2, mean ± SD: Self-management/compliance: **G1a:** 46.38 ± 6.57 **G1b:** 50.75 ± 4.46 **Educational/ cognitive/ academic attainment:** T2: SBSS-2, mean ± SD: Academic behavior: **G1a:** 51.38 ± 2.20* **G1b:** 48.50 ± 4.21 T3: Academic behavior: **G1a:** 50.38 ± 2.45 **G1b:** 52.75 ± 4.03 **Social skills:** T2: SBSS-2, mean ± SD: Peer relations: **G1a:** 43.88 ± 4.92 **G1b:** 41.63 ± 5.26
Pan 2010 (continued)	**Co-interventions held stable during treatment:** Yes **Concomitant therapies, n (%):** Occupational therapy: 6 (37.5) Physical therapy: 2 (12.5) Group therapy: 3 (18.75)	Both groups were split 4/4 for high-functioning autism and asperger syndrome **Other characteristics:** Height, mean/cm ± SD: **G1a:** 128.75 ± 7.83 **G1b:** 124.43 ± 4.04 Weight, mean kg ± SD:	**Motor skills:** HAAR, mean ± SD: HAAR stage 1-mental adjustment: **G1a:** 95 ± 9.26 **G1b:** 100 ± 0 HAAR stage II-intro to water: **G1a:** 51.25 ± 15.53	Social competence total: **G1a:** 46.25 ± 3.99 **G1b:** 43.88 ± 3.48 T3: SBSS-2, mean ± SD: Peer relations: **G1a:** 45.50 ± 5.45

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	Speech therapy: 1 (6.25) Community-based physical activity program: 4 (25) Ritalin for ADD symptoms: 2 (12.5) **N at enrollment:** **G1a:** 8 **G1b:** 8 **N at follow-up:** **G1a:** 8 **G1b:** 8	**G1a:** 30.54 ± 8.73 **G1b:** 25.59 ± 5.77 BMI mean kg/m^2 ± SD: **G1a:** 18.27 ± 4.32 G1b: **16.40 ± 2.80**	**G1b:** 58.75 ± 13.56 HAAR Stage III-rotations: **G1a:** 0 ± 0 **G1b:** 4.16 ± 11.77 HAAR Stage IV-balance & controlled movement: **G1a:** 25 ± 9.45 **G1b:** 32.81 ± 17.60 HAAR Stage V-independent movement in water: **G1a:** 0 ± 0 **G1b:** 8.33 ± 15.41	**G1b:** 47.13 ± 3.44 Social competence total: G1a: 46.50 ± 5.07 G1b: 49.63 ± 3.11** **Problem behavior:** T2: SBSS-2, mean ± SD: Hostile/irritable: **G1a:** 46.25 ±5.18* **G1b:** 53.25 ± 7.89 Antisocial/aggressive: **G1a:** 45 ± 4.44* **G1b:** 48.75 ± 7.07 Defiant/disruptive: **G1a:** 45.88 ± 6.47* **G1b:** 51.63 ± 7.23 Antisocial behavior total: **G1a:** 45.75 ± 5.44* **G1b:** 51.75 ± 7.38 T3: SBSS-2, mean ± SD: Hostile/irritable: G1a: 53.25 ± 7.72** G1b: 43.75 ± 2.92** Antisocial/ aggressive: **G1a:** 48.75 ± 5.73 **G1b:** 44.75 ± 2.76
Pan 2010 (continued)				Defiant/disruptive: **G1a:** 51.75 ± 8.19 **G1b:** 45 ± 4.54 Antisocial behavior total: **G1a:** 51.63 ± 7.35 **G1b:** 44 ± 2.73** **P* < 0.01 compared to

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				baseline (T1) within groups **$P < 0.01$ compared to T2 **Motor skills:** HAAR, mean ± SD: T2: HAAR stage 1-mental adjustment: **G1a:** 100 ± 0 **G1b:** 100 ± 0 T3: **G1a:** 100 ± 0 **G1b:** 100 ± 0 HAAR stage II-intro to water: T2: **G1a:** 90 ± 11.95 ($P < 0.01$ compared to T1, $P < 0.01$ compared to G1b) **G1b:** 58.75 ± 13.56 T3: **G1a:** 86.28 ± 17.68 **G1b:** 87.50 ± 14.88 ($P < 0.01$ compared to T2)
Pan 2010 (continued)				HAAR Stage III-rotations: T2: **G1a:** 33.33 ± 25.21 ($P < 0.01$ compared to T1, $P < 0.01$ compared to G1b) **G1b:** 4.16 ± 11.77 T3: **G1a:** 33.33 ± 25.21 **G1b:** 20.83 ± 24.80 HAAR Stage IV-balance & controlled movement: T2: **G1a:** 71.88 ± 17.36 ($P < 0.01$ compared to T1,

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				P < 0.01 compared to G1b) **G1b:** 32.81 ± 17.60 T3: **G1a:** 71.88 ± 17.36 **G1b:** 68.75 ± 18.90 (*P* < 0.01 compared to T2)
Pan 2010 (continued)				HAAR Stage V-independent movement in water: T2: **G1a:** 64.60 ± 18.78 (*P* < 0.01 compared to T1, *P* < 0.01 compared to G1b) **G1b:** 8.33 ± 15.41 T3: **G1a:** 64.60 ± 18.78 **G1b:** 52.08 ± 20.79 (*P* < 0.01 compared to T2) **G1a:** NS for differences between T2 and T3 **G1b:** NS for differences between T1 and T2 **Harms** NR **Modifiers** NR
Author: Reed et al. 2010 **Country:** England **Practice setting:** Academic **Intervention setting:** School, home **Enrollment period:** NR	**Intervention:** For a period of 1 year, children received one of three early teaching interventions: a 1:1 authority-provided home-based program (PACTS), a general special nursery for children with all types of learning difficulty, or an autistic special nursery for children only with ASDs. Special nurseries had eclectic interventions	**Inclusion criteria:** • ages 2 years 6 months to 4 years 0 months at the start of their intervention • Receiving no other major intervention during the period of the assessment • Diagnosis of ASD given by an independent pediatrician **Exclusion criteria:** • See above **Age, mean/months ± SD:** **G1:** 44.3 ± 4.8	**Overall ratings:** GARS autism quotient, mean ± SD: **G1:** 98.5 ± 11.6 **G2:** 95.9 ± 8.0 **G3:** 95.1 ± 11.6 **Educational/ cognitive/ academic attainment:** PEP–R overall, mean ± SD: **G1:** 47.7 ± 22.3 **G2:** 58.1 ± 15.5	**Overall ratings:** GARS change from baseline score, mean ± SD: **G1:** 2.2 ± 9.5 *P* > 0.40 **G2: -**5.9 ± 8.7 *P* > 0.09 **G3:** 1.6 ± 6.2 *P* > 0.30 **Educational/ cognitive/ academic attainment:**

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Funding: NR **Design:** Prospective cohort	Intervention time (hours/week), mean ± SD: **G1:** 11.5 ± 6.0 **G2:** 16.3 ± 3.3 **G3:** 12.6 ± 2.3 **Assessments:** Psycho-Educational Profile-Revised (PEP-R); British Abilities Scale; Vineland Adaptive Behavior Scales; Gilliam Autism Rating Scale (GARS) Assessments were performed by an educational psychologist at the child's home at baseline. The follow up assessments were performed by the same psychologist at the child's home 9 months later. **Groups:** **G1:** General Special Nursery **G2:** Autistic Special Nursery **G3:** PACTS **Provider:** Psychologist **Treatment manual followed:** NR	**G2:** 42.8 ± 3.9 **G3:** 40.8 ± 5.6 **Mental age:** NR **Gender, n (% of group):** **G1:** M: 11 (92) F: 1 (8) **G2:** M: 7 (87.5) F: 1 (12.5) **G3:** M: 12 (92) F: 1 (8) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** Independent pediatrician **Diagnostic category:** NR **Other characteristics:** Characteristics interventions:	**G3:** 49.3 ± 13.2 BAS cognitive ability, mean ± SD: **G1:** 55.0 ± 14.0 **G2:** 61.9 ± 10.2 **G3:** 52.4 ± 10.0 **Adaptive behavior:** Vineland composite, mean ± SD: **G1:** 51.1 ± 4.5 **G2:** 55.8 ± 3.5 **G3:** 56.2 ± 4.1	PEP–R overall score, mean ± SD: **G1:** 56.6 ± 24.1 *P* < 0.07, ES = 0.63 **G2:** 70.1 ± 16.3 *P* < 0.05, ES = 0.7 **G3:** 55.9 ± 21.5 *P* > 0.10, ES = 0.5 **Educational functioning:** BAS cognitive ability, mean ± SD: **G1:** 63.4 ± 16.2 *P* < 0.01 **G2:** 69.0 ± 14.9 *P* > 0.10 **G3:** 57.6 ± 12.6 *P* < 0.05 **Adaptive behavior:** Vineland composite, mean ± SD: **G1:** 54.2 ± 9.3 *P* > 0.10, ES = 1.2 **G2:** 59.3 ± 5.1 *P* < 0.05, ES = 0.8 **G3:** 55.8 ± 5.6) ES = -0.1
Reed et al. 2010 (continued)	**Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** Yes **Concomitant therapies:** No other major interventions during assessment period **N at enrollment:** **G1:** 12 **G2:** 8 **G3:** 13 **N at follow-up:** **G1:** 12 **G2:** 8	**Intervention hours/week, range:** **G1:** 3-21 **G2:** 13-23 **G3:** 11-20 **1:1 teaching, hours/week ± SD:** **G1:** 2.6 ± 2.5 **G2:** 1.8 ± 1.0 **G3:** 12.2 ± 2.5 **Group teaching, hours/week ± SD:** **G1:** 8.9 ± 5.5 **G2:** 14.6 ± 2.6 **G3:** 0.5 ± 0.9 **Tutors, mean n ± SD:**		Significant improvements for 3 developmental age outcomes relative to baseline for all 3 groups were observed **Harms:** NR **Modifiers:** Relationship between overall gains and temporal input: **G1 & G2:** Posiitve (gains = 1.4 +0.3

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	G3: 13	**G1:** 2.83 ± 0.6 **G2:** 3.1 ± 0.6 **G3:** 3.1 ± 1.0 **Family tutors, mean n ± SD:** **G1:** 0.50 ± 0.9 **G2:** 0 **G3:** 0.6 ± 0.8 **Service providers, n** **G1:** 5 **G2:** 2 **G3:** 1		hrs/week, r^2 = 0.10) **G3:** Negative (gains = 18.1-0.50, r^2 = 0.21)
Author: Whalen et al., 2010 **Country:** US (CA) **Practice setting:** Specialized school program **Intervention setting:** Classroom **Enrollment period:** NR **Funding:** Agency/NR **Design:** RCT (randomized by classroom, no individual randomization)	**Intervention:** *TeachTown: Basics* is a computer-assisted intervention (CAI) with supplementary off-computer activities. This intervention was implemented for 3 months and consisted of 20 minutes/day on the computer and 20 minutes/day in supplementary activities. 8 classrooms in 4 schools were randomly assigned to standard teaching or to *TeachTown: Basics* . **Groups:** **G1a:** *TeachTown: Basics* Preschool, school 1 **G1b:** *TeachTown: Basics* K-1, school 1 **G1c:** *TeachTown: Basics* Preschool, school 2 **G1d:** *TeachTown: Basics* K-1, school 2 **G2a:** Control, Preschool, school 3 **G2b:** Control, K-1, school 3**G2c:** Control, Preschool, school 4 **G2d:** Control, K-1, school 4 **Provider:** • Teacher **Treatment manual followed:** No	**Inclusion criteria:** • Children aged 3-6 years with autism • Attended Los Angeles Unified School District's Intensive Comprehensive Autism Program (ICAP) **Exclusion criteria:** See inclusion criteria **Age, in years (range):** 3-6 **Mental age:** NR **Gender:** NR Race/ethnicity: NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** NR **Diagnostic tool/method**: Diagnostic method NR; CARS administered by each child's teacher for measurement of disease severity **Diagnostic category, n (%):** Autism: 47 (100) **Other characteristics:** NR	**CARS score, mean**: **G1:** 42 **G1a:** 33 **G1b:** 39 **G1c:** 44 **G1d:** 52 **G2:** 43 **G2a:** 45 **G2b:** 37 **G2c:** 45 **G2d:** 45 **Peabody Picture Vocabulary Test (PPVT), mean:** **G1a+c:** 8.82 **G2a+c:** 9.67	**Communication/ language:** **PPVT, mean:** **G1a+c:** 23.36 **G2a+c:** 14.92 *P* = 0.036 G1b+d vs. G2b+d (values NR): *P* = 0.577 **EVT:** (values NR) G1a+c vs. G2a+c: *P* = 0.444 G1b+d vs. G2b+d: *P* = 0.375 Brigance Inventory of Early Development (values NR) scores and subscores: no significant differences between G1 and G2 Significant correlation between number of lessons mastered in G1 with overall pre-post change in Brigance score (*P* = 0.042) **Harms** NR

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	Defined protocol followed: Yes **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR			
Whalen et al., 2010 (continued)	**Concomitant therapies, n (%):** **G1:** speech , language & occupational interventions delivered but values NR **G2:** none **N at enrollment:** **G1:** 22 **G1a:** 6 **G1b:** 5 **G1c:** 5 **G1d:** 6 **G2:** 25 **G2a:** 7 **G2b:** 5 **G2c:** 6 **G2d:** 7 **N at follow-up:** **G1:** 22 **G1a:** 6 **G1b:** 5 **G1c:** 5 **G1d:** 6 **G2:** 25 **G2a:** 7 **G2b:** 5 **G2c:** 6 **G2d:** 7			**Modifiers** 15 children in G1 mastered lessons in the software program during the 3 month study period; no significant difference in Brigance scores between these children and the 7 G1 children who did not master a lesson. Significant correlation between time spent on the software and the total number of lessons mastered in G1 (*P* = 0.01)
Author: Adams et al., 2009 (A) Adams et al., 2009 (B)† **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:**	**Intervention:** Phase I: Application of lotion that contained glutathione or placebo 1x per day after bath, with child rubbing it on for 7 days; all children received oral DMSA at 10 mg/kg 3x per day for 3 days Phase II: children then received either DMSA or placebo for up to 3 rounds (each round consisted of 3 days followed by 11 days of no DMSA/ placebo) • Children who received	**Inclusion criteria:** **Phase I:** • Age 3-8 years • ASD, diagnosed by a psychiatrist, psychologist, or developmental pediatrician • No mercury amalgam dental fillings • No previous DMSA or other prescription chelators • No anemia or currently being treated for anemia due to low iron • No known allergies to DMSA	**Overall ratings:** ATEC SPLC, mean ± SD: **G1:** 13.4 ± 7.7 **G2:** 12 ± 8.4 ATEC Total, mean ± SD: **G1:** 80.8 ± 24 **G2:** 66.2 ± 20.7 AWP/C composite (sensory + ritual + social pragmatic + semantic + arousal + fears + aggressive), mean ± SD: **G1:** 105 ± 58.6 (n=25)	**Overall ratings:** ATEC SPLC, mean ± SD: **G1:** 10.6 ± 7 **G2:** 10.5 ± 8.9 **G1/BL:** *P* < 0.001 **G2/BL:** *P* = NS ATEC Total, mean ± SD: **G1:** 60.14 ± 27.9 **G2:** 53.4 ± 23.5 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.01 AWP/C composite, mean

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
NR **Author industry relationship disclosures:** None **Design:** RCT	glutathione lotion received DSMA, those who received placebo lotion received placebo in Phase II • All participants received vitamin/mineral supplements for ≥ 2 months prior to and through the study period Duration: NR Frequency: NR **Assessments:** Phase I: ATEC and Heavy Metal Exposure Questionnaire completed by parents at baseline Phase II: ADOS administered by clinician following the completion of Phase I (at onset and completion of Phase II); parent completed the PDD-BI and SAS (at onset and completion of Phase II); Parental Global Impressions questionnaire (post-treatment only, answers range from -3 “much worse” to +3 “much better”); clinician working with child to complete ATEC for the child (post-treatment only)	• No liver or kidney disease • Well hydrated **Phase II:** • Excretion of high amounts of toxic metals in Phase I • Normal liver function (serum transaminases ALT and AST), normal renal function, and complete blood cell count was not below the normal reference range • No changes in medication, supplements, diet, or behavioral interventions during the study • At least a two-month history of taking a multi-vitamin/mineral supplement with a least the RDA of zinc, and continuing to take that during Phase II • Continue to stay well hydrated **Exclusion criteria:** • See inclusion criteria **Age, years:**† **G1:** 6.7 **G2:** 6.5 **Mental age:** NR	**G2:** 93.8 ± 29.5 REXSCA/C composite (social approach + express + LMRL), mean ± SD: **G1:** 127 ± 52.7 (n=25) **G2:** 135 ± 65.5 Autism composite (sensory + ritual + social problems – social approach behaviors – expressive language), mean ± SD: **G1:** -53.1 ± 66.4 (n=25) **G2:** -63.5 ± 65.1 SAS score, phase 1 onset, mean ± SD: **G1:** 5.2 ± 2.2) **G2:** 5.5 ± 2.7) **Social skills:** ATEC Sociability, mean ± SD: **G1:** 16.6 ± 8.5 **G2:** 14.9 ± 6.8 PDD-BI Social pragmatic problems, mean ± SD: **G1:** 16.9 ± 9.2 (n=25) **G2:** 13.9 ± 7.5	± SD: **G1:** 79.5 ± 49.9 **G2:** 71.6 ± 38.8 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 REXSCA/C composite: **G1:** 139 ± 54.5 **G2:** 150 ± 53.6 **G1/BL:** *P* < 0.01 **G2/BL:** *P* < 0.05 Autism composite: **G1:** -73.3 ± 67.9 **G2:** -88.8 ± 58.3 **G1/BL:** *P* < 0.01 **G2/BL:** *P* < 0.01 SAS score, completion of phase 2, mean ± SD: **G1:** 4.2 ± 2 **G2:** 4.5 ± 2.6 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.01 **Social skills:** ATEC Sociability, mean ± SD: **G1:** 12.1 ± 6.5 **G2:** 11.2 ± 6.5 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.05
Adams et al., 2009 (A) Adams et al., 2009 (B)† (continued)	**Groups:** **G1:** treatment (7 rounds of treatment) **G2:** placebo (1 round of treatment followed by 6 rounds of placebo) **Provider(s):** NR **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** Phase 1: 82 Phase 2 :49 **N at follow-up:**	**Gender, n:**† Male: **G1:** 24 **G2:** 14 Female: **G1:** 2 **G2:** 1 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** Initially diagnosed by community clinicians independent of this study, confirmed by ADOS-certified evaluator	AWP/C Social approach behaviors, mean ± SD: **G1:** 63.8 ± 20.6 (n=25) **G2:** 68.2 ± 25.4 ADOS Sociability, mean: **G1:** 9.3 **G2:** 8.1 ADOS Communication + sociability, mean: **G1:** 17 **G2:** 14.7 **Communication/ language:** PDD-BI Semantic/pragmatic	PDD-BI Social pragma-tic problems, mean ± SD: **G1:** 14.5 ± 9.2 **G2:** 9.9 ± 7.5 **G1/BL:** *P* = NS **G2/BL:** *P* < 0.01 AWP/C Social approach behaviors, mean ± SD: **G1:** 70.8 ± 23.6 **G2:** 72.6 ± 20.2 **G1/BL:** *P* < 0.01 **G2/BL:** *P* = NS ADOS Sociability, mean (% change): **G1:** 8.3 (-10)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	Phase 1: 65 **G1:** 26 G2: **15**	**Diagnostic Tool:** ADOS **Diagnostic category, %:†** Autism: **G1:** 96 **G2:** 100 Asperger's: **G1:** 4 **G2:** 0 **Other characteristics:** NR	problems: **G1:** 15.2 ± 7.6 n=25) **G2:** 11.1 ± 5.6 AWP/C Express (phono-logical + semantic pragmatic), mean ± SD: **G1:** 41.4 ± 28.2 (n=25) **G2:** 44 ± 34.9 AWP/C Learning, memory, and receptive language, mean ± SD: **G1:** 22.7 ± 8.1 (n=25) **G2:** 23.2 ± 10.1 ADOS Communication, mean: **G1:** 7.8 **G2:** 6.7 ADOS Communication + sociability, mean: **G1:** 17 **G2:** 14.7	**G2:** 7.9 (-2) **G1/BL:** *P* < 0.01 **G2/BL:** *P* = NS ADOS Communication + sociability, mean (% change): **G1:** 15.4 (-9) **G2:** 13.7 (-7) **G1/BL:** *P* < 0.001 **G2/BL:** *P* = NS **Communication /language:** PDD-BI Semantic/prag-matic problems, mean ± SD: **G1:** 12.5 ± 7.3 **G2:** 9.6 ± 4.5 **G1/BL:** *P* = NS **G2/BL:** *P* = NS AWP/C Express, mean ± SD: **G1:** 43.6 ± 27.1 **G2:** 51.3 ± 31.5 **G1/BL:** *P* = NS **G2/BL:** *P* < 0.05
Adams et al., 2009 (A) Adams et al., 2009 (B)† (continued)			**Problem behavior:** PDD-BI Ritualisms/resistance to change, mean ± SD: **G1:** 13.9 ± 10.5 (n=25) **G2:** 15 ± 8.5 PDD-BI Arousal regulation problems, mean ± SD: **G1:** 17.9 ± 9 (n=25) **G2:** 14.9 ± 6.6 PDD-BI Aggressiveness, mean ± SD: **G1:** 13.4 ± 9.8 (n=25) **G2:** 11.4 ± 8.1 **Adaptive behavior:** ATEC Health/physical behavior, mean ± SD: **G1:** 29.9 ± 14.4 **G2:** 21.5 ± 9.4 PDD-BI Specific fears, mean ± SD: **G1:** 21.7 ± 16 (n=25)	AWP/C Learning, memory, and receptive language, mean ± SD: **G1:** 25.4 ± 8.7 **G2:** 26.5 ± 8.9 **G1/BL:** *P* < 0.05 **G2/BL:** *P* < 0.01 ADOS Communication, mean (% change): **G1:** 7.1 (-9) **G2:** 5.9 (-11) **G1/BL:** *P* = NS **G2/BL:** *P* = NS ADOS Communication + sociability, mean (% change): **G1:** 15.4 (-9) **G2:** 13.7 (-7) **G1/BL:** *P* <

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
			G2: 18.7 ± 10.3 ADOS Play, mean: **G1:** 3.2 **G2:** 2.8 ADOS SBRI, mean: **G1:** 3.9 **G2:** 3.5 **Sensory:** ATEC Sensory/cognitive awareness, mean ± SD: **G1:** 16 ± 7.4 **G2:** 13 ± 6.8 PDD-BI Sensory/perceptual approach behaviors, mean ± SD: **G1:** 22.8 ± 14.7 (n=25) **G2:** 20 ± 13.6	0.001 **G2/BL:** *P* = NS **Problem behavior:** PDD-BI Ritualisms/resistance to change, mean ± SD: **G1:** 10 ± 7.8 **G2:** 11.5 ± 8.2 **G1/BL:** *P* < 0.01 **G2/BL:** *P* < 0.01 PDD-BI Arousal regulation problems, mean ± SD: **G1:** 13.9 ± 8.5 **G2:** 12.1 ± 8.8 **G1/BL:** *P* < 0.01 **G2/BL:** *P* = NS PDD-BI Aggressiveness, mean ± SD: **G1:** 9.8 ± 6.7 **G2:** 8.4 ± 7.2 **G1/BL:** *P* < 0.05 **G2/BL:** *P* < 0.05
Adams et al., 2009 (A) Adams et al., 2009 (B)† (continued)				**Adaptive behavior:** ATEC Health/physical behavior, mean ± SD: **G1:** 21.6 ± 10.1 **G2:** 18.3 ± 9.2 **G1/BL:** *P* < 0.01 **G2/BL:** *P* = NS PDD-BI Specific fears, mean ± SD: **G1:** 14.6 ± 12.1 **G2:** 15.9 ± 11.1 **G1/BL:** *P* < 0.01 **G2/BL:** *P* = NS ADOS Play, mean (% change): **G1:** 3 (-5) **G2:** 2.8 (0) **G1/BL:** *P* = NS **G2/BL:** *P* = NS ADOS SBRI, mean (% change): **G1:** 3.5 (-9) **G2:** 3.5 (-2) **G1/BL:** *P* = NS

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G2/BL: *P* = NS **Sensory:** ATEC Sensory/cognitive awareness, mean ± SD: **G1:** 11.7 ± 7.9 **G2:** 9.6 ± 5.9 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.05 PDD-BI Sensory/perceptual approach behaviors, mean ± SD: **G1:** 17.8 ± 13.9 **G2:** 13.7 ± 13.4 **G1/BL:** *P* < 0.05 **G2/BL:** *P* < 0.01
Adams et al., 2009 (A) Adams et al., 2009 (B)† (continued)				Parent global impression, overall category, score, %:** **G1:** +3 “much better”: **G1:** 29 **G2:** 27 +2 “better”: **G1:** 33 **G2:** 27 +1 “slightly better”: **G1:** 25 **G2:** 27 0 “no change”: **G1:** 4 **G2:** 18 -1 “slightly worse”: **G1:** 4 **G2:** 0 -2: “worse”: **G1:** 4 **G2:** 0 -3 “much worse”: **G1:** 0 **G2:** 0 Parent global impression, category, mean score:** Parent global impression Overall: **G1:** 1.7

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G2: 1.6 Parent global impression Expressive language **G1:** 2 **G2:** 1.6 Parent global impression Receptive language: **G1:** 1.8 **G2:** 1.9
Adams et al., 2009 (A) Adams et al., 2009 (B)† (continued)				Parent global impression Cognition/ thinking **G1:** 1.8 **G2:** 1.8 Parent global impression Play skills: **G1:** 1.5 **G2:** 1.6 Parent global impression Sociability **G1:** 1.3 **G2:** 1.8 Parent global impression Eye contact: **G1:** 1.1 **G2:** .8 Parent global impression Tantruming: **G1:** 0.5 **G2:** 0.3 Parent global impression Stools/gastro-intestinal issues: **G1:** 0 **G2:** -0.2 Parent global impression Sleep: **G1:** -0.3 **G2:** -0.1 Parent global impression Hyperactivity: **G1:** -0.5 **G2:** -0.1 **Harms:†** Withdrew from

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				phase 2 due to adverse events: **G1:** 2 **G2:** 2 Withdrew from phase 2 due to low urinary excretion of metals: **G1:** 2 **G2:** 0
Adams et al., 2009 (A) Adams et al., 2009 (B)† (continued)				Sleep problems, worsening of some behavior and skills, more self-stimulatory behavior, and some regression **Modifiers:** NR

Comments: * Baseline results reported for participants who completed Phase 2 of study.
** There were no significant differences between G1 (n=24) and G2 (n=12) on the PGI.

Author: Aman et al., 2009 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic and home **Enrollment period:** NR **Funding:** NIMH; Johnson and Johnson provided risperidone **Author industry relationship disclosures:** 7 of 28 Abbott (1) Boehringer-Ingelheim (1) Bristol-Myers Squibb (5) CureMark (1) Eli Lilly (1) Forest (2) Janssen (2) Johnson & Johnson (2) Neuropharm (3)	**Intervention:** Risperidone administered over first 4 weeks Dosage by weight: • 14-20 kg: 0.25 mg/day with gradual increases to maximum of 1.75 mg • 20-45 kg: 0.5 mg/day with gradual increases to maximum of 2.5 mg • > 45 kg: 0.5 mg/day with gradual increases to maximum of 3.5 mg If response to risperidone was unsatisfactory, treatment was switched to aripiprazole, which was increased as risperidone was tapered Parent training: delivered by one therapist/parent or couple; 11 core treatment sessions and 3 optional treatment sessions/ booster session and two follow-up phone consults **Assessments:** Stanford Binet IQ, LIPS, MSEL Diagnostic assessment, medical evaluation (including electrocardiogram, medical history, routine	**Inclusion criteria:** • Presence of PDD (autism, PDD-NOS, Asperger's) established by DSM-IV-TR clinical criteria and corroborated by ADI-R • Age 4-13 years • Score of ≥ 18 on ABC irritability subscale • CGI-S score ≥ 4 • Medication free 2 weeks for most psychotropic drugs and 4 weeks for fluoxetine and/or depot neuroleptics • IQ ≥ 35 or mental age ≥ 18 months as assessed by Stanford Binet, LIPS, or Mullen Scales of Development • If taking anticonvulsant, seizure-free ≥ 6 months and with stable dose for 4 weeks **Exclusion criteria:** • Positive HCG pregnancy test for females • Previous adequate trial of risperidone • Other PDD (e.g., Rett's, childhood disintegrative disorder)	**Social skills:** ABC social withdrawal score, mean ± SD: **G1:** 17.1 ± 8.37 **G2:** 15.2 ± 9.01 VABS socialization score, mean ± SD: **G1:** 53.5 ± 14.4 **G2:** 59.5 ± 15.0 **Communication/ language:** ABC inappropriate speech score, mean ± SD: **G1:** 6.37 ± 4.03 **G2:** 5.75 ± 3.43 VABS communication score, mean ± SD: **G1:** 53.2 ± 19.9 **G2:** 61.1 ± 20.9 **Repetitive behavior:** ABC stereotypic behavior score, mean ± SD: **G1:** 10.6 ± 5.46 **G2:** 7.59 ± 5.2 **Problem behavior:** Home Situations Questionnaire score, mean ± SD: **G1:** 4.16 ± 1.47	**Social skills:** ABC social withdrawal score, week 24, mean ± SD **G1:** 6.44 ± 7.16 **G2:** 4.26 ± 5.17 **G1/G2:** $P = 0.78$ **Communication/ language:** ABC inappropriate speech score, week 24, mean ± SD: **G1:** 3.30 ± 3.66 **G2:** 2.56 ± 2.93 **G1/G2:** $P = 0.20$ **Repetitive behavior:** ABC stereotypic behavior score, week 24, mean ± SD: **G1:** 6.25 ± 5.68 **G2:** 3.20 ± 4.09 **G1/G2:** $P = 0.04$ **Problem behavior:** Home Situations Questionnaire score, week 24, mean ± SD: **G1:** 1.68 ± 1.36 **G2:** 1.23 ± 1.36

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Novartis (1) Noven (1) Organon (1) Shire (2) Sigma Tau (1) Supernus (1) Targacept (1) **Design:** RCT	lab tests), ADI-R interview, parent ratings on Home Situations Questionnaire and ABC, and IQ testing; VABS, CGI-S, CY-BOCS Assessed at 8 weeks for response to risperidone At 16 weeks, a face-to-face "booster" session and 2 follow-up phone consultations (conducted at 2 week intervals) to maintain treatment gains **Groups:** **G1:** risperidone **G2:** risperidone plus parent training	• Lifetime diagnosis of schizophrenia, other psychotic disorder, or bipolar disorder • Current diagnosis of major depression, obsessive-compulsive disorder, or substance abuse • Significant medical condition (e.g., heart, liver, renal, pulmonary disease), unstable seizure disorder, or significant abnormality on routine laboratory tests **Age, years ± SD:** **G1:** 7.5 ± 2.80 **G2:** 7.38 ± 2.21	**G2:** 4.31 ± 1.67 ABC irritability score, mean ± SD: **G1:** 29.7 ± 6.10 **G2:** 29.3 ± 6.97 ABC hyperactivity/ noncompliance score, mean ± SD: **G1:** 36.1 ± 6.86 **G2:** 35.3 ± 9.30 **Adaptive behavior:** VABS daily living skills score, mean ± SD: **G1:** 41.1 ± 19.8 **G2:** 50.8 ± 18.5	**G1/G2:** $P = 0.006$ ABC irritability score, week 24, mean ± SD: **G1:** 14.53 ± 9.90 **G2:** 10.96 ± 6.64 **G1/G2:** $P = 0.01$ ABC hyperactivity/ noncompliance score, week 24, mean ± SD: **G1:** 20.78 ± 12.38 **G2:** 15.38 ± 10.23 **G1/G2:** $P = 0.04$
Aman et al., 2009 (continued)	**Co-interventions held stable during treatment:** NR **Treatment fidelity assessed:** Yes **Frequency of contact during study:** Weekly for first 18 weeks **Concomitant therapies, n (%):** Anticonvulsant medication: **G1:** 4 (8.2) **G2:** 0 **N at enrollment:** **G1:** 49 **G2:** 75 **N at 24 week follow-up:** **G1:** 40 **G2:** 55	**Mental age:** NR **Gender, n (%):** Male: 105 (85) Female: 19 (15) **Race/ethnicity, n (%):** White/non-Hispanic: **G1:** 34 (69.4) **G2:** 59 (78.7) Hispanic: **G1:** 7 (14.3) **G2:** 4 (5.3) African American: **G1:** 7 (14.3) **G2:** 9 (12.1) Asian American: **G1:** 0 **G2:** 3 (4.0) Native American **G1:** 1 (2.0) **G2:** 0 (0) **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** ADI, DSM-IV **Diagnostic category, n (%):** Autism: **G1:** 32 (65.3) **G2:** 49 (65.3) PDD-NOS: **G1:** 13 (26.5) **G2:** 22 (29.3) Aspergers:	**Commonly occurring comorbidities:** CYBOCS score, mean ± SD: **G1:** 16.22 ± 2.47 **G2:** 14.72 ± 2.85 Home Situations Questionnaire, "yes" count, mean ± SD: **G1:** 18.9 ± 3.46 **G2:** 18.6 ± 4.65 CGI-S score, n (%): Moderate/4: **G1:** 14 (28.6) **G2:** 25 (33.3) Marked/5: **G1:** 19 (38.8) **G2:** 33 (44.0) Severe/6: **G1:** 15 (30.6) **G2:** 17 (22.7) Extreme/7: **G1:** 1 (2.0) **G2:** 0 (0) VABS composite score, mean ± SD: **G1:** 45.8 ± 15.5 **G2:** 53.1 ± 15.7 **Educational/ cognitive/ academic attainment:** IQ category, n (%): Average: **G1:** 11 (22.5) **G2:** 28 (38.4)	**Commonly occurring comorbidities:** CYBOCS score, week 24, mean ± SD: **G1:** 11.86 ± 4.47 **G2:** 10.11 ± 3.83 **G1/G2:** $P = 0.62$ **Harms, n (%):** Rhinitis: **G1:** 39 (79.6) **G2:** 60 (80.0) **G1/G2:** $P = 0.96$ Cough: **G1:** 39 (79.6) **G2:** 58 (77.3) **G1/G2:** $P = 0.77$ Appetite increase: **G1:** 38 (77.6) **G2:** 55 (73.3) **G1/G2:** $P = 0.6$ Fatigue: **G1:** 33 (67.5) **G2:** 60 (80) **G1/G2:** $P = 0.11$ Weight increase: **G1:** 40 (81.6) **G2:** 53 (70.7) **G1/G2:** $P = 0.17$ Somnolence: **G1:** 24 (49.0) **G2:** 32 (42.7) **G1/G2:** $P = 0.49$ Vomiting: **G1:** 19 (38.8) **G2:** 34 (45.3)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
		G1: 4 (8.2) **G2:** 4 (5.3) **Other characteristics:** Educational placement, n (%): Full time, regular education: **G1:** 10 (20.4) **G2:** 18 (24.0) Full time, regular education, with aide: **G1:** 0 **G2:** 3 (4.0)	Borderline: **G1:** 12 (24.5) **G2:** 18 (24.7) Mild intellectual disability (ID): **G1:** 9 (18.4) **G2:** 14 (19.2) Moderate ID: **G1:** 17 (34.7) **G2:** 13 (17.8)	**G1/G2:** P = 0.47 Excessive saliva: **G1:** 16 (32.7) **G2:** 36 (48.0) **G1/G2:** P = 0.09 Enuresis: **G1:** 16 (32.7) **G2:** 32 (42.7) **G1/G2:** P = 0.26 Insomnia: **G1:** 24 (49.0) **G2:** 23 (30.7) **G1/G2:** P = 0.04
Aman et al., 2009 (continued)		Regular education, with some special education: **G1:** 5 (10.2) **G2:** 4 (5.3) Special education classroom: **G1:** 8 (10.3) **G2:** 14 (18.7) Special elementary school: **G1:** 3 (6.1) **G2:** 2 (2.7) Home school: **G1:** 4 (8.2) **G2:** 5 (6.7) Special preschool: **G1:** 11 (22.4) **G2:** 11 (14.7) Regular preschool: **G1:** 6 (12.2) **G2:** 8 (10.7) No school: **G1:** 2 (4.1) **G2:** 12 (16.0)		Headache: **G1:** 18 (36.7) **G2:** 25 (33.3) **G1/G2:** P = 0.7 Diarrhea: **G1:** 17 (34.7) **G2:** 24 (32.0) **G1/G2:** P = 0.76 Constipation: **G1:** 18 (36.7) **G2:** 21 (28.0) **G1/G2:** P = 0.31 Skin rash: **G1:** 12 (24.5) **G2:** 24 (32.0) **G1/G2:** P = 0.37 Anxiety: **G1:** 14 (28.6) **G2:** 22 (29.3) **G1/G2:** P = 0.93 Dyspepsia: **G1:** 9 (18.4) **G2:** 21 (28.0) **G1/G2:** P = 0.22 Polydipsia: **G1:** 11 (22.5 **G2:** 17 (22.7) **G1/G2:** P = 0.98 Nausea: **G1:** 12 (24.5) **G2:** 15 (20.0) **G1/G2:** P = 0.55 Pyrexia: **G1:** 8 (16.3) **G2:** 18 (24.0) **G1/G2:** P = 0.3 Dry mouth: **G1:** 14 (28.6) **G2:** 11 (14.7) **G1/G2:** P = 0.06 Pharyngitis: **G1:** 9 (18.4) **G2:** 14 (8.7) **G1/G2:** P = 0.97

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				Tachycardia: **G1:** 7 (14.3) **G2:** 11 (14.7) **G1/G2:** $P = 0.95$
Author: Bass et al., 2009 **Country:** US **Practice setting:** Academic **Intervention setting:** Residential center **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Therapeutic horseback riding sessions, 1 hour per week over the span of 12 weeks, consisting of: • Mounting/dismounting: 5 minute instruction sessions aimed at stimulating verbal communication • Exercises: 10 minute warm-up with stretches, side walkers practice giving verbal/modeled/ physical prompts • Riding Skills: 15 minutes riding skill practice aimed to stimulate sensory seeking, gross fine motor domains • Mounted Games: 20 minute segment focusing on group and individual games to stimulate social and communication skills • Horsemanship: 10 minutes of taking part in grooming activities **Assessment:** SRS and Sensory Profile, pre- and post-intervention **Groups:** **G1:** therapeutic horseback riding **G2:** waitlist group **Provider:** Staff at the Good Hope Equestrian Training Center **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** Yes **Concomitant therapies, n:** None: **G1:** 8 **G2:** 3	**Inclusion criteria:** • Met criteria for DSM-IV-TR autism spectrum diagnosis • Parents had to consent to pre-testing, 12 weeks of therapeutic horseback riding, and one post testing session • No previous exposure to equine activities **Exclusion criteria:** • See inclusion criteria **Age, years ± SD (range):** **G1:** 6.95 ± 1.67 (5-10) **G2:** 7.73 ± 1.65 (4-10) **Mental age:** NR **Gender, n:** Male: **G1:** 17 **G2:** 12 Female: **G1:** 2 **G2:** 3 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** DSM-IV-TR **Diagnostic category, n:** Mild autism: **G1:** 6 (18) **G2:** 5 (15) Moderate autism: **G1:** 10(29) **G2:** 6(18) Severe autism: **G1:** 2 (6) **G2:** 3(9) Aspergers: **G1:** 1(3) **G2:** 1(3)	**Social skills:** SRS score, mean ± SD: Total: **G1:** 85.9 ± 37.5 **G2:** 89.3 ± 35.4 Social cognition: **G1:** 20.8 ± 7.3 **G2:** 11.5 ± 3.6 Social awareness: **G1:** 12.1 ± 4.7 **G2:** 11.5 ± 3.6 Social motivation: **G1:** 17.3 ± 7.1 **G2:** 18.2 ± 7.1 **Motor skills:** Sensory Profile score, mean ± SD: Fine motor/ perception: **G1:** 8.9 ± 3.5 **G2:** 8.6 ± 2.9 Sedentary: **G1:** 13.5 ± 5 **G2:** 11.9 ± 5.1 **Sensory:** Sensory Profile score, mean ± SD: Total: **G1:** 237.6 ± 55.9 **G2:** 240.9 ± 50.9 Sensory seeking: **G1:** 58.4 ± 10.6 **G2:** 53.9 ± 10.9 Sensory sensitivity: **G1:** 15.7 ± 3.6 **G2:** 16.1 ± 4.6 **Educational/ cognitive/ academic attainment:** Sensory Profile inattention/distractibility score, mean ± SD: **G1:** 21 ± 7.1 **G2:** 21.6 ± 4.6	**Social skills:** SRS score, mean ± SD: Total: **G1:** 73.6 ± 24.1 **G2:** 94.4 ± 32.1 **G1/BL:** $P < 0.017$ **G2/BL:** P = NS **G1/G2:** $P < 0.05$ Social cognition: **G1:** 16.1 ± 5.8 **G2:** 18.9 ± 6.6 **G1/G2:** P = NS Social awareness: **G1:** 9.9 ± 2.7 **G2:** 11.1 ± 3.2 **G1/G2:** P = NS Social motivation: **G1:** 12.5 ± 5.9 **G2:** 16.2 ± 6.7 **G1/BL:** $P < 0.003$ **G2/BL:** P = NS **G1/G2:** $P < 0.05$ **Motor skills:** Sensory Profile score, mean ± SD: Fine motor/ perception: **G1:** 9.4 ± 3.0 **G2:** 8.7 ± 3.1 **G1/G2:** P = NS Sedentary: **G1:** 16 ± 3.3 **G2:** 11.3 ± 4.8 **G1/BL:** $P < 0.001$ **G2/BL:** P = NS **G1/G2:** $P < 0.01$ **Sensory:** Sensory Profile score, mean ± SD: Total: **G1:** 269.4 ± 51.6 **G2:** 245.7 ± 50.3 **G1/BL:** $P < 0.001$ **G2/BL:** $P = 0.101$ **G1/G2:** $P < 0.01$

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Bass et al., 2009 (continued)	Occupational therapy: **G1:** 6 **G2:** 5 Occupational/speech therapy: **G1:** 2 **G2:** 0 Occupational/speech/ physical therapy: **G1:** 0 **G2:** 1 Occupational/physical therapy: **G1:** 2 **G2:** 5 Speech therapy: **G1:** 1 **G2:** 1 **N at enrollment:** **G1:** 19 **G2:** 15 **N at follow-up:** **G1:** 19 **G2:** 15	**Other characteristics, n:** Verbal: **G1:** 9 **G2:** 6 Non-verbal **G1:** 10 **G2:** 9		Sensory seeking: **G1:** 62 ± 9.0 **G2:** 53.2 ± 10.5 **G1/BL:** $P < 0.001$ **G2/BL:** P = NS **G1/G2:** $P < 0.01$ Sensory sensitivity: **G1:** 17.2 ± 2.6 **G2:** 15.7 ± 4.8 **G1/BL:** $P < 0.001$ **G2/BL:** P = NS **G1/G2:** $P < 0.001$ **Educational/ cognitive/ academic attainment:** Sensory Profile inattention/distrac-tibility score, mean ± SD: **G1:** 27 ± 4.6 **G2:** 21.4 ± 4.5 **G1/BL:** $P < 0.001$ **G2/BL:** P = NS **G1/G2:** $P < 0.01$ **Harms:** NR **Modifiers:** NR
Author: Chan et al., 2009 **Country:** China **Practice setting:** Academic **Intervention setting:** Academic **Enrollment period:** NR **Funding:** Culture Homes Ltd. **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Seven-star needle stimulation, 5-10 minute treatment sessions, 5 days a week for 6 weeks. Therapist tapped the child's skin quickly (approximately 20 times every 5 seconds) with dermatoneural medical hammer; stimulation was performed three times each on the 2 sides of the child's back along the spine, along the midline of the front side of the body, and on dorsal and pos-terior parts of the head **Assessments:** Children were assessed before and after the treatment group underwent seven-star needle stimulation (baseline and 6 weeks); Parent's Rating Question-naire, developed for the	**Inclusion criteria:** • Children with autism **Exclusion criteria:** • See inclusion criteria **Age, mean** ± SD **G1:** 6.85 ± 1.76 **G2:** 6.89 ± 1.77 **Mental age:** TONI, IQ ± SD: **G1:** 84.06 ± 15.75 **G2:** 86.82 ± 19.91 **Gender, n:** Male: **G1:** 13 **G2:** 13 Female: **G1:** 3 **G2:** 3 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral from special education centers **Diagnostic tool/method:**	**Overall ratings:** Parent's Rating Questionnaire score, mean ± SD: Language: **G1:** NR **G2:** NR Social interaction: **G1:** NR **G2:** NR Stereotyped behavior: **G1:** NR **G2:** NR Motor functioning: **G1:** NR **G2:** NR Overall: **G1:** NR **G2:** NR **Sensory:** QEEG spectral amplitude, mean ± SD: Delta: **G1:** 244.80 ± 86.32 (n=7)	**Overall ratings:** Parent's Rating Questionnaire score, mean change ± SD: Language: **G1:** 1.21 ± 0.73 **G2:** 0.43 ± 0.35 **G1/G2:** $P < 0.01$ Social interaction: **G1:** 1.07 ± 0.77 **G2:** 0.42 ± 0.49 **G1/G2:** $P < 0.01$ Stereotyped behavior: **G1:** 0.55 ± 1.08 **G2:** 0.34 ± 0.67 **G1/G2:** P = NS Motor functioning: **G1:** 1.03 ± 1.15 **G2:** 0.59 ± 0.71 **G1/G2:** P = NS Overall: **G1:** 0.97 ± 0.73 **G2:** 0.41 ± 0.41 **G1/G2:** $P < 0.05$

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	study, on language, social interaction and behavioral problems, as well as motor functioning; quantitative electro-encephalogram (qEEG) **Groups:** **G1:** needle stimulation **G2:** waitlist control **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** 5 days a week for 6 weeks, assessed at baseline and 6 weeks after treatment **Concomitant therapies** NR **N at enrollment:** **G1:** 16 **G2:** 16 **N at follow-up:** **G1:** 16 **G2:** 16	NR **Diagnostic category:** NR **Other characteristics:** NR	**G2:** 178.20 ± 38.81 (n=9) Theta: **G1:** 107.71 ± 31.90 (n=7) **G2:** 78.73 ± 16.90 (n=9) Alpha: **G1:** 61.86 ± 26.66 (n=7) **G2:** 45.62 ± 12.21 (n=9) Beta: **G1:** 33.71 ± 17.16 (n=7) **G2:** 20.20 ± 4.60 (n=9) High beta: **G1:** 34.23 ± 18.51 (n=7) **G2:** 24.19 ± 3.68 (n=9)	**Sensory:** QEEG spectral amplitude, mean ± SD: Delta: **G1:** 165.77 ± 81.61 (n=7) **G2:** 197.34 ± 51.35 (n=9) ANOVA: treatment x time (*P* < 0.05) **G1/G2:** *P* < 0.05 Theta: **G1:** 70.50 ± 15.62 (n=7) **G2:** 73.80 ± 12.21 (n=9) ANOVA: treatment x time (*P* < 0.05) **G1/G2:** *P* < 0.05
Chan et al., 2009 (continued)				Alpha: **G1:** 49.89 ± 13.44 (n=7) **G2:** 43.36 ± 6.35 (n=9) ANOVA: treatment (*P* < 0.05), time x treatment (*P* = NS) **G1/G2:** *P* = NS Beta: **G1:** 26.61 ± 13.82 (n=7) **G2:** 28.93 ± 9.68 (n=9) ANOVA: treatment x time (*P* < 0.05) **G1/G2:** *P* < 0.05 High beta: **G1:** 18.76 ± 7.58 **G2:** 29.54 ± 13.47 ANOVA: treatment x time (*P* < 0.05) **G1/G2:** *P* < 0.05 **Harms:** NR **Modifiers:** NR
Author: Correia et al., 2009 **Country:**	**Intervention:** Risperidone administered with progressive increments each 2 weeks,	**Inclusion criteria:** • Met the algorithm cut-off for the ADI-R and ADOS	**Autism Treatment Evaluation Checklist (ATEC), mean ± SD.:**	**Overall ratings:** ATEC total, mean ± SD: 34.71 ± 23.63

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Portugal **Practice setting:** Clinic **Intervention setting:** Home **Enrollment period:** NR **Funding:** Fundacao para a Ciencia e a Tecnologia (FCT) **Author industry relationship disclosures:** NR **Design:** Prospective case series	according to weight: (i) <20 kg—beginning with 0.25mg until a maximum 1.0 mg; (ii) 20–45 kg—beginning with 0.5mg until a maximum 2.0 mg; (iii) >45 kg—beginning with 0.5mg until a maximum 3.0 mg. Dose adjusted to obtain clinical improvement and minimize motor and other side effects. **Assessments:** CBRF, ATEC, & BPI. Final assessment at 12 months **Groups:** **G1:** Risperidone **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** at 1, 3, 6, and 12 months **Concomitant therapies, n (%):** received antipsychotics, no details reported **N at enrollment:** **G1:** 45 **N at follow-up:** **G1:** 31	• Developmental level or IQ> 30 and functional age > 18 months • Free of any medication for ≥3 months • Behavioral alterations of clinical significance in the health/physical/ behavior subtest of the ATEC (moderate or serious problem on ≥2 items with no improvement after adequate educational and behavioral intervention) **Exclusion criteria:** • See inclusion criteria **Age, mean years ± SD (range):** 8.67 ± 4.30 (3–21) **Mental age, mean/yrs (range):** NR **Age at diagnosis mean ± SD (range):** 4.98 ± 2.99 (2–14) **Gender, n (%):** M: 34 (75.6) F: 11 (24.4) **Race/ethnicity, n (%):** Caucasian: 44 (97.8) African: 1 (2.2) **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** NR **Diagnostic tool/method**: ADI-R and ADOS **Diagnostic category:** NR	Total: 71.36 ± 25.73 Sociability: 19.27 ± 8.22 Speech: 12.73 ± 8.02 Cognition: 15.69 ± 7.50 Behavior: 23.53 ± 8.37 **Nisonger Child Behavior Rating Form (CBRF), mean ± SD:** Compliant/calm: 5.56 ± 2.78 Adaptive/social: 3.00 ± 2.26 Conduct problem: 13.62 ± 6.65 Insecure/anxious: 6.58 ± 6.04 Hyperactive: 17.33 ± 5.41 Self-injury/ stereotyped: 3.20 ± 3.57 Self-isolated / ritualistic: 4.13 ± 3.00 Overly sensitive: 5.31 ± 3.77 **Behavior Problems Inventory (BPI), mean ± SD:** Self-injurious behavior, frequency: 3.07 ± 3.85 Self-injurious behavior, intensity: 2.27 ± 2.68 Stereotypic behavior, frequency: 12.4 ± 10.16 Stereotypic behavior, intensity: 7.80 ± 6.08 Aggressive/destructive behavior, frequency: 9.07 ± 9.97	$P = 1.581 \times 10^{-10}$ **Social skills:** ATEC sociability, mean ± SD: 9.29 ± 7.64 $P=2.646 \times 10^{-11}$ **Communication/ language:** ATEC speech, mean ± SD: 8.32 ± 7.53 $P = 1.373 \times 10^{-05}$ **Repetitive behavior:** CBRF self-injury/stereotyped, mean ± SD: 0.81 ± 1.78 $P = 2.364 \times 10^{-4}$ CBRF self-isolated/ritualistic, mean ± SD: 1.90 ± 1.42 $P = 3.336 \times 10^{-5}$ BPI stereotypic behavior, frequency, mean ± SD: 6.29 ± 6.88 $P = 3.515 \times 10^{-3}$ BPI stereotypic behavior, intensity, mean ± SD: 3.87 ± 3.98 $P = 2.149 \times 10^{-3}$ **Problem behavior:** ATEC behavior, mean ± SD: 6.55 ± 4.50 $P = 3.211 \times 10^{-15}$
Correia et al., 2009 (continued)		**Other characteristics, n (%):** **Etiology:** Idiopathic : 41 (91.1) Fragile X: 2 (4.4) Chromosomal abnormalities: 1 (2.2)	Aggressive/destructive behavior, intensity: 6.58 ± 6.81	CBRF conduct problem, mean ± SD: 3.58 ± 2.32 $P = 2.529 \times 10^{-6}$ CBRF hyperactive, mean

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
		Mitochondrial disease: 1 (2.2) **Obesity:** 2 (4.4) **Mental retardation:** Absent (IQ≥70): 17 (37.8) Mild (IQ 50-69): 14 (31.1) Moderate (IQ 35-49): 11 (24.4) Severe (IQ<35): 3 (6.7) **Epilepsy:** 1 (2.2) **Language status:** Non-verbal: 25 (55.6) Verbal: 20 (44.4) **Verbal regression:** 5 (11.1) **Risperidone administration pattern:** Once a day: 4 (8.9) Twice a day: 36 (80.0) Three times a day: 2 (4.4) **Weight:** 37.89 ± 21.19 **BMI:** 19.29 ± 5.04 **Waist Circumference:** 66.61 ± 16.88 **Prolactin:** 13.71 ± 12.50		± SD: 5.13 ± 3.74 $P = 2.515\text{x}10^{-6}$ CBRF overly sensitive, mean ± SD: 1.42 ± 1.48 $P = 1.638\text{x}10^{-5}$ BPI self-injurious behavior, frequency, mean ± SD: 0.58 ± 1.26 $P = 5.526\text{x}10^{-4}$ BPI self-injurious behavior, intensity, mean ± SD: 0.68 ± 1.64 $P = 4.676\text{x}10^{-3}$ BPI aggressive/destructive behavior, frequency, mean ± SD: 1.77 ± 3.87 $P = 1.412\text{x}10^{-4}$ BPI aggressive/destructive behavior, intensity, mean ± SD: 1.65 ± 3.42 $P = 1.658\text{x}10^{-4}$ **Adaptive behavior:** CBRF compliant/calm, mean ± SD: 1.74 ± 1.24 $P = 1.027\text{x}10^{-5}$
Correia et al., 2009 (continued)				CBRF adaptive/social, mean ± SD: 0.61 ± 0.84 $P = 1.842\text{x}10^{-5}$ CBRF insecure/anxious, mean ± SD: 0.97 ± 1.38 $P = 2.638\text{x}10^{-5}$ **Educational/ cognitive/ academic attainment:** ATEC cognition, mean ± SD:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				10.55 ± 7.97 $P = 2.148 \times 10^{-5}$ **Harms:** Weight, mean kg ± SD: 42.67 ± 22.66 BMI, mean kg/m^2 ± SD: 21.11 ± 5.55 $P = 1.923 \times 10^{-7}$ Waist circumference, mean cm ± SD: 73.92 ± 19.01 $P = 2.053 \times 10^{-9}$ Prolactin, mean ng/mL ± SD: 34.50 ± 22.39 $P = 3.179 \times 10^{-4}$ 1 observed case of galactorrhea No extrapyramidal AEs or excessive sedation observed
Correia et al., 2009 (continued)				**Modifiers:** Significant modifiers of ATEC total score changes included baseline ATEC score ($P < 1 \times 10^{-16}$); gender ($P = 0.007$); and genetic polymorphisms including HTR2A c.-1538G > A status (AA+AG vs GG; $P = 0.019$); HTR2C c.-995G > A status (A present vs A absent; $P = 0.035$); DRD3 c.25T > C (p.S9G) (TC+CC(Gly/-) vs TT (Ser/Ser); $P = 0.012$); and ABCB1 c.1236C > T (p.G412G) (TT+CT vs CC; $P = 0.002$). Significant modifiers of BMI changes included baseline BMI ($P <$

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				$1x10^{-16}$); age (*P* = $7.123x10^{-7}$); and genetic polymorphisms including HTR2C c.68G > C (p.C23S) (G allele absent vs present; *P* = 0.037) and CYP2D6 (UM vs homozygous EM; *P* = 0.002).
Correia et al., 2009 (continued)				Significant modifiers of Waist circumference changes included baseline Waist circumference (*P* < $1x10^{-16}$); age (*P* = $1.476x10^{-6}$); and genetic polymorphisms including HTR2C c.68G > C (p.C23S) (G allele absent vs present; *P* = $6.057x\ 10^{-5)}$ and CYP2D6 (PM vs. homozygous EM; *P* = 0.001). Significant modifiers of Prolactin changes included baseline prolactin levels (*P* = 0.017); Dose (*P* = $2.735x\ 10^{-6)}$and genetic polymorphisms including HTR2A c.-1438G > A (AA+AG vs. GG, *P* = 0.018); HTR2C c.68G > C (p.C23S) (G allele absent vs. present, *P* = 0.006) ; HTR6 c.715-2542C > T (TC+CC vs. T, *P* = $9.534\ x\ 10^{-5}$**)** and BDNF c.196G > A (p.V66M) AA+AG (Met/-) vs. GG (Val/Val), *P* = 0.016

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Author: Cotugno, 2009 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective cohort series	**Intervention:** Social competency and social skills training and intervention program, 1 hour weekly group sessions for 30 weeks, employing a peer-based, group model within a stage-based cognitive-behavioral framework using group therapy, cognitive-behavioral, and skill instruction Control group: matched sample of non-ASD children not receiving treatment **Assessments:** WMS completed by teachers; SCDS completed by parents, six items selected from scale, two items each addressing stress/anxiety management, joint attention, and flexibility/transitions **Groups:** **G1:** social competency and social skills training and intervention program **G2:** non-ASD controls **Ga:** younger children (ages 7.0-8.2) **Gb:** older children (ages 10.0-11.0) **Provider:** Licensed group clinician **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1a:** 10 **G1b:** 8 **G2a:** 5 **G2b:** 5	**Inclusion criteria:** **G1:** • Families self-referred to MGH/Youth Care • Between the ages of 7 and 11 • Received a prior diagnosis on the autism spectrum meeting DSM-IV criteria, confirmed by neuropsychological evaluation by professionals with no connection to the program • Obtained a Full Scale or Verbal Scale IQ on the WISC-IV within the average range (80-119) or higher • Demonstrated no significant language or communication deficits • Participated in at least a partial inclusion program in a regular education curriculum **G2:** o Randomly selected from two local public schools to match the ages and grades of the intervention groups o No prior diagnosis of ASD o Had never been referred to nor ever received any special education services o Receiving no current psychological or school-based services (i.e. individual, group therapy, or counseling) o Had no prior contact with MGH/Youth Care **Exclusion criteria:** • See inclusion criteria **Age, range (years):** **G1a:** 7.0-8.2 **G1b:** 10.0-11.0 **G2a:** 7-8 **G2b:** 10-11	**Overall ratings:** WMS score, mean: **G1a:** 121.4 **G1b:** 120.5 **G2a:** 159.0 **G2b:** 187.0 **Social Skills:** WMS, teacher preferred social behavior subscale, mean: **G1a:** 46.2 **G2b:** 44.5 **G2a:** 59.6 **G2b:** 69.4 WMS, peer-preferred social behavior subscale, mean: **G1a:** 43.8 **G1b:** 44.0 **G2a:** 60.8 **G2b:** 74.0 SCDS, participants with scores of 1 or 2 on joint attention questions, n (%):* **G1a:** 12 (60) **G1b:** 11 (69) **Adaptive behavior:** WMS, school adjustment behavior subscale, mean: **G1a:** 31.4 **G1b:** 32.0 **G2a:** 40.6 **G2b:** 43.6 SCDS, participants with scores of 1 or 2 on flexibility/ transitions questions, n (%):* **G1a:** 17 (85) **G1b:** 11 (69)	**Overall ratings:** WMS score, 9 months, mean: **G1a:** 138.3 **G1b:** 136.4 **G2a:** 163.6 **G2b:** 181.4 **G1a/BL:** $P < 0.05$ **G1b/BL:** $P < 0.01$ **G2a/BL:** P = NS **G2b/BL:** P = NS **Social skills:** WMS, teacher preferred social behavior sub-scale, 9 months, mean: **G1a:** 52.7 **G1b:** 48.8 **G2a:** 60.4 **G2b:** 65.2 **G1a/BL:** $P < 0.05$ **G1b/BL:** $P < 0.05$ **G2a/BL:** P = NS **G2b/BL:** P = NS WMS, peer-preferred social behavior sub-scale, 9 months, mean: **G1a:** 50.9 **G1b:** 47.0 **G2a:** 63.2 **G2b:** 72.4 **G1a/BL:** $P < 0.05$ **G1b/BL:** $P < 0.05$ **G2a/BL:** P = NS **G2b/BL:** P = NS SCDS, 9 months, participants with scores of 1 or 2 on joint attention questions, n (%):* **G1a:** 7 (35) **G1b:** 4 (25)
Cotugno, 2009 (continued)	**N at follow-up:** **G1a:** 10 **G1b:** 8 **G2a:** 5	**Mental age:** **G1:** See inclusion criteria **G2:** NR **Gender:**	**Commonly occurring co-morbidities:** SCDS, participants	**Adaptive behavior:** WMS, school adjustment

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	G2b: 5	NR **Race/ethnicity, n (%):** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** DSM-IV **Diagnostic category:** NR **Other characteristics:** NR	with scores of 1 or 2 on anxiety and stress management questions, n (%):* **G1a:** 17 (85) **G1b:** 16 (100)	behavior subscale, 9 months, mean: **G1a:** 34.6 **G1b:** 41.1 **G2a:** 40.0 **G2b:** 43.8 **G1a/BL:** *P* < 0.05 **G1b/BL:** *P* < 001 **G2a/BL:** *P* = NS **G2b/BL:** *P* = NS SCDS, 9 months, participants with scores of 1 or 2 on flexibility/ transi-tions questions, n (%):* **G1a:** 11 (55) **G1b:** 5 (31) **Commonly occurring co-morbidities:** SCDS, 9 months, participants with scores of 1 or 2 on anxiety and stress manage-ment questions, n (%):* **G1a:** 9 (45) **G1b:** 7 (44) **Harms:** NR **Modifiers:** NR

Comments: *A score of 1 or 2 reflects no or very limited demonstrations of positive adaptive behavior.

Author: Hayward et al., 2009 Eikeseth et al., 2009† **Country:** UK **Practice setting:** Academic **Intervention setting:** Home and clinic **Enrollment period:** Autumn 1998 to Spring 2005 **Funding:** NIH **Author industry**	**Intervention:** UCLA intensive ABA, either clinic based (G1) or parent managed (G2) Duration: 1 year Frequency, hours/week, mean ± SD: **G1:** 37.4 ± 3.47 **G2:** 34.2 ± 5.29 **G1/G2:** *P* = NS Supervision intensity per month, hours (range):† **G2:** 5.2 (2.9-7.8) Cumulative supervision intensity, hours ± SD (range):† **G2:** 73.05 ± 24.80 (40-109.5) **Assessments:** ADI-R, administered by	**Inclusion criteria:** • Joined UK Young Autism Project within the enrollment period • Diagnosis of autism according to ICD-10 criteria • Age at intake between 24-42 months • No other severe medical conditions certified by medical practitioner **Exclusion criteria:** • See inclusion criteria **Age, months** ± **SD:** **G1:** 35.7 ± 6.2 **G2:** 34.4 ± 5.7 **Mental age:** See baseline measures **Gender, n:**	**Communication/ language:** RDLS score, mean ± SD: Comprehension: **G1:** 20.0 ± 0.0 **G2:** 20.7 ± 2.8 **G1/G2:** *P* = NS Expressive: **G1:** 20.2 ± 1.0 **G2:** 20.7 ± 3.3 **G1/G2:** *P* = NS **Adaptive behavior:** VABS composite score, mean ± SD: **G1:** 62.3 ± 6.8 **G2:** 65.1 ± 10.4 **G1/G2:** *P* = NS **Educational/ cognitive/**	**Communication/ language:** RDLS score, mean ± SD: Comprehension: **G1:** 26.7 ± 7.0 **G2:** 28.4 ± 9.5 **G1/G2:** *P* = NS **G1+G2/BL:** *P* < 0.01 Expressive: **G1:** 26.4 ± 6.1 **G2:** 27.6 ± 7.6 **G1/G2:** *P* = NS **G1+G2/BL:** *P* < 0.01 **Adaptive behavior:** VABS composite score, mean ±

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
relationship disclosures: 3 of 5† NOVA Institute for Children with Developmental Disorders (1) UK YAP (3) **Design:** Prospective cohort study Retrospective case series (subgroup analysis)†	first author BSID-R or WPPSI-R (depending on chronological age), Merrill-Palmer Scale of Mental Tests, RDLS, and VABS conducted by an independent psychologist **Groups:** **G1:** clinic based ABA **G2:** parent managed ABA **Provider:** Clinic-based: • Tutors: received basic and advanced theory seminars, a 60-hour practicum, continued training and supervision from senior tutor and program consultant • Senior tutor: ≥ 1 year experience working as a tutor with > 3 children • Program consultant: ≥ 3 years clinical experience as both tutor and senior tutor	Male: **G1:** 19 **G2:** 15 Female: **G1:** 4 **G2:** 6 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral, confirmed in study **Diagnostic tool/method:** Confirmed by ADI-R **Diagnostic category:** NR **Other characteristics:** NR	**academic attainment:** IQ, mean ± SD: **G1:** 53.5 ± 15.1 **G2:** 54.1 ± 15.1 **G1/G2:** *P* = NS Visual-spatial IQ, mean ± SD: **G1:** 74.8 ± 22.6 **G2:** 76.2 ± 18.2 **G1/G2:** *P* = NS	SD: **G1:** 68.4 ± 14.5 **G2:** 72.5 ± 17.3 **G1/G2:** *P* = NS **G1+G2/BL:** *P* < 0.001 **Educational/ cognitive/ academic attainment:** IQ, mean ± SD: **G1:** 70.9 ± 19.6 **G2:** 68.9 ± 22.1 **G1/G2:** *P* = NS **G1+G2/BL:** *P* < 0.001 Visual-spatial IQ, mean ± SD: **G1:** 89.4 ± 29.2 **G2:** 82.1 ± 28.0 **G1/G2:** *P* = NS **G1+G2/BL:** *P* < 0.001 **Harms:** NR
Hayward et al., 2009 (continued)	Parent-based: • Parents were supervised for > 6 hours every 6 weeks by program consultant from clinic-based program **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** Yes Concomitant therapies: NR **N at enrollment:** **G1:** 23 **G2:** 21 **N at follow-up:** **G1:** 23 **G2:** 21 **G2:** 19†			**Modifiers:** Visual-spatial IQ at intake was significantly correlated with change in VABS composite score at 1 year (r = 0.64; *P* < 0.01) and change in IQ at 1 year (r = 0.38; *P* < 0.05) In G2, intensity of supervision was significantly correlated with change in IQ at 14 month follow-up (r = 0.45; P < 0.05); estimated linear regression line has slope of 0.210 (*P* < 0.05)† In G2, visual-spatial IQ at intake was significantly correlated with change in IQ at 14

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				month follow-up (r = 0.63; *P* < 0.01)†
Author: Granpeesheh et al., 2009 **Country:** US **Practice setting:** Specialty treatment center **Intervention setting:** Community **Enrollment period:** 1995 to 2007 **Funding:** NR **Author industry relationship disclosures:** None **Design:** Retrospective case series	**Intervention:** Early Intensive Behavioral Intervention **Assessments:** WISC-R and WISC-III, SB-FE, MPS, LIPS-R, MESL (AGS edition), BSID-II, DAS **Groups:** **G1:** intervention **Provider:** NR **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 38 **N at follow-up:** **G1:** 38	**Inclusion criteria:** • No longer presented with developmental delay in any area of functioning of which author is aware • Placed in regular education classrooms and were earning passing grades without any special assistance • Reason for discharge from author's treatment was the absence of any apparent need for treatment • Agreement of criteria must be met between a minimum of two senior clinicians who were familiar with the course and outcome of a patient's treatment • Patient record had to contain cognitive testing within 6 months of start of ABA services and within 6 months of stopping ABA services **Exclusion criteria:** • See inclusion criteria **Age, months ± SD (range):** **G1:** 40.32 ± 7.27 (24-55) **Mental age:** NR **Gender:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** NR **Diagnostic category, %:** Autism: 100 **Other characteristics:** NR	**Adaptive behavior:** VABS composite score, mean ± SD (range): **G1:** 68.04 ± 7.79 (57-82) **Educational/ cognitive/ academic attainment:** IQ, mean ± SD (range): **G1:** 83.6 ± 19.15 (50-133)	**Adaptive behavior:** VABS composite, mean ± SD (range): **G1:** 88.87 ± 11.02 (69-111) **Educational/ cognitive/ academic attainment:** IQ, mean ± SD (range): **G1:** 107.9 ± 9.59 (89-128) **Harms:** NR **Modifiers:** NR
Author: Handen, et al., 2009 **Country:** US **Practice setting:** Academic	**Intervention:** Randomized, double-blind, placebo-controlled, parallel groups, involving 12 centers in the US. Oral human immuneglobulin (IGOH; Oralgam), 140, 420, or 840 mg/day	**Inclusion criteria:** • Met diagnostic criteria for autism per DSM-IV, corroborated by ADI-R • CGI severity scale > 3 (autistic symptoms) • History of chronic, persistent GI disturbance		**Overall ratings:** CGI, physician rated, n (%): Very much or much improved: **G1a:** 3/29 (10.3) **G1b:** 9/26 (34.6) **G1c:** 5/28 (17.9)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Intervention setting: Clinic **Enrollment period:** NR **Funding:** PediaMed Pharmaceuticals **Author industry relationship disclosures:** 2 of 7 Alarus Developmental International (1) PediaMed Pharmaceuticals (1) PRA International (1) **Design:** RCT	for 12 weeks (administered in divided doses of 3 capsules in the morning and 3 capsules in the evening) or placebo A computerized system used to assign and verify 1:1:1:1 randomization, with subjects balanced by site and age **Assessments:** MGIS (response to treatment after 12 weeks); weekly, daily status of GI signs and symptoms completed by parents Behavioral measures (ABC), CGI-I to assess the severity of behavioral symptom as completed by parents and clinicians General safety and tolerability assessed **Groups:** **G1a:** IGOH 140 mg/day **G1b:** IGOH 420 mg/day **G1c:** IGOH 840 mg/day **G2:** placebo **Co-interventions held stable during treatment:** Yes **Frequency of contact during study:** 2 weeks and 12 weeks **Concomitant therapies:** NR **N at enrollment:** **G1a:** 32 **G1b:** 31 **G1c:** 31 **G2:** 31	(> 6 weeks duration) • One of following must be present: abnormal gaseousness, bloating, or symptoms of moderate-to-severe abdominal pain or discomfort • No elective changes in concurrent therapy during the study **Exclusion criteria:** • Evidence of a GI infection based on stool laboratory tests at baseline • Known diagnosis of other GI pathology • Current use of antibiotics or antifungal medications, chelation therapy, medication affecting GI transit (stool softeners and bulking agents were permitted if constant doses were used for ≥ 30 days prior to screening visit and no changes in dosing was planned during the course of the study) • Changes in diet intervention within 30 days prior to the screening visit • Changes in alternative medical therapies • DSM-IV diagnosis of a pervasive developmental disorder other than autism • Evidence of a seizure disorder, Fragile X syndrome, Tuberous Sclerosis Complex, liver or pancreatic disease, cystic fibrosis, or chronic infection		**G2:** 11/28 (39.3) Minimally improved or unchanged: **G1a:** 25/29 (86.2) **G1b:** 14/26 (53.9) **G1c:** 21/28 (75.0) **G2:** 15/28 (53.6) Minimally, much or very much worse: **G1a:** 1/29 (3.4) **G1b:** 3/26 (11.5) **G1c:** 2/28 (7.1) **G2:** 2/28 (7.1) **G1a/G1b/G1c/ G2:** P = 0.5 CGI, parent rated, n (%): Very much or much improved **G1a:** 6/29 (20.7) **G1b:** 12/26 (46.2) **G1c:** 7/28 (25.0) **G2:** 16/29 (55.2) Minimally improved or unchanged: **G1a:** 21/29 (72.4) **G1b:** 12/26 (46.2) **G1c:** 17/28 (60.7) **G2:** 12/29 (41.4) Minimally, much, or very much worse: **G1a:** 2/29 (6.9) **G1b:** 2/26 (7.6) **G1c:** 4/28 (14.3) **G2:** 1/29 (3.4) **G1a/G1b/G1c/ G2:** P = 0.047
Handen, et al., 2009 (continued)	**N at follow-up:** **G1a:** 27 **G1b:** 23 **G1c:** 24 **G2:** 26	• Previous GI surgery with the exception of fundoplication, appendectomy, gastrostomy, endoscopy, pyloromyotomy, or herniorraphy • Pregnancy • Participation in another investigational study		Responders to treatment, MGIS, ITT population, n: **G1a:** 11/32 **G1b:** 9/31 **G1c:** 11/31 **G2:** 14/31 **G1/G2:** P = 0.22 Dose-response

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
		within 60 days prior to screening visit • IgA deficiency (serum IgA < 5 mg/dl) • A history of severe hypersensitivity to human immunoglobulin • Treatment with any human immunoglobulin and/or immunoglobulin products within 90 days prior to screening visit • Concurrent medication that would compromise tolerance of drug or compliance with the protocol **Additional exclusion criteria during screening:** • Clinically significant abnormal laboratory test values • Failure of parent or guardian to record at least 11/14 days of daily diary assessments or the weekly assessments • GI Symptoms Score of < 5 for week 1 or 2 of the screening period • MGIS score moderately or substantially improved during week1 or 2 of the screening period • Parent or guardian's inability or unwillingness to follow directions or inability to understand how to use the electronic diary data entry system **Age, years ± SD (range):** **G1a:** 7.4 ± 3.1 (3-13) **G1b:** 8.0 ± 4.1 (2-17) **G1c:** 7.6 ± 3.5 (3-13) **G2:** 6.2 ± 3.3 (2-14)		trend: *P* = 0.52 Responders to treatment, MGIS, CE population, n: **G1a:** 9/20 **G1b:** 6/20 **G1c:** 8/20 **G2:** 10/22 **G1/G2:** *P* = NR ("similar to ITT population") Dose-response trend: *P* = 0.59 **Medical:** Responders to treatment by predominant bowel pattern, n: Diarrhea: **G1a:** 3/11 **G1b:** 2/9 **G1c:** 6/15 **G2:** 5/14 Dose-response trend: *P* = 0.69 Constipation: **G1a:** 7/20 **G1b:** 7/20 **G1c:** 3/11 **G2:** 7/12 Dose-response trend: *P* = 0.22 Alternating: **G1a:** 1/1 **G1b:** 0/2 **G1c:** 2/5 **G2:** 2/5 Dose-response trend: *P* = 0.79
Handen, et al., 2009 (continued)		Age, n (%): 2-11 years: **G1a:** 28 (87.5) **G1b:** 27 (87.1) **G1c:** 27 (87.1) **G2:** 27 (87.1) 12-17 years: **G1a:** 4 (12.5) **G1b:** 4 (12.9) **G1c:** 4 (12.9) **G2:** 4 (12.9) **Mental age:**		Responders to treatment with regression-onset of autistic symptoms, n **G1a:** 6/18 **G1b:** 7/20 **G1c:** 9/21 **G2:** 9/21 Dose-response trend: *P* = 0.85 Responders to

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
		NR **Gender, n (%):** Male: **G1a:** 28 (87.5) **G1b:** 28 (90.3) **G1c:** 26 (83.9) **G2:** 25 (80.6) Female: **G1a:** 4 (12.5) **G1b:** 3 (9.7) **G1c:** 5 (16.1) **G2:** 6 (19.4) **Race/ethnicity, n (%):** Caucasian: **G1a:** 28 (87.5) **G1b:** 27 (87.1) **G1c:** 27 (87.1) **G2:** 23 (74.2) African-American: **G1a:** 1 (3.1) **G1b:** 0(0) **G1c:** 0(0) **G2:** 2 (6.5) Asian: **G1a:** 0(0) **G1b:** 1 (3.1) **G1c:** 0(0) **G2:** 0(0) Hispanic: **G1a:** 2 (6.3) **G1b:** 2 (6.5) **G1c:** 1 (3.2) **G2:** 4 (12.9) Other: **G1a:** 0 (0) **G1b:** 2 (6.5) **G1c:** 3 (9.7) **G2:** 2 (6.5) **SES:** Maternal education: NR Household income: NR		treatment by age, n: 2–11 years: **G1a:** 9/28 **G1b:** 7/27 **G1c:** 9/27 **G2:** 13/27 Dose-response trend: *P* = 0.36 12–17 years: **G1a:** 2/4 **G1b:** 2/4 **G1c:** 2/4 **G2:** 1/4 Dose-response trend: *P* = 0.58 **Harms, n (%):** One or more AEs, %: **G1a:** 77.4 **G1b:** 74.2 **G1c:** 74.2 **G2:** 80.6 Discontinued due to AEs, n: **G1a:** 2 **G1b:** 2 **G1c:** 3 **G2:** 1 Infections and infestations:** **G1a:** 14 (45.2) **G1b:** 17 (54.8) **G1c:** 15 (48.4) **G2:** 16 (51.6) Gastrointestinal disorders:** **G1a:** 12 (38.7) **G1b:** 14 (45.2) **G1c:** 10 (32.3) **G2:** 9 (29.0)
Handen, et al., 2009 (continued)		**Diagnostic approach:** In Study/Referral Referral – experienced physicians In Study – using scale **Diagnostic tool/method:** DSM-IV, ADI-R **Diagnostic category, n (%):** Autism: 125 **Other characteristics, n (%):** Predominant bowel pattern: Diarrhea: **G1a:** 11 (34.4)		Psychiatric disorders:** **G1a:** 6 (19.4) **G1b:** 5 (16.1) **G1c:** 6 (19.4) **G2:** 6 (19.4) Respiratory, thoracic, and mediastinal disorders:** **G1a:** 8 (25.8) **G1b:** 5 (16.1) **G1c:** 2 (6.5) **G2:** 4 (12.9) Skin and subcutaneous

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
		G1b: 9 (29.0) **G1c:** 15 (48.4) **G2:** 14 (45.2) Constipation: **G1a:** 12 (38.7) **G1b:** 20 (62.5) **G1c:** 20 (64.5) **G2:** 11 (35.5) Alternating: **G1a:** 1 (3.1) **G1b:** 2 (6.5) **G1c:** 5 (16.1) G2: **5 (16.1)**		tissue disorders:** **G1a:** 8 (25.8) **G1b:** 2 (6.5) **G1c:** 2 (6.5) **G2:** 3 (9.7) General disorders and administration site conditions:** **G1a:** 3 (9.7) **G1b:** 5 (16.1) **G1c:** 1 (3.2) **G2:** 2 (6.5) Nervous system disorders:** **G1a:** 2 (6.5) **G1b:** 2 (6.5) **G1c:** 3 (9.7) **G2:** 0 Injury, poisoning, and procedural complications:** **G1a:** 2 (6.5) **G1b:** 0 **G1c:** 3 (9.7) **G2:** 1 (3.2) Investigations:** **G1a:** 1 (3.2) **G1b:** 0 **G1c:** 2 (6.5) **G2:** 1 (3.2) Metabolism and nutrition disorders:** **G1a:** 1 (3.2) **G1b:** 1 (3.2) **G1c:** 1 (3.2) **G2:** 1 (3.2)
Handen, et al., 2009 (continued)				Eye disorders:** **G1a:** 1 (3.2) **G1b:** 2 (6.5) **G1c:** 0 **G2:** 0 Blood and lymphatic system disorders:** **G1a:** 1 (3.2) **G1b:** 0 **G1c:** 0 **G2:** 1 (3.2) Renal and urinary disorders:** **G1a:** 0 **G1b:** 0 **G1c:** 0 **G2:** 2 (6.5) Ear and labyrinth disorders:**

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G1a: 1 (3.2) **G1b:** 0 **G1c:** 0 **G2:** 0 Immune system disorders:** **G1a:** 1 (3.2) **G1b:** 0 **G1c:** 0 **G2:** 0 Vascular disorders:** **G1a:** 0 **G1b:** 0 **G1c:** 1 (3.2) **G2:** 0 **Modifiers:** NR

Comments: *Each subject was considered a responder if he or she was moderately improved or substantially improved on at least 2 of the last 4 assessments or somewhat improved for all of the last 4 assessments of the MGIS.
**There were no significant differences in adverse events between treatment groups.

Author: Posey et al., 2007* Jahromi et al., 2009^ RUPP, 2005† **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** November 2001 to September 2003 **Funding:** NIH, Korczak Foundation **Author industry relationship disclosures:** NR† 8 of 18* Abbott (1) Amgen (1) Bard CR (1) Bristol-Myers Squibb (4) Cephalon (1) Forest (3) GSK (1) Jannssen (4)	**Intervention, test dose phase:** Day 1: placebo pill; then 2 days each of 3 different doses of methylphenidate (0.125, 0.250, 0.500 mg/kg per dose) 3 times daily (3rd dose daily at half of the earlier doses), in a stepwise fashion; if participants had intolerable side effects to methylphenidate, they did not continue to trial phase **Intervention, randomized crossover phase:** Subjects tolerating methylphenidate during the test-dose phase received a week of placebo and one week each of 3 different dose levels (low, medium, high) of methylphenidate, administered by subject weight. Participants who could not tolerate the high dose of methylphenidate received two weeks of the medium dose (n=16; leading to 77 trials of medium dose in 62 subjects); the high dose did not follow the placebo phase to avoid abrupt	**Inclusion criteria:** • Children aged 5-14 years with a diagnosis of autistic disorder, Asperger disorder, or PDD-NOS based on DSM-IV criteria • Interfering symptoms of hyperactivity and/or impulsiveness that were present for at least 6 months and began prior to the age of 7 years • Severity confirmed by CGI severity subscale score of ≥ 4 and a total score ≥ 27 on both parent- and teacher-rated Swanson, Nolan and Pelham version IV ADHD scale, with a score of at least 10 on the hyperactivity/ impulsivity subscale; children also eligible if hyperactivity/impulsivity subscale was ≥ 15 even in the absence of notable inattentiveness • No concurrent psychotropic medications for at least 1-3 weeks (1 week for stimulants and clonidine hydrochloride; 2 weeks for anti-	**Overall ratings:** CGI severity subscale rating, n (%): Moderately ill: 20 (30.3) Markedly ill: 35 (52.0) Severely ill: 11 (16.7) **Educational/cognitive/academic attainment:** Slosson IQ, mean ± SD (range): 62.6 ± 32.9 (16-135) **Social skills:** VBS score, mean ± SD (range):† Socialization: 61.7 ± 16.7 (20-109) **Communication/ language:** VABS Communication: 62.8 ± 21.8 (20-126) **Adaptive behavior:** VABS composite: 56.2 ± 21.0 (20-109) VABS Daily living skills: 54.4 ± 19.8 (20-110) **Problem behavior:** ABC score, parent-	**Overall ratings:** Responded to treatment, subjects completing cross-over phase, n (%): Total: 44 (76) Optimal/best treatment:† Placebo: 9 (20) Low: 11 (25) Medium: 14 (32) High: 10 (23) Response rate, by dose, n (%):† **G1:** 20/61 (33) **G2:** 27/77 (35) **G3:** 18/47 (38) **G5:** 12/61 (20) **G1/G5:** P = 0.18 **G2/G5:** P = 0.05 (including first medium dose) **G2/G5:** P = 0.06 (including first and second medium dose when applicable) **G3/G5:** P = 0.07 **Social skills:^** Joint attention (n=33), mean ± SD Initiations: **G1:** 23.29 ± 16.62

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Johnson and Johnson (2) Lilly (5) McNeil (1) Merck (1) Novartis (2) Pediamed (2) Pfizer (3) Shire (2) UCB (1) Wyeth (2)	exposure to the drug. The 4 pm dose could be dropped by the prescribing clinician to reduce insomnia if it occurred. 3 daily doses administered at 8 am, 12 pm, and 4 pm, respectively; dosage (mg) by weight: 16 to < 24 kg (n=29): Low: 2.5, 2.5, 2.5 Medium: 5.0, 5.0, 2.5 High: 10.0, 10.0, 5.0 24-34 kg (n=20): Low: 5.0, 5.0, 2.5 Medium: 10.0, 10.0, 5.0 High: 15.0, 15.0, 10.0	depressants except fluoxetine and citalopram hydrobromide; 3 weeks for fluoxetine, citalopram hydrobromide, or antipsychotics) • Mental age of ≥ 18 months as determined by intelligence testing • No other neuro-psychiatric disorders that might require alternative medical management • For those with a tic disorder, severity had to be mild or less on a CGI-severity subscale rating pertaining to tics only	rated, mean ± SD (range):† Irritability: 16.9 ± 10.1 (0-41) Lethargy/social withdrawal: 12.1 ± 8.9 (0-33) Stereotypy: 7.6 ± 5.9 (0-21) Hyperactivity: 33.2 ± 8.7 (2-47) Inappropriate speech: 6.0 ± 4.1 (0-12) ABC score, teacher-rated, mean ± SD (range):† Irritability: 16.1 ± 9.4 (0-43)	**G2:** 20.85 ± 13.01 **G3:** 19.27 ± 14.23 **G4:** 25.09 ± 15.55 **G5:** 18.59 ± 12.03 **G1/G5:** $P < 0.05$ **G2/G5:** P = NS **G3/G5:** P = NS **G4/G5:** $P < 0.05$ Responses: **G1:** 2.48 ± 1.45 **G2:** 1.69 ± 1.42 **G3:** 1.93 ± 1.48 **G4:** 2.24 ± 1.69 **G5:** 1.90 ± 1.71 **G1/G5:** $P < 0.01$ **G2/G5:** P = NS **G3/G5:** P = NS **G4/G5:** P = NS
Posey et al., 2007* Jahromi et al., 2009^ (continued) 7 of 15^ Bristol-Myers Squibb (6) Forest (3) Jannssen (4) Lilly (4) McNeil (3) Neuropharm (3) Novartis (2) Organon (1) Pfizer (1) Shire (3) Supernus (2) UCB (1) Wyeth (1) **Design:** Randomized crossover trial with open label extension phase	> 34 kg (n=17): Low: 5.0, 5.0, 2.5 Medium: 10.0, 10.0, 5.0 High: 20.0, 20.0, 10.0 **Intervention, open label extension phase:** Participants meeting the criteria for positive response during ≥ 1 week in the crossover phase underwent best-dose determination with respect to the ABC hyperactivity subscale. If positive response during 1 week only, that dose was labeled best dose; if subject responded during more than 1 week of treatment, the prescribing and rating clinicians ranked the weeks of response in order from best to worst, then the prescribing physician broke the blind for this best dose. If this best/ optimal dose was methylphenidate, the participant entered the continuation phase. Participants with no response at any week and those responding best to placebo exited the study. **Assessments:** CGI rated by clinician at each weekly visit;	• No significant medical conditions (e.g., heart or liver disease) that could make treatment with methylphenidate unsafe • For those with seizure disorder, no seizures in the past 6 months and stable anticonvulsant dose for ≥ 1 month • No hypertension • No treatment with an adequate trial of methyl-phenidate hydrochloride (0.4 mg/kg per dose given at least twice daily for ≥ 2 weeks) within the past 2 years • No history of severe adverse response to methylphenidate **Exclusion criteria:** • See inclusion criteria **Age, yrs ± SD (range):** 7.5 ± 2.2 (5.0-13.7) **Mental age, children completing social observation and regulation substudy, months ± SD (range):** 43.91 ± 19.72 (20-84) **Gender, n (%):** Male: 59 (89.4) Female: 7 (10.6) **Race/ethnicity, n (%):** White: 48 (72.7) African American: 9 (13.6) Asian: 6 (9.1)	Lethargy/social withdrawal: 15.5 ± 10.9 (0-42) Stereotypy: 7.6 ± 5.1 (0-19) Hyperactivity: 30.9 ± 7.9 (16-45) Inappropriate speech: 5.8 ± 3.6 (0-12) SNAP-IV, parent-rated, mean ± SD:* ADHD: 39.82 ± 8.09 Inattention: 20.21 ± 5.17 Hyperactivity/ impulsivity: 19.61 ± 4.22 Oppositional defiant disorder: 9.61 ± 6.19 SNAP-IV, teacher-rated, mean ± SD:* ADHD: 37.23 ± 7.04 Inattention: 19.30 ± 4.32 Hyperactivity/ impulsivity: 17.93 ± 4.81 Oppositional defiant disorder: 8.83 ± 5.19 CYBOCS-PDD, clinician-rated, mean ± SD:* 13.30 ± 3.74	Requesting: **G1:** 4.04 ± 2.25 **G2:** 3.81 ± 2.65 **G3:** 3.69 ± 3.27 **G4:** 4.13 ± 2.58 **G5:** 3.67 ± 2.40 **G1/G5:** P = NS **G2/G5:** P = NS **G3/G5:** P = NS **G4/G5:** P = NS Competing demands task (n=33), mean ± SD: Self-regulating behavior: **G1:** 19.77 ± 10.89 **G2:** 16.21 ± 9.03 **G3:** 15.80 ± 12.65 **G4:** 16.47 ± 13.91 **G5:** 12.47 ± 11.29 **G1/G5:** $P = 0.09$ **G2/G5:** $P < 0.01$ **G3/G5:** P = NS **G4/G5:** $P = 0.09$ Regulated affective state: **G1:** 12.91 ± 4.98 **G2:** 12.96 ± 3.85 **G3:** 11.67 ± 5.53 **G4:** 12.47 ± 4.99 **G5:** 9.57 ± 6.72 **G1/G5:** P = NS **G2/G5:** $P < 0.05$ **G3/G5:** $P < 0.05$ **G4/G5:** $P = 0.09$ Clean-up task (n=33), mean ±

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	CYBOCS-PDD rated by clinician weekly; JAMES administered weekly by experimenter; ABC-C rated by teacher; SNAP-IV rated weekly by parent and teacher **Groups:** **G1:** Low dose of methylphenidate **G2:** Medium dose of methylphenidate **G3:** High dose of methylphenidate **G4:** Best dose of methylphenidate **G5:** Placebo	Hispanic or Latino: 3 (4.6) **SES:** Maternal education, n (%): High school graduate/GED or less: 8 (12.1) Some college or post-high school: 25 (37.9) College/advanced graduate or professional degree: 33 (50.0) Household income: NR Employed mother, n (%): 44 (66.7)	VABS Maladaptive behaviors total: 29.2 ± 9.2 (13-51) **Motor skills:** Motor skills: 69.2 ± 17.8 (44-113)	SD: Compliance behaviors: **G1:** 3.67 ± 4.87 **G2:** 3.67 ± 5.64 **G3:** 4.06 ± 4.55 **G4:** 3.94 ± 4.88 **G5:** 3.47 ± 5.41 **G1/G5:** *P* = NS **G2/G5:** *P* = NS **G3/G5:** *P* = NS **G4/G5:** *P* = NS
Posey et al., 2007* Jahromi et al., 2009^ (continued)	**Co-interventions held stable during treatment:** NR **Frequency of contact during study:** Nightly phone contact during test dose phase; weekly clinic visits during crossover trial; visits at 4 and 8 weeks during continuation phase **Concomitant therapies:** NR **N enrolled, test dose phase:** Total: 72 **N randomized, double-blind crossover phase:** Total: 66 **G1:** 66 **G2:** 66 **G3:** 50 **G4:** NA **G5:** 66 **N completing double-blind crossover phase:** Total: 58 **N continuing to open label extension phase (responders to methylphenidate):** 35 **N completing extension phase:** 32 **SNAP-IV, parent-rated, n:*** **G1:** 62 **G2:** 63 **G3:** 47	Employed father, n (%): 59 (89.4) Married, n (%): 53 (80.3) **Diagnostic approach:** In Study Diagnostic tool/method: ADI-R administered to corroborate the DSM-IV diagnosis of autistic disorder based on a clinical interview and examination; since ADI-R does not have specific criteria for Asperger disorder and PDD-NOS, these diagnoses followed DSM-IV **Diagnostic category, n (%):** Autism: 47 (71.2) PDD-NOS: 14 (21.2) Aspergers: 5 (7.6) **Other characteristics:** Prior medications, n (%): Stimulant: 6 (9.1) Alpha-2 adrenergic agonist: 5 (7.6) Antipsychotic: 3 (4.6) SSRI: 3 (4.6) Other: 4 (6.1)		Regulated affective state: **G1:** 8.10 ± 5.18 **G2:** 6.88 ± 4.86 **G3:** 6.65 ± 6.03 **G4:** 7.42 ± 5.05 **G5:** 7.33 ± 4.86 **G1/G5:** *P* = NS **G2/G5:** *P* = NS **G3/G5:** *P* = NS **G4/G5:** *P* = NS **Repetitive behavior:†** See notes **Problem behavior:** ABC-hyperactivity subscale score, mean ± SD:† Parent-rated: **G1:** 23.0 ± 11.29 **G2:** 20.6 ± 10.27 **G3:** 22.1 ± 9.67 **G4:** 17.2 ± 9.87 **G5:** 26.0 ± 9.90 **G1/G5:** *P* = 0.03 (es = 0.29) **G2/G5:** *P* < 0.001 (es = 0.54) **G3/G5:** *P* = 0.003 (es = 0.40) **G4/G5:** *P* < 0.001 (es = 0.89) Teacher-rated: **G1:** 22.9 ± 12.84 **G2:** 23.6 ± 12.53 **G3:** 20.3 ± 11.94 **G4:** 20.1 ± 12.40 **G5:** 26.0 ± 11.66 **G1/G5:** *P* = 0.03

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	G4: 64 **G5:** 61 **SNAP-IV, teacher-rated, n:*** **G1:** 46 **G2:** 48 **G3:** 33 **G4:** 55 **G5:** 46			(es = 0.25) **G2/G5:** *P* = 0.008 (es = 0.20) **G3/G5:** *P* = 0.002 (es = 0.48) **G4/G5:** *P* < 0.001 (es = 0.48)
Posey et al., 2007* Jahromi et al., 2009^ (continued)	**Clinician CYBOCS-PDD score, n:*** **G1:** 61 **G2:** 62 **G3:** 47 **G4:** 63 **G5:** 61			SNAP-IV inattention, mean ± SD:* Parent-rated: **G1:** 14.58 ± 6.56 **G2:** 13.38 ± 6.48 **G3:** 14.30 ± 6.35 **G4:** 11.83 ± 6.02 **G5:** 15.59 ± 6.51 **G1/G5:** *P* = 0.15 (es = 0.15) **G2/G5:** *P* < 0.001 (es = 0.34) **G3/G5:** *P* = 0.06 (es = 0.20) **G4/G5:** *P* < 0.001 (es = 0.60) Teacher-rated: **G1:** 15.24 ± 6.34 **G2:** 14.27 ± 6.93 **G3:** 14.67 ± 6.88 **G4:** 13.98 ± 6.46 **G5:** 16.15 ± 6.10 **G1/G5:** *P* = 0.21 (es = 0.15) **G2/G5:** *P* < 0.001 (es = 0.29) **G3/G5:** *P* = 0.02 (es = 0.23) **G4/G5:** *P* = 0.003 (es = 0.35) SNAP-IV hyperactivity/ impulsivity, mean ± SD:* Parent-rated: **G1:** 13.39 ± 5.87 **G2:** 12.19 ± 6.06 **G3:** 13.49 ± 6.41 **G4:** 10.80 ± 5.99 **G5:** 15.33 ± 5.81 **G1/G5:** *P* = 0.02 (es = 0.33) **G2/G5:** *P* < 0.001 (es = 0.53) **G3/G5:** *P* = 0.01 (es = 0.30) **G4/G5:** *P* < 0.001 (es = 0.77)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Posey et al., 2007* Jahromi et al., 2009^ (continued)				Teacher-rated: **G1:** 12.76 ± 6.84 **G2:** 13.00 ± 6.71 **G3:** 11.45 ± 7.01 **G4:** 11.26 ± 6.26 **G5:** 14.41 ± 6.095 **G1/G5:** *P* = 0.08 (es = 0.24) **G2/G5:** *P* = 0.01 (es = 0.21) **G3/G5:** *P* = 0.005 (es = 0.42) **G4/G5:** *P* = 0.005 (es = 0.48) SNAP-IV oppositional defiant disorder, mean ± SD:* Parent-rated: **G1:** 6.77 ± 5.62 **G2:** 7.02 ± 5.90 **G3:** 7.53 ± 5.90 **G4:** 5.86 ± 4.70 **G5:** 7.69 ± 5.80 **G1/G5:** *P* = 0.14 (es = 0.16) **G2/G5:** *P* = 0.25 (es = 0.12) **G3/G5:** *P* = 0.66 (es = 0.03) **G4/G5:** *P* < 0.001 (es = 0.35) Teacher-rated: **G1:** 5.89 ± 5.43 **G2:** 6.65 ± 5.10 **G3:** 6.75 ± 5.63 **G4:** 5.61 ± 4.85 **G5:** 7.02 ± 5.80 **G1/G5:** *P* = 0.11 (es = 0.20) **G2/G5:** *P* = 0.17 (es = 0.07) **G3/G5:** *P* = 0.35 (es = 0.05) **G4/G5:** *P* = 0.04 (es = 0.26)
Posey et al., 2007* Jahromi et al., 2009^ (continued)				CYBOCS-PDD, clinician-rated, mean ± SD:* **G1:** 12.82 ± 4.15 **G2:** 12.31 ± 4.27 **G3:** 13.02 ± 4.11 **G4:** 12.13 ± 4.22 **G5:** 13.05 ± 3.46 **G1/G5:** *P* = 0.90 (es = 0.06) **G2/G5:** *P* = 0.21

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				(es = 0.19) **G3/G5:** *P* = 0.80 (es = 0.01) **G4/G5:** *P* = 0.08 (es = 0.24) **Commonly occurring co-morbidities:** SNAP-IV ADHD, mean ± SD:* Parent-rated: **G1:** 27.97 ± 11.62 **G2:** 25.57 ± 11.66 **G3:** 27.79 ± 11.63 **G4:** 22.63 ± 11.19 **G5:** 30.92 ± 11.55 **G1/G5:** *P* = 0.04 (es = 0.25) **G2/G5:** *P* < 0.001 (es = 0.46) **G3/G5:** *P* = 0.02 (es = 0.27) **G4/G5:** *P* < 0.001 (es = 0.73) Teacher-rated: **G1:** 28.00 ± 12.12 **G2:** 27.27 ± 12.21 **G3:** 26.12 ± 12.64 **G4:** 25.24 ± 11.53 **G5:** 30.57 ± 11.84 **G1/G5:** *P* = 0.10 (es = 0.21) **G2/G5:** *P* = 0.001 (es = 0.27) **G3/G5:** *P* = 0.005 (es = 0.36) **G4/G5:** *P* = 0.003 (es = 0.46)
Posey et al., 2007* Jahromi et al., 2009^ (continued)				**Harms:** Withdrawn due to inability to tolerate medium or high doses of study drug, test-dose phase, n: 6/72 Withdrawn due to AEs, cross-over phase, n: **G1:** 1 **G2:** 3 **G3:** 3 **Adverse effects, n (%):** Appetite decrease: **G1:** 3 (4.6)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G2: 16 (24.2) **G3:** 12 (24.0) **G5:** 2 (3.0) **G2/G5:** $P \leq 0.001$ **G3/G5:** $P \leq 0.01$ Difficulty falling asleep: **G1:** 7 (10.6) **G2:** 12 (18.2) **G3:** 8 (16.0) **G5:** 1 (1.5) **G1/G5:** $P \leq 0.05$ **G2/G5:** $P \leq 0.01$ **G3/G5:** $P \leq 0.05$ Stomach or abdominal discomfort: **G1:** 2 (3.0) **G2:** 5 (7.6) **G3:** 6 (12.0) **G5:** 1 (1.5) Irritability: **G1:** 5 (7.6) **G2:** 8 (12.1) **G3:** 5 (10.0) **G5:** 2 (3.0) **G2/G5:** $P \leq 0.05$ Emotional outburst: **G1:** 5 (7.6) **G2:** 9 (13.6) **G3:** 5 (10.0) **G5:** 0 **G2/G5:** $P \leq 0.01$
Posey et al., 2007* Jahromi et al., 2009^ (continued)				Anxiety: **G1:** 3 (4.6) **G2:** 1 (1.5) **G3:** 4 (8.0) **G5:** 2 (3.0) Depression: **G1:** 1 (1.5) **G2:** 3 (4.6) **G3:** 4 (8.0) **G5:** 0 Repetitive behaviors and thoughts: **G1:** 2 (3.0) **G2:** 4 (6.1) **G3:** 3 (6.0) **G5:** 2 (3.0) Self-injury: **G1:** 1 (1.5) **G2:** 3 (4.6) **G3:** 3 (6.0) **G5:** 2 (3.0) Headache:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G1: 2 (3.0) **G2:** 1 (1.5) **G3:** 3 (6.0) **G5:** 0 Diarrhea: **G1:** 3 (4.6) **G2:** 3 (4.6) **G3:** 3 (6.0) **G5:** 4 (6.1) Social withdrawal: **G1:** 2 (3.0) **G2:** 4 (6.1) **G3:** 2 (4.0) **G5:** 0 Increased motor activity: **G1:** 4 (6.1) **G2:** 1 (1.5) **G3:** 1 (2.0) **G5:** 1 (1.5) Bradycardia: **G1:** 3 (4.6) **G2:** 0 **G3:** 0 **G5:** 4 (6.1)
Posey et al., 2007* Jahromi et al., 2009^ (continued)				Tiredness or fatigue: **G1:** 1 (1.5) **G2:** 4 (6.1) **G3:** 0 **G5:** 0 **Modifiers:** No effect of age, IQ, diagnosis, or weight on teacher-rated or parent-rated ABC hyperactivity subscale scores. **Response rate by dose, subjects with Asperger or PDD-NOS, n (%):** **G1:** 7/19 (37) **G2:** 7/19 (37) **G3:** 6/19 (32) **G5:** 6/19 (32) **G1/G5:** P = NS **G2/G5:** P = NS **G3/G5:** P = NS **Response rate by dose, subjects with autistic disorder, n (%):** **G1:** 13/47 (28)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G2: 15/47 (32) **G3:** 12/47 (25) **G5:** 6/47 (13) **G1/G5:** *P* < 0.001 **G2/G5:** *P* < 0.001 **G3/G5:** *P* < 0.001 Nonsignificant trend toward moderating effect of diagnosis on effect (*P* = 0.07). Age group, IQ, weight group, or diagnosis did not moderate treatment effect on SNAP-IV or CYPBOCS-PDD scores.

Comments: **Subjects randomized during crossover phase

Author: Kim et al., 2008* Kim et al., 2009† **Country:** South Korea **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Graduate School of Music Therapy, Institute for Communication and Psychology, Aalbord University, Denmark **Author industry relationship disclosures:** NR **Design:** RCT, Cross-over design	**Intervention:** 12 weekly 30 minute improvisational music therapy sessions vs. 12 weekly 30 minute play sessions with toys; half of the children had music therapy first, the others play sessions first (24 sessions total competed over 7-8 months) Music and play therapy sessions conducted by different therapists; sessions were divided into child lead first, then therapist lead second **Assessments:** Parent and provider report (PDDBI, CARS, Korean PEP-R), clinician direct observation and assessment (ESCS, video coding); frequency & duration of observed behaviors recorded by trained research assistants. Predefined target behaviors were undertaken on selected 4 minute samples taken from the undirected and more directed parts of the session, and from selected sessions (1, 4, 8, 12). Each target behavior	**Inclusion criteria:** • DSM-IV criteria for autistic disorder • no previous music or play therapy experience • Aged 3-5 years **Exclusion Criteria:** • See inclusion criteria **Age, months ± SD (range):** 51.20 ± 12.08 (39-71) **Mental age:** See IQ under baseline measures **Gender, n (%):** Enrollment: Male: 13 (87) Female: 2 (13) Follow-up: Male: 10 (100) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referred from Child and Adolescent Psychiatry at Seoul National University Hospital **Diagnostic tool/method:** Met DSM-IV criteria as well as cutoff on the Korean version of the CARS; ADOS administered for 4/10 children, who all met	**CARS, mean ± SD (range):** 36.10 ± 3.41(32-42.5) **Korean PEP-DQ, mean ± SD (range):** 70.29 ± 9.97 (60-89) **Korean SMS-SQ, mean ± SD (range):** 58.84 ± 7.80 (47.40-71) **PDDBI score:** NR (graphs only) **ESCS score:** NR (graphs only)	**Overall ratings:*** PDDBI score: NR (graphs only) ANOVA: scores increase with time *P* < 0.0001 **Communication/ language:*** ESCS joint attention score: NR (graphs only) ANOVA: time-group interaction (music therapy more effective than play) *P* = 0.01 Eye Contact: NR (graphs only) ANOVA: Longer duration in music therapy than play *P* < 0.0001 Turn-Taking: NR (graphs only) ANOVA: Longer duration in music therapy than play *P* < 0.0001 **Social skills:†** Joy, mean ± SD: Duration: **G1:** 13.28 ± 22.98 **G2:** 2.81 ± 7.93 **G1/G2:** *P* < 0.001 Frequency:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	was coded during joint engagement episodes. **Groups:** All participants received music therapy and play therapy **G1:** music therapy **G2:** toy play sessions **Providers, n:** Music therapists: 2 Play therapist: 1 Music therapy graduate students: 3 **Treatment manual followed:** "semi-flexible treatment manual developed and used for both conditions"	criteria (Korean version unavailable for earlier 6 participants) **Diagnostic category, n (%):** Autistic disorder: 10 (100) **Other characteristics, n (%):** Non-verbal: 5 (50) Verbal: 5 (50)		**G1:** 3.00 ± 4.64 **G2:** 1.02 ± 2.59 **G1/G2:** $P < 0.001$ ANOVA: Significant difference between selected sessions ($P < 0.01$) and undirected and directed parts ($P < 0.01$)
Kim et al., 2008* Kim et al., 2009† (continued)	**Defined protocol followed:** NR **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1=G2:** 15 **N at follow-up:** **G1=G2:** 10			Initiation of engagement by child, frequency, mean ± SD: **G1:** 3.41 ± 4.98 **G2:** 0.28 ± 0.71 **G1/G2:** $P < 0.001$ ANOVA: Significant difference between selected sessions ($P < 0.01$) and undirected and directed parts ($P = 0.03$) Initiation of interaction by therapist, frequency, mean ± SD: **G1:** 8.05 ± 5.13 **G2:** 10.05 ± 6.47 **G1/G2:** $P < 0.01$ **Communication/ language:†** Emotional synchronicity, mean ± SD: Duration: **G1:** 12.18 ± 22.20 **G2:** 2.44 ± 9.35 **G1/G2:** $P < 0.001$ Frequency: **G1:** 1.91 ± 3.45 **G2:** 0.38 ± 1.01 **G1/G2:** $P < 0.001$ ANOVA: Significant difference between

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				selected sessions (P < 0.001) and undirected and directed parts (P < 0.001) **Problem behavior:**† Compliant response, frequency, mean ± SD: **G1:** 4.61 ± 3.22 **G2:** 4.16 ± 4.00 **G1/G2:** P < 0.001
Kim et al., 2008* Kim et al., 2009† (continued)				ANOVA: Significant difference between selected sessions (P < 0.05) No response, frequency, mean ± SD: **G1:** 1.43 ± 1.79 **G2:** 3.04 ± 2.68 **G1/G2:** P < 0.001 **Harms:** NR **Modifiers:** None of the tested two- and three-way interactions of the predictors were significant for any of the outcomes.
Author: King et al., 2009 **Country:** US **Practice setting:** Academic **Intervention setting:** Academic **Enrollment period:** NR **Funding:** NIH **Author industry relationship disclosures:** 8 of 13 Abbot Labs (3) Aspect Medical	**Intervention:** Citalopram 10 mg/5 mL or placebo Dosing: children < 40 kg: 2.5 mg/day increased by 2.5 mg increments until day 43, then increased bi-weekly in 5 mg increments, up to 20 mg/day Children ≥ 40 kg: 2.5 mg dosage increased in weekly intervals until day 36, then increased by 5 mg biweekly up to 20 mg/day; if treating clinician suspected a dose-limiting adverse effect, the dosage could be lowered in 2.5 mg increments **Assessments:** Two masked clinicians	**Inclusion criteria:** • 5 to 17 years old • Met DSM-IV_TR criteria for autistic disorder, Asperger disorder or PDD-NOS • CGI-S illness severity rating at least moderate • Compulsive behaviors score at least moderate on CYBOCS-PDD **Exclusion criteria:** • Rhett disorder • Child disintegrative disorder • Seizure within past 6 months • Weight less than 15 kg • Medical condition that might interfere with study participation • Clinically significant	**Overall ratings:** CGI-I score, n (%): 4: **G1:** 21 (28.8) **G2:** 22 (28.8) 5: **G1:** 37 (50.7) **G2:** 37 (48.7) 6: **G1:** 14 (19.2) **G2:** 16 (21.1) 7: **G1:** 1 (1.4) **G2:** 1 (1.3) **Social skills:** ABC-C social withdrawal sub-scale, mean ± SD: **G1:** 11.4 ± 8.2 **G2:** 11.1 ± 8.0 **Communication/ language:**	**Overall ratings:** CGI-I score, 12 weeks, mean: **G1:** NR* **G2:** NR* G1+G2/BL: P < 0.001 **G1/G2:** P = NS Positive response, 12 weeks, %: CGI-I criteria: **G1:** 32.9 **G2:** 34.2 **G1/G2:** P = NS CYBOCS-PPD and CGI-I criteria: **G1:** 20.6 **G2:** 13.2 **G1/G2:** P = NS **Social skills:** ABC-C social withdrawal

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Systems (1) BioMarin (1) Boehringer-Ingelheim (1) Bristol-Myers Squibb (5) Eli Lilly (4) Forest Labs (3) Impax (1) IntegraGen (1) Janssen (4) Johnson & Johnson (3) McNeil (1) Nastech (2) Neuropharm (5) Novartis (1) Otsuka (1) Pfizer (1) Sanofi-Aventis (2) Seaside Therapeutics (2) Shire Pharma (2) Supernus (1) UCB Pharma (2) Wyeth (2) **Design:** RCT	met with participants during each scheduled evaluation. The treating clinician reviewed efficacy ratings, monitored and recorded adverse events. The evaluating clinician was blinded to adverse events and monitored efficacy using CGI-I, CYBOCS-PDD, RBS-R, ABC-C questionnaires. **Groups:** **G1:** citalopram **G2:** placebo **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** Baseline and at week 12 **Concomitant therapies, n:** Sleep medication: NR **N at enrollment:** **G1:** 73 **G2:** 76 **N at follow-up:** **G1:** 60 **G2:** 63	abnormal baseline laboratory test results • History of adverse events or failed treatment while taking two or more SSRIs • Prior treatment with citalopram or escitalopram oxalate • Recent initiation of behavior therapy • History of bipolar disorder or manic episode • Concomitant treatment with psychotropic medications or medication having known interactions with citalopram **Age, years ± SD (range):** **G1:** 9.1 ± 3.2 (5.0-17.3) **G2:** 9.6 ± 3.1 (5.1-17.1) **Mental age:** Non-verbal IQ > 70, n (%): **G1:** 43 (61.4) **G2:** 43 (60.6) **Gender, n (%):** **Male:** **G1:** 64 (87.7) **G2:** 64 (84.2)	ABC-C inappropriate speech subscale, mean ± SD: **G1:** 5.3 ± 3.7 **G2:** 5.0 ± 3.7 **Repetitive behavior:** CYBOCS-PDD, mean ± SD: **G1:** 15.1 ± 1.8 **G2:** 15.0 ± 2.1 RBS-R subscale, mean ± SD: Compulsive **G1:** 7.0 ± 5.4 **G2:** 5.9 ± 4.3 Restrictive: **G1:** 4.7 ± 2.8 **G2:** 4.1 ± 3.0 Ritualistic: **G1:** 7.0 ± 4.8 **G2:** 6.9 ± 4.5 Sameness: **G1:** 11.2 ± 7.4 **G2:** 10.2 ± 6.9 Self-injurious: **G1:** 2.8 ± 3.0 **G2:** 2.6 ± 2.6	subscale, 12 weeks, mean change ± SD: **G1:** -3.4 ± 6.1 **G2:** -2.9 ± 5.0 **G1/G2:** *P* = NS **Communication/ language:** ABC-C inappro-priate speech subscale, 12 weeks, mean change ± SD: **G1:** -0.8 ± 2.9 **G2:** -0.8 ± 2.5 **G1/G2:** *P* = NS **Repetitive behavior:** CYBOCS-PDD, 12 weeks, mean change ± SD: **G1:** -2.0 ± 3.4 **G2:** -1.9 ± 2.5 **G1/G2:** *P* = NS RBS-R subscale, 12 weeks, mean change ± SD: Compulsive: **G1:** -1.8 ± 3.9 **G2:** -1.3 ± 3.2 **G1/G2:** *P* = NS
King et al., 2009 (continued)		**Race/ethnicity, n (%):** Hispanic: **G1:** 9 (12.5) **G2:** 8 (10.5) American Indian or Alaskan native: **G1:** 0 **G2:** 2 (2.6) Asian: **G1:** 6 (8.2) **G2:** 8 (10.5) Black: **G1:** 7 (9.6) **G2:** 10 (13.2) Native Hawaiian: **G1:** 1 (1.4) **G2:** 0 White: **G1:** 53 (72.6) **G2:** 55 (72.4) Other: **G1:** 6 (8.2) **G2:** 4 (5.3) **SES:** Maternal education: NR Household income: NR	Stereotyped: **G1:** 6.8 ± 4.0 **G2:** 6.1 ± 3.9 ABC-C stereotypy subscale, mean ± SD: **G1:** 7.2 ± 4.8 **G2:** 7.2 ± 4.5 **Commonly occurring co-morbidities:** ABC-C irritability subscale, mean ± SD: **G1:** 13.2 ± 8.8 **G2:** 11.2 ± 8.5 ABC-C hyper-activity subscale, mean ± SD: **G1:** 20.2 ± 11.7 **G2:** 20.2 ± 11.2	Restrictive: **G1:** -0.6 ± 2.6 **G2:** -0.9 ± 2.5 **G1/G2:** *P* = NS Ritualistic: **G1:** -1.6 ± 3.5 **G2:** -1.5 ± 3.4 **G1/G2:** *P* = NS Sameness: **G1:** -3.0 ± 6.0 **G2:** -2.4 ± 5.3 **G1/G2:** *P* = NS Self-injurious: **G1:** -0.4 ± 3.0 **G2:** -0.7 ± 2.0 **G1/G2:** *P* = NS Stereotyped: **G1:** -1.2 ± 3.2 **G2:** -1.1 ± 2.7 **G1/G2:** *P* = NS ABC-C stereo-typy subscale, 12 weeks, mean change ± SD: **G1:** -0.7 ± 4.5 **G2:** -1.0 ± 3.3

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
		Diagnostic approach: In Study **Diagnostic tool/method:** DSM-IV-TR, ADI-R, ADOS **Diagnostic category:** See inclusion criteria **Other characteristics:** Tanner Stage, n (%): 1: **G1:** 52 (73.2) **G2:** 48 (63.2) 2: **G1:** 10 (14.1) **G2:** 12 (15.8) > 3: **G1:** 9 (12.7) **G2:** 16 (21.1)		**G1/G2:** *P* = NS **Commonly occurring co-morbidities:** ABC-C irritability subscale, 12 weeks, mean change ± SD: **G1:** -3.2 ± 6.5 **G2:** -0.9 ± 6.0 **G1/G2:** *P* = 0.03 ABC-C hyper-activity subscale, 12 weeks, mean change ± SD: **G1:** -1.6 ± 7.8 **G2:** -3.1 ± 7.8 **G1/G2:** *P* = NS **Harms, n (%):** Any adverse event: **G1:** 71 (97.3) **G2:** 66 (86.8) **G1/G2:** *P* = 0.03
King et al., 2009 (continued)				Energy level increased: **G1:** 28 (38.4) **G2:** 15 (19.7) **G1/G2:** *P* = 0.02 Anger or irritability: **G1:** 18 (24.7) **G2:** 13 (17.1) **G1/G2:** *P* = 0.31 Aggression or hostility: **G1:** 17 (23.3) **G2:** 13 (17.1) **G1/G2:** *P* = 0.42 Headache or migraine: **G1:** 15 (20.5) **G2:** 10 (13.2) **G1/G2:** *P* = 0.28 Restlessness or difficulty settling down: **G1:** 13 (17.8) **G2:** 7 (9.2) **G1/G2:** *P* = 0.15 Disinhibited, impulsive, or intrusive behavior: **G1:** 14 (19.2) **G2:** 5 (6.6) **G1/G2:** *P* = 0.03 Silliness:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G1: 9 (12.3) **G2:** 10 (13.2) **G1/G2:** *P* = 0.99 Anxiety: **G1:** 8 (11.0) **G2:** 9 (11.8) **G1/G2:** *P* = 0.99 Mood lability: **G1:** 7 (9.6) **G2:** 9 (11.8) **G1/G2:** *P* = 0.79 Increased speech: **G1:** 8 (11.0) **G2:** 4 (5.3) **G1/G2:** *P* = 0.24
King et al., 2009 (continued)				Attention and concentration decreased: **G1:** 9 (12.3) **G2:** 2 (2.6) **G1/G2:** *P* = 0.03 Hyperactivity: **G1:** 9 (12.3) **G2:** 2 (2.6) **G1/G2:** *P* = 0.03 Stereotypy: **G1:** 8 (11.0) **G2:** 1 (1.3) **G1/G2:** *P* = 0.02 Nightmares: **G1:** 5 (6.8) **G2:** 0 **G1/G2:** *P* = 0.03 Seizures: **G1:** 2 (2.7) **G2:** 0 **G1/G2:** *P* = NR Diarrhea or loose stools: **G1:** 19 (26.0) **G2:** 9 (11.8) **G1/G2:** *P* = 0.04 Abdominal discomfort: **G1:** 13 (17.8) **G2:** 9 (11.8) **G1/G2:** *P* = 0.36 Vomiting or nausea: **G1:** 14 (19.2) **G2:** 6 (7.9) **G1/G2:** *P* = 0.06 Insomnia: Any: **G1:** 28 (38.4) **G2:** 17 (22.4) **G1/G2:** *P* = 0.05

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				Initial, or difficulty falling asleep: **G1:** 17 (23.3) **G2:** 7 (9.2) **G1/G2:** *P* = 0.03 Midcycle or other: **G1:** 13 (17.8) **G2:** 9 (11.8) **G1/G2:** *P* = 0.36
King et al., 2009 (continued)				Cold, flu, or other systemic infection: **G1:** 31 (42.5) **G2:** 26 (34.2) **G1/G2:** *P* = 0.32 Appetite: Decreased: **G1:** 11 (15.1) **G2:** 10 (13.2) **G1/G2:** *P* = 0.82 Increased: **G1:** 7 (9.6) **G2:** 8 (10.5) **G1/G2:** *P* = 0.99 Rash: **G1:** 12 (16.4) **G2:** 8 (10.5) **G1/G2:** *P* = 0.34 Other skin or subcutaneous tissue disorder: **G1:** 9 (12.3) **G2:** 1 (1.3) **G1/G2:** *P* = 0.01 Fatigue: **G1:** 10 (13.7) **G2:** 10 (13.2) **G1/G2:** *P* = 0.99 Allergies: **G1:** 15 (20.5) **G2:** 11 (14.5) **G1/G2:** *P* = 0.39 Cough: **G1:** 10 (13.7) **G2:** 5 (6.6) **G1/G2:** *P* = 0.18 Any serious adverse event: **G1:** 1 (1.4) **G2:** 0 **G1/G2:** *P* = 0.49
King et al., 2009 (continued)				**Modifiers:** Results for primary and secondary outcomes remained consistent when

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				adjusted for dosage, adherence, and relevant baseline characteristics. There was no significant effect of IQ on treatment response.

**Comments: ***Data only illustrated graphically.

Author: Laud et al., 2009 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** December 2000 to February 2008 **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Case series	**Intervention:** Intensive Interdisciplinary Feeding Program Behavior therapy – Consisted of systematic meal sessions with individualized behavior protocols involving antecedent and consequence manipulations in the meals Oral motor therapy – Conducted by speech pathologist/occupational therapist used to determine a child's skill and safety in eating by providing oral exercises Duration: Average: 47 days Frequency: Inpatients (n=23): 3 hrs/day behavioral and 1 hr/day oral therapy 7 days/week Outpatients (n=23): 3 hrs/day behavioral and 1 hr/day oral therapy 5 days/week **Assessments:** Participant feeding behaviors such as acceptance, refusal behaviors, negative vocalizations, and grams consumed Caregiver assessment measures (conducted upon admission and before discharge) included the CEBI, caregiver satisfaction scores, and follow-up survey **Groups:**	**Inclusion criteria:** • ≥ 3 years of age • Diagnosis of ASD **Exclusion criteria:** • Discharged early for medical reason making involvement in treatment unsafe or for personal reasons of care giver **Age, years (range):** 69 (36-145) **Mental age:** NR **Gender, n (%):** Male: 40 (87) Female: 6 (13) **Race/ethnicity, n (%):** White: 24 (52) African American: 5 (11) Asian: 3 (7) Latinos: 3 (7) American Indian: 1 (2) Other: 10 (22) **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** NR **Diagnostic category, n (%):** ASD: 46 (100) **Other characteristics, n (%):** Failure to Thrive: 7 (15.2) GER: 26 (56.6) Food allergies: 8 (17.4) Nissen fundoplication: 7 (15.2) Esophagitis/gastritis/ duodenitis: 22 (23.9) Chronic lung disease: 6 (13.0) Cerebral palsy: 5 (10.9) TEF: 0	**Feeding behaviors:** Acceptance, mean %: **G1:** 15.56 Refusal behaviors, mean rate per trial: **G1:** 25.00 Negative vocalize-tions, mean %: **G1:** 19.93 Grams consumed, mean: **G1:** 24.41 **Caregiver assessment:** CEBI total eating problems score, mean: **G1:** 107.12 Caregiver satis-faction score, mean: **G1:** NA	**Feeding behaviors:** Acceptance, mean %: **G1:** 91.42, **G1/BL:** *P* < 0.000 Refusal behaviors, mean rate per trial: **G1:** 21 **G1/BL:** *P* < 0.007 Refusal behaviors, follow-up survey, years from baseline, n (%): Improved: 1-3: 10/14 (71.4) 3+: 15/15 (100) Same: 1-3: 0/14 3+: 0/15 Worsened: 1-3: 1/14 (7.1) 3+: 0/15 Negative vocalize-tions, mean %: **G1:** 4.45 **G1/BL:** *P* < 0.000 Grams consumed, mean: **G1:** 247.82 **G1/BL:** *P* < 0.000 Variety of foods follow-up survey, years from baseline, n (%): Greater: 1-3: 11/14 (78.6) 3+: 8/15 (53.3) Same: 1-3: 1/14 (7.1) 3+: 3/15 (20) Less: 1-3: 0/14 3+: 0/15

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	G1: intensive behavioral/ oral therapy	Tracheostomy: 0 Cleft palate: 0		Texture of foods follow-up survey, years from baseline, n (%): Higher: 1-3: 4/14 (28.6) 3+: 9/15 (60)
Laud et al., 2009 (continued)	**Provider:** • Main care providers: behavioral therapist, occupational and/or speech pathologist • Others: gastroenter-ologist, pediatrician, nurse practitioner, and nutritionist • Social worker for care providers of children **Measure of treatment fidelity reported:** No **Measure of inter-rater reliability reported:** Yes **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 46 **N at follow-up:** **G1:** 29	Prematurity, n (%): < 32 weeks: 6 (13) 32-38 weeks: 9 (19.6)		Same: 1-3: 7/14 (50) 3+: 4/15 (26.7) Lower: 1-3: 1/14 (7.1) 3+: 1/15 (6.7) Protocol usage, follow-up survey, years from baseline, n (%): Using: 1-3: 7/14 (50.0) 3+: 5/15 (33.3) Using modified version: 1-3: 3/14 (21.4) 3+: 3/15 (20) Not using: 1-3: 4/14 (28.6) 3+: 6/15 (40) **Caregiver Assessment:** CEBI total eating problems score, mean: **G1:** 99.62 **G1/BL:** $P < 0.004$ Caregiver satis-faction score, mean: **G1:** 4.48 Program recom-mendation, follow-up survey, years, n (%): Yes: 1-3: 12/14 (85.7) 3+: 15/15 (100) Depends: 1-3: 2/14 (14.3) 3+: 0/15 No: 1-3: 0/14 3+: 0/15 **Harms:** NR **Modifiers:** NR
Author: Marcus et al.,	**Intervention:** Aripiprazole, 2 mg/day for	**Inclusion criteria:** • Autistic disorder	**Overall ratings:** CGI-S score, LOCF,	**Overall ratings:** CGI-S, week 8,

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
2009 **Country:** US **Practice setting:** Pharmaceutical company **Intervention setting:** Multi-site clinics **Enrollment period:** June 2006 to June 2008 **Funding:** Bristol Myers Sqibb, Otsuka Pharmaceutical Co. **Author industry relationship disclosures:** 5 of 7 Bristol-Myers Squibb (5) Forest (1) Johnson & Johnson (1) Otsuka (2) **Design:** RCT, multicenter study **Note:** See related study Owen et al. 2009 ({#5714})	week 1, increased to 5 mg/day for week 2 and increased in 5 mg increments until assigned daily dose (5, 10, 15 mg/day) reached **Assessments:** ABC rated by caregiver at each visit; CGI-severity and improvement rated by clinician at each visit, Yale Brown Obsessive Compulsion Scale (compulsion scale only, weeks 0,4,8), administrator/rater NR; Pediatric QoL Inventory, Caregiver Strain Questionnaire assessed at baseline and week 8. Simpson-Angus Scale, Barnes Akathisia Rating Scale, Abnormal Involuntary Movement Scale used by clinician to rate adverse events **Groups:** **G1a:** aripiprazole 5 mg/day **G1b:** aripiprazole 10 mg/day **G1c:** aripiprazole 15 mg/day **G2:** placebo **Co-interventions held stable during treatment:** All psychotropic medications discontinued prior to study; sleep aids, anti-anxiety medication diphenhydramine, psychotropic medications for acute treatment of unforeseen events, benztropine, propranolol administered at investigators discretion **Frequency of contact during study:** Weekly clinic visits; telephone contact at week 7	diagnosis (DSMIV, ADI-R) and demonstrated tantrums, aggression, self-injurious behavior, or combination • CGI-S score ≥ 4 at screening and baseline • ABC irritability score ≥ 18 at screening and baseline • Weight ≥ 15 kg • Age 6-17 yrs **Exclusion criteria:** Current diagnosis of bipolar disorder, psychosis, schizophrenia, major depression, or fragile X syndrome • Diagnosis of another disorder on the autism spectrum including PDD-NOS, Asperger syndrome, Rett syndrome, or childhood disintegrative disorder • History of neuroleptic malignant syndrome • Significant risk for suicide • Seizure in past year • History of severe head trauma or stroke • History or evidence of unstable medical conditions • Clinically significant lab or diagnostic test result • Demonstrated resistance to antipsychotic medication or allergy/ hypersensitivity to aripiprazole • Unstable/inconsistent non-pharmacologic therapies **Age, years ± SD:** **G1a:** 9.0 ± 2.8 **G1b:** 10.0 ± 3.2 **G1c:** 9.5 ± 3.1 **G2:** 10.2 ± 3.1	mean (SE): **G1a:** 5.0 (0.1) (n=44) **G1b:** 4.9 (0.1) (n=52) **G1c:** 5.1 (0.1) (n=44) **G2:** 4.7 (0.1) (n=41) **Social skills:** ABC lethargy/social withdrawal score, LOCF, mean (SE): **G1a:** 17.7 (1.4) (n=52) **G1b:** 16.8 (1.3) (n=59) **G1c:** 18.9 (1.4) (n=53) **G2:** 18.0 (1.5) (n=49) **Repetitive behavior:** ABC stereotypy score, LOCF, mean (SE): **G1a:** 11.4 (0.8) (n=52) **G1b:** 11.6 (0.8) (N=59) **G1c:** 11.6 (0.8) (n=53) **G2:** 10.7 (0.8) (n=49) **Problem behavior:** ABC hyperactivity score, LOCF, mean (SE): **G1a:** 33.1 (1.4) (n=52) **G1b:** 33.7 (1.3) (n=59) **G1c:** 32.2 (1.4) (n=53) **G2:** 31.0 (1.4) (n=49)	LOCF, mean change (SE): **G1a:** -0.9 (0.2) (n=44) **G1b:** -1.0 (0.1) (n=52) **G1c:** -1.1 (0.2) (n=44) **G2:** -0.6 (0.2) (n=41) **G1a/G2:** *P* = NS **G1b/G2:** *P* ≤ 0.05 **G1c/G2:** *P* = ≤ 0.05 **Response rate, week 8, n (%)** **G1a:** 29 (55.8) (n=52; *P* ≤ 0.05) **G1b:** 29 (49.2) (n=59; *P* = NS) **G1c:** 28 (52.8) (n=53; *P* = NS) **G2:**17 (34.7) (n=49; *P* = NS) **Social skills:** ABC lethargy/ social withdrawal score, week 8, LOCF, mean change (SE): **G1a:** -5.8 (1.2) (n=52) **G1b:** -4.9 (1.1) (n=59) **G1c:** -7.9 (1.1) (n=53) **G2:** -5.2 (1.2) (n=49) **G1a/G2:** *P* = NS **G1b/G2:** *P* = NS **G1c/G2:** *P* = NS
Marcus et al., 2009 (continued)	**Concomitant therapies, %:** Analgesics and antipyretics: **G1a:** 23.1 **G1b:** 30.2	**Mental age:** NR **Gender, n (%):** Male: **G1a:** 47 (88.7) **G1b:** 50 (84.7)	**Communication/ language:** ABC inappropriate speech score, LOCF, mean (SE): **G1a:** 5.8 (0.6)	**Communication/ language:** ABC inappropriate speech score, week 8, LOCF, mean (SE):

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	G1c: 22.2 **G2:** 17.6 Anticholinergics: **G1a:** 3.8 **G1b:** 1.7 **G1c:** 9.3 **G2:** 0 Anxiolytics: **G1a:** 3.8 **G1b:** 1.7 **G1c:** 1.9 **G2:** 5.9 Hypnotics and sedatives: **G1a:** 3.8 **G1b:** 1.7 **G1c:** 1.9 **G2:** 3.9 Propranolol: **G1a:** 3.8 **G1b:** 0 **G1c:** 0 **G2:** 2.0 **N at enrollment:** **G1a:** 53 **G1b:** 59 **G1c:** 54 **G2:** 52 **N at follow-up:** **G1a:** 44 **G1b:** 49 **G1c:** 47 **G2:** 38	**G1c:** 50 (92.6) **G2:** 48 (92.3) **Race/ethnicity, n (%):** White: **G1a:** 37 (69.8) **G1b:** 41 (69.5) **G1c:** 42 (77.8) **G2:** 35 (67.3) Black: **G1a:** 13 (24.5) **G1b:** 15 (25.4) **G1c:** 9 (16.7) **G2:** 13 (25.0) Asian: **G1a:** 1 (1.9) **G1b:** 2 (3.4) **G1c:** 0 **G2:** 3 (5.8) Other: **G1a:** 2 (3.8) **G1b:** 1 (1.7) **G1c:** 3 (5.6) **G2:** 1 (1.9) **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** ADI-R **Diagnostic category, %:** Autistic disorder: **G1:** 100 **G2:** 100 **Other characteristics:** Weight, kg mean ± SD: **G1a:** 38.9 ± 18.3 **G1b:** 44.8 ± 22.4 **G1c:** 42.2 ± 23.0 **G2:** 45.6 ± 20.0	(n=52) **G1b:** 6.8 (0.5) (n=59) **G1c:** 6.3 (0.5) (n=53) **G2:** 5.9 (0.6) (n=48) CY-BOCS compulsions score, LOCF, mean (SE): **G1a:** 13.9 (0.6) (n=52) **G1b:** 13.5 (0.5) (n=59) **G1c:** 14.1 (0.5) (n=53) **G2:** 13.7 (0.6) (n=48) **Other:** Serum prolactin, ng/mL: **G1a:** 7.2 **G1b:** 6.5 **G1c:** 6.7 **G2:** 6.9 Weight, kg, mean (SE): **G1a:** 39.0 (3.1) **G1b:** 45.2 (2.9) **G1c:** 42.3 (3.0) **G2:** 46.3 (3.2) BMI, kg/m^2, mean (SE): **G1a:** 20.2 (1.0) **G1b:** 21.1 (1.0) **G1c:** 20.8 (1.0) **G2:** 21.0 (1.1) QTcF interval, milliseconds: mean: **G1a:** 373.5 **G1b:** 380.2 **G1c:** 378.2 **G2:** 384.6	**G1a:** -2.0 (0.5) (n=52) **G1b:** -1.8 (0.4) (n=59) **G1c:** -2.3 (0.4) (n=53) **G2:** -1.1 (0.5) (n=48) **G1a/G2:** *P* = NS **G1b/G2:** *P* = NS **G1c/G2:** *P* ≤ 0.05 **Repetitive behavior:** ABC stereotypy score, 8 weeks. LOCF, mean change (SE): **G1a:** -4.5 (0.68) (n=52) **G1b:** -4.2 (0.63) (n=59) **G1c:** -4.5 (0.66) (n=53) **G2:** -1.8 (0.69) (n=49) **G1a/G2:** *P* ≤ 0.005 **G1b/G2:** *P* ≤ 0.05 **G1c/G2:** *P* ≤ 0.005 **Problem behavior:** ABC hyperactivity score, 8 weeks, LOCF, mean change(SE): **G1a:** -14.0 (1.6) (n=52) **G1b:** -13.3 (1.5) (n=59) **G1c:** -16.3 (1.6) (n=53) **G2:** -7.7 (1.7) (n=49) **G1a/G2:** *P* ≤ 0.005 **G1b/G2:** *P* ≤ 0.05 **G1c/G2:** *P* ≤ 0.001
Marcus et al., 2009 (continued)		Previous psychotropic medication, n (%): Any nervous system: **G1a:** 24/52 (46.2) **G1b:** 32/59 (54.2) **G1c:** 31/54 (57.4) **G2:** 22/51 (43.1) Any psychotic:		CY-BOCS compulsions, 8 weeks, LOCF, mean change (SE): **G1a:** -2.6 (0.5) (n=52) **G1b:** -2.4 (0.4) (n=59)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
		G1a: 9/52 (17.3) **G1b:** 14/59 (23.7) **G1c:** 10/54 (18.5) **G2:** 11/51 (21.6) Aripiprazole: **G1a:** 1/52 (1.9) **G1b:** 1/59 (1.7) **G1c:** 2/54 (3.7) **G2:** 3/51 (5.9) Anxiolytic: **G1a:** 8/52 (15.4) **G1b:** 9/59 (15.3) **G1c:** 10/54 (18.5) **G2:** 8/51 (15.7) Antidepressant: **G1a:** 8/52 (15.4) **G1b:** 6/59 (10.2) **G1c:** 13/54 (24.1) **G2:** 3/51 (5.9) Psychostimulant: **G1a:** 3/52 (5.8) **G1b:** 11/59 (18.6) **G1c:** 7/54 (13.0) **G2:** 5/51 (9.8)		**G1c:** -3.2 (0.5) (n=53) **G2:** -1.7 (0.5) (n=48) **G1a/G2:** *P* = NS **G1b/G2:** *P* = NS **G1c/G2:** *P* ≤ 0.05 **Other:** Pediatric QoL Inventory combined scales total score, LSQ treatment difference (95% CI): **G1a:** NR (NS) **G1b:** NR (NS) **G1c:** 8.2 (1.2-15.2) **Harms:** Experienced ≥ 1 harm, safety sample, n (%) **G1a:** 46/52 (88.5) **G1b:** 53/59 (89.8) **G1c:** 46/54 (85.2) **G2:** 37/51 (75.5) Harms (incidence ≥ 5% in G1a, G1b or G1c and twice G2 rate), n (%): Sedation: **G1a:** 9 (17.3) **G1b:** 17 (28.8) **G1c:** 13 (24.1) **G2:** 3 (5.9) Tremor: **G1a:** 4 (7.7) **G1b:** 7 (11.9) **G1c:** 6 (11.1) **G2:** 0 Somnolence: **G1a:** 4 (7.7) **G1b:** 5 (8.5) **G1c:** 5 (9.3) **G2:** 2 (3.9)
Marcus et al., 2009 (continued)				Drooling: **G1a:** 2 (3.8) **G1b:** 8 (13.6) **G1c:** 5 (9.3) **G2:** 0 Headache: **G1a:** 3 (5.8) **G1b:** 5 (8.5) **G1c:** 5 (9.3) **G2:** 2 (3.9) Extrapyramidal

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				disorder: **G1a:** 2 (3.8) **G1b:** 4 (6.8) **G1c:** 6 (11.1) **G2:** 0 Lethargy: **G1a:** 4 (7.7) **G1b:** 3 (5.1) **G1c:** 3 (5.6) **G2:** 0 Hypersomnia: **G1a:** 3 (5.8) **G1b:** 0 **G1c:** 2 (3.7) **G2:** 0 Vomiting: **G1a:** 5 (9.6) **G1b:** 12 (20.3) **G1c:** 5 (9.3) **G2:** 4 (7.8) Salivary hyper-secretion: **G1a:** 1 (1.9) **G1b:** 4 (6.8) **G1c:** 6 (11.1) **G2:** 1 (2.0) Nausea: **G1a:** 1 (1.9) **G1b:** 3 (5.1) **G1c:** 4 (7.4) **G2:** 1 (2.0) Abdominal pain upper: **G1a:** 2 (3.8) **G1b:** 1 (1.7) **G1c:** 4 (7.4) **G2:** 1 (2.0)
Marcus et al., 2009 (continued)				Fatigue: **G1a:** 2 (3.8) **G1b:** 13 (22.0) **G1c:** 10 (18.5) **G2:** 0 Pyrexia: **G1a:** 3 (5.8) **G1b:** 7 (11.9) **G1c:** 5 (9.3) **G2:** 0 Thirst: **G1a:** 3 (5.8) **G1b:** 1 (1.7) **G1c:** 1 (1.9) **G2:** 1 (2.0) Cough: **G1a:** 8 (15.4) **G1b:** 4 (6.8) **G1c:** 0 **G2:** 2 (3.9)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				Rhinorrhea: **G1a:** 2 (3.8) **G1b:** 5 (8.5) **G1c:** 1 (1.9) **G2:** 1 (2.0) Nasal congestion: **G1a:** 1 (1.9) **G1b:** 1 (1.7) **G1c:** 4 (7.4) **G2:** 1 (2.0) Epistaxis: **G1a:** 0 **G1b:** 4 (6.8) **G1c:** 1 (1.9) **G2:** 0 Nasopharyngitis: **G1a:** 6 (11.5) **G1b:** 5 (8.5) **G1c:** 5 (9.3) **G2:** 2 (3.9) Gastroenteritis viral: **G1a:** 1 (1.9) **G1b:** 3 (5.1) **G1c:** 1 (1.9) **G2:** 0 Upper respiratory tract infection: **G1a:** 2 (3.8) **G1b:** 0 **G1c:** 3 (5.6) **G2:** 0
Marcus et al., 2009 (continued)				Increased appetite: **G1a:** 10 (19.2) **G1b:** 3 (5.1) **G1c:** 7 (13.0) **G2:** 2 (3.9) Decreased appetite: **G1a:** 5 (9.6) **G1b:** 5 (8.5) **G1c:** 3 (5.6) **G2:** 1 (2.0) Rash: **G1a:** 0 **G1b:** 3 (5.1) **G1c:** 1 (1.9) **G2:** 1 (2.0) Weight increased: **G1a:** 4 (7.7) **G1b:** 1 (1.7) **G1c:** 2 (3.7) **G2:** 1 (2.0) Enuresis: **G1a:** 0 **G1b:** 1 (1.7)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G1c: 3 (5.6) **G2:** 1 (2.0) **Other:** Serum prolactin, 8 weeks, mean change (ng/mL): **G1a:** -5.4 **G1b:** -5.2 **G1c:** -5.8 **G2:** 0.9 **G1a/G2:** P < 0.001 **G1a/G2:** P < 0.001 **G1a/G2:** P < 0.001 Weight, 8 weeks, LOCF, mean change (kg) (SE): **G1a:** 1.3 (0.3) **G1b:** 1.3 (0.3) **G1c:** 1.5 (0.3) **G2:** 0.3 (0.3) **G1a/G2:** P < 0.05 **G1a/G2:** P < 0.05 **G1a/G2:** P < 0.05
Marcus et al., 2009 (continued)				BMI, 8 weeks, LOCF, mean change (kg/m^2) (SE): **G1a:** 0.6 (0.2) **G1b:** 0.6 (0.2) **G1c:** 0.8 (0.2) **G2:** 0.2 (0.2) **G1a/G2:** P = NS **G1a/G2:** P = NS **G1a/G2:** P < 0.05 Subjects with clinically relevant (≥ 7%) body weight gain, 8 weeks, LOCF, %: **G1a:** 32.7 **G1b:** 15.3 **G1c:** 30.2 **G2:** 8.2 **G1a/G2:** P < 0.005 **G1b/G2:** P = NS **G1c/G2:** P < 0.005 QTcF interval, 8 weeks, mean change (milli-seconds): **G1a:** -0.8 **G1b:** -4.5

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G1c: -4.4 **G2:** -2.0 **G1a/G2:** P = NS **G1a/G2:** P = NS **G1a/G2:** P = NS **Modifiers:** NR
Author: Owen et al., 2009 **Country:** US **Practice setting:** Pharmaceutical company **Intervention setting:** Multi-site clinics **Enrollment period:** June 2006 to February 2008 **Funding:** Bristol Myers Sqibb, Otsuka Pharmaceutical Co. **Author industry relationship disclosures:** 8 of 8 Abbott (1) Addrenex (1) Astra Zeneca (1) Bristol Myers Squibb (6) Curemark (1) Forest (1) GlaxoSmithKline (1) Janssen (1) Johnson & Johnson (1) KemPharm (1) Lilly (2) Lundbeck (1) Neuropharm (2) Novartis (1) Organon (1) Otsuka (4) Pfizer (2) Sanofi-Aventis (1) Seaside Pharma (1) Sepracore (1) Shire (1) Solvay (1)	**Intervention:** An 8 week treatment phase with Aripiprazole, 2 mg/day with target dosage of 5,10, or 15 mg/day (maximum 15 mg/day) **Assessments:** ABC rated by caregiver at each visit; CGI severity and improvement rated by clinician at each visit, CY-BOCS (compulsion scale only, weeks 0, 4, and 8), administrator/rater NR; Pediatric QoL Inventory, Caregiver Strain Questionnaire assessed at baseline and week 8. Simpson-Angus Scale, Barnes Akathisia Rating Scale, Abnormal Involuntary Movement Scale used by clinician to rate adverse events **Groups:** **G1:** aripiprazole **G2:** placebo **Co-interventions held stable during treatment:** All psychotropic medications discontinued prior to study; lorazepam or alprazolam, sleep aids, diphenhydramine, benztropine, propranolol administered at investigators discretion **Frequency of contact during study:** Weekly clinic visits; telephone contact at week 7 **Concomitant therapies, %:** Analgesics/anti-pyretics: **G1:** 19.1 **G2:** 22.0 Hypnotics/sedatives: **G1:** 2.1 **G2:** 12.0 **N at enrollment:***	**Inclusion criteria:** • Autistic disorder diagnosis (DSM-IV, ADI-R) and demon-strated tantrums, aggression, self- injurious behavior, or a combination thereof • CGI-S score ≥ 4 at screening and baseline • ABC irritability score ≥ 18 at screening and baseline • Weight ≥ 15 kg • Age 6-17 years **Exclusion criteria:** • Current diagnosis of bipolar disorder, psychosis, schizophrenia, major depression, or fragile X syndrome • Diagnosis of another disorder on the autism spectrum including PDD-NOS, Asperger syndrome, Rett syndrome, or childhood disintegrative disorder • History of neuroleptic malignant syndrome • Significant risk for suicide • Seizure in past year • History of severe head trauma or stroke • History or evidence of unstable medical conditions • Clinically significant lab or diagnostic test result • Demonstrated resistance to antipsychotic medication or allergy/ hypersensitivity to aripiprazole • Unstable/inconsistent non-pharmacologic therapies **Age 6-17y, mean ± SD:** **G1:** 9.7 ± 3.2	**Overall ratings:*** CGI-S, mean: **G1:** 4.9 (n=40) **G2:** 4.8 (n=40) Serum prolactin, ng/ml, mean: **G1:** 9.8 **G2:** 6.8 QTcF interval, milliseconds, mean: **G1:** 377.6 **G2:** 376.3 **Social skills:** ABC lethargy/social withdrawal score, mean: **G1:** 19.9 **G2:** 18.1 **Communication/ language:** ABC inappropriate speech score, mean: **G1:** 7.0 **G2:** 7.0 **Repetitive behavior:** ABC stereotypy score, mean: **G1:** 11.9 **G2:** 10.7 **Problem behavior:** ABC irritability score, mean: **G1:** 29.6 **G2:** 30.8 ABC hyperactivity score, mean: **G1:** 34.1 **G2:** 34.7 CY-BOCS score (compulsions only), mean: **G1:** 12.8 (n=43) **G2:** 13.7 (n=44)	**Overall ratings:** CGI-I at week 8, LOCF, efficacy sample, %: Very much/much improved: **G1:** 67 **G2:** 16 Minimally improved: **G1:** 15 **G2:** 20 No change: **G1:**13 **G2:**45 Minimally worse: **G1:**4 **G2:**10 Much/very much worse: **G1:** 0 **G2:** 8 CGI-I score, week 8, mean: **G1:** 2.2 **G2:** 3.6 **G1/G2:** $P < 0.001$ LSQ mean treat-ment difference (95% CI): -1.4 (-1.9,-1.0) CGI-S, week 8, mean change: **G1:** -1.2 (n=40) **G2:** -0.4 (n=40) **G1/G2:** $P < 0.001$ LSQ mean treat-ment difference (95% CI): -0.8 (-1.2,-0.4) Serum prolactin, ng/ml, week 8, mean change: **G1:** -6.3 **G2:** 1.6 **G1/G2:** $P < 0.001$ Weight gain, week 8, % **G1:** 28.9 **G2:** 6.1

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Wyeth (1)	**G1:** 47 **G2:** 51	**G2:** 8.8 ± 2.6 **Age 6-12y, n (%):** **G1: 37** (78.7) **G2:** 46 (90.2)		**G1/G2:** *P* < 0.01
Owen et al., 2009 (continued) **Design:** Double-blind, RCT, permuted block randomiza-tion; multicenter study **Note:** See related study Marcus et al., 2009	**N at follow-up:** **G1:** 39 **G2:** 36	**Mental age:** NR **Gender, n (%):** Male: G1 :42 (89.4) **G2:** 44 (86.3) **Race/ethnicity, n (%):** White: **G1:** 32 (68.1) **G2:** 41 (80.4) Black: **G1:** 11 (23.4) **G2:** 7 (13.7) Asian: **G1:** 2 (4.3) **G2:** 0 Other: **G1:** 2 (4.3) **G2:** 3 (5.9) **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** ADI-R **Diagnostic category, n (%):** **G1:** Autistic disorder: **G1:** 47 (100) **G2:** 51 (100) PDD-NOS: **G1:** 0 **G2:** 0 Asperger syndrome: **G1:** 0 **G2:** 0 **Other characteristics:** Weight, kg ± SD: **G1:** 43.9 ± 19.2 **G2:** 40.6 ± 18.9		QTcF interval, milliseconds, week 8, mean change: **G1:** 0.6 **G2:** 4.5 **G1/G2:** *P* = 0.381 **Social skills:** ABC lethargy/ social withdrawal score, week 8, mean change: **G1:** -7.9 **G2:** -6.2 **G1/G2:** *P* = NS **Communication/ language:** ABC inappropriate speech score, week 8, mean change: **G1:** -2.5 **G2:** -0.4 **G1/G2:** *P* < 0.001 LSQ mean treat-ment difference (95% CI): -2.0 (-3.1,-1.0) **Repetitive behavior:** ABC stereotypy score, 8 weeks, mean change: **G1:** -4.8 **G2:** -2.0 **G1/G2:** *P* < 0.001 LSQ mean treat-ment difference (95% CI): -2.9 (-4.5,-1.2) **Problem behavior:** ABC irritability score, 8 weeks, mean change: **G1:** -12.9 **G2:** -5.0 **G1/G2:** *P* < 0.001 LSQ mean treat-ment difference (95% CI): -7.9 (-11.7,-4.1)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Owen et al., 2009 (continued)				ABC hyperactivity score, 8 weeks, mean change: **G1:** -12.7 **G2:** -2.8 **G1/G2:** *P* < 0.001 LSQ mean treatment difference (95% CI): -9.9 (-13.8,-5.9) CY-BOCS (compulsions only), 8 weeks, mean change: **G1:** -3.8 (n=43) **G2:** -0.8 (n=44) **G1/G2:** *P* < 0.001 LSQ mean treatment difference (95% CI): -3.0 (-4.3,-1.6) **Harms :** Occurring in ≥ 5% of any group, n (%): Any AE: **G1:** 43/47 (91.5) **G2:** 36/50 (72.0) Headache: **G1:** 3/47 (6.4) **G2:** 8/50 (16.0) Somnolence: **G1:** 8/47 (17.0) **G2:** 2/50 (4.0) Sedation: **G1:** 5/47 (10.6) **G2:** 1/50 (2.0) Drooling: **G1:** 4/47 (8.5) **G2:** 0 Tremor: **G1:** 4/47 (8.5) **G2:** 0 Diarrhea: **G1:** 4/47 (8.5) **G2:** 5/50 (10.0) Vomiting: **G1:** 7/47 (14.9) **G2:** 2/50 (4.0) Insomnia: **G1:** 3/47 (6.4) **G2:** 4/50 (8.0)
Owen et al., 2009 (continued)				Aggression: **G1:** 4/47 (8.0) **G2:** 1/50 (2.1)Fatigue: **G1:** 10/47 (21.3)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G2: 2/50 (4.0) Pyrexia: **G1:** 4/47 (8.5) **G2:** 1/50 (2.0) Upper respiratory tract infection: **G1:** 1/47 (2.1) **G2:** 5/50 (10.0) Nasopharyngitis: **G1:** 2/47 (4.3) **G2:** 3/50 (6.0) Nasal congestion: **G1:** 3/47 (6.4) **G2:** 1/50 (2.0) Increased appetite: **G1:** 7/47 (14.9) **G2:** 5/50 (10.0) Enuresis: **G1:** 3/47 (6.4) **G2:** 4/50 (8.0) Any EPS event: **G1:** 7/47 (14.9) **G2:** 4/50 (8.0) Tremor: **G1:** 4/47 (8.5) **G2:** 0 Extrapyramidal disorder: **G1:** 1/47 (2.1) **G2:** 0 Muscle rigidity: **G1:** 1/47 (1.2) **G2:** 0 Muscle spasms: **G1:** 0 **G2:** 1/50 (2.0) Akathisia: **G1:** 0 **G2:** 1/50 (2.0) Psychomotor hyperactivity: **G1:** 1/47 (2.1) **G2:** 2/50 (4.0) Hypokinesia: **G1:** 1 (2.1) **G2:** 0 Hyperkinesia: **G1:** 0 **G2:** 1/50 (2.0)
Owen et al., 2009 (continued)				**Modifiers:** NR
Author: Panerai et al., 2009 **Country:** Italy	**Intervention:** TEACCH in a residential center vs. TEACCH at home and at mainstream schools after a parent	**Inclusion criteria:** • Attending primary school • Evaluated for at least a 3-year period • Assessment included	**Overall ratings:** PEP-R composite score, mean ± SD: **G1:** 43.36 ± 24.36 **G2:** 54.15 ± 26.46	**Overall ratings:** PEP-R composite score, 3 years, mean ± SD: **G1:** 57.45 ± 29.76

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Practice setting: Research center **Intervention setting:** Residential, clinic, and/or school **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective cohort study	psychoeducational training vs. inclusive education in mainstream schools (i.e., treatment as usual, nonspecific program) Duration: 3 years in setting TEACHH residential – In residence education with regular intervals home and no additional school involvement TEACCH home based – Attended mainstream classes with support teacher; psycho-educational training of parents for 4 weeks, then repeated 2 week stays on 6 month basis **Assessments:** CARS, LAP-R, PEP-R, VABS **Groups:** **G1:** TEACCH in a residential center **G2:** TEACCH parent training **G3:** inclusive education in mainstream school (no protocol) **Provider:** **G1:** Educators with support of the management team (a psychologist, educational coordinator, neurologist, and doctor specializing in normal and special education)	PEP-R • Diagnosed with autistic disorder and mental retardation **Exclusion criteria:** • See inclusion criteria **Age, years ± SD:** **G1:** 9.66 ± 2.31 **G2:** 8.66 ± 2.01 **G3:** 9.09 ± 2.07 **Mental age, months ± SD:** **G1:** 20.63 ± 9.52 **G2:** 23.69 ± 10.5 **G3:** 20.4 ± 6.93 **Gender, n (%):** Male: 34 (100) Female: 0 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study Diagnostic tool/method: DSM-IV, CARS, ADI-R Diagnostic category, n (%): Autism: 34 (100) PDD-NOS: 0 Aspergers: 0 **Other characteristics:** Severe Mental Retardation n (%): 34 (100) CARS score, mean ± SD: **G1:** 45.75 ± 5.23 **G2:** 42.42 ± 2.41 **G3:** 42.9 ± NR	**G3:** 46.4 ± 21.9 **G1/G2/G3:** *P* = NS VABS composite scale, mean ± SD: **G1:** 100.72 ± 42.92 **G2:** 109.69 ± 33.83 **G3:** 94.8 ± 27.89 **G1/G2/G3:** *P* = NS **Social skills:** VABS socialization score, mean ± SD: **G1:** 16.1 ± 11.6 **G2:** 16.23 ± 7.45 **G3:** 16 ± 5.29 **G1/G2/G3:** *P* = NS **Communication/ language:** VABS communication score, mean ± SD: **G1:** 15.9 ± 14.9 **G2:** 19.46 ± 11.24 **G3:** 18.1 ± 10.48 **G1/G2/G3:** *P* = NS **Problem behavior:** VABS maladaptive behaviors score, mean ± SD: **G1:** 16.18 ± 7.33 **G2:** 17.92 ± 6.57 **G3:** 18.5 ± 7.38 **G1/G2/G3:** *P* = NS **Adaptive behavior:** VABS daily living score, mean ± SD: **G1:** 33.1 ± 12.9 **G2:** 31.92 ± 11.62 **G3:** 27.8 ± 11.14 **G1/G2/G3:** *P* = NS **Motor skills:** PEP-R fine motor score, mean ± SD: **G1:** 8.54 ± 4.18 **G2:** 9.61 ± 3.69 **G3:** 9.3 ± 3.8 **G1/G2/G3:** *P* = NS	**G2:** 69.54 ± 22.54 **G3:** 49 ± 25.24 **G1/BL:** *P* = 0.02 **G2/BL:** *P* = 0.022 **G3/BL:** *P* = NS **G1/G2/G3:** *P* = 0.009 **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = 0.001 VABS composite score, 3 years, mean ± SD: **G1:** 127.81 ± 45.07 **G2:** 155.23 ± 39.89 **G3:** 109.6 ± 33.52 **G1/BL:** *P* = 0.02 **G2/BL:** *P* = 0.02 **G3/BL:** *P* = NS Composite score with motor skills: **G1/G2/G3:** *P* = NS **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = NS Composite score w/o motor skills: **G1/G2/G3:** *P* = 0.038 **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = 0.01 **Social skills:** VABS socialization score, 3 years, mean ± SD: **G1:** 25.5 ± 12.2 **G2:** 27.46 ± 10.89 **G3:** 16 ± 6.14 **G1/BL:** *P* = 0.02 **G2/BL:** *P* = 0.018 **G3/BL:** *P* = NS
Panerai et al., 2009 (continued)	**G2:** Support teacher, specific generalist team (psychologist, doctor specializing in normal and special education, educator-coordinator, educator, social worker, psycho-motor and speech therapists), and parent **G3:** Support teacher and general education	ADI-R score, mean ± SD: Communication: **G1:** 15.18 ± 2.79 **G2:** 14.15 ± 2.76 **G3:** 13.6 ± 2.01 Social impairment: **G1:** 27.45 ± 2.8 **G2:** 24.92 ± 4.54 **G3:** 26.4 ± 2.55 Repetitive behavior: **G1:** 7.09 ± 2.43	PEP-R gross motor score, mean ± SD: **G1:** 11.45 ± 3.14 **G2:** 13.23 ± 4.64 **G3:** 13.4 ± 4.03 **G1/G2/G3:** *P* = NS PEP-R eye-hand coordination score, mean ± SD: **G1:** 4.82 ± 2.89 **G2:** 5.54 ± 3.53	Total score: **G1/G2/G3:** *P* = 0.009 **G1/G2:** *P* = NS **G1/G3:** *P* = 0.017 **G2/G3:** *P* = 0.006 Interpersonal relationships: **G1/G2/G3:** *P* = 0.017 **G1/G2:** *P* = NS

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	teachers **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies, n:** **G1:** NR **G2:** NR **G3:** Outpatient treatments (including psychomotor therapy and speech therapy): NR **N at enrollment:** **G1:** 11 **G2:** 13 **G3:** 10 **N at follow-up:** **G1:** 11 **G2:** 13 **G3:** 10	**G2:** 7.2 ± 2.65 **G3:** 6.6 ± 1.78 LAP-R developmental age, months ± SD: Language and literacy: **G1:** 19.55 ± 9.76 **G2:** 20.82 ± 8.59 **G3:** 18.7 ± 6.78 Emotional and social skills: **G1:** 22.55 ± 9.44 **G2:** 22.15 ± 6.96 **G3:** 20.6 ± 6.29 Pre-writing: **G1:** 22.36 ± 14.47 **G2:** 26.77 ± 12.79 **G3:** 26.4 ± 16.11 Self help skills: **G1:** 29.64 ± 13.9 **G2:** 31.08 ± 17.69 **G3:** 27.5 ± 9.08	**G3:** 4.6 ± 2.95 **G1/G2/G3:** *P* = NS VABS motor skills score, mean ± SD: **G1:** 37.5 ± 7.79 **G2:** 42.15 ± 10.94 **G3:** 33.9 ± 8.99 **G1/G2/G3:** *P* = NS **Educational/ cognitive/ academic attainment:** PEP-R developmental age, months ± SD: **G1:** 20.64 ± 9.52 **G2:** 23.69 ± 10.55 **G3:** 20.04 ± 6.93 **G1/G2/G3:** *P* = NS PEP-R cognitive performances score, mean ± SD: **G1:** 4.82 ± 5.47 **G2:** 7.61 ± 6.2 **G3:** 6.5 ± 6.04 **G1/G2/G3:** *P* = NS PEP-R cognitive verbal performances score ± SD: **G1:** 2.09 ± 4.99 **G2:** 2.85 ± 4.08 **G3:** 0.6 ± 0.07 **G1/G2/G3:** *P* = NS **Additional:** PEP-R imitation score, mean ± SD: **G1:** 3.45 ± 4.86 **G2:** 5.77 ± 4.81 **G3:** 4.1 ± 3.69 **G1/G2/G3:** *P* = NS	**G1/G3:** *P* = 0.035 **G2/G3:** *P* = 0.008 **Communication/ language:** VABS communication score, 3 years, mean ± SD: **G1:** 22.1 ± 16.5 **G2:** 28.92 ± 16.43 **G3:** 21.4 ± 11.01 **G1/BL:** *P* = 0.05 **G2/BL:** *P* = 0.02 **G3/BL:** *P* = NS **G1/G2/G3:** *P* = NS **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = NS **Problem behavior:** VABS maladaptive behaviors score, 3 years, mean ± SD: **G1:** 12.27 ± 7.04 **G2:** 17.23 ± 7.35 **G3:** 24.1 ± 9.69 **G1/BL:** *P* = 0.02 **G2/BL:** *P* = 0.02 **G3/BL:** *P* = NS **G1/G2/G3:** *P* = 0.038 **G1/G2:** *P* = NS **G1/G3:** *P* = 0.032 **G2/G3:** *P* = 0.044
Panerai et al., 2009 (continued)			PEP-R perception score, mean ± SD: **G1:** 8 ± 2.76 **G2:** 9.54 ± 2.47 **G3:** 7.9 ± 3.66 **G1/G2/G3:** *P* = NS	**Adaptive behavior:** VABS daily living skills score, 3 years, mean ± SD: **G1:** 42.2 ± 14 **G2:** 44.85 ± 10.95 **G3:** 31 ± 12.9 **G1/BL:** *P* = 0.02 **G2/BL:** *P* = 0.02 **G3/BL:** *P* = NS Total: **G1/G2/G3:** *P* = 0.033 **G1/G2:** *P* = NS **G1/G3:** *P* = NS

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G2/G3: *P* = 0.009 Personal: **G1/G2/G3:** *P* = 0.049 **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = 0.022 **Motor skills:** PEP-R fine motor score, 3 years, mean ± SD: **G1:** 9.82 ± 4.17 **G2:** 11.46 ± 2.44 **G3:** 9.3 ± 3.9 **G1/BL:** *P* = NS **G2/BL:** *P* = 0.024 **G3/BL:** *P* = NS **G1/G2/G3:** *P* = NS **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = NS PEP-R gross motor score, 3 years, mean ± SD: **G1:** 14.1 ± 4.66 **G2:** 15.8 ± 3.24 **G3:** 13.8 ± 4.49 **G1/BL:** *P* < 0.05 **G2/BL:** *P* = 0.018 **G3/BL:** *P* = NS **G1/G2/G3:** *P* = 0.031 **G1/G2:** *P* = NS **G1/G3:** *P* = 0.026 **G2/G3:** *P* = 0.032
Panerai et al., 2009 (continued)				PEP-R eye-hand coordination score, 3 years, mean ± SD: **G1:** 6.09 ± 3.11 **G2:** 7.85 ± 2.82 **G3:** 5.9 ± 4.77 **G1/BL:** *P* = 0.02 **G2/BL:** *P* = 0.018 **G3/BL:** *P* = NS **G1/G2/G3:** *P* = NS **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = NS VABS motor skills score, 3 years, mean ± SD: **G1:** 42.1 ± 6.41 **G2:** 54.08 ± 13.9

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G3: 39.4 ± 11.28 **G1/BL:** *P* = 0.02 **G2/BL:** *P* = 0.02 **G3/BL:** *P* = NS **G1/G2/G3:** *P* = NS **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = NS **Educational/ cognitive/ academic attainment:** PEP-R developmental age, 3 years, months ± SD: **G1:** 25.82 ± 12.03 **G2:** 29.15 ± 10.01 **G3:** 21.5 ± 8.36 **G1/BL:** *P* = 0.02 **G2/BL:** *P* = 0.022 **G3/BL:** *P* = NS **G1/G2/G3:** *P* = 0.005 **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = 0.005
Panerai et al., 2009 (continued)				PEP-R cognitive verbal performances score, 3 years, mean ± SD: **G1:** 3.91 ± 5.72 **G2:** 4 ± 5.07 **G3:** 1 ± 1.63 **G1/BL:** *P* = NS **G2/BL:** *P* = NS **G3/BL:** *P* = NS **G1/G2/G3:** *P* = 0.006 **G1/G2:** *P* = NS **G1/G3:** *P* = 0.034 **G2/G3:** *P* = 0.002 PEP-R cognitive performances score, 3 years, mean ± SD: **G1:** 8.09 ± 6.59 **G2:** 10.46 ± 5.62 **G3:** 5.9 ± 6.04 **G1/BL:** *P* = 0.032 **G2/BL:** *P* = 0.018 **G3/BL:** *P* = NS **G1/G2/G3:** *P* = NS **G1/G2:** *P* = NS

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G1/G3: *P* = NS **G2/G3:** *P* = NS **Additional:** PEP-R imitation score, 3 years, mean ± SD: **G1:** 5.9 ± 6.12 **G2:** 8.69 ± 4.4 **G3:** 4.3 ± 4.14 **G1/BL:** *P* < 0.05 **G2/BL:** *P* = 0.018 **G3/BL:** *P* = NS **G1/G2/G3:** *P* = 0.013 **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = 0.004
Panerai et al., 2009 (continued)				PEP-R perception score, 3 years, mean ± SD: **G1:** 9.54 ± 3.17 **G2:** 11.31 ± 1.75 **G3:** 8.8 ± 3.85 **G1/BL:** *P* = NS **G2/BL:** *P* = 0.02 **G3/BL:** *P* < 0.05 **G1/G2/G3:** *P* = NS **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = NS **Harms:** NR **Modifiers:** NR
Author: Piravej, et al. 2009 **Country:** Thailand **Practice setting:** Academic medical center **Intervention setting:** Clinic **Enrollment period:** NR **Funding**: Asia Research Centre, Chulalongkorn University	**Intervention:** Thai traditional massage (TTM), 2 sessions/week for 8 weeks (1 hour per session) Sessions utilized Just Right Challenge, The Adaptive Response, Actice Engagement, and Child Directed principles of sensory integration **Assessments:** Conners' Parent Rating Scales (CPRS) at baseline and 8 weeks; Conners' Teacher Rating Scales (CTRS) completed by occupational therapist at baseline and 8 weeks Sleep diary completed by	**Inclusion criteria:** • Autism diagnosis made by psychiatrist based on DSM IV criteria • Age between 3-10 years • Recruited from rehabilitation center of Thai Red Cross Scoeity **Exclusion criteria:** • Contraindications for TTM including hematologic disorders, fractures, arthritis, joint dislocation, fevers, cardiovascular and pulmonary diseases • Inability to complete 80% of the treatment program or receive total of 13 massage sessions • Non-cooperative parents or guardians	**Problem behavior:** CPRS, mean ± SD: Conduct problem: **G1:** 0.69 ± 0.31 **G2:** 0.59 ± 0.34 Impulsivity-hyperactivity: **G1:** 1.62 ± 0.60 **G2:** 1.65 ± 0.65 Hyperactivity: **G1:** 1.45 ± 0.51 **G2:** 1.53 ± 0.48 CTRS, mean ± SD: Conduct problem: **G1:** 0.98 ± 0.38 **G2:** 1.11 ± 0.27 Hyperactivity:	**Problem behavior:** CPRS, mean ± SD: Conduct problem: **G1:** 0.60 ± 0.26 *P* = 0.07 **G2:** 0.63 ± 0.33 *P* = 0.27 Impulsivity-hyperactivity: **G1:** 1.44 ± 0.40 *P* = 0.16 **G2:** 1.69 ± 0.57 Hyperactivity: **G1:** 1.32 ± 0.41 *P* = 0.10 **G2:** 1.42 ± 0.42 *P* = 0.27 CTRS, mean ± SD:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Design: RCT	parents every week **Groups:** **G1:** TTM plus sensory intergration (SI) **G2:** SI only **Provider:** Occupational therapist (SI); masseuse for TTM **Treatment manual followed:** No **Defined protocol followed:** Yes **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies, n (%):** NR **N at enrollment:** **G1:** 30 **G2:** 30	**Age, mean/yrs ± SD:** **G1:** 4.84 ± 1.86 **G2:** 4.48 ± 1.80 **Gender:** **G1, n (%):** M: 25 (83.3) F: 5 (16.7) **G2, n (%):** M: 24 (80) F: 6 (20) **Race/ethnicity:** NR **SES:** NR Maternal education: NR Household income: NR **Diagnostic approach:** Referral Diagnostic tool/method: DSM-IV **Diagnostic category, n (%):** Autism: 60 (100)	**G1:** 1.78 ± 0.46 **G2:** 2.01 ± 0.34 Inattention-passivity: **G1:** 1.56 ± 0.41 **G2:** 1.67 ± 0.27 Hyperactivity index: **G1:** 1.59 ± 0.49 **G2:** 1.80 ± 0.36 **Educational/ cognitive/ academic attainment:** CPRS, mean ± SD: Learning problem: **G1:** 1.86 ± 0.55 **G2:** 2.02 ± 0.56 **Commonly occurring comorbidities:** CPRS, mean ± SD: Psychosomatic: **G1:** 0.41 ± 0.45 **G2:** 0.43 ± 0.34 Anxiety: **G1:** 0.76 ± 0.53 **G2:** 0.62 ± 0.49	Conduct problem: **G1:** 0.64 ± 0.35 *P* = 0.00 **G2:** 0.71 ± 0.26 *P* = 0.00 Hyperactivity: **G1:** 1.24 ± 0.50 *P* = 0.00 **G2:** 1.49 ± 0.37 *P* = 0.00 Inattention-passivity: **G1:** 1.18 ± 0.51 *P* = 0.00 **G2:** 1.34 ± 0.36 *P* = 0.00 Hyperactivity index: **G1:** 1.10 ± 0.49 *P* = 0.00 **G2:** 1.28 ± 0.40 *P* = 0.00 **Educational/ cognitive/ academic attainment:** CPRS, mean ± SD: Learning problem: **G1:** 1.76 ± 0.48 *P* = 0.38 **G2:** 1.87 ± 0.53 *P* = 0.32
Piravej, et al. 2009 (continued)	**N at follow-up:** **G1:** 30 **G2:** 30	**Other characteristics:** Years since diagnosis, mean ± SD: **G1:** 2.95 ± 1.79 G2: 2.62 ± 1.79	Sleep behavior: **G1:** 11.50 ± 9.23 **G2:** 13.90 ± 7.67	**Commonly occurring comorbidities:** CPRS, mean ± SD: Psychosomatic: **G1:** 0.41 ± 0.32 *P* = 0.53 **G2:** 0.39 ± 0.25 *P* = 0.50 Anxiety: **G1:** 0.62 ± 0.56 *P* = 0.04 **G2:** 0.73 ± 0.5 *P* = 0.17 Sleep behavior: **G1:** 5.33 ± 3.28 *P* = 0.00 **G2:** 8.20 ± 6.83 *P* = 0.00

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				Comparison of mean differences b/t groups: CPRS, mean difference ± SD: Conduct problem: **G1:** 0.09 ± 0.27 **G2:** -0.04 ± 0.23 *P* = 0.03 Learning problem: **G1:** 0.10 ± 0.53 **G2:** 0.15 ± 0.65 *P* = 0.75 Psychosomatic: **G1:** -0.01 ± 0.40 **G2:** 0.03 ± 0.27 *P* = 0.23 Impulsivity-hyperactivity: **G1:** 0.17 ± 0.58 **G2:** -0.03 ± 0.79 *P* = 0.38 Anxiety: **G1:** 0.14 ± 0.32 **G2:** -0.11 ± 0.61 *P* = 0.01 Hyperactivity: **G1:** 0.14 ± 0.41 **G2:** 0.11 ± 0.45 *P* = 0.60
Piravej, et al. 2009 (continued)				CTRS, mean difference ± SD: Conduct problem: **G1:** 0.33 ± 0.24 **G2:** 0.39 ± 0.22 *P* = 0.21 Hyperactivity: **G1:** 0.54 ± 0.35 **G2:** 0.52 ± 0.34 *P* = 0.80 Inattention-passivity: **G1:** 0.38 ± 0.22 **G2:** 0.32 ± 0.22 P = 0.28 Hyperactivity index: **G1:** 0.49 ± 0.26 **G2:** 0.52 ± 0.29 *P* = 0.74

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				Sleep behavior: **G1:** 6.17 ± 7.14 **G2:** 5.70 ± 8.56 *P* = 0.85 **Harms** NR **Modifiers** NR
Author: Quirmbach et al., 2009 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Two social stories training sessions one week apart. Baseline and four other trials were completed each day. The last trial was a generalization trial, where games were switched. **Assessments:** Observation/direct assessment (ADOS, WISC-IV, PIAT-R); observation (turn-taking games 5 times per day in play room): total game playing skill score 0-8, 2 points per skill (greeting behaviors, requesting to play a game, asking another person what they want to play, accepting another's choice of game) **Groups:** **G1:** social story, standard condition (both training days) **G2:** social story, directive condition (both training days) **G3:** control story condition unrelated to social skills (control story first day, randomly assigned to either standard or directive story on the second day) **G1a:** G1 with VCI > 68 **G2a:** G2 with VCI > 68 **G3a:** G3 with VCI > 68 **G3s:** G3a with standard second day **G3d:** G3a with directive second day **Provider:**	**Inclusion criteria:** • ASD diagnosis **Exclusion criteria:** • Insufficient reading skills (less than first grade level on PIAT-R) **Age, yrs ± SD (range):** **G1:** 9.49 ± 2.09 (7-12) **G2:** 10.33 ± 2.53 (7-14) **G3:** 8.85 ± 1.59 (7-12) **G1a:** 9.49 ± 2.04 (7-12) **G2a:** 9.72 ± 2.61 (7-14) **G3a:** 8.79 ± 1.38 (7-11) **Mental age:** See IQ under baseline **Gender, n (%):** Male: **G1:** 14 (93) **G2:** 14 (93) **G3:** 14 (93) Female: **G1:** 1 (7) **G2:** 1 (7) **G3:** 1 (7) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** NR **Diagnostic tool/method:** ADOS **Diagnostic category, n (%):** Autism: 42 (93) ASD: 3 (7) **Other characteristics:** NR	**Overall ratings:** ADOS score, mean ± SD: **G1:** 15.00 ± 4.99 **G2:** 14.40 ± 3.81 **G3:** 15.60 ± 4.87 **G1a:** 11.90 ± 2.42 **G2a:** 12.60 ± 3.20 **G3a:** 13.20 ± 2.94 **Educational/cog-nitive/academic attainment:** WISC-IV score, mean ± SD: FSIQ: **G1:** 86.20 ± 22.80 **G2:** 81.00 ± 20.26 **G3:** 79.47 ± 22.68 **G1a:** 98.80 ± 16.25 **G2a:** 91.70 ± 14.87 **G3a:** 91.50 ± 16.47 VCI: **G1:** 82.07 ± 28.04 **G2:** 79.33 ± 24.85 **G3:** 78.80 ± 27.86 **G1a:** 98.70 ± 17.32 **G2a:** 93.50 ± 16.34 **G3a:** 95.10 ± 17.92 PRI: **G1:** 99.47 ± 13.83 **G2:** 95.20 ± 13.18 **G3:** 90.67 ± 18.89 **G1a:** 103.20 ± 14.64 **G2a:** 100.90 ± 8.49 **G3a:** 97.80 ± 17.12 PIAT-R score, mean ± SD: Reading recognition: **G1:** 4.09 ± 3.55 **G2:** 3.66 ± 3.00 **G3:** 2.49 ± 1.41 **G1a:** 5.36 ± 3.76 **G2a:** 4.29 ± 3.51 **G3a:** 2.96 ± 1.51 Reading comprehension:	**Social skills:** Total game playing skills score, mean ± SD: Day 1, trial 2: **G1:** 4.53 ± 3.48 **G2:** 3.73 ± 2.96 **G3:** NR **G1a:** 6.30 ± 2.83 **G2a:** 5.10 ± 2.60 **G3a:** NR **G3s:** 2.40 ± 1.14 **G3d:** 2.40 ± 1.14 Day 1, trial 3: **G1:** 4.53 ± 3.25 **G2:** 4.87 ± 2.90 **G3:** NR **G1a:** 6.40 ± 2.07 **G2a:** 6.30 ± 2.45 **G3a:** NR **G3s:** 2.80 ± 1.30 **G3d:** 2.20 ± 0.84 Day 1, trial 4: **G1:** 4.07 ± 3.17 **G2:** 5.07 ± 2.84 **G3:** NR **G1a:** 5.90 ±2.03 **G2a:** 6.40 ± 2.27 **G3a:** NR **G3s:** 2.40 ± 1.67 **G3d:** 2.20 ± 0.84 ANOVA (only trials 1-4): **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 Improvement across trials: *P* < 0.001 **G1a/G3a:** *P* < 0.001 **G2a/G3a:** *P* < 0.001 Improvement across trials: *P* < 0.001

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	Research assistant **Treatment manual followed:** NR **Defined protocol followed:** NR		**G1:** 3.82 ± 3.72 **G2:** 3.81 ± 3.72 **G3:** 2.85 ± 2.50 **G1a:** 5.00 ± 4.10 **G2a:** 4.68 ± 4.35 **G3a:** 3.66 ± 2.74	
Quirmbach et al., 2009 (continued)	**Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 15 **G2:** 15 **G3:** 15 **G1a:** 10 **G2a:** 10 **G3a:** 10 **G3s:** 5 **G3d:** 5		Total game playing skills score, trial 1, mean ± SD: **G1:** 1.87 ± 1.30 **G2:** 2.40 ± 1.18 **G3:** NR **G1a:** 2.50 ± 0.97 **G2a:** 2.90 ± 0.88 **G3a:** NR **G3s:** 2.80 ± 0.84 **G3d:** 2.40 ± 0.89	Day 1, trial 5 (generalization): **G1:** 3.67 ± 2.82 **G2:** 4.33 ± 2.66 **G3:** NR **G1a:** 5.30 ± 1.77 **G2a:** 5.70 ± 2.06 **G3a:** NR **G3s:** 2.20 ± 1.48 **G3d:** 2.40 ± 1.14 Day 2, trial 6: **G1:** 4.53 ± 3.27 **G2:** 3.93 ± 1.94 **G3:** NR **G1a:** 6.50 ± 1.84 **G2a:** 4.70 ± 1.95 **G3a:** NR **G3s:** 3.00 ± 0.71 **G3d:** 3.00 ± 1.00 Day 2, trial 7: **G1:** 5.20 ± 3.28 **G2:** 4.93 ± 3.13 **G3:** NR **G1a:** 7.20 ± 1.69 **G2a:** 6.40 ± 2.63 **G3a:** NR **G3s:** 4.80 ± 3.03 **G3d:** 5.60 ± 1.82 Day 2, trial 8: **G1:** 5.07 ± 3.31 **G2:** 4.93 ± 2.99 **G3:** NR **G1a:** 7.10 ± 1.66 **G2a:** 5.90 ± 2.64 **G3a:** NR **G3s:** 6.40 ± 2.19 **G3d:** 4.80 ± 2.17 Day 2, trial 9: **G1:** 5.07 ± 3.17 **G2:** 5.80 ± 2.57 **G3:** NR **G1a:** 7.00 ± 1.70 **G2a:** 6.40 ± 1.78 **G3a:** NR **G3s:** 6.40 ± 2.19 **G3d:** 4.60 ± 2.30
Quirmbach et al., 2009 (continued)				Day 2, trial 10 (generalization): **G1:** 4.80 ± 3.36 **G2:** 5.20 ± 2.73

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G3: NR **G1a:** 6.80 ± 1.93 **G2a:** 6.50 ± 2.27 **G3a:** NR **G3s:** 5.40 ± 1.95 **G3d:** 6.60 ± 1.67 ANOVA (only groups G1 & G2, trials 1-10): **G1/G2:** *P* = NS Improvement across trials: *P* < 0.001 **Harms:** NR **Modifiers:** Condition-trial interaction (G1 and G2 improve across trials 1-4, G3 no improvement): *P* < 0.001 Condition-trial interaction (G1a and G2a improve across trials 1-4, G3a no improvement): *P* < 0.001 WISC-IV VCI: *P* < 0.001
Author: Reaven et al., 2009 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Organization for Autism Research; Doug Flutie Foundation; US DHHS Administration on Developmental Disabilities **Author industry relationship disclosures:** NR	**Intervention:** 12 weekly 1.5 hour CBT sessions targeting anxiety reduction, including large group time, separate parent and child group meetings, and parent-child dyads **Assessment:** Two to three 2 hour assessment sessions; diagnostic and developmental batteries (ADOS, SCQ, WASI, K-SADS-PL, SCARED) administered by research team (clinical psychologist with extensive experience in autism, graduate student, postdoctoral fellow) **Groups:** **G1:** active treatment **G2:** waitlist control **Provider:** Clinicians, parents **Measure of treatment fidelity reported:**	**Inclusion criteria:** • Aged 7-14 years • Diagnosis on the autism spectrum as verified by exceeding the criteria on module III of the ADOS, exceeding the cutoff on the Social Communication Questionnaire, and receiving a current clinical diagnosis of ASD by a licensed clinical psychologist with extensive experience with children with autism • Overall IQ ≥ 70 • Verbally fluent as evidenced by participation in Module III of the ADOS • Significant anxiety symptoms (parent report of clinically significant symptoms of a social phobia, separation anxiety, or generalized anxiety on the Kiddie-	**Commonly occurring comorbidities:** SCARED score, parent report, mean ± SD (range): Total: **G1:** 32.70 ± 12.21 (20-54) **G2:** 29.35 ± 10.69 (7-51) Panic symptoms: **G1:** 4.40 ± 4.2 (0-15) **G2:** 4.91 ± 4.55 (1-18) Generalized anxiety: **G1:** 9.94 ± 2.61 (5-13) **G2:** 9.84 ± 3.82 (3-16) Separation anxiety: **G1:** 4.92 ± 3.87 (1-13) **G2:** 5.13 ± 4.39 (0-16) Social anxiety:	**Commonly occurring comorbidities:** SCARED, parent report, mean ± SD (range) Total: **G1:** 19.53 ± 8.82 (9-38) **G2:** 27.33 ± 8.85 (9-52) ANOVA: time (*P* = 0.01), treatment X time interaction (*P* = 0.01) Panic symptoms: **G1:** 2.34 ± 2.54 (0-7) **G2:** 5.76 ± 4.44 (1-19) Generalized anxiety **G1:** 6.20 ± 2.86 (2-12) **G2:** 9.14 ± 3.16 (2-17) Separation

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Design: Non-randomized controlled trial	Yes **Co-interventions held stable during treatment:** No* **Concomitant therapies, n (%):** Anti-anxiety or antidepressant medications: **G1:** 5 (50) **G2:** 9 (39.1) Other psychotropic medications: **G1:** 4 (40) **G2:** 13 (56.5) Vitamins and supplements: **G1:** 6 (60) **G2:** 20 (87) Restricted diet: **G1:** 2 (20) **G2:** 8 (34)	Schedule for Affective Disorders and Schizo-phrenia; or exceeding the subscale cutoffs on the SCARED) **Exclusion criteria:** • Children with primary symptoms of obsessive-compulsive disorder • Receiving group or individual therapy focused on anxiety reduction **Age, months ± SD (range):** 132.20 ± 22.80 (97-177) **Mental age:** FSIQ, months ± SD (range): 102.46 ± 16.22 (65-141) Verbal IQ, months ± SD (range): 101.76 ± 19.51 (65-141) Nonverbal IQ, months ± SD (range): 101.76 ± 15.07 (75-144)	**G1:** 9.40 ± 3.12 (5-14) **G2:** 6.82 ± 5.32 (0-14) School anxiety: **G1:** 1.80 ± 2.09 (0-7) **G2:** 2.43 ± 1.94 (0-7) SCARED, child report, mean ± SD (range): Total: **G1:** 25.67 ± 9.84 (4-34) **G2:** 26.09 ± 11.99 (3-48) Panic symptoms: **G1:** 4.67 ± 4.72 (1-15) **G2:** 6.04 ± 3.67 (0-15)	anxiety: **G1:** 2.60 ± 2.63 (0-8) **G2:** 4.60 ± 2.81 (0-11) Social anxiety: **G1:** 6.80 ± 2.25 (4-12) **G2:** 6.57 ± 3.47 (0-14) School anxiety: **G1:** 1.5 ± 1.95 (0-3) **G2:** 1.27 ± 1.16 (0-3)
Reaven et al., 2009 (continued)	Number of prescribed medications, n (%): None: 11 (33.3) One: 9 (27.3) Two: 6 (18.2) Three: 2 (6.1) Four: 0 Five: 5 (15.2) Medications, n (detail): Anti-anxiety medication PRN: 2 (1 clonipin; 1 busparone) SSRI: 14 (3 fluvoxamine; 3 fluoxetine; 4 sertraline; 2 paroxetine; 2 citalopram) Trazedone: 3 Mood stability: 4 (1 lithium; 2 depakote; 1 trileptal) Second generation antipsychotics: 6 (3 risperidone; 2 seroquel; 1 abilify) Attention deficit medication: 15 (9 Concerta; 5 Adderall; 1 Tenex) Multivitamins and general nutritional supplements: 21	**Gender, n (%):** Male: **G1:** 7 (70) **G2:** 19 (82.6) Female: **G1:** 3 (30) **G2:** 4 (17.4) **Race/ethnicity, n (%):** White: **G1:** 8 (80) **G2:** 19 (82.6) African American: **G1:** 1 (10) **G2:** 1 (4.3) Hispanic: **G1:** 1 (10) **G2:** 1 (4.3) Other: **G1:** 0 **G2:** 2 (8.6) **SES:** Maternal education, n (%): High school: **G1:** 0 **G2:** 2 (8.7) Some college: **G1:** 3 (30) **G2:** 6 (26.1) College graduate: **G1:** 4 (40) **G2:** 8 (34.8)	Generalized anxiety: **G1:** 5.33 ± 4.15 (0-14) **G2:** 6.23 ± 3.89 (0-14) Separation anxiety: **G1:** 4 ± 3.87 (0-11) **G2:** 6.09 ± 3.09 (0-13) Social anxiety: **G1:** 6.89 ± 3.44 (2-13) **G2:** 7.23 ± 4.25 (1-14) School anxiety: **G1:** 2.44 ± 1.87 (0-5) **G2:** 2.05 ± 1.60 (0-6) Percentage of children in both groups obtaining SCARED scores within the clinically significant range:** Panic: Parent report: 27.3 Child report: 38.7 Generalized: Parent report: 69.7 Child report: 19.4	SCARED, child report, mean ± SD (range): Total: **G1:** 20.50 ± 12.69 (1-31) **G2:** 24.85 ± 16.34 (4-64) ANOVA: time (*P* = 0.67), treatment X time interaction (*P* = 0.99) Panic symptoms: **G1:** 3.33 ± 3.07 (0-8) **G2:** 5.60 ± 5.94 (0-21) Generalized anxiety: **G1:** 4.33 ± 2.50 (0-7) **G2:** 6.45 ± 6.14 (0-16) Separation anxiety: **G1:** 2.83 ± 2.40 (0-6) **G2:** 5.90 ± 5.14 (0-21) Social anxiety: **G1:** 6.33 ± 3.72

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	Omega-3 supplements: 8 **N at enrollment:** **G1:** 10 **G2:** 23 **N at follow-up:** **G1:** 10 **G2:** 21	Postcollege: **G1:** 3 (30) **G2:** 6 (26.1) Missing: **G1:** 0 **G2:** 1 (4.3) Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** See inclusion criteria **Diagnostic category, n (%):** Autism: **G1:** 3 (30) **G2:** 12 (52.2) PDD-NOS: **G1:** 2 (20) **G2:** 2 (8.7) Aspergers: **G1:** 5 (50) **G2:** 9 (39.1)	Separation: Parent report: 54.5 Child report: 51.6 Social: Parent report: 51.5 Child report: 45.2 School: Parent report: 33.3 Child report: 41.9 Total anxiety symptoms: Parent report: 66.7 Child report: 51.6	(0-10) **G2:** 6.50 ± 4.53 (0-14) School anxiety: **G1:** 2.83 ± 2.10 (1-6) **G2:** 0.91 ± 0.03 (0-2) Percentage of children in both groups obtaining SCARED scores within the clinically significant range:** Panic: Parent report: 16 Child report: 17.6 Generalized: Parent report: 8 Child report: 17.6
Reaven et al., 2009 (continued)		**Other characteristics, n (%):** Primary anxiety diagnosis: Generalized anxiety: **G1:** 7 (70) **G2:** 15 (65.2) Separation anxiety: **G1:** 2 (20) **G2:** 4 (17.3) Social anxiety: **G1:** 1 (10) **G2:** 4 (17.4) **Food allergies and restricted diet:** 10 (31.2)		Separation: Parent report: 24 Child report: 29.4 Social: Parent report: 32 Child report: 47.1 School: Parent report: 16 Child report: 17.6 Total anxiety symptoms: Parent report: 28 Child report: 41.2 **Harms:** NR **Modifiers:** NR

**Comments: ***1 child in G1 was placed on a different mood stabilizer and 2 children in G2 received higher doses of medicine for attentional difficulties; data on changes in therapy not available for 13 participants.
**Chi-square analyses for the entire sample on pretreatment and post-treatment assessments indicated significant differences in clinical classification for parent report (P = 0.03), but not for child report (P = 0.48).

Author: Reed et al., 2009 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR	**Intervention:** Parent-based sleep education workshops, each workshop consisted of 3 sessions conducted over 3 consecutive weeks, with each session lasting 2 hours **Assessments:** Children's Sleep Habits Questionnaire, Family Inventory of Sleep Habits, Parental Concerns	**Inclusion criteria:** • Families with children between the ages of 3 and 10 years • Child with clinical diagnosis of ASD • Families expressed that sleep was a concern **Exclusion criteria:** • Primary sleep disorders (e.g., sleep apnea, narcolepsy)	**Social skills:** PCQ social interactions score, mean ± SD: **G1:** 2.80 ± 0.95 **Communication/ language:** PCQ language use/ understanding score, mean ± SD: **G1:** 3.00 ± 1.12 **Repetitive behavior:**	**Social skills:** PCQ social interactions score, mean ± SD: **G1:** 2.55 ± 0.89 **G1/BL:** P = NS **Communication/ language:** PCQ language use/understanding score, mean ± SD: **G1:** 2.85 ± 1.04

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Funding: NR **Author industry relationship disclosures:** None **Design:** Case series, prospective	Questionnaire (PCQ), PSI-SF, RBS, sleep diaries completed by parents at baseline and again approximately 1 month after final session of workshop; actigraphy was downloaded at conclusion of each baseline and post-treatment week **Groups:** **G1:** sleep education workshop **G1a:** children who took more than 20 minutes to fall asleep on baseline actigraphy readings **G1b:** children with night wakings on actigraphy readings **Provider:** Neurology sleep specialist and a pediatrician with expertise in ASD with assistance from a nurse educator and educational consultant **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** Taking psychotropic medications, n: 6 **N at enrollment:** **G1:** 25	• Neurological or medical conditions that may contribute to disordered sleep (e.g., epileptic seizures) **Age, years ± SD:** 5.8 ± 2.7 **Mental age:** **PPVT receptive language score, mean ± SD:** 74.6 ± 25 **Gender, n (%):** Male: 16 (80) Female: 4 (20) **Race/ethnicity, n:** White: 15 African-American: 4 Asian: 1 **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In study **Diagnostic tool/method:** ADOS **Diagnostic category, n:** Autism: 15 ASD: 5 **Other characteristics:** Reported sleep concerns, %: Difficulty falling asleep: 75 Night waking: 60 Early morning awakenings: 35 Cosleeping with parents: 35	RBS restricted behavior score, mean ± SD: **G1:** 5.11 ± 3.6 PCQ score, mean ± SD: Compulsive behavior: **G1:** 2.20 ± 0.89 Self-stimulatory behavior: **G1:** 2.47 ± 1.17 Self-injurious behavior: **G1:** 1.60 ± 0.88 **Problem behavior:** Children's Sleep Habits Question-naire, bedtime resistance score, mean ± SD: **G1:** 10.50 ± 3.65 PCQ score, mean ± SD: Aggression: **G1:** 2.15 ± 1.04 Hyperactivity: **G1:** 3.15 ± 1.04 Mood swings: **G1:** 2.10 ± 1.02 **Adaptive behavior:** Family Inventory of Sleep Habits score, mean ± SD: Exercise during the day: **G1:** 4.25 ± 0.85	**G1/BL:** *P* = NS **Repetitive behavior:** RBS restricted behavior score, mean ± SD:* **G1:** 3.89 ± 3.1 **G1/BL:** *P* = 0.007 PCQ score, mean ± SD: Compulsive behavior: **G1:** 1.80 ± 0.83 **G1/BL:** *P* = NS Self-stimulatory behavior: **G1:** 2.05 ± 0.91 **G1/BL:** *P* = 0.021 Self-injurious behavior: **G1:** 1.45 ± 0.69 **G1/BL:** *P* = NS **Problem behavior:** Children's Sleep Habits Question-naire, bedtime resistance score, mean ± SD: **G1:** 8.45 ± 2.84 **G1/BL:** *P* = 0.001 PCQ score, mean ± SD: Aggression: **G1:** 1.95 ± 0.94 **G1/BL:** *P* = NS Hyperactivity: **G1:** 2.60 ± 0.99 **G1/BL:** *P* = NS
Reed et al., 2009 (continued)	**N at follow-up:** **G1:** 20	Sleep problems present since birth: 50 Sleep problems occurring around the time of the autism diagnosis: 50	Wakes up about same time each day: **G1:** 3.70 ± 0.86 Relaxing activities before bed: **G1:** 2.95 ± 1.19 Goes to bed at same time each night: **G1:** 3.94 ± 1.16 Follow regular bedtime routine: **G1:** 3.39 ± 1.24 PCQ attention span score, mean ± SD: **G1:** 2.90 ± 0.79 **Commonly**	Mood swings: **G1:** 1.85 ± 0.93 **Adaptive behavior:** Family Inventory of Sleep Habits score, mean ± SD: Exercise during the day: **G1:** 4.50 ± 0.69 **G1/BL:** *P* = NS Wakes up about same time each day: **G1:** 4.05 ± 0.22 **G1/BL:** *P* = NS Relaxing activities

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
			occurring co-morbidities: Children's Sleep Habits Question-naire score, mean ± SD: Sleep onset delay: **G1:** 2.30 ± 0.80 Sleep duration: **G1:** 6.53 ± 2.22 Sleep anxiety: **G1:** 7.00 ± 2.27 Night wakings: **G1:** 5.55 ± 1.90 Daytime sleepiness: **G1:** 13.95 ± 4.32 Modified total: **G1:** 28.63 ± 6.15 Total score: **G1:** 56.63 ± 9.21 Family Inventory of Sleep Habits score, mean ± SD: Napping during the day: **G1:** 1.95 ± 1.00 Bedroom used for "time out" during day: **G1:** 1.15 ± 0.37	before bed: **G1:** 4.05 ± 0.60 **G1/BL:** *P* = 0.001 Goes to bed at same time each night: **G1:** 4.06 ± 0.87 **G1/BL:** *P* = NS Follow regular bedtime routine**:** **G1:** 4.17 ± 0.79 **G1/BL:** *P* = 0.022 PCQ attention span score, mean ± SD: **G1:** 2.95 ± 0.76 **G1/BL:** *P* = NS **Commonly occurring co-morbidities:** Children's Sleep Habits Question-naire score, mean ± SD: Sleep onset delay: **G1:** 1.50 ± 0.61 **G1/BL:** *P* = 0.004 Sleep duration: **G1:** 4.79 ± 2.07 **G1/BL:** *P* = 0.003 Sleep anxiety: **G1:** 5.85 ± 1.73 **G1/BL:** *P* = 0.022
Reed et al., 2009 (continued)			Bedroom used as play area during the day: **G1:** 3.05 ± 1.23 Caffeine after 5pm: **G1:** 1.70 ± 0.86 Stimulating activities before bed: **G1:** 2.60 ± 1.05 Sleeps better with certain sleepwear: **G1:** 2.22 ± 1.44 Sleeps better with certain sheets: **G1:** 2.37 ± 1.38 Sleeps better when room certain temperature: **G1:** 2.44 ± 1.15 Room is dark or dimly lit at bedtime: **G1:** 4.61 ± 1.04 Room is quiet at	Night wakings: **G1:** 4.85 ± 1.79 **G1/BL:** *P* = NS Daytime sleepiness: **G1:** 13.25 ± 3.43 **G1/BL:** *P* = NS Modified total: **G1:** 22.84 ± 5.43 **G1/BL:** *P* = 0.000 Total score: **G1:** 49.74 ± 9.24 **G1/BL:** *P* = 0.004 Reported fewer nights of cosleeping, n: 5/7 Reported fewer early morning wakings, n: 1/3 Family Inventory of Sleep Habits score, mean ± SD:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
			bedtime: **G1:** 4.17 ± 1.15 Has favorite comfort object for sleep: **G1:** 2.94 ± 1.86 Parent stays in child's room until sleep: **G1:** 2.56 ± 1.65 Parent checks on child before he or she falls asleep: **G1:** 3.11 ± 1.60 Child watches TV, videos, or DVDs to fall asleep: **G1:** 2.28 ± 1.36 Child listens to music to fall asleep: **G1:** 2.61 ± 1.46 Parent keeps interactions brief if child awakens: **G1:** 4.00 ± 1.29	Napping during the day: **G1:** 1.85 ± 0.99 **G1/BL:** *P* = NS Bedroom used for "time out" during day: **G1:** 1.15 ± 0.37 **G1/BL:** *P* = NS Bedroom used as play area during the day: **G1:** 2.60 ± 1.19 **G1/BL:** *P* = NS Caffeine after 5pm: **G1:** 1.50 ± 0.51 **G1/BL:** *P* = NS Stimulating activities before bed: **G1:** 1.80 ± 0.95 **G1/BL:** *P* = 0.001 Sleeps better with certain sleepwear: **G1:** 2.11 ± 1.23 **G1/BL:** *P* = NS
Reed et al., 2009 (continued)			Parent returns child to bed if child awakens: **G1:** 2.82 ± 1.33 Children who took more than 20 minutes to fall asleep on actigraphy readings, n: 9/12 Average time to fall asleep, minutes ± SD: **G1a:** 62.2 ± 33.3 Problems with night wakings, n: 5/12 Wake time after sleep onset, minutes ± SD: **G1b:** 5, 24.5 ± 9.8 Time in bed, minutes ± SD: **G1:** 575.21 ± 53.5 (n=12) PCQ score, mean ± SD: Anxiety: **G1:** 2.30 ± 0.98 Sleep disturbance:	Sleeps better with certain sheets: **G1:** 2.47 ± 1.47 **G1/BL:** *P* = NS Sleeps better when room certain temperature: **G1:** 2.50 ± 1.34 **G1/BL:** *P* = NS Room is dark or dimly lit at bedtime: **G1:** 4.78 ± 0.43 **G1/BL:** *P* = NS Room is quiet at bedtime: **G1:** 4.56 ± 0.51 **G1/BL:** *P* = NS Has favorite comfort object for sleep: **G1:** 2.83 ± 1.62 **G1/BL:** *P* = NS Parent stays in child's room until sleep: **G1:** 1.94 ± 1.30 **G1/BL:** *P* = NS Parent checks on

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
			G1: 3.40 ± 0.94 Eating habits: **G1:** 3.00 ± 1.12 PSI-SF score, mean ± SD: Total: **G1:** 96.10 ± 23.40 Parental distress: **G1:** 32.05 ± 11.08 Parent-child interaction: **G1:** 25.90 ± 6.70 Difficult child: **G1:** 38.15 ± 8.80 Ease in establishing sleeping/eating schedule: **G1:** 4.05 ± 1.03	child before he or she falls asleep: **G1:** 2.72 ± 1.32 **G1/BL:** *P* = NS Child watches TV, videos, or DVDs to fall asleep: **G1:** 1.50 ± 1.04 **G1/BL:** *P* = 0.004 Child listens to music to fall asleep: **G1:** 2.17 ± 1.34 **G1/BL:** *P* = NS Parent keeps interactions brief if child awakens: **G1:** 4.46 ± 1.13 **G1/BL:** *P* = NS
Reed et al., 2009 (continued)			**Medical:** Children's Sleep Habits Questionnaire score, mean ± SD: Parasomnias: **G1:** 10.50 ± 2.24 Sleep-disordered breathing: **G1:** 3.42 ± 0.84 **Sensory:** PCQ sensory issues score, mean ± SD: **G1:** 2.85 ± 0.99	Parent returns child to bed if child awakens: **G1:** 4.36 ± 0.67 **G1/BL:** *P* = NS Average time to fall asleep, minutes ± SD: **G1a:** 45.6 ± 27.6 **G1/BL:** *P* = 0.039 Problems with reported improvement in night wakings, n: Actigraphy and parent report: 2/5 Parent report only: 1/5 Wake time after sleep onset, minutes ± SD: **G1b:** 32.2 ± 24.7 Time in bed, minutes ± SD: **G1:** 541.91 ± 36.2 (n=12) **G1/BL:** *P* = 0.039 PCQ score, mean ± SD: Anxiety: **G1:** 2.05 ± 0.94 **G1/BL:** *P* = NS Sleep disturbance: **G1:** 2.20 ± 1.01 **G1/BL:** *P* = 0.000 Eating habits: **G1:** 2.70 ± 1.26

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G1/BL: P = NS PSI-SF score, mean ± SD: Total: **G1:** 94.00 ± 23.00 **G1/BL:** P = NS Parental distress: **G1:** 31.10 ± 10.58 **G1/BL:** P = NS Parent-child interaction: **G1:** 26.50 ± 8.58 **G1/BL:** P = NS
Reed et al., 2009 (continued)				Difficult child: **G1:** 36.40 ± 7.79 **G1/BL:** P = NS Ease in establishing sleeping/eating schedule: **G1:** 3.32 ± 1.33 **G1/BL:** P = 0.021 End of workshop parent survey, n (%): Presenters competent and knowledgeable, 18/18 (100) Would recom-mend workshop: 18/18 (100) Believed child's sleep habits improved: 14/18 (77) Conveying of information relevant and useful: 17/18 (94) Total duration of workshop suf-ficient: 10/18 (58) **Medical:** Children's Sleep Habits Question-naire score, mean ± SD: Parasomnias: **G1:** 10.05 ± 2.37 **G1/BL:** P = NS Sleep-disordered breathing: **G1:** 3.32 ± 0.75 **G1/BL:** P = NS **Sensory:** PCQ sensory

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				issues score, mean ± SD: **G1:** 2.70 ± 0.73 **G1/BL:** *P* = NS **Harms:** NR
Reed et al., 2009 (continued)				**Modifiers:** The PPVT receptive language score did not correlate significantly with either the total or modified total Children's Sleep Habits Questionnaire score

Comments: *The authors reported no improvement on other subscales of the RBS.

Author: Rossignol et al., 2009 **Country:** US **Practice setting:** Specialty **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** International Hyperbarics Association **Author industry relationship disclosures:** 8 of 11 Clinicians deriving revenue from hyperbaric treatment (8) International Hyperbaric Association (3) OxyHealth (1) **Design:** Prospective RCT (Double-blind, Rx in parallel groups)	**Intervention:** 40 sessions of 1 hour-long hyperbaric treatments at 1.3 atm and 24% oxygen Controls received 40 hour-long treatments in slightly pressurized air (1.03 atm) and 21% oxygen **Groups:** **G1:** hyperbaric treatment **G2:** control **Assessments:** ABC, ATEC, CGI **Co-interventions held stable during treatment:** Yes **Frequency of contact during study:** 40 sessions for each group: twice a day, 5 days/week for 4 consecutive weeks **Concomitant therapies, n (%):** Nutritional supplements, medications: **G1:** 23/33 **G2:** 20/29 ABA therapy: **G1:** 15/33 **G2:** 11/29 Medications: **G1:** 16/33 **G2:** 10/29 **G1/G2:** *P* = NS Children not allowed to	**Inclusion criteria:** • Autistic disorder • Ages 2-7 years • No previous hyperbaric treatment **Exclusion criteria:** • Aspergers, PDD-NOS • Seizure disorder, current ear infection, uncontrolled asthma, inability to equalize ear pressure, fragile X, ongoing chelation treatment **Age, yrs ± SD (range):** Total: 4.92 ± 1.21 (2-7) **G1:** 4.97 ± 1.29 (NR) **G2:** 4.86 ± 1.13 (NR) **Mental age, mean/yrs (range):** NR **Gender, n (%):** Male: **G1:** 30 (90.9) **G2:** 22 (75.9) Female: **G1:** 3 (9.1) **G2:** 7 (24.1) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral diagnosis of autistic disorder **Diagnostic tool/method:** ADOS and ADI-R, plus	**Overall ratings:** ABC total score, mean ± SD: **G1:** 55.2 ± 28.7 **G2:** 53.3 ± 24.0 ATEC total score, mean ± SD: **G1:** 75.3 ± 19.5 **G2:** 75.6 ± 21.0 **Social skills:** ABC social withdrawal score, mean ± SD: **G1:** 10.5 ± 6.9 **G2:** 11.2 ± 6.9 ATEC sociability score, mean ± SD: **G1:** 17.4 ± 6.6 **G2:** 17.8 ± 6.2 **Communication/ language:** ABC speech score, mean ± SD: **G1:** 3.4 ± 3.1 **G2:** 3.6 ± 3.6 ATEC speech/ language/communication score, mean ± SD: **G1:** 16.3 ± 5.0 **G2:** 15.9 ± 6.1 **Repetitive behavior:** ABC stereotypy score, mean ± SD: **G1:** 7.5 ± 4.9 **G2:** 6.2 ± 4.7 **Problem behavior:**	**Overall ratings:** CGI score, clinician-rated, mean ± SD: **G1:** 2.87 ± 0.78 **G2:** 3.62 ± 0.75 **G1/BL:** *P* = 0.0008 **G2/BL:** *P* = NS CGI score, clinician-rated, n (%): 1 or 2: **G1:** 9/30 (30) **G2:** 2/26 (7.7) (*P* = 0.0471) 1/2/3: **G1:** 24/30 (80) **G2:** 10/26 (38) (*P* = 0.0024) 4/5: **G1:** 6/30 (20) **G2:** 16/26 (62) (*P* = 0.0024) 5: **G1:** 0 **G2:** 2/26 (7.7) **G1/G2:** *P* = 0.211 Significant improvement in G1 compared to G2 in CGI subscales, Receptive language (*P* <

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	begin new or terminate ongoing therapies during the study **N at enrollment:** **G1:** 33 **G2:** 29 **N at follow-up:** **G1:** 29 **G2:** 26	DSM-IV criteria **Diagnostic category, n (%):** Autism: 62 (100) PDD-NOS: 0 Aspergers: 0 **Other characteristics:** NR	ABC irritability score, mean ± SD: **G1:** 13.2 ± 9.5 **G2:** 12.2 ± 7.9 ABC hyperactivity score, mean ± SD: **G1:** 20.7 ± 9.9 **G2:** 20.1 ± 8.2	0.0001), social interaction (*P* = 0.0473), eye contact (*P* = 0.01) & activity level (*P* = 0.05). CGI score, parent-rated, mean ± SD: **G1:** 2.7 ± .81 **G2:** 3.17 ± .73 **G1/BL:** *P* = 0.0336 **G2/BL:** *P* = NS
Rossignol et al., 2009 (continued)			**Sensory:** ATEC sensory/ cognitive awareness score, mean ± SD: **G1:** 18.1 ± 5.2 **G2:** 19.6 ± 5.6 **Medical:** ATEC health/ physical/behavioral score, mean ± SD: **G1:** 23.5 ± 11.5 **G2:** 22.4 ± 8.3	CGI score, parent-rated, n (%): 1, 2 or 3: **G1:** 27/30 (90) **G2:** 19/26 (73) **G1/G2:** *P* = NS More children improved in G1 compared to G2 in parent- rated CGI receptive language (*P* = 0.02) and eye contact (*P* = 0.03) ABC total score, mean ± SD: **G1:** 46.4 ± 24.7 **G2:** 45.5 ± 17.3 **G1/G2:** *P* = NS **G1/BL:** *P* = 0.01 **G2/BL:** *P* = NS ATEC total score, mean ± SD: **G1:** 65.9 ± 16.4 **G2:** 70.1 ± 21.9 **G1/G2:** *P* = NS **G1/BL:** *P* = 0.002 **G2/BL:** *P* = 0.04 **Social skills:** ABC social withdrawal score, mean ± SD: **G1:** 9.3 ± 6.7 **G2:** 8.9 ± 5.6 **G1/G2:** *P* = NS **G1/BL:** *P* = NS **G2/BL:** *P* = NS ATEC sociability score, mean ± SD:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G1: 14.5 ± 6.5 **G2:** 16.0 ± 6.8 **G1/G2:** *P* = NS **G1/BL:** *P* = 0.0009 **G2/BL:** *P* = 0.01
Rossignol et al., 2009 (continued)				**Communication/ language:** ABC speech score, mean ± SD: **G1:** 2.6 ± 2.5 **G2:** 3.3 ± 3.2 **G1/G2:** *P* = NS **G1/BL:** *P* = 0.02 **G2/BL:** *P* = NS ATEC speech/ language/communication score, mean ± SD: **G1:** 15.5 ± 5.1 **G2:** 15.4 ± 6.6 **G1/G2:** *P* = NS **G1/BL:** *P* = NS **G2/BL:** *P* = NS **Repetitive behavior:** ABC stereotypy score, mean ± SD: **G1:** 6.2 ± 5.1 **G2:** 5.4 ± 4.0 **G1/G2:** *P* = NS **G1/BL:** *P* = 0.01 **G2/BL:** *P* = NS **Problem behavior:** ABC irritability score, mean ± SD: **G1:** 10.5 ± 7.4 **G2:** 11.3 ± 6.4 **G1/G2:** *P* = NS **G1/BL:** *P* = 0.01 **G2/BL:** *P* = NS ABC hyperactivity score, mean ± SD: **G1:** 17.8 ± 9.2 **G2:** 16.8 ± 7.7 **G1/G2:** *P* = NS **G1/BL:** *P* = 0.02 **G2/BL:** *P* = NS
Rossignol et al., 2009 (continued)				**Medical:** ATEC health/physical/behavioral score, mean ±

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				SD: **G1:** 20.8 ± 8.7 **G2:** 20.2 ± 7.3 **G1/G2:** *P* = NS **G1/BL:** *P* = 0.04 **G2/BL:** *P* = NS **Sensory:** ATEC sensory/ cognitive awareness score, mean ± SD: **G1:** 15.1 ± 3.9 **G2:** 18.5 ± 6.2 **G1/G2:** *P* = 0.04 **G1/BL:** *P* = 0.002 **G2/BL:** *P* = NS **Harms:** Increased asthma in one participant, but not associated with study. Increased urine frequency and skin rash in one child. Anxiety in one child. In control group, one child with abdominal distension and diarrhea, one with worsened eczema **Modifiers:** Children's age: More improvement in ABC total score for children over age five (*P* = 0.048)
Rossignol et al., 2009 (continued)				Children in G1 over age five showed more improvement in ABC irritability (*P* = 0.015), social withdrawal (*P* = 0.009), and stereotypy (*P* = 0.04), and ATEC sociability (*P* = 0.01) and sensory/cognitive awareness (*P* = 0.04). For children age five and under, there was no significant difference

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				between groups. No significant age difference was observed with either parental or physician CGI scale. Autism severity: Children in G1 with baseline ADOS below the 50th percentile showed improvement in ABC irritability (*P* = 0.03) and stereotypy (*P* = 0.04), and ATEC sociability (*P* = 0.03). For children above the 50[th] percentile, there was no significant difference between groups. No significant autism severity difference was observed with either parental or physician CGI scale
Author: Silva et al., 2009 **Country:** US **Practice setting:** Academic **Intervention setting:** School/home **Enrollment period:** NR **Funding:** Curry Stone Foundation **Author industry relationship disclosures:** NR **Design:** RCT **Note:** See related papers Silva et al.,	**Intervention:** Qigong massage treatment (trainers met with families for 20 visits over 5 months, at each visit child receives qigong massage treatment from the therapist and parents receive training and support in the follow-through massage given daily by parent to child) **Assessments:** PDDBI (questionnaire filled out by parents and teachers), ABC (questionnaire filled out by teacher), Sense and Self-regulation Checklist (parent questionnaire developed by authors) and VABS-II (parents completed selected portions) administered before intervention,	**Inclusion criteria:** • Age < 6 years • Eligible for early intervention services for autism **Exclusion criteria:** • Complicating medical diagnoses or chronic medication **Age, months** ± **SD (range):** **G1:** 65.2 ± 20.7 (25-117) **G2:** 53.3 ± 18.7 (27-92) **Mental age:** NR **Gender, n:** Male: **G1:** 19 **G2:** 18 Female: **G1:** 6 **G2:** 3 **Race/ethnicity:** NR **SES:**	**Overall ratings:** ABC score, mean ± SD: **G1:** 48.5 ± 20.8 **G2:** 64.3 ± 33.8 **G1/G2:** *P* = NS PDDBI autism composite score, mean ± SD: Teacher-rated: **G1:** NR **G2:** NR **G1/G2:** *P* = NS Parent-rated: **G1:** 49.3 ± 11.7 **G2:** NR **G1/G2:** *P* < 0.05* **Communication/ language:** PDDBI receptive/ expressive social communication abilities composite score, mean ± SD: Teacher-rated:	**Overall ratings:** Overall treatment effect: Teacher-rated: MANCOVA:** treatment (*P* = 0.019; partial η^2 = 0.316) Parent-rated: MANCOVA:** treatment (*P* = 0.029; partial η^2 = 0.412) ABC score, mean ± SD: **G1:** 33.9 ± 18.6 **G2:** 59.4 ± 35.4 **G1/BL:** *P* < 0.00 **G2/BL:** *P* = NS ANCOVA:** treatment (*P* < 0.003; partial η^2 = 0.237) PDDBI autism composite score,

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
2007, 2008 ({#302; #58})	immediately after final massage session, and 5 months after the intervention was completed **Groups:** **G1:** qigong massage **G2:** waitlist control **Co-interventions held stable during treatment:** Yes **Frequency of contact during study:** 20 training and treatment visits over 5 months **Concomitant therapies, n:** Early intervention preschools (5-10 hours per week): “majority of children” Oregon’s Regional Prog-ram Autism Training Sites preschool program: 4 **N at enrollment:** **G1:** 25 **G2:** 21	Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** NR **Diagnostic category:** Regressive autism: **G1:** 13 **G2:** 9 Nonregressive autism: **G1:** 12 **G2:** 12 **Other characteristics:** NR	**G1:** 53.7 ± 9.7 **G2:** 47.0 ± 13.0 **G1/G2:** *P* = NS Parent-rated: **G1:** 57.5 ± 6.8 **G2:** 49.0 ± 13.10 **G1/G2:** *P* < 0.05* **Problem behavior:** PDDBI maladaptive behaviors score, mean ± SD: Teacher-rated: **G1:** 50.9 ± 10.4 **G2:** 56.5 ± 13.3 **G1/G2:** *P* = NS Parent-rated: **G1:** 56.8 ± 11.5 **G2:** 59.5 ± 10.7 **G1/G2:** *P* = NS **Sensory:** PDDBI sensory score, mean ± SD: Teacher-rated: **G1:** NR **G2:** NR **G1/G2:** *P* < 0.01*	mean ± SD: Teacher-rated: **G1:** NR **G2:** NR ANCOVA:** treat-ment (*P* < 0.05; partial η^2 = 0.109) Parent-rated: **G1:** 38.5 ± 11.7 **G2:** NR ANCOVA:** treat-ment (*P* < 0.001; partial η^2 = 0.299) Parent-rated, 5 month follow-up: **G1:** 38.6 ± 9.9 (n=19)
Silva et al., 2009 (continued)	**N at follow-up:** **G1:** 25 **G2:** 21		Parent-rated: **G1:** 54.2 ± 9.6 **G2:** 56.0 ± 9.6 **G1/G2:** *P* = NS Sense and Self-regulation Checklist score, mean ± SD: Sense: **G1:** 16.4 ± 6.2 **G2:** 19.5 ± 6.1 **G1/G2:** *P* = NS Systems: **G1:** 8.2 ± 3.7 **G2:** 10.1 ± 4.5 **G1/G2:** *P* = NS	**Communication/ language:** **Teacher PDDBI** PDDBI receptive/ expressive social communication abilities composite score, mean ± SD: Teacher-rated: **G1:** 56.7 ± 9.7 **G2:** 47.6 ± 12.1 **G1/BL:** *P* < 0.01 **G2/BL:** *P* = NS ANCOVA:** treat-ment (*P* < 0.01; partial η^2 = 0.182) Parent-rated: **G1:** 61.1 ± 7.0 **G2:** 49.2 ± 12.8 **G1/BL:** *P* < 0.01 **G2/BL:** *P* = NS ANCOVA:** treat-ment (*P* < 0.007; partial η^2 = 0.200) Parent-rated, 5 month follow-up: **G1:** 59.8 ± 9.2 (n=19) **Problem**

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				behavior: PDDBI maladaptive behaviors score, mean ± SD: Teacher-rated: **G1:** 44.0 ± 7.6 **G2:** 49.7 ± 12.2 **G1/BL:** $P < 0.00$ **G2/BL:** $P = 0.01$ ANCOVA:** treatment (P = NS) Parent-rated: **G1:** 45.6 ± 10.8, **G2:** 57.5 ± 10.4 **G1/BL:** $P < 0.00$ **G2/BL:** P = NS ANCOVA:** treatment ($P < 0.0003$; partial $\eta^2 = 0.328$)
Silva et al., 2009 (continued)				Parent-rated, 5 month follow-up: **G1:** 43.9 ± 8.3 (n=19) **Sensory:** PDDBI sensory score, mean ± SD: Teacher-rated: **G1:** NR **G2:** NR Parent-rated: **G1:** 46.2 ± 9.1 **G2:** 55.3 ± 10.0. **G1/BL:** $P < 0.00$ **G2/BL:** P = NS ANCOVA:** treatment ($P < 0.005$; partial $\eta^2 = 0.216$) Parent-rated, 5 month follow-up: **G1:** 43.5 ± 9.6 (n=19) Sense and Self-regulation Checklist score, mean ± SD: Sense **G1:** 10.8 ± 5.6 **G2:** 18.7 ± 6.6 **G1/BL:** $P < 0.00$ **G2/BL:** P = NS Systems: **G1:** 4.8 ± 3.3 **G2:** 10.1 ± 3.4 **G1/BL:** $P < 0.00$ **G2/BL:** P = NS

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				Overall: ANCOVA:** treatment (P < 0.0002; partial η^2 = 0.346) **Harms:** NR **Modifiers:** NR

Comments: *Computed using Bonferroni adjusted post-hoc ANOVA
**with age in months as the covariate

Author: Vismara et al., 2009 **Country:** US **Practice setting:** Academic **Intervention setting:** Varied including children's hospital, clinical-research university, private intervention agency and a public school **Enrollment period:** NR **Funding:** NIH, gift from anonymous foundation **Author industry relationship disclosures:** NR **Design:** Case series	**Intervention:** Early Start Denver Model (ESDM); incorporates the Denver model (a relationship and play-based developmental intervention) and Pivotal Response Training (ABA application to optimize motivation to increase communication, language, and play skills) Phase I: direct intervention of the ESDM included manualized instruction in the teaching principles, intervention techniques, goal development and data collection methods, and fidelity system (5 months) Phase II: parent coaching of the ESDM included teaching therapists to educate parents on how to carry out the ESDM principles (5 months) Both training phases consisted of an initial baseline session followed by three training conditions, each lasting approximately 5-6 weeks: (i) self-instruction with the training materials using print and video materials provided on a DVD; (ii) a 10 hour didactic training seminar for direct treatment and a 3 hour didactic training seminar for parent coaching; and (iii) four hours of team supervision for specific discussion of each site's	**Inclusion criteria:** • Age 12-60 months • Diagnosis of ASD • No significant health concerns • No serious or specific medical, genetic, neurological, or sensory condition • Parental consent for videotaping • At least 75% parental attendance if the family continued onto the parent training phase • No participation in additional services exceeding 10 hours per week during the study **Exclusion criteria:** • See inclusion criteria **Age, months ± SD:** **G1a:** 33 ± 7.3 **G1b:** 33 ± 7.7 **G2a:** 33 ± 4.4 **G2b:** 31 ± 6 **Mental age:** NR **Gender:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** Initially diagnosed by community clinicians independent of this study, confirmed by trained physician or psychologist **Diagnostic Tool:** DSM-IV, ADOS	**Overall ratings:** MSEL developmental age, months ± SD: Receptive language: **G1a:** 22 ± 13 **G1b:** 14 ± 9.2 **G2a:** 15 ± 12.3 **G2b:** 15 ± 12.8 Expressive language: **G1a:** 23 ± 10 **G1b:** 16 ± 6.9 **G2a:** 13 ± 11 **G2b:** 14 ± 12.5 ADOS score, module 1, mean ± SD: **G1a:** 13 ± 4.4 **G1b:** 15 ± 4.9 **G2a:** 17 ± 3.9 **G2b:** 15 ± 5.3 **Social skills:** Number of words, phase I, mean (SE): **G1:** 9.5 (4.63) Number of words, phase II, mean ± SD: **G2:** 22.29 ± 27.13 Number of imitations, mean ± SD: **G1:** NR **G2:** 14.57 ± 10.67 Attention score, mean ± SD: **G1:** NR **G2:** 3.00 ± 0.75 Social initiations, mean ± SD: **G1:** NR **G2:** 2.84 ± 0.45 Therapist treatment fidelity, score, mean (SE): **G1a:** NR**	**Social skills:** Number of words, phase I, mean (SE): **G1i:** 10.3 (4.63) **G1ii:** 21.4 (4.63) **G1iii:** 13.5 (4.63) **G1i/BL:** P = NS **G1i/G1ii:** P < 0.01 **G1ii/G1iii:** P < 0.05 Number of words, phase II, mean ± SD: **G2i:** 15.5 ± 10.99 **G2ii:** 20.89 ± 16.1 **G2iii:** 28.22 ± 23.42 **G2i/G2ii/G2iii/BL:** P = NS Number of imitations, mean ± SD: **G1i:** NR **G1ii:** NR **G1iii:** NR **G2i:** 11 ± 8.38 **G2ii:** 13.56 ± 9.81 **G2iii:** 8.11 ± 9.83 **G1i/G1ii/G1iii/BL:** P = NS **G2i/G2ii/G2iii/BL:** P = NS Attention score, mean ± SD: **G1i:** NR** **G1ii:** NR** **G1iii:** NR** **G2i:** 3.26 ± 0.66 **G2ii:** 3.46 ± 0.63 **G2iii:** 3.54 ± 0.79 **G1i/BL:** P < 0.05 **G1i/G1ii+G1iii:** P < 0.05 **G1ii/G1iii:** P = NS **G2i/G2ii/G2iii/BL:** P = NS

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	training cases. These three training conditions were provided sequentially to all ten therapists at four sites, two remote via telehealth conferencing	**Diagnostic category, n (%):** Autism: 32 (100)	**G1b:** NR** Therapist-parent coaching fidelity score, mean (SE): **G2a:** NR** **G2b:** NR**	Social initiations, mean ± SD: **G1i:** NR** **G1ii:** NR** **G1iii:** NR** **G2i:** 3.07 ± 0.51 **G2ii:** 3.14 ± 0.60 **G2iii:** 3.13 ± 0.68
Vismara et al., 2009 (continued)	**Assessments:** MSEL adminisitered at start of study; therapists' and parents' fidelity of implementation of the ESDM (all measures of fidelity increased over time), frequency of child social communicative behaviors, CBRS, and therapist satisfaction (conducted once post-intervention) **Groups:** **G1:** phase I **G2:** phase II **Ga:** live **Gb:** telehealth **Gi:** self-instruction **Gii:** didactic seminar **Giii:** team supervision **Provider(s):** • Psychologists • SLP • Autism specialist • OT • Case manager • Program director • Early childhood special educator • Behavior specialist **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** Total: 32 **N at follow-up:** Total: 29 **N used for analysis:*** **G1a:** 5 **G1b:** 5 **G2a:** 5 **G2b:** 5	**Other characteristics:** NR	Parent fidelity score, mean (SE): **G2a:** NR** **G2b:** NR**	**G1i/BL:** $P < 0.05$ **G1i/G1ii+G1iii:** $P < 0.05$ **G1ii/G1iii:** P = NS **G2i/G2ii/G2iii/BL:** P = NS Therapist treatment fidelity, score, mean (SE): **G1ai:** NR** **G1aii:** NR** **G1aiii:** NR** **G1bi:** NR** **G1bii:** NR** **G1biii:** NR** **G1a/G1b:** P = NS **G1i/BL:** $P < 0.05$ **G1i/G1ii+G1iii:** $P = 0.05$ **G1ii/G1iii:** P = NS Therapist-parent coaching fidelity score, mean (SE): **G2ai:** NR** **G2aii:** NR** **G2aiii:** NR** **G2bi:** NR** **G2bii:** NR** **G2biii:** NR** **G2a/G2b:** P = NS **G2i/BL:** $P < 0.05$ **G2i/G2ii:** $P = 0.001$ **G2ii/G2iii:** P = NS Parent fidelity score, mean (SE): **G2ai:** NR** **G2aii:** NR** **G2aiii:** NR** **G2bi:** NR** **G2bii:** NR** **G2biii:** NR** **G2a/G2b:** P = NS **G2/BL:** $P < 0.05$ **Harms:** NR

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Vismara et al., 2009 (continued)				**Modifiers:** In phase I, there was a significant relationship between therapist fidelity and both social initiations (*P* < 0.01) and and attention (*P* < 0.001) In phase II, there was a significant relationship between parent fidelity and social initiations (*P* < 0.001), imitations (*P* < 0.01), and attention (*P* < 0.001)

Comments: *Authors report that data related to only one randomly selected child per therapist was used in the analysis; data from 2 children are included in both Phase I and II.
**data only illustrated graphically

Author: Whitingham et al., 2009 Whitingham et al., 2009† **Country:** Australia **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** School of Psychology, University of Queensland **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Stepping Stones Triple P Positive Parenting Program: participants in groups of 4-5 based on level of functioning, included parent training, practice and feedback, using strategies including descriptive praise, planned ignoring, comic strip conversations and social stories **Assessments:** Family background questionnaire; ECBI; parenting scale (7-point likert scale: minimum 1, maximum 7); being a parent scale (6-point likert scale; 1=strongly agree, 6=strongly disagree); PAQ **Groups:** **G1:** intervention **G2:** wait-list control **Provider:** Probationary psychologists enrolled in clinical psychology program; all attended a two-day workshop and received	**Inclusion criteria:** • 2.5 to 4 years old at start of intervention • Received no other major interventions during the assessment period • Diagnosed with ASD **Exclusion criteria:** • See Inclusion Criteria **Age, years ± SD:** Total: 5.91 ± 1.90 **G1:** 5.62 ± 1.74 **G2:** 6.2 ± 2.04 **Mental age:** NR **Gender, n (%):** Male: **G1:** 24 (83) **G2:** 23 (77) Female: **G1:** 5 (17) **G2:** 7 (23) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Independent pediatrician and confirmed in study **Diagnostic tool/method:** Semi-structured interview based on DSM-IV and	**Problem behavior:** ECBI intensity score, mean ± SD: **G1:** 144.14 ± 31.32 **G2:** 142.19 ± 31.73 ECBI problem score, mean ± SD: **G1:** 18.06 ± 7.71 **G2:** 19.72 ± 6.83 Parenting scale score, mean ± SD: Laxness: **G1:** 2.8 ± 0.76 **G2:** 2.87 ± 0.75 Over-reactivity: **G1:** 2.97 ± 0.75 **G2:** 2.9 ± 0.86 Verbosity: **G1:** 3.26 ± 0.97 **G2:** 3.38 ± 0.78 Being a parent scale score, mean ± SD: Efficacy: **G1:** 25.73 ± 5.35 **G2:** 26.57 ± 5.35 Satisfaction: **G1:** 32.85 ± 5.79 **G2:** 33.43 ± 7.21 PAQ child-referent bad behavior score, mean ± SD:† Internality: **G1:** 7.26 ± 1.79	**Problem behavior:** ECBI intensity score, mean ± SD: **G1:** 121.40 ± 25.28 **G2:** 148.63 ± 30.33 ES = 0.26, *P* < 0.001 ECBI problem score, mean ± SD: **G1:** 11.21 ± 6.77 **G2:** 18.82 ± 8.32 ES = 0.16, *P* < 0.002 Parenting scale score, mean ± SD: Laxness: **G1:** 2.61 ± 0.45 **G2:** 3.30 ± 0.60 ES = 0.22, *P* < 0.001 Over-reactivity: **G1:** 2.11 ± 0.59 **G2:** 3.01 ± 0.85 ES = 0.25, *P* < 0.001 Verbosity: **G1:** 2.51 ±.84

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	accreditation in stepping stones **Measure of treatment fidelity reported:** NR **Co-interventions held stable during treatment:** NR **Concomitant therapies:** Professional help sought for child's emotional or behavioral problems, n: **G1:** 12 **G2:** 13 **N at enrollment:** **G1:** 29 **G2:** 30	Gillberg's criteria for Asperger syndrome **Diagnostic category, n (%):** ASD: **G1:** 11 (38) **G2:** 11 (37) Autism: **G1:** 4 (14) **G2:** 4 (13) Asperger syndrome: **G1:** 12 (41) **G2:** 15 (50) ASD-NOS: **G1:** 2 (7%) **G2: 0**	**G2:** 6.82 ± 1.76 Stability: **G1:** 5.70 ± 1.66 **G2:** 6.59 ± 1.68 Controllability: **G1:** 6.30 ± 1.69 **G2:** 5.86 ± 1.75 PAQ child-referent good behavior score, mean ± SD:† Internality: **G1:** 6.83 ± 1.37 **G2:** 6.36 ± 0.90 Stability: **G1:** 7.04 ± 1.33 **G2:** 7.00 ± 1.15 Controllability: **G1:** 7.43 ± 1.27 **G2:** 6.86 ± 1.67	**G2:** 3.37 ±.84 ES = 0.16, *P* < 0.01 Being a parent scale score, mean ± SD: Efficacy: **G1:** 18.79 ± 5.99 **G2:** 23.30 ± 5.93 Satisfaction: **G1:** 39.41 ± 6.04 **G2:** 35.23 ± 7.60 Significant trend, *P* < 0.05
Whitingham et al., 2009 Whitingham et al., 2009† (continued)	**N at follow-up:** **G1:** 29 **G2:** 30	**Other characteristics:** Current language abilities (for age), n (%): No language: **G1:** 1 (3) **G2:** 4 (13) Little language: **G1:** 6 (21) **G2:** 7 (23) Verbal: **G1:** 22 (76) **G2:** 19 (63) Current marital status of parents, n: Married: **G1:** 21 **G2:** 26 Defacto: **G1:** 2 **G2:** 2 Divorced: **G1:** 2 **G2:** 1 Separated: **G1:** 3 **G2:** 1 Never married/defacto: **G1:** 1 **G2:** 0 Family situation, n: Original: **G1:** 22 **G2:** 27 Step-Family: **G1:** 1 **G2:** 1 Sole Parent: **G1:** 5	PAQ child-referent ASD-related behavior score, mean ± SD:† Internality: **G1:** 7.56 ± 1.34 **G2:** 7.14 ± 1.25 Stability: **G1:** 6.87 ± 1.63 **G2:** 7.00 ± 1.85 Controllability: **G1:** 5.30 ± 1.64 **G2:** 4.95 ± 1.84	PAQ child-referent bad behavior score, mean ± SD:† Internality: **G1:** 6.17 ± 1.11 **G2:** 6.95 ± 1.53 Stability: **G1:** 5.35 ± 1.61 **G2:** 5.86 ± 1.78 Controllability: **G1:** 6.91 ± 1.56 **G2:** 6.59 ± 1.65 PAQ child-referent good behavior score, mean ± SD:† Internality: **G1:** 6.74 ± 1.48 **G2:** 6.50 ± 1.18 Stability: **G1:** 7.22 ± 1.73 **G2:** 6.86 ± 1.52 Controllability: **G1:** 7.56 ± 1.50 **G2:** 7.00 ± 1.60 PAQ child-referent ASD-related behavior score, mean ± SD:† Internality: **G1:** 7.22 ± 1.35 **G2:** 6.77 ± 1.11 Stability: **G1:** 6.26 ± 1.68 **G2:** 7.27 ± 1.52 Controllability:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
		G2: 2 Extended: **G1:** 1 **G2:** 0 Both Parents: **G1:** 15 **G2:** 20 Relationship of primary participating parent to child, n: Mother: **G1:** 29 **G2:** 25 Father: **G1:** 0 **G2:** 4		**G1:** 5.65 ± 1.72 **G2:** 5.54 ± 1.53 **Harms:** NR **Modifiers:** NR
Whitingham et al., 2009 Whitingham et al., 2009† (continued)		Grandmother: **G1:** 0 **G2:** 1		
Author: Wood et al., 2009 **Country:** US **Practice setting:** Academic **Intervention setting:** School, home **Enrollment period:** March 2006 to August 2007 **Funding:** Cure Autism Now Foundation, NIH **Author industry relationship disclosures:** NR **Design:** RCT **Note:** Methodology data extracted from Wood et al. 2009 ({#3618}), where more detailed information can be found	**Intervention:** Immediate treatment or 3-month wait list Therapists worked with families for 16 weekly sessions, each lasting 90 min (about 30 min with the child and 60 min with the parents/family), implementing a version of the *Building Confidence* CBT program **Assessments:** Posttreatment assess-ments were completed on the final day of treatment or within 1 week of termination; post-waitlist assessments were conducted 3 months after the baseline assessment but before initializing CBT **Groups:** **G1:** immediate treatment **G2:** 3-month waitlist **Provider:** Four doctoral students in clinical or educational psychology, and one postdoctoral fellow in psychology; therapists received training and weekly supervision **Measure of treatment fidelity reported:** Yes **Co-interventions held**	**Inclusion criteria:** • Met research criteria for ASD • Had at least one anxiety disorder • Psychiatric medication, if used, was at a stable dose prior to intake and throughout the trial **Exclusion criteria:** • IQ less than 70 • Concurrent psychotherapy **Age, years ± SD (range):** 9.37 ± 1.42 (7-11) **Mental age:** NR **Gender, n (%):** Male: 16 (84) Female: 3 (16) **Race/ethnicity, n (%):** Caucasian: 10 (53) Asian: 4 (21) Native American/ caucasian: 2 (11) Latino/Asian: 1 (5) African American/ caucasian: 1 (5) **SES:** Maternal education: NR Primary parent, college degree, n (%): 15 (79) Household income: NR **Diagnostic approach:** In Study and Referral **Diagnostic tool/method**: ADI-R; ADOS – Module 3;	**Social skills:** SRS total score, mean ± SD (range): **G1:** 113 ± 18.27 (87-145) **G2:** 116 ± 30.19 (61-151) SRS T-score ≥ 70, n: **G1:** 9/9 **G2:** 9/10	**Social skills:** SRS total score, mean ± SD (range): **G1:** 89 ± 26.39 (53-140) **G2:** 110.30 ± 29.22 (53-146) **G1/G2:** *P* < 0.05 SRS T-score ≥ 70, immediate post-treatment, n: **G1:** 7/9 **G2:** 9/10 SRS T-score ≥ 70, 3 months post-treatment, LOCF, n: **G1:** 4/9 **G2:** NA SRS social motivation score, mean: **G1:** NR **G2:** NR **G1/G2:** *P* < 0.05 (favoring G1) SRS social awareness score, mean: **G1:** NR **G2:** NR **G1/G2:** *P* < 0.05 (favoring G1) SRS social cognition score, mean:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	stable during treatment: Yes **Concomitant therapies, n:** Psychiatric medication: NR **N at enrollment:** **G1:** 9 **G2:** 10 **N at post-treatment follow-up:** **G1:** 9 **G2:** 10	a checklist regarding circumscribed interests; review of previous assessment records **Diagnostic category, n (%):** Autism: 19 (100) **Other characteristics:** NR		**G1:** NR **G2:** NR **G1/G2:** *P* = 0.10 (favoring G1) SRS autistic mannerisms score, mean: **G1:** NR **G2:** NR **G1/G2:** *P* = NS
Wood et al., 2009 (continued)	**N at 3-month follow-up:** **G1:** 4 **G2:** NA			**Communication/ language:** SRS social communication score, mean: **G1:** NR **G2:** NR **G1/G2:** *P* < 0.05 (favoring G1) **Harms:** NR **Modifiers:** Post-treatment SRS scores were predicted by ADIS-C/P Clinician's Rating Scale change scores and baseline SRS total scores (*P* < 0.01) Post-treatment ADIS-C/P scores were predicted by baseline ADIS-C/P scores and SRS change scores (*P* < 0.01)
Author: Wood et al., 2009 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** September 2004 to December 2007 **Funding:**	**Intervention:** Building Confidence CBT program (modified) – includes coping skills training followed by in vivo exposure (facing fearful situation repeatedly while using coping skills and remaining in situation until habituation). Hierarchy of fearful situations created and the child moves through the hierarchy. Parent training involves supporting in vivo,	**Inclusion criteria:** • Met research criteria for diagnosis of autism, Asperger syndrome, or PDD-NOS • Met research criteria for one of the following: separation anxiety disorder (SAD), social phobia, or obsessive compulsive disorder (OCD) • Not taking any psychiatric medication at baseline or were on a	**Commonly occurring comorbidities:** ADIS-CSR score, mean ± SD (range): **G1:** 5 ± 0.68 (4-6) **G2:** 5.14 ± 0.56 (4-6) Parent MASC score, mean ± SD (range): **G1:** 71.25 ± 17.07 (36-98) **G2:** 75.38 ± 12.98 (56-103) Child MASC score,	**Overall ratings:** Meeting CGI response criteria, n (%): **G1:** 13 (92.9) **G2:** 2 (9.1) **G1/G2:** *P* < 0.0001 **Commonly occurring co-morbidities:** ADIS-CSR score, mean ± SD (range): **G1:** 2.36 ± 1.15

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Cure Autism Now Foundation, NIH **Author industry relationship disclosures:** None **Design:** RCT **Note:** See follow-up paper with additional participants, Wood et al., 2009 ({#5523})	positive reinforcement, and using communication skills to encourage independence in daily routines Schedule: 16 weekly sessions each lasting 90 minutes (30 minutes with child; 60 minutes with parents) **Assessments:** Trained graduate student independent evaluators who were blind to the intervention condition of each family conducted diagnostic interviews before and immediately after intervention or waitlist (ADIS-C/P); MASC, CGI-I Measures were completed over the course of two days; post-treatment assessments were completed on the final day of treatment or within a week of termination; post-waitlist assessments were conducted three months after the baseline assessment but before initiating CBT (readministering all anxiety measures) **Groups:** **G1:** CBT program **G2:** waitlist	stable dose of psychiatric medication • If medication was being used, children maintained the same dose throughout the study **Exclusion criteria:** • Verbal IQ less than 70 • Currently in psychotherapy or social skills training, or was receiving behavioral interventions such as applied behavior analysis • Family was currently in family therapy or a parenting class • Child began psychiatric medication or changed dose during intervention • The child or parents appeared unable to participate in the intervention program for any reason **Age, years ± SD:** **G1:** 9.18 ± 1.42 **G2:** 9.22 ± 1.57 **Mental age:** NR **Gender, n (%):** Male: **G1:** 12 (71) **G2:** 15 (65) Female: **G1:** 5 (29) **G2:** 8 (35)	mean ± SD (range): **G1:** 56.66 ± 16.84 (20-77) **G2:** 54.69 ± 16.8 (25-85)	(1-4) **G2:** 4.77 ± 0.81 (3-6) **G1/G2:** *P* < 0.0001 Parent MASC score, mean ± SD (range): **G1:** 58.48 ± 14.72 (40-98) **G2:** 76.57 ± 14.65 (56-103) **G1/G2:** *P* < 0.0001 Child MASC score, mean ± SD (range): **G1:** 46.93 ± 14.76 (27-72) **G2:** 46.5 ± 15.83 (22-79) **G1/G2:** *P* = 0.87 **Harms:** NR **Modifiers:** NR
Wood et al., 2009 (continued)	**Provider:** Doctoral students in clinical or educational psychology and doctoral-level psychologists **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** See inclusion/exclusion criteria **Concomitant therapies:** Psychiatric medication: SSRI: **G1:** 2 (12) **G2:** 3 (13) Atypical antipsychotic:	**Race/ethnicity, n (%):** **G1:** Caucasian: **G1:** 8 (47) **G2:** 11 (48) Latino/Latina: **G1:** 2 (12) **G2:** 3 (13) Asian/Pacific Islander: **G1:** 4 (23) **G2:** 2 (9) African American: **G1:** 0 **G2:** 1 (4) Asian/Caucasian: **G1:** 1 (6) **G2:** 1 (4) Asian/Latino:		

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	G1: 3 (18) **G2:** 3 (13) Stimulant or atomoxetine: **G1:** 4 (24) **G2:** 7 (30) **N at enrollment:** **G1:** 17 **G2:** 23 **N at follow-up:** **G1:** 14 **G2:** 22	**G1:** 0 **G2:** 1 (4) African American/ Caucasian: **G1:** 0 **G2:** 2 (9) Latino/Caucasian: **G1:** 1 (6) **G2:** 1 (4) Middle Eastern/Caucasian: **G1:** 1 (6) **G2:** 0 Multiracial (> 3): **G1:** 0 **G2:** 1 (4) **SES:** Parent college graduate, n (%): **G1:** 12 (71) **G2:** 13 (60) Household income (n=37 parents), n (%): <$40K: 9 (24.3) $40-90K: 10 (27.1) >$90K: 18 (48.6) **Diagnostic approach:** In Study **Diagnostic tool/method:** ADI-R and ADOS		
Wood et al., 2009 (continued)		**Diagnostic category, n (%):** Autistic disorder: **G1:** 9 (53) **G2:** 11 (48) PDD-NOS: **G1:** 6 (35) **G2:** 11 (48) Asperger syndrome: **G1:** 2 (12) **G2:** 1 (4) **Other characteristics, n (%):** **Other comorbid diagnoses:** ADHD: **G1:** 9 (53) **G2:** 15 (65) Dysthymia/MDD: **G1:** 3 (18) **G2:** 0 ODD/CD: **G1:** 2 (12) **G2:** 6 (26) PTSD: **G1:** 0 **G2:** 1 (4) **Baseline anxiety**		

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
		disorders: Social phobia: **G1:** 13 (76) **G2:** 22 (96) SAD: **G1:** 8 (47) **G2:** 16 (70) OCD: **G1:** 8 (47) **G2:** 9 (39) GAD: **G1:** 11 (65) **G2:** 8 (35) Parent married/re-married: **G1:** 14 (82) **G2:** 19 (83)		
Author: Yoder and Stone, 2006a, 2006b Yoder and Lieberman, 2009† **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** January 2000 to March 2003 **Funding:** NIH **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Two communication interventions: Picture Exchange Communication System (PECS) and Responsive Education and Prelinguistic Milieu Teaching (RPMT), delivered three times/week in 20 minute sessions for 6 months, an average of 60 ± 7.1 sessions (range 33-70) Parents given up to 15 hours of training to complement material covered in the children's treatment sessions Parent training hours, mean ± SD: **G1:** 7.9 ± 2.3 **G2:** 10.6 ± 2.2 **G1/G2:** $P < 0.01$ **Assessments:** Pre- and post-treatment: ESCS-abridged, an unstructured free-play session with an examiner, a measure of turn taking and a free-play session with the primary caregiver Spoken communication assessed at pretreatment, post treatment and at 6-month follow-up period {#487} All assessments were conducted by examiners who were not the children's therapists	**Inclusion criteria:** • Diagnosis of autistic disorder or PDD-NOS • Age 18-60 months • Used fewer than 10 words during all of three communication samples • Passed hearing screenings administered outside of the project **Exclusion criteria:** • Severe sensory/motor deficits • English not the primary language spoken at home **Age, years ± SD (range):** **G1:** 3.1 ± 0.8 (7.8-4.5) **G2:** 2.7 ± 0.5 (1.9-3.5) **Mental age, months ± SD:** Nonverbal: **G1:** 18.8 ± 4.5 (11.5-26.5) **G2:** 18.6 ± 3.2 (13-23.5) Verbal: **G1:** 11.7 ± 3.4 (7-19) **G2:** 11.9 ± 2.5 (7-19) **Gender, n (%):** Male: 31 (86) Female: 5 (14) **Race/ethnicity, n (%):** White: 25 (69) African American: 8 (22) Other: 3(8) **SES:** Primary parent education, median: 3-4 years of college Parental occupational status, mean ± SD (range): **G1:** 43 ± 22 (10-87) **G2:** 51 ± 21 (8-80)	**Communication/ language:** ESCS, number of requests, mean ± SD: Total: 11.9 ± 7.3 **G1:** 13 ± 8 **G2:** 11 ± 6 Unstructured free play, number of requests, mean ± SD: Total: 4.2 ± 9.2 ESCS, number of joint attention initiations, mean ± SD: Total: 2.7 ± 3.5 **G1:** 3 ± 4 **G2:** 2 ± 2 Unstructured free play, number of joint attention initiations, mean ± SD: Total: 2.7 ± 4.5 Number of object exchange turns, mean ± SD: Total: 3.7 ± 4.5 **G1:** 5 ± 5 **G2:** 2 ± 3 ADOS communication algorithm score, mean ± SD:† **G1:** 5.79 ± 1.18 **G2:** 6.35 ± 1.27 **G1/G2:** P = NS ADOS social algorithm score mean ± SD:† **G1:** 10.32 ± 2.36	**Communication/ language:** ESCS, number of requests, mean ± SD: Total: 17.7 ± 10.7 **G1+G2/BL:** P = 0.002 Unstructured free play, number of requests, mean ± SD: Total: 4.5 ± 5.7 **G1+G2/BL:** P = NS ESCS, number of joint attention initiations, mean ± SD: Total: 4.7 ± 4.8 **G1+G2/BL:** P = 0.01 Unstructured free play, number of joint attention initiations, mean ± SD: Total: 8 9 ± 0.24 **G1+G2/BL:** P = 0.02 Number of object exchange turns, mean ± SD: Total: 5.5 ± 4.7 **G1+G2/BL:** P = 0.008 Number of object exchange turns, mean (SE): **G1:** 4 (0.81) **G2:** 7.1 (0.86)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	Groups: **G1:** PECS **G2:** RPMT **Provider:** • Master's level professsionals • Closely supervised paraprofessionals **Treatment manual followed:** Yes	**Diagnostic approach:** Referral **Diagnostic tool/method:** ADOS **Diagnostic category, n (%):** Autism: 33 (91.7) PDD-NOS: 3 (8.3) Aspergers: 0	**G2:** 11.64 ± 1.17 **G1/G2:** *P* = 0.038 MSEL expressive language, standard score, mean ± SD:† **G1:** 19.47 ± 1.26 **G2:** 21.59 ± 3.36 **G1/G2:** *P* = 0.024	**G1/G2:** *P* = 0.019 Picture exchanges, mean ± SD:† **G1:** 3.84 ± 4.5 **G2:** 1.06 ± 1.3 ANOVA: time (*P* < 0.001), time x treatment (*P* < 0.001)
Yoder and Stone, 2006a, 2006b Yoder and Lieberman, 2009† (continued)	**Defined protocol followed:** Yes **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** NR **Concomitant therapies, mean ± SD:** {#487} Rx phase: 16.8 ± 22.7 6 months: 34.4 ± 39 *P* = 0.002 **Community based speech therapy, hrs/ month, mean ± SD:** Rx phase: 7.4 ± 4.2 6 months: 9.3 ± 5.9 *P* = 0.07 **Community based speech therapy, hrs/month, mean change ± SD:** **G1:** 4.0 ± 6.9 **G2:** -0.3 ± 5.19 **G1/G2:** *P* = 0.05 **N at enrollment:** **G1:** 19 **G2:** 17 **N at follow-up:** **G1:** 19 **G2:** 17	**Other characteristics:** IQ, mean ± SD (range): **G1:** 55 ± 7 (49-67) **G2:** 54 ± 6 (49-67) Number of words used across ESCS and unstructured free play, mean ± SD (range): **G1:** 0.6 ± 1 (0-5) **G2:** 0.4 ± 0.7 (0-2) Number of spoken acts across ESCS and unstructured free play, mean ± SD (range): **G1:** 1.1 ± 2 (0-6) **G2:** 0.6 ± 1 (0-4) Number of initiating joint attention in ESCS, mean ± SD (range): **G1:** 3 ± 4 (0-18) **G2:** 2 ± 2 (0-7) Number of requests in ESCS, mean ± SD (range): **G1:** 13 ± 8 (1-26) **G2:** 11 ± 6 (2-20) Number of object exchanges in turn-taking procedure, mean ± SD (range): **G1:** 5 ± 5 (0-16) **G2:** 2 ± 3 (0-8) Parent report of words understood, mean ± SD (range): **G1:** 108 ± 87 (3-291) **G2:** 62 ± 49 (1-141) Fidelity of prescription: **G1:** 2.88 ± 0.09 **G2:** 2.99 ± 0.17 **Other characteristics**, **mean ± SD (range):** Cognitive standard score: 51 ± 5.3 (48-67) Number of different nonimitative words used in	MSEL receptive language, standard score, mean ± SD:† **G1:** 19.26 ± 0.45 **G2:** 19.41 ± 0.51 **G1/G2:** *P* = NS IQ (derived from Mullen), mean ± SD:† **G1:** 50.32 ± 5.2 **G2:** 51.76 ± 5.41 **G1/G2:** *P* = NS Picture exchanges, mean:† **G1:** 0.05 **G2:** 0.06 Frequency of non-imitative spoken acts, study entry, mean ± SD: 0.25 ± 0.84 Number of different non-imitative words, study entry, mean ± SD: 0.17 ± 0.56	Frequency of non-imitative spoken acts, end of Rx, mean ± SD: 2.2 ± 3.9 Number of different non-imitative words, end of Rx, mean ± SD: 1.6 ± 2.8 Frequency of nonimitative spoken acts, 6 months, mean ± SD: 5.5 ± 10.4 *P* = 0.005 Number of different non-imitative words, 6 months, mean ± SD: 3 ± 5.8 *P* = 0.001 Frequency of non-imitative spoken acts, end of Rx, adjusted* group mean ± SD: **G1:** 3.6 ± 4.8 **G2:** 0.6 ± 4.8 *P* = 0.03 Number of different non-imitative words, end of Rx, adjusted* group mean ± SD: **G1:** 2.4 ± 3.6 **G2:** 0.6 ± 3.6 *P* = 0.04 Frequency of non-imitative spoken acts, 6 months, adjusted* group

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
		SFPE: 0.17 ± 0.56 (0-3)		mean ± SD: **G1:** 5.5 ± 3.2 **G2:** 5.4 ± 3.2 *P* = 0.96
Yoder and Stone, 2006a, 2006b Yoder and Lieberman, 2009† (continued)		Number of nonimitative spoken communication acts in SFPE: 0.25 ± 0.84 (0-4) Number of communication acts in SFPE: 8.4 ± 10.5 (0-56) Proportion of communication acts that are intentional communication in SFPE: 0.89 ± 0.21 (0-1.0) Proportion of communication acts that are spoken words in SFPE: 0.05 ± 0.18 (0-1.0)		Number of different non-imitative words, 6 months, adjusted* group mean ± SD: **G1:** 3.1 ± 2.4 **G2:** 2.9 ± 2.4 *P* = 0.93 **Harms:** NR **Modifiers:** Baseline ADOS negatively correlated with post-treatment frequency of requests in the ESCS (r = -0.35, *P* = 0.04) and initiating joint attention in the unstructured free play session (r = -0.40, *P* = 0.007) Baseline object exchange turns correlated with post-treatment frequency of object exchange turns (r = 0.65, *P* < 0.001) Baseline initiating joint attention predicted differential treatment effects on post-treatment initiating joint attention (*P* < 0.001) and differential response to treatments on post-treatment requests in the ESCS (*P* = 0.003)
Yoder and Stone, 2006a, 2006b Yoder and Lieberman, 2009† (continued)				Interaction between initial interest in a variety of objects and treatment (*P* = 0.01) predicting

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				growth in the number of non-imitative words. Children low in initial object exploration benefited more from RPMT & those high in initial object exploration benefited more from PECS
Author: Itzchak et al., 2009 **Country:** Israel **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective cohort **Note:** See related studies: Ben Itzchak et al. 2007{#252}, Zachor et al. 2007{#5652}, Ben Itzchak et al. 2007{#538}; overlap among these not clear	**Intervention:** Participants received either behavioral (n=40) or eclectic (n=28) treatment. Behavioral was 1-to-1 individualized treatment for 35 hrs/week addressing various skills such as imitation, receptive and expressive language, joint attention, non-verbal communication, pre-academic skills, play, fine motor skills and adaptive living skills Eclectic was small-group activities supervised by special education teacher, individual therapy with various therapists (i.e., speech and language, occupational and music therapies, and structured cognitive teaching; each provided 2 hr of individual, 1 hr of group therapy, and 1 hr of consultation to the team), and included parent training to address problem behaviors **Groups:** **G1:** Unchanged diagnosis at 1 year **G2:** Improved autism diagnosis to ASD or off spectrum at 1 year **Provider:** Special education teacher, speech and language therapists, occupational therapists, music therapists, behavior	**Inclusion criteria:** • Meeting criteria for autism disorder on each of the measures (DSM-IV, ADI-R, ADOS) **Exclusion criteria:** • See inclusion criteria **Age, months ± SD:** **G1:** 25.1 ± 3.8 **G2:** 26.3 ± 4.6 **Mental age:** NR **Gender, n (%):** Male: **G1:** 49 (92) **G2:** 13 (87) Female: **G1:** 4 (8) **G2:** 2 (13) **Race/ethnicity:** NR **SES:** Parental education, years ± SD: **G1:** 14.8 ± 2.8 **G2:** 3.7 ± 3.5 Maternal education, years ± SD: **G1:** 14.5 ± 2.5 **G2:** 14.9 ± 2.5 Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** Clinical evaluation by a neuro-developmental pediatrician; ADOS, ADI **Diagnostic category, n (%):** Autism: 68 (100) **Other characteristics:** Parental age, years ± SD: **G1:** 36.2 ± 6.5	**Overall measures:** ADOS algorithm, mean ± SD: **G1:** 18.3 ± 2.6 **G2:** 15.9 ± 2.7 **Communication/ language:** MSEL receptive language score, mean ± SD: **G1:** 28.1 ± 13.9 **G2:** 37.4 ± 14.1 MSEL expressive language score, mean ± SD: **G1:** 27.4 ± 10.4 **G2:** 32.9 ± 14.6 **Social Skills:** VABS socialization score, mean ± SD: **G1:** 69.2 ± 7.9 **G2:** 68.6 ± 8.3 **Educational/ cognitive/ academic attainment:** MSEL visual score, mean ± SD: **G1:** 38.2 ± 12 **G2:** 40.8 ± 11.2 **Motor skills:** MSEL fine motor score, mean ± SD: **G1:** 31.7 ± 14 **G2:** 36.7 ± 12.5 VABS motor skills score, mean ± SD: **G1:** 86.2 ± 11.9 **G2:** 88.5 ± 9.9 **Adaptive behavior:** VABS communication score, mean ± SD:	**Overall measures:** ADOS algorithm, 1 year, mean ± SD: **G1:** 16.6 ± 3.2 **G2:** 9.3 ± 2 **Communication/ language:** MSEL receptive language score, 1 year, mean ± SD: **G1:** 34 ± 13 **G2:** 45.7 ± 10.5 **G1/BL:** P < 0.001 **G2/BL:** *P* < 0.01 MSEL expressive language score, 1 year, mean ± SD: **G1:** 32.2 ± 13.8 **G2:** 43.8 ± 13.3 **G1/BL:** *P* < 0.01 **G2/BL:** *P* < 0.01 **Social Skills:** VABS socialization score, 1 year, mean ± SD: **G1:** 70.1 ± 14.2 **G2:** 77 ± 10.5 **G1/BL:** *P* = NS **G2/BL:** *P* < 0.05 **Educational/ cognitive/ academic attainment:** MSEL visual score, 1 year, mean ± SD: **G1:** 35.5 ± 14.6 **G2:** 50 ± 7.41 **G1/BL:** *P* = NS **G2/BL:** *P* < 0.05 **Motor skills:**

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	analysts **Assessment:** ADI-R, ADOS, MSEL, VABS, changes in the severity of stereotyped behaviors. **Measure of treatment fidelity reported:** No	**G2:** 36.4 ± 5.9 Maternal age, years ± SD: **G1:** 32.5 ± 5.4 **G2:** 33.7 ± 5	**G1:** 67.8 ± 10.1 **G2:** 67.6 ± 6.4 VABS daily living score, mean ± SD: **G1:** 68.3 ± 6.9 **G2:** 69.3 ± 5.9	MSEL fine motor score, 1 year, mean ± SD: **G1:** 30 ± 13 **G2:** 35.9 ± 15.9 **G1/BL:** *P* = NS **G2/BL:** *P* = NS
Itzchak et al., 2009 (continued)	**Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 53 **G2:** 15 **N at follow-up:** **G1:** 53 **G2:** 15			VABS motor skills score, 1 year, mean ± SD: **G1:** 75.6 ± 13.1 **G2:** 80.9 ± 16.3 **G1/BL:** *P* < 0.001 **G2/BL:** *P* = NS **Adaptive behavior:** VABS communication score, 1 year, mean ± SD: **G1:** 72.3 ± 16.1 **G2:** 82.2 ± 12.9 **G1/BL:** *P* < 0.05 **G2/BL:** *P* < 0.001 VABS daily living score, 1 year, mean ± SD: **G1:** 69.2 ± 7.9 **G2:** 75.4 ± 13.3 **G1/BL:** *P* = NS **G2/BL:** *P* = NS **Harms:** NR **Modifiers:** There was a significant (time X group) interaction in the ADOS stereotyped behaviors score (*P* < 0.05); a significant decrease in stereotyped behavior and restricted interests was noted for G1 (*P* < 0.000) but not for G2.
Author: Akhondzadeh et al., 2008 **Country:** Iran **Practice setting:** Academic	**Intervention:** Piracetam, titrated up to 800 mg/day (200 mg/day starting dose with 200 mg increments every 2 days) Risperidone, dosage by weight: • 10-40 kg: titrated up to	**Inclusion criteria:** • Age 3-11 years • Diagnosis of autism **Exclusion criteria:** • Previously received neuroleptics or any psychotropic drug treatment 6 months prior	**Problem behavior:** ABC-C total score, mean ± SD: **G1:** 23.15 ± 5.80 **G2:** 24.00 ± 8.25 **G1/G2:** *P* = 0.70	**Problem behavior:** ABC-C total score, week 10, mean change ± SD: **G1:** -11.9 ± 3.79 **G2:** -5.15 ± 3.04

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Intervention setting: Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** RCT, double blind, placebo controlled	2 mg/day fixed dose (0.5 mg starting dose with 0.5 mg increments in weekly dose for first 3 weeks) • > 40 kg: titrated up to 3 mg/day fixed dose Duration: 10 weeks **Assessments:** ABC-C, Extrapyramidal Symptoms Rating Scale administered by blinded rater in clinic **Groups:** **G1:** piracetam + risperidone **G2:** placebo + risperidone **Co-interventions held stable during treatment:** NA **Frequency of contact during study:** Ratings at weeks 0, 2, 4, 6, 8, and 10 **Concomitant therapies:** NR **N at enrollment:** **G1:** 20 **G2:** 20 **N at follow-up:** **G1:** 20 **G2:** 20	to recruitment • Significant active medical problem • Children without definitive diagnosis of autism as in severe/ profound mental retardation **Age, years ± SD (range):** **G1:** 6.9 ± 1.86 (3-11) **G2:** 6.75 ± 1.8 (3-11) **Mental age:** NR **Gender, n (%):** Male: **G1:** 16 (80) **G2:** 14 (70) Female: **G1:** 4 (20) **G2:** 6 (30) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In-study confirmation **Diagnostic tool/method:** Semistructured interview with a score of ≥ 6 on the DSM-IV diagnosis criteria and clinical evaluation **Diagnostic category, n (%):** Autism: 40 (100) **Other characteristics, n:** Extrapyramidal symptoms: **G1:** 6 **G2:** 8 **G1/G2:** *P* = 0.74		**G1/G2:** *P* < 0.0001 **Harms:** Treatment-related AEs, n (%): Constipation: **G1:** 4 (20) **G2:** 3 (15) **G1/G2:** *P* = NS Nervousness: **G1:** 1 (5) **G2:** 2 (10) **G1/G2:** *P* = NS Daytime drowsiness: **G1:** 7 (35) **G2:** 9 (45) **G1/G2:** *P* = NS Morning drowsiness: **G1:** 11 (55) **G2:** 8 (40) **G1/G2:** *P* = NS Increased appetite: **G1:** 7 (30) **G2:** 6 (30) **G1/G2:** *P* = NS Dry mouth: **G1:** 4 (20) **G2:** 3 (15) **G1/G2:** *P* = NS Fatigue: **G1:** 5 (25) **G2:** 3 (15) **G1/G2:** *P* = NS Loss of appetite: **G1:** 1 (5) **G2:** 1 (5) **G1/G2:** *P* = NS **Modifiers:** NR
Author: Allam et al., 2008 **Country:** Egypt **Practice setting:** Academic **Intervention setting:** Acupuncture clinic **Enrollment period:** 9 months (dates NR) **Funding:**	**Intervention:** Language therapy 2 times per week with or without scalp acupuncture 2 times per week for 9 months (cycle of 20 minutes twice weekly for 2 months followed by 2 weeks rest) **Groups:** **G1:** language therapy **G2:** language therapy and acupuncture **Provider:** • Same language	**Inclusion criteria:** • Age 4-7 years • Diagnosed with autism according to DSM-IV-T criteria • Diagnosed with autism according to interview with parents using ADI-R • CARS score ≥ 30 **Exclusion criteria:** • See inclusion criteria **Age, years ± SD:** **G1:** 5.5 ± 1.22 **G2:** 5.5 ± 1.22	**Communication/ language:** Language evaluation score, mean ± SD: Attention: **G1:** 1.4 ± 0.9 **G2:** 1.5 ± 0.8 Receptive semantics: **G1:** 5.2 ± 3.6 **G2:** 5.0 ± 2.7 Expressive semantics: **G1:** 0.9 ± 0.6 **G2:** 0.7 ± 0.5 Receptive syntax: **G1:** NR*	**Communication/ language:** Language evaluation score, mean ± SD: Attention: **G1:** 2.8 ± 0.8 **G2:** 3.1 ± 0.8 **G1/BL:** *P* = 0.021 **G2/BL:** *P* = 0.001 **G1/G2:** *P* = 0.008 Receptive semantics: **G1:** 7.0 ± 3.8 **G2:** 9.4 ± 3.1

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
NR **Author industry relationship disclosures:** NR **Design:** RCT	therapist (blinded) worked with both groups • Scalp acupuncture performed by physician (specialized pediatric acupuncturist) **Assessments:** Battery of examinations before and after treatment, including communicative assessment and an Arab language test **Co-interventions held stable during treatment:** None **Frequency of contact during study:** Assessments conducted once prior to initiation of therapy and once post-therapy; twice a week during therapy **Concomitant therapies:** NR **N at enrollment:** **G1:** 10 **G2:** 10 **N at follow-up:** **G1:** 10 **G2:** 10	**Mental age:** NR **Gender, n:** **G1, n:** Male: **G1:** 5 **G2:** 7 Female: **G1:** 5 **G2:** 3 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/ method:** DSM-IV-T, parent-rated ADI-R **Diagnostic category, n (%):** Autism: 20 (100) **Other characteristics, n (%):** Delayed language development: 20 (100)	**G2:** NR* Expressive syntax: **G1:** NR* **G2:** NR* Phonology: **G1:** NR* **G2:** NR* Pragmatics: **G1:** NR* **G2:** NR*	**G1/BL:** $P = 0.021$ **G2/BL:** $P = 0.001$ **G1/G2:** $P = 0.034$ Expressive semantics: **G1:** 4.4 ± 3.4 **G2:** 4.1 ± 3.4 **G1/BL:** $P = 0.031$ **G2/BL:** $P = 0.021$ **G1/G2:** $P = 0.545$ Receptive syntax: **G1:** NR* **G2:** NR* **G1/BL:** P = NS **G2/BL:** P = NS **G1/G2:** P = NS Expressive syntax: **G1:** NR* **G2:** NR* **G1/BL:** P = NS **G2/BL:** P = NS **G1/G2:** P = NS Phonology: **G1:** NR* **G2:** NR* **G1/BL:** P = NS **G2/BL:** P = NS **G1/G2:** P = NS Pragmatics: **G1:** NR* **G2:** NR* **G1/BL:** P = NS **G2/BL:** P = NS **G1/G2:** P = NS **Harms:** NR
Allam et al., 2008 (continued)				**Modifiers:** NR

Comments: *Data for nonsignificant results was not reported.

Author: Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ **Country:** US	**RCT intervention (8 weeks):** Risperidone or placebo Dosage by weight: • 20-45 kg: Initial dose of 0.5 mg at bedtime; increased to 0.5 mg twice daily on day 4; gradually increased in 0.5 mg increments to a maximum of 2.5 mg/ day (1.0 mg AM, 1.5 mg bedtime) by day 29 • > 45 kg: slightly accelerated dose schedule, with maximal dose of	**Inclusion criteria:** • Children meeting DSM-IV criteria for autistic disorder, with tantrums, aggression, self-injurious behavior, or a combination of these problems • Aged 5 to 17 years • Weight ≥ 15 kg • Mental age ≥ 18 months • Clinically significant behavioral problems with clinician-determined rating of ≥ moderate on CGI-S and score ≥ 18 on	**Overall ratings:** RLRS score, mean ± SD:^ Overall: **G1:** 0.94 ± 0.36 **G2:** 1.03 ± 0.37 Affectual reactions: **G1:** 1.68 ± 0.64 **G2:** 1.84 ± 0.64 **Social skills:** RLRS social relationship to people score, mean ± SD:^ **G1:** 0.60 ± 0.43 **G2:** 0.72 ± 0.43	**Overall ratings:** Rate of positive response (≥ 25% improvement on ABC irritability subscale and rating of much improved or very much improved on CGI-I scale), post-RCT, n (%):‡ **G1:** 34 (69)** **G2:** 6 (12) **G1/G2:** $P < 0.001$ Rate of positive response, 8 week

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Practice setting: Academic centers **Intervention setting:** Clinic **Enrollment period:** June 1999 to April 2001 **Funding:** NIH; Kor-czak Foundation; Janssen (provided study medication) **Author industry relationship disclosures:** NR^‡ª¥ 1 of 15† Lilly (1) McNeil (1) Novartis (1) Noven (1) Shire (1) Sigma Tau (1) 8 of 17º Abbott (2) AGS Publishing (2 VABS royalties) AstraZenca (1)	1.5 mg AM and 2.0 mg bedtime • < 20 kg: initial dose 0.25 mg/day Scheduled dose increase could be delayed due to AEs or marked improve-ment at lower dose; dose reductions to manage side effects allowed at any time; no dose increases after day 29 Daily dose during final study week, mean mg (range): **G1:** 1.8 ± 0.7 (0.5-3.5) **G2:** 2.4 ± 0.6 (1.0-3.5) **Open label extension trial (8 weeks):** The 46 RCT placebo non-responders underwent an open label trial of risperidone after the RCT, with the same dosage schedule as the RCT **Assessments:** Lab tests, ECGS, prolactin and VABS maladaptive behavior pre- and post-RCT and post-extension Vital signs, height, weight, side effects, sleep log, SARS, AIMS at each visit	ABC Irritability subscale rated by parent and confirmed by caregiver (children reassessed at baseline, 7-14 days after initial assessment to confirm first values) **Exclusion criteria:** • Serious medical disorders • Other psychiatric disorders requiring medication • Children receiving a psychotropic drug that was deemed effective for the treatment of aggression, tantrums, or self-injurious behavior **Age, RCT population, years (range):** 8.8 ± 2.7 (5-17) Prepubertal, RCT population, n (%): 88 (87) **Mental age:** Mental development, RCT population, n (%): Average or above average IQ: **G1:** 3/46 (7) **G2:** 2/45 (4) Borderline IQ: **G1:** 8/46 (17) **G2:** 4/45 (9) Mild or moderate retardation: **G1:** 20/46 (43) **G2:** 23/45 (51)	VABS socialization score, mean ± SD:‡ **G1:** 49.1 ± 16.6 **G2:** 47.4 ± 10.1 **Communication/ language:** RLRS language score, mean ± SD:^ **G1:** 0.28 ± 0.38 **G2:** 0.46 ± 0.42 VABS communica-tion score, mean ± SD:‡ **G1:** 45.0 ± 16.7 **G2:** 42.0 ± 14.3 **Repetitive behavior:** ABC stereotypy score, mean ± SD:‡ **G1:** 10.6 ± 4.9 **G2:** 9.0 ± 4.4 **Problem behavior:** ABC score, mean ± SD:‡ Irritability: **G1:** 26.2 ± 7.9 **G2:** 25.5 ± 6.6 Social withdrawal: **G1:** 16.4 ± 8.2 **G2:** 16.1 ± 8.7 Hyperactivity: **G1:** 31.8 ± 9.6 **G2:** 32.3 ± 8.5	open label trial, n (%):^ **G1:** 29/46 (63) RLRS overall score, mean ± SD:^ Post-RCT: **G1:** 0.45 ± 0.31 **G2:** 0.88 ± 0.40 **G1/G2:** *P* < 0.001 (ES = 1.08) Post-extension phase: **G1:** 0.39 ± 0.35 RLRS affectual reactions score, mean ± SD:^ Post-RCT: **G1:** 0.88 ± 0.56 **G2:** 1.60 ± 0.71 **G1/G2:** *P* < 0.001 (ES = 1.10) Post-extension phase: **G1:** 0.78 ± 0.58 **Social skills:** RLRS social relationship to people score, mean ± SD:^ Post-RCT: **G1:** 0.15 ± 0.42 **G2:** 0.46 ± 0.52 **G1/G2:** *P* = NS (ES = 0.68)
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued) Bristol-Myers Squibb (3) Cephalon (1) Forest (1) Jannssen (5)	RLRS at pre-, mid- and post-RCT, monthly thereafter CYBOCS, CGI and ABC bi-weekly during RCT and monthly thereafter Target symptoms, California VLT, Dot Test, Cancellation and Purdue Peg Board tasks pre-, mid- and post-RCT VABS at pre-RCT and post-extension **Groups:** **G1:** risperidone **G2:** placebo **Co-interventions held stable during treatment:**	Severe retardation: **G1:** 15/46 (33) **G2:** 16/45 (36) **Gender, RCT population, n (%):** Male: **G1:** 39 (80) **G2:** 43 (52) Female: **G1:** 10 (20) **G2:** 9 (17) **Race/ethnicity, RCT population, n (%):** White: 67 (66) Black: 11 (11) Hispanic: 7 (7) Asian: 8 (8) Other: 8 (8) **SES:**	Inappropriate speech: **G1:** 4.8 ± 4.1 **G2:** 6.5 ± 3.6 VABS maladaptive behavior score, mean ± SD:^ Part 1: **G1:** 24.89 ± 6.91 **G2:** 25.22 ± 5.72 Part 2: **G1:** 8.37 ± 2.59 **G2:** 8.29 ± 3.66 Total: **G1:** 33.26 ± 8.38 **G2:** 33.51 ± 8.29 **Adaptive behavior:** VABS score, mean ± SD:‡	Post-extension phase: **G1:** 0.00 ± 0.42 VABS socializa-tion, standard score, post-extension phase, mean change ± SD:º **G1:** 1.83 ± 9.64 (n=48) **G1/BL:** *P* = NS (ES = 0.14) **Communication/ language:** RLRS language score, mean ± SD:^ Post-RCT:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Lilly (5) McNeil (2) Novartis (1) Noven (1) Pediamed (1) Pfizer (4) Shire (2) Sigma Tau (1) Targacept (1) Wyeth (1) 7 of 17§ Bristol-Myers Squibb (6) Forest (3) Jannssen (4) Johnson and Johnson (1) Lilly (4) McNeil (3) Neuropharm (3) Novartis (2) Organon (1) Pfizer (1) Shire (3) Supernus (2) UCB (1) Wyeth (1)	NR **Frequency of contact during study:** Weekly during RCT, monthly thereafter **Concomitant therapies:** NR **N at RCT enrollment:** **G1:** 49 **G2:** 52 **N at start of 8 week extension trial:** **G1:** 46	Education of parent or primary caregiver, n (%): High school or less: **G1:** 9 (18) **G2:** 13 (25) Trade school or college: **G1:** 33 (67) **G2:** 31 (60) Advanced degree: **G1:** 7 (14) **G2:** 8 (15) Annual household income, n (%): < $20,000: **G1:** 5/48 (10) **G2:** 8/51 (16) $20,001-$40,000: **G1:** 12/48 (25) **G2:** 16/51 (31) $40,001-$60,000: **G1:** 10/48 (21) **G2:** 7/51 (15) > $60,000: **G1:** 21/48 (44) **G2:** 20/51 (39) **Diagnostic approach:** In Study **Diagnostic tool/method:** Diagnosis corroborated by ADI-R, administered by a clinician with special training and systematic review to ensure reliability	Daily living: **G1:** 40.8 ± 21.0 **G2:** 34.0 ± 15.6 **Medical:** CYBOCS score, mean ± SD:^ **G1:** 15.51 ± 2.73 **G2:** 15.18 ± 3.88 BMI, CDC standard score, mean ± SD: **G1:** 0.4 ± 1.4 **G2:** 0.7 ± 1.3 SARS score, mean ± SD: **G1:** 0.27 ± 0.70 **G2:** 0.54 ± 1.60 AIMS score, mean ± SD: **G1:** 0.36 ± 0.99 **G2:** 0.23 ± 1.02 Sleep time, mean hours/day: **G1:** 9.66 **G2:** 9.42 Serum prolactin, mean ng/mL ± SD:ª **G1:** 9.3 ± 7.5 (n=42) **G2:** 9.3 ± 7.6 (n=36) **Motor skills:** Purdue pegboard, mean ± SD:§	**G1:** 0.03 ± 0.29 **G2:** 0.34 ± 0.41 **G1/G2:** *P* = NS (ES = 0.81) Post-extension phase: **G1:** 0.10 ± 0.36 VABS communi-cation, standard score, post-extension phase, mean change ± SD:º **G1:** 1.63 ± 8.91 (n=48) **G1/BL:** *P* = NS (ES = 0.11) **Repetitive behavior:** ABC stereotypy score, mean ± SD: Post-RCT:‡ **G1:** 5.8 ± 4.6 **G2:** 7.3 ± 4.8 **G1/G2:** *P* < 0.001 (ES = 0.8) (ES = 1.2)
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued) **Design:** Randomized trial with open label continuation phase		**Diagnostic category:** See inclusion criteria CGI-S, RCT population, n (%) Moderate: **G1:** 9/49 (18) **G2:** 9/49 (18) Marked: **G1:** 27/49 (55) **G2:** 28/49 (57) Severe: **G1:** 12/49 (24) **G2:** 12/49 (24) Extreme: **G1:** 1/49 (2) **G2:** 0 **Other characteristics, n (%):** Educational placement of child, RCT population: Regular class: **G1:** 5/47 (11) **G2:** 3/50 (6) Special education program:	Dominant hand insert: **G1:** 32.76 ± 17.4 (n=17) **G2:** 24.08 ± 10.5 (n=13) Nondominant hand insert: **G1:** 26.82 ± 18.4 (n=17) **G2:** 22.38 ± 9.9 (n=13) Dominant hand drops: **G1:** 2.35 ± 1.9 (n=17) **G2:** 2.77 ± 2.4 (n=13) Nondominant hand drops: **G1:** 3.24 ± 3.0 (n=17) **G2:** 2.31 ± 2.4 (n=13)	**Problem behavior:** ABC irritability score, post-RCT, mean ± SD:‡ **G1:** 11.3 ± 7.4 **G2:** 21.9 ± 9.5 **G1/G2:** *P* < 0.001 ABC lethargy/ social withdrawal score, mean ± SD: Post-RCT:‡ **G1:** 8.9 ± 6.4 **G2:** 12.0 ± 8.3 **G1/G2:** *P* = 0.03 (ES = 0.4) ABC hyperactivity score, mean ± SD: Post-RCT:‡ **G1:** 17.0 ± 9.7 **G2:** 27.6 ± 10.6 **G1/G2:** *P* < 0.001 (ES = 1.0) ABC inappropriate

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
		G1: 42/47 (89) **G2:** 46/50 (92) Residential school: **G1:** 0 **G2:** 1/50 (2) Current anticonvulsant treatment, RCT population: **G1:** 2/49 (4) **G2:** 2/49 (4) Previous medication, RCT population: None: **G1:** 8/41 (20) **G2:** 10/35 (29) Antipsychotic agent: **G1:** 4/41 (10) **G2:** 1/35 (3) SSRI: **G1:** 6/41 (15) **G2:** 10/35 (29) Stimulant: **G1:** 14/41 (34) **G2:** 7/35 (20) Alpha-2 adrenergic agonist: **G1:** 9/41 (22) **G2:** 7/35 (20) Child living at home with at least 1 parent, RCT population: 92 (91)	Both hands inserts: **G1:** 59.59 ± 35.3 (n=17) **G2:** 46.46 ± 19.5 (n=13) Both hands drops: **G1:** 5.59 ± 4.0 (n=17) **G2:** 5.08 ± 4.3 (n=13) **Sensory:** RLRS score, mean ± SD:^ Sensory motor behaviors: **G1:** 1.00 ± 0.52 **G2:** 0.93 ± 0.58 Sensory responses: **G1:** 1.13 ± 0.53 **G2:** 1.21 ± 0.53	speech score, mean ± SD: Post-RCT:‡ **G1:** 3.0 ± 3.1 **G2:** 5.9 ± 3.8 **G1/G2:** *P* = 0.03 (ES = 0.3) VABS maladaptive behavior score, part 1, mean ± SD:^ Post-RCT: **G1:** 14.89 ± 5.93 **G2:** 22.97 ± 5.99 **G1/G2:** *P* < 0.001 (ES = 1.17) Post-extension phase: **G1:** 16.55 ± 6.87 VABS maladaptive behavior score, part 2, mean ± SD:^ Post-RCT: **G1:** 5.45 ± 3.25 **G2:** 7.30 ± 3.45 **G1/G2:** *P* = 0.02 (ES = 0.49)
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued)			**Educational/ cognitive/ academic attainment:** Cancellation task, mean ± SD:§ Correct detections: **G1:** 126.75 ± 46.9 (n=12) **G2:** 110.71 ± 56.3 (n=7) Commissions: **G1:** 6.50 ± 22.2 (n=12) **G2:** 2.29 ± 4.3 (n=7) Omissions: **G1:** 11.75 ± 22.6 (n=12) **G2:** 19.00 ± 20.3 (n=7) Analogue classroom task, mean ± SD:§ Number attempted: **G1:** 22.88 ± 14.7 (n=8) **G2:** 31.63 ± 11.0 (n=8) Number correct:	Post-extension phase: **G1:** 5.04 ± 3.20 VABS maladaptive behavior total score, mean ± SD:^ Post-RCT: **G1:** 20.34 ± 7.93 **G2:** 30.27 ± 8.87 **G1/G2:** *P* < 0.001 (ES = 1.03) Post-extension phase: **G1:** 21.60 ± 9.50 Target symptom ratings (lower scores better) post-RCT, mean ± SD:† **G1:** 2.8 ± 1.16 (n=44) **G2:** 4.5 ± 1.28 (n=43) **G1/G2:** *P* < 0.001 (ES = 1.39) **Adaptive behavior:**

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
			G1: 19.25 ± 11.4 (n=8) **G2:** 24.50 ± 10.5 (n=8) Verbal learning task, mean ± SD:§ Immediate recall: **G1:** 28.50 ± 11.9 (n=12) **G2:** 25.00 ± 8.8 (n=8) Delayed recall: **G1:** 6.20 ± 4.6 (n=12) **G2:** 4.67 ± 2.9 (n=8) Recognition: **G1:** 77.87 ± 19.1 (n=12) **G2:** 81.00 ± 11.6 (n=8)	VABS standard score, post-extension phase, mean change ± SD:º Composite: **G1:** -0.29 ± 12.53 (n=48) **G1/BL:** *P* = NS (ES = -0.02) Daily living skills: **G1:** 0.96 ± 10.35 (n=48) **G1/BL:** *P* = NS (ES = 0.06) **Medical:** CYBOCS score, post-RCT, mean ± SD:^ **G1:** 11.65 ± 4.02 **G2:** 14.21 ± 4.81 **G1/G2:** *P* = 0.005 (ES = 0.55)
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued)			Dot test, mean ± SD:§ Average distance: **G1:** 2.40 ± 1.0 (n=4) **G2:** 3.52 ± 1.8 (n=4) Average distance-delay: **G1:** 7.19 ± 2.34 (n=4) **G2:** 4.95 ± 2.2 (n=4) Difference: **G1:** 4.79 ± 2.0 (n=4) **G2:** 1.43 ± 1.5 (n=4) **Harms:** Potential harms, %: Difficulty falling asleep: **G1:** 32.7 **G2:** 50.0 Tired during day: **G1:** 14.3 **G2:** 23.1 Enuresis: **G1:** 40.8 **G2:** 32.7 Anxiety: **G1:** 20.4 **G2:** 32.7 Rhinitis: **G1:** 12.2 **G2:** 17.3 Excessive appetite: **G1:** 12.2 **G2:** 11.5	Weight increase, post-RCT, mean kg ± SD:‡ **G1:** 2.7 ± 2.9 **G2:** 0.8 ± 2.2 **G1/G2:** *P* < 0.001 Weight increase, extension phase, mean kg ± SD (range):¥ **G1:** 5.6 ± 3.9 (-4.0 -15.3) BMI, CDC standard score, post-RCT, mean ± SD: **G1:** 1.0 ± 1.2 **G2:** 0.8 ± 1.3 **G1/G2:** *P* < 0.001 BMI increase, extension phase, mean kg/m^2 ± SD:¥ **G1:** 2.0 ± 1.9 SARS score, post-RCT, mean ± SD: **G1:** 0.52 ± 1.33 **G2:** 0.69 ± 2.48 **G1/G2:** *P* = NS SARS score, maximum value during extension ± SD: **G1:** 0.71 ± 2.67

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
			Coughing: **G1:** 8.2 **G2:** 19.2 Dry mouth: **G1:** 12.2 **G2:** 11.5 Nausea/vomiting: **G1:** 4.1 **G2:** 5.8 Diarrhea: **G1:** 8.2 **G2:** 9.6 Difficulty waking: **G1:** 14.3 **G2:** 19.2	AIMS score, post-RCT, mean ± SD: **G1:** 0.17 ± 0.57 **G2:** 0.22 ± 0.73 **G1/G2:** *P* = NS AIMS score, maximum values during extension ± SD: **G1:** 0.11 ± 0.50 Sleep time, mean hours/day, RCT phase: **G1:** 10.33 **G2:** 9.70 **G1/G2:** *P* = NS
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued)			Constipation: **G1:** 16.3 **G2:** 11.5 Skin rash: **G1:** 8.2 **G2:** 7.7 Headaches: **G1:** 10.2 **G2:** 5.8 Dyspepsia: **G1:** 0 **G2:** 1.9 Excessive saliva: **G1:** 4.1 **G2:** 7.7 Dizziness/loss of balance: **G1:** 0 **G2:** 1.9 Tachycardia: **G1:** 2.0 **G2:** 1.9 Muscles appear stuck: **G1:** 0 **G2:** 5.8 Tongue movements: **G1:** 4.1 **G2:** 3.8	Serum prolactin, post-RCT, mean ng/mL ± SD:ª **G1:** 39.0 ± 19.2 **G2:** 10.1 ± 8.8 **G1/G2:** *P* < 0.0001 Serum prolactin, 6 months, mean ng/mL ± SD:ª **G1:** 32.4 ± 17.8 (n=43) **G1/BL:** *P* < 0.0001 **G1/PE:** *P* = 0.009 Serum prolactin, 22 ± 2 months, mean ng/mL ± SD:ª **G1:** 25.3 ± 15.6 (n=30) **G1/BL:** *P* < 0.0001 **Motor skills:** Purdue pegboard, post-RCT, mean ± SD:§ Dominant hand insert: **G1:** 34.59 ± 16.0 (n=17) **G2:** 28.38 ± 13.9 (n=13) ANOVA: time (*P* ≤ 0.05) Nondominant hand insert: **G1:** 29.53 ± 14.7 (n=17) **G2:** 24.23 ± 10.3 (n=13)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				Dominant hand drops: **G1:** 4.00 ± 3.4 (n=17) **G2:** 3.00 ± 2.6 (n=13)
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued)				Nondominant hand drops: **G1:** 4.00 ± 3.00 (n=17) **G2:** 3.54 ± 2.9 (n=13) Both hands inserts: **G1:** 64.12 ± 30.0 (n=17) **G2:** 52.62 ± 23.2 (n=13) Both hands drops: **G1:** 8.00 ± 5.5 (n=17) **G2:** 6.54 ± 4.9 (n=13) **Sensory:** RLRS-sensory motor behaviors mean ± SD:^ Post-RCT: **G1:** 0.59 ± 0.42 **G2:** 0.91 ± 0.60 **G1/G2:** *P* = 0.002 (ES = 0.45) Post-extension phase: **G1:** 0.60 ± 0.49 RLRS sensory responses score, mean ± SD:^ Post-RCT: **G1:** 0.60 ± 0.38 **G2:** 1.07 ± 0.54 **G1/G2:** *P* = 0.004 (ES = 0.77) Post-extension phase: **G1:** 0.45 ± 0.37
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§				**Educational/ cognitive/ academic attainment:** Cancellation task, post-RCT, mean ± SD:§ Correct detections: **G1:** 138.50 ± 59.7 (n=12)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Martin et al., 2004¥ (continued)				**G2:** 95.29 ± 59.7 (n=7) ANOVA: drug x time ($P \leq 0.05$) Commissions: **G1:** 0.08 ± 0.3 (n=12) **G2:** 4.09 ± 9.7 (n=7) Omissions: **G1:** 10.00 ± 19.3 (n=12) **G2:** 27.75 ± 33.8 (n=7) Analogue classroom task, post-RCT, mean ± SD:§ Number attempted: **G1:** 24.50 ± 5.8 (n=8) **G2:** 32.50 ± 15.7 (n=8) Number correct: **G1:** 20.50 ± 6.6 (n=8) **G2:** 26.63 ± 18.0 (n=8)
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued)				Verbal learning task, post-RCT, mean ± SD:§ Immediate recall: **G1:** 31.92 ± 11.6 (n=12) **G2:** 29.88 ± 8.9 (n=8) ANOVA: time ($P \leq 0.01$) Delayed recall: **G1:** 7.40 ± 2.7 (n=12) **G2:** 4.83 ± 2.9 (n=8) Recognition: **G1:** 83.17 ± 15.4 (n=12) **G2:** 81.00 ± 11.6 (n=8) ANOVA: drug x time ($P \leq 0.05$) Dot test, post-RCT, mean ± SD:§ Average distance: **G1:** 2.57 ± 1.3 (n=4)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G2: 2.90 ± 1.3 (n=4) Average distance-delay: **G1:** 5.08 ± 2.4 (n=4) **G2:** 5.27 ± 2.6 (n=4) Difference: **G1:** 2.52 ± 2.0 (n=4) **G2:** 2.38 ± 2.9 (n=4) ANOVA: drug x time ($P \leq 0.05$) **Harms:** AEs during RCT, n (%):‡ Mild increased appetite: **G1:** 24/49 (49) **G2:** 13/51 (25) **G1/G2:** $P = 0.03$
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued)				Moderate increased appetite: **G1:** 12/49 (24) **G2:** 2/51 (4) **G1/G2:** $P = 0.01$ Nasal congestion: **G1:** 25/49 (51) **G2:** 20/51 (39) **G1/G2:** $P = 0.32$ Fatigue: **G1:** 29/49 (59) **G2:** 14/51 (27) **G1/G2:** $P = 0.003$ Enuresis: **G1:** 15/49 (31) **G2:** 15/51 (29) **G1/G2:** $P = 0.93$ Drowsiness: **G1:** 24/49 (49) **G2:** 6/51 (12) **G1/G2:** $P < 0.001$ Vomiting: **G1:** 16/49 (33) **G2:** 12/51 (24) **G1/G2:** $P = 0.24$ Insomnia: **G1:** 7/49 (14) **G2:** 15/51 (29) **G1/G2:** $P = 0.11$ Anxiety: **G1:** 12/49 (24) **G2:** 10/51 (20) **G1/G2:** $P = 0.73$ Diarrhea:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G1: 9/49 (18) **G2:** 11/51 (22) **G1/G2:** P = 0.88 Constipation: **G1:** 14/49 (29) **G2:** 6/51 (12) **G1/G2:** P = 0.06 Sleep problems: **G1:** 11/49 (22) **G2:** 9/51 (18) **G1/G2:** P = 0.73 Skin irritation: **G1:** 11/49 (22) **G2:** 7/51 (14) **G1/G2:** P = 0.38
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued)				Drooling: **G1:** 13/49 (27) **G2:** 3/51 (6) **G1/G2:** P = 0.02 Headache: **G1:** 9/49 (18) **G2:** 6/51 (12) **G1/G2:** P = 0.52 Stomachache: **G1:** 5/49 (10) **G2:** 9/51 (18) **G1/G2:** P = 0.43 Dry mouth: **G1:** 9/49 (18) **G2:** 5/51 (10) **G1/G2:** P = 0.34 Increased thirst: **G1:** 6/49 (12) **G2:** 5/51 (10) **G1/G2:** P = 0.94 Dizziness: **G1:** 8/49 (16) **G2:** 2/51 (4) **G1/G2:** P = 0.05 Dyskinesia: **G1:** 6/49 (12) **G2:** 3/51 (6) Nausea: **G1:** 4/49 (8) **G2:** 5/51 (10) **G1/G2:** P = 0.95 Decreased appetite: **G1:** 3/49 (6) **G2:** 5/51 (10) **G1/G2:** P = 0.76 Tremor: **G1:** 7/49 (14) **G2:** 1/51 (2) **G1/G2:** P = 0.06 Tachycardia: **G1:** 6/49 (12)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G2: 1/51 (2) **G1/G2:** *P* = 0.06 Upper respiratory tract infection: **G1:** 5/49 (10) **G2:** 2/51 (4) **G1/G2:** *P* = 0.40
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued)				Earache: **G1:** 2/49 (4) **G2:** 4/51 (8) **G1/G2:** *P* = 0.71 Muscle rigidity: **G1:** 5/49 (10) **G2:** 1/51 (2) Sore throat: **G1:** 5/49 (10) **G2:** 1/51 (2) **G1/G2:** *P* = 0.11 Restlessness: **G1:** 3/49 (6) **G2:** 3/51 (6) **G1/G2:** *P* = 0.71 Elevated serum glutamic-oxaloacetic transaminase level: **G1:** 1 **G2:** 1 Elevated serum glutamic-pyruvic transaminase level: **G1:** 0 **G2:** 1 Nonspecific, clinically insignificant changes in cardiac conduction: **G1:** 0 **G2:** 1 Fever in association with documented time-limited illness, n: **G1:** 8 **G2:** 10 Withdrew due to AEs, RCT study: **G1:** 0 **G2:** 0
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003†				AEs during RCT, % (overall symptom *P*-values): Difficulty falling asleep:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued)				Mild: **G1:** 24.5 **G2:** 30.8 Moderate/severe: **G1:** 22.4 **G2:** 34.6 **G1/G2:** *P* = 0.02 Tired during day Mild: **G1:** 57.1 **G2:** 42.3 Moderate/severe: **G1:** 36.8 **G2:** 11.5 **G1/G2:** *P* < 0.0001 Enuresis: Mild: **G1:** 32.7 **G2:** 19.2 Moderate/severe: **G1:** 32.7 **G2:** 28.8 **G1/G2:** *P* = 0.11 Anxiety: Mild: **G1:** 18.1 **G2:** 14.2 Moderate/severe: **G1:** 32.7 **G2:** 15.4 **G1/G2:** *P* = 0.05 Rhinitis: Mild: **G1:** 38.8 **G2:** 36.5 Moderate/severe: **G1:** 16.3 **G2:** 7.7 **G1/G2:** *P* = NS Excessive appetite: Mild: **G1:** 49.0 **G2:** 28.8
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al.,				Moderate/severe: **G1:** 32.6 **G2:** 9.6 **G1/G2:** *P* < 0.0001 Coughing: Mild: **G1:** 40.8 **G2:** 21.2 Moderate/severe: **G1:** 6.1 **G2:** 15.4

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
2004¥ (continued)				**G1/G2:** *P* = NS Dry mouth: Mild: **G1:** 40.8 **G2:** 26.9 Moderate/severe: **G1:** 2.0 **G2:** 1.9 **G1/G2:** *P* = 0.15 Nausea/vomiting: Mild: **G1:** 36.7 **G2:** 23.1 Moderate/severe: **G1:** 4.0 **G2:** 5.8 **G1/G2:** *P* = 0.20 Diarrhea: Mild: **G1:** 26.5 **G2:** 19.2 Moderate/severe: **G1:** 4.1 **G2:** 9.6 **G1/G2:** *P* = NS Difficulty waking: Mild: **G1:** 34.7 **G2:** 19.2 Moderate/severe: **G1:** 12.2 **G2:** 7.7 **G1/G2:** *P* = 0.05 Constipation: Mild: **G1:** 28.6 **G2:** 13.5 Moderate/severe: **G1:** 10.2 **G2:** 11.5 **G1/G2:** *P* = 0.14
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued)				Skin rash: Mild: **G1:** 24.5 **G2:** 15.4 Moderate/severe: **G1:** 2.0 **G2:** 1.9 **G1/G2:** *P* = NS Headaches: Mild: **G1:** 18.4 **G2:** 11.5 Moderate/severe: **G1:** 4.1 **G2:** 5.8 **G1/G2:** *P* = NS

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				Dyspepsia: Mild: **G1:** 10.2 **G2:** 11.5 Moderate/severe: **G1:** 0 **G2:** 5.8 **G1/G2:** *P* = 0.19 Excessive saliva: Mild: **G1:** 24.5 **G2:** 9.6 Moderate/severe: **G1:** 4.0 **G2:** 1.9 **G1/G2:** *P* = 0.04 Dizziness/loss of balance: Mild: **G1:** 16.3 **G2:** 7.7 Moderate/severe: **G1:** 6.1 **G2:** 0 **G1/G2:** *P* = 0.04 Tachycardia: Mild: **G1:** 6.1 **G2:** 7.7 Moderate/severe: **G1:** 2.0 **G2:** 0 **G1/G2:** *P* = NS
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued)				Muscles appear stuck: Mild: **G1:** 4.1 **G2:** 3.8 Moderate/severe: **G1:** 4.1 **G2:** 1.9 **G1/G2:** *P* = NS Tongue movements: Mild: **G1:** 6.1 **G2:** 3.8 Moderate/severe: **G1:** 4.0 **G2:** 0 **G1/G2:** *P* = NS AEs, 8 week open label trial, %: Difficulty falling asleep: Mild: **G1:** 54.1

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				Moderate/severe: **G1:** 10.8 Tired during day Mild: **G1:** 83.8 Moderate/severe: **G1:** 2.7 Enuresis: Mild: **G1:** 43.2 Anxiety: Mild: **G1:** 35.1 Moderate/severe: **G1:** 2.7 Rhinitis: Mild: **G1:** 45.9 Excessive appetite: Mild: **G1:** 73.0 Coughing: Mild: **G1:** 35.1 Dry mouth: Mild: **G1:** 37.8
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued)				Nausea/vomiting: Mild: **G1:** 27.0 Diarrhea: Mild: **G1:** 32.4 Difficulty waking: Mild: **G1:** 54.1 Moderate/severe: **G1:** 10.8 Constipation: Mild: **G1:** 18.9 Moderate/severe: **G1:** 2.7 Skin rash: Mild: **G1:** 18.9 Headaches: Mild: **G1:** 13.5 Moderate/severe: **G1:** 2.7 Dyspepsia: Mild: **G1:** 8.1 Excessive saliva: Mild:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				G1: 35.1 Dizziness/loss of balance: Mild: **G1:** 13.5 Moderate/severe: **G1:** 2.7 Tachycardia: Mild: **G1:** 10.8 Muscles appear stuck: Mild: **G1:** 5.4 Moderate/severe: **G1:** 2.7 Tongue movements: Mild: **G1:** 2.7
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued)				AEs, pre-extension phase, %: Excessive appetite: **G1:** 54.0 Enuresis: **G1:** 41.3 Tired during day: **G1:** 22.2 Dry mouth: **G1:** 20.6 Coughing: **G1:** 19.0 Anxiety: **G1:** 19.0 Rhinitis: **G1:** 15.9 Excess saliva: **G1:** 12.7 Nausea/vomiting: **G1:** 6.3 Difficulty falling asleep: **G1:** 6.3 Gynecomastia: **G1:** 3.2 Difficulty waking: **G1:** 4.8 Diarrhea: **G1:** 6.3 Constipation: **G1:** 6.3 Skin rash: **G1:** 1.6 Muscles "stuck": **G1:** 3.2 AEs, extension

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				phase, month 4, %: Excessive appetite: **G1:** 49.1 Enuresis: **G1:** 35.1 Tired during day: **G1:** 21.1
Aman et al., 2005 McDougle et al., 2005^ Arnold et al., 2003† RUPP, 2002‡ Williams et al, 2006º Anderson et al., 2007ª Aman et al., 2008§ Martin et al., 2004¥ (continued)				Dry mouth: **G1:** 15.8 Coughing: **G1:** 12.3 Anxiety: **G1:** 14.0 Rhinitis: **G1:** 15.8 Excess saliva: **G1:** 15.8 Nausea/vomiting: **G1:** 10.5 Difficulty falling asleep: **G1:** 10.5 Gynecomastia: **G1:** 7.0 Difficulty waking: **G1:** 5.3 Diarrhea: **G1:** 3.5 Constipation: **G1:** 3.5 Skin rash: **G1:** 8.8 Muscles "stuck": **G1:** 3.5 Withdrew due to AEs, extension phase: **G1:** 1 (constipation) **Modifiers:** No clinical complaints or physical findings associated with changes in prolactin; no significant effects of DRD2 poly-morphisms on changes in serum prolactin from baseline to end of RCTª

Comments: * 30 from the RCT risperidone group, 30 from the placebo non-responders, and 3 who did not meet open label response criteria but were still included in phase.

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
**Gains in risperidone group maintained for 6 month extension phase in 23 of 34 children (68%) with positive responses during RCT. Of the other 11 responders, 4 did not enter extension phase. 2 children's parents decided to seek other treatment in addition to risperidone, 4 were withdrawn because treatment was no longer effective, and 1 was withdrawn due to an unrelated medical problem.‡				
Author: Anan et al., 2008 **Country:** US **Practice setting:** Private practice **Intervention setting:** Clinic and home **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Group Intensive Family Training (GIFT); 12 hour didactic weekend followed by a 12 week (180 hour, 3 hours each weekday) of parent training in EIBI **Groups:** **G1:** intervention group **Assessments:** Prior to treatment, skill strengths and deficits were evaluated; informal preference assessments conducted to identify effective reinforcers for acquisition of new skills; problem behaviors MSEL, VABS **Provider:** Parents trained by a board-certified behavior analyst and 4 staff members with experience implementing behavior analytic training **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 81 **N at follow-up:** **G1:** 72	**Inclusion criteria:** • Children diagnosed with ASD using the DSM-IV criteria by experienced physicians and/or clinical psychologists in the community • Significant impairment relative to chronological age (e.g., score on measures of cognitive and/or adaptive functioning more than 2 SD below the mean) **Exclusion criteria:** • See inclusion criteria **Age, months ± SD (range):** 44 ± 12.6 (25-68) **Mental age:** NR **Gender, %:** Male: 84.7 Female: 15.3 **Race/ethnicity:** NR **SES:** Parent/caregiver years of post-high school education, mean: 3 Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** DSMIV clinical interview **Diagnostic category, n (%):** Autism: 72 (100) **Other characteristics:** NR	**Overall ratings:** MSEL composite score, mean ± SD: **G1:** 51.69 ± 6.27 MSEL visual reception score, mean ± SD: **G1:** 60.10 ± 11.84 VABS composite score, mean ± SD: **G1:** 53.11 ± 7.39 **Social skills:** VABS socialization: score, mean ± SD: **G1:** 56.17 ± 5.29 **Communication/ language:** MSEL receptive language score, mean ± SD: **G1:** 56.58 ± 5.62 MSEL expressive language score, mean ± SD: **G1:** 56.31 ± 5.24 VABS communication score, mean ± SD: **G1:** 54.61 ± 8.35 **Adaptive behavior:** VABS daily living skills score, mean ± SD: **G1:** 57.59 ± 7.96 **Motor skills:** MSEL fine motor score, mean ± SD: **G1:** 57.35 ± 7.59 VABS motor skills score, mean ± SD: **G1:** 62.74 ± 13.50 **Educational/ cognitive/ academic attainment:** MSEL developmental age, months ± SD: Composite: **G1:** 16.99 ± 5.64	**Overall ratings:** MSEL composite score, mean ± SD: **G1:** 59.65 ± 16.58 **G1/BL:** *P* < 0.001 MSEL composite score ≥ 70, n (%): **G1:** 10 (14) MSEL visual reception score, mean ± SD: **G1:** 70.99 ± 23.00 **G1/BL:** *P* < 0.001 VABS composite score, mean ± SD: **G1:** 58.27 ± 9.59 **G1/BL:** *P* < 0.001 VABS composite score ≥ 70, n (%): **G1:** 8 (11) **Social skills:** VABS socialization: score, mean ± SD: **G1:** 61.54 ± 8.39 **G1/BL:** *P* < 0.001 **Communication/ language:** MSEL receptive language score, mean ± SD: **G1:** 63.94 ± 20.86 **G1/BL:** *P* < 0.001 MSEL expressive language score, mean ± SD: **G1:** 63.81 ± 19.40 **G1/BL:** *P* < 0.001 VABS communication score, mean ± SD: **G1:** 60.09 ± 12.19 **G1/BL:** *P* < 0.001 **Adaptive behavior:** VABS daily living skills score, mean ± SD: **G1:** 59.70 ± 8.65 **G1/BL:** *P* < 0.01

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Anan et al., 2008 (continued)			Visual reception: **G1:** 20.90 ± 6.52 Fine motor: **G1:** 21.44 ± 5.30 Receptive language: **G1:** 13.39 ± 7.17 Expressive language: **G1:** 12.21 ± 7.12 VABS develop-mental age, months ± SD: Composite: **G1:** 15.91 ± 3.60 Communication: **G1:** 11.90 ± 4.71 Socialization: **G1:** 10.30 ± 2.56 Daily living skills: **G1:** 17.86 ± 3.96 Motor skills: **G1:** 23.57 ± 6.20	**Motor skills:** MSEL fine motor score, mean ± SD: **G1:** 65.29 ± 18.97 **G1/BL:** $P < 0.001$ VABS motor skills score, mean ± SD: **G1:** 70.06 ± 16.20 **G1/BL:** $P < 0.001$ **Educational/ cognitive/ academic attainment:** MSEL develop-mental age, months ± SD: Composite: **G1:** 25.20 ± 7.93 Visual reception: **G1:** 29.51 ± 7.61 Fine motor: **G1:** 28.46 ± 8.81 Receptive language: **G1:** 21.85 ± 10.22 Expressive language: **G1:** 21.00 ± 10.36 VABS develop-mental age, months ± SD: Composite: **G1:** 21.65 ± 5.71 Communication: **G1:** 17.87 ± 6.37 Socialization: **G1:** 15.75 ± 4.83 Daily living skills: **G1:** 21.68 ± 5.67 Motor skills: **G1:** 30.99 ± 9.41 **Harms:** NR **Modifiers:** NR
Author: Andersen et al., 2008 **Country:** US **Practice setting:** Academic **Intervention setting:**	**Intervention:** Melatonin given 30 minutes to one hour before bedtime Children under 6 started on 0.75-1 mg and increased by 1 mg every 2 weeks up to 3 mg if no response at lower dose Children 6 and older	**Inclusion criteria:** • Clinical diagnosis of ASD based on DSM-IV criteria • Confirmed use of supplemental melatonin for sleep concerns based on medication records at follow-up clinical visits	**Overall ratings:** Sleep complaints, %: Sleep-onset insomnia only: 23 Sleep-maintenance insomnia only: 8 Both sleep-onset and sleep-maintenance	**Overall ratings:** Quality of sleep, n (%): No longer reported sleep concerns: 27 (25) Improved sleep, but still some concerns in follow-up visits: 64

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** None **Design:** Retrospective case series	started on 1.5 mg and increased to 3 mg after 2 weeks if no response All children who did not show a response after 4 weeks were increased to 6 mg Sleep hygiene techniques were suggested with start of melatonin **Assessments:** Parent report in medical chart; children were from a single pediatrician's practice (specializing in ASD) **Groups:** **G1:** melatonin (dose range: 0.75-6.0 mg) **Measure of treatment fidelity reported:** Parental compliance with sleep hygiene techniques documented in 65 (58%) children **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** 2-6 month intervals for an average of 1.8 ± 1.4 years after initiating melatonin (18 children had only 1 documented follow-up visit after initiation of melatonin)	**Exclusion criteria:** • Comorbid childhood bipolar disorder **Age, years (range):** NR (2-18) **Mental age:** NR **Gender, %:** Male: 80 Female: 20 **Race/ethnicity, %:** Caucasian: 60 African American: 6 Race unknown: 34 **SES:** Maternal education: NR Household income: NR **Diagnostic approach:**NR Diagnostic tool/method: Chart review, based on DSM-IV criteria **Diagnostic category, %:** Autistic disorder: 71 PDD-NOS: 19 Aspergers: 5 **Other characteristics, n (%)**: Epileptic seizures: 21 (20) Refractory epilepsy: 4 (4) Comorbid psychiatric diagnoses, including ADHD, OCD, depression, ODD, anxiety: 31 (29) Mean age at onset of sleep problems, years ± SD: 6.7 ± 3.8 Mean age at start of melatonin, years ± SD: 8 ± 3.9	insomnia: 68 Early awakening: 1 Medication-free at baseline, n (%):* 45 (42)	(60)** Sleep still a major concern: 14 (13) Worse sleep after melatonin: 1 (1) Undetermined response: 1 (1) **Harms:** Morning sleepiness, fogginess, increased enuresis, n: 3 **Modifiers:** No significant difference in melatonin response between medication-free before taking melatonin vs. prescribed psychotropic medication.
Andersen et al., 2008 (continued)	**Concomitant therapies, n (%):** Any psychotropic medication use: 96 (90) Antidepressants: 60 (56) Antipsychotics: 68 (64) Sedative/hypnotics: 50 (45) Antiepileptics: 36 (34) Stimulants: 46 (43) **N at enrollment:** **G1:** 107 **N at follow-up:** **G1:** 107			

Comments: *34 of these 45 children started psychotropic medication within 2-6 months after initiation of melatonin. **7 initially reported improvement, but sleep problems returned after 3-12 months

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Author: Beaumont et al., 2008 **Country:** Australia **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** 1 of 2 The Junior Detective Training Program (future royalties) **Design:** RCT	**Intervention:** The Junior Detective Training Program: group social skills training, parent training, teacher handouts and a computer game 2 hour training sessions for 7 consecutive weeks: • Sessions 1 & 2: 1 hour training, 1 hour group therapy and parent training • Sessions 3 & 4: 45 min training, 75 min group therapy and parent training • Sessions 5 & 6: little group therapy and parent training • Session 7: 1 hour group therapy, 1 hour re-assessment **Provider:** • Chief investigator • Two intern therapists enrolled in post-graduate clinical psychology and counseling degrees **Assessments:** Developmental history questionnaire; CAST; SSQ parent and teacher forms; ERSSQ; WISC-III short-form; Assessment of Perception of Emotion from Facial Expression (Spence, 1995b); Assess-ment of Perception of Emotion from Posture Cues (Spence, 1995c); James and the Maths Test (Attwood, 2004a); Dylan is Being Teased (Attwood, 2004b) **Groups:** **G1:** new treatment **G2:** wait-list **Measure of treatment fidelity reported:** Yes	**Inclusion criteria:** • AS diagnosis confirmed by pediatrician • WISC-III pro-rated IQ score of ≥ 85 • Age 7.5-11 years at intake **Exclusion criteria:** • See inclusion criteria **Age: years ± SD (range):** **G1:** 9.64 ± 1.21 (7.5-11.7) **G2:** 9.81 ± 1.26 (8.1-11.7) **Mental age:** WISC-III IQ, mean ± SD (range): **G1:** 107.15 ± 11.94 (85-130) **G2:** 107.43 ± 14.21 (85-138) **Gender, n:** Male: **G1:** 23 **G2:** 21 Female: **G1:** 3 **G2:** 2 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** AS diagnosis confirmed by pediatrician; parents completed questionnaire including diagnostic items and CAST **Diagnostic category, n (%):** Asperger Syndrome: 49 (100) **Other characteristics:** CAST score, mean ± SD (range): **G1:** 21.63 ± 3.51 (17-29) **G2:** 21.61 ± 2.78 (17-26)	**Social Skills:** SSQ score, parent rated, mean ± SD (range): **G1:** 25.30 ± 7.43 (12-41) **G2:** 23.16 ± 9.05 (7-44) SSQ score, parent rated, follow-up group, mean ± SD (range): **G1:** 25.30 ± 7.43 (12-41) **G2:** 25.09 ± 7.34 (7-42)* ERSSQ score, mean ± SD (range): **G1:** 39.78 ± 10.17 (23-64) **G2:** 39.64 ± 12.52 (17-64) ERSSQ score, follow-up group, mean ± SD (range): **G1:** 39.78 ± 10.17 (23-64) **G2:** 39.96 ± 10.27 (12-64)* **Emotion Recognition:** Assessment of Perception of Emotion score, mean ± SD (range): Facial expression: **G1:** 17.44 ± 2.67 (12-24) **G2:** 18.30 ± 2.46 (13-22) Body posture: **G1:** 20.48 ± 3.15 (14-24) **G2:** 20.96 ± 2.44 (16-24)	**Social skills:** SSQ score, parent rated, mean ± SD (range): **G1:** 38.08 ± 9.84 (15-55) **G2:** 25.11 ± 7.91 (7-42) **G1/BL:** $P < 0.001$ **G2/BL:** P = NS **G1/G2:** $P < 0.05$ SSQ score, parent rated, follow-up group, mean ± SD (range): Post-treatment: **G1:** 38.08 ± 9.84 (15-55) **G2:** 41.50 ± 8.55 (29-58)* **G1/BL:** $P < 0.001$ **G2/BL:** $P < 0.001$ 6 weeks: **G1:** 43.24 ± 8.81 (24-58) **G2:** 39.96 ± 9.46 (22-59)* **G1/BL:** $P < 0.001$ **G2/BL:** $P < 0.001$ 5 months: **G1:** 40.64 ± 12.85 (13-60) **G2:** 41.17 ± 8.48 (28-58)* **G1/BL:** $P < 0.001$ **G2/BL:** $P < 0.001$ ERSSQ score, mean ± SD (range): **G1:** 57.38 ± 13.40 (32-80) **G2:** 40.14 ± 10.69 (12-64) **G1/BL:** $P < 0.001$ **G2/BL:** P = NS **G1/G2:** $P < 0.05$
Beaumont et al., 2008 (continued)	**Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR		Assessment of Perception of Emotion score, follow-up group, mean ± SD (range):	ERSSQ score, follow-up group, mean ± SD (range): Post-treatment:

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	N at enrollment: **G1:** 26 **G2:** 23 **N at follow-up:** **G1:** 25 **G2:** 21		Facial expression: **G1:** 17.40 ± 2.75 (12-24) **G2:** 19.35 ± 2.82 (15-24)* Body posture: **G1:** 20.44 ± 3.16 (14-24) **G2:** 20.96 ± 2.44 (16-24)* **Emotion Management:** Dylan is Being Teased score, mean ± SD (range): **G1:** 2.93 ± 1.62 (0-6) **G2:** 2.78 ± 1.59 (0-6) Dylan is Being Teased score, follow-up group, mean ± SD (range): **G1:** 3.00 ± 1.55 (0-6) **G2:** 2.39 ± 1.67 (0-6)* James and the Maths Test score, mean ± SD (range): **G1:** 1.70 ± 1.07 (0-4) **G2:** 1.74 ± 1.21 (0-4) James and the Maths Test score, follow-up group, mean ± SD (range): **G1:** 1.76 ± 1.09 (0-4) **G2:** 1.91 ± 0.95 (0-4)*	**G1:** 57.38 ± 13.40 (32-80) **G2:** 61.87 ± 8.91 (47-81)* **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 6 weeks: **G1:** 64.24 ± 9.27 (45-82) **G2:** 58.61 ± 11.99 (36-83)* **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 5-months: **G1:** 62.12 ± 12.90 (36-88) **G2:** 61.19 ± 10.96 (46-79)* **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **Emotion Recognition:** Assessment of Perception of Emotion score, mean ± SD (range): Facial expression: **G1:** 19.92 ± 2.67 (13-24) **G2:** 19.73 ± 2.80 (15-24) ANOVA: time (*P* < 0.001), treatment (*P* = NS) Body posture: **G1:** 21.81 ± 2.97 (13-24) **G2:** 21.32 ± 2.82 (15-24) ANOVA: time (*P* < 0.02), treatment (*P* = NS) Assessment of Perception of Emotion score, follow-up group, mean ± SD (range):
Beaumont et al., 2008 (continued)				Facial expression: Post-treatment: **G1:** 19.88 ± 2.71 (13-24) **G2:** 20.65 ± 2.46 (14-24)* **G1/BL:** *P* < 0.05 **G2/BL:** *P* < 0.05

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				6 weeks: **G1:** 20.32 ± 4.76 (17-24) **G2:** 21.35 ± 2.31 (16-24)* **G1/BL:** P = NS **G2/BL:** P = NS Body posture: Post-treatment: **G1:** 21.76 ± 3.02 (13-24) **G2:** 22.57 ± 1.95 (17-24)* **G1/BL:** $P < 0.05$ **G2/BL:** P = NS 6 weeks: **G1:** 22.20 ± 2.52 (15-24) **G2:** 22.91 ± 1.98 (17-24)* **G1/BL:** $P < 0.05$ **G2/BL:** P = NS **Emotion Management:** Dylan is Being Teased score, mean ± SD (range): **G1:** 5.08 ± 2.23 (2-10) **G2:** 2.64 ± 1.56 (0-7) **G1/BL:** $P < 0.001$ **G2/BL:** P = NS **G1/G2:** $P < 0.05$
Beaumont et al., 2008 (continued)				Dylan is Being Teased score, follow-up group, mean ± SD (range): Post-treatment: **G1:** 5.16 ± 2.23 (2-10) **G2:** 4.04 ± 2.31 (1-10)* **G1/BL:** $P < 0.05$ **G2/BL:** $P < 0.05$ 6 weeks: **G1:** 4.36 ± 2.27 (1-9) **G2:** 4.22 ± 2.32 (1-9)* **G1/BL:** P = NS **G2/BL:** P = NS James and the Maths Test score, mean ± SD

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				(range): **G1:** 3.81 ± 1.58 (1-7) **G2:** 2.00 ± 1.11 (0-4) **G1/BL:** *P* < 0.001 **G2/BL:** *P* = NS **G1/G2:** *P* < 0.05 James and the Maths Test score, follow-up group, mean ± SD (range): Post-treatment: **G1:** 3.92 ± 1.50 (1-7) **G2:** 2.87 ± 1.63 (1-8)* **G1/BL:** *P* < 0.05 **G2/BL:** *P* < 0.05 6 weeks: **G1:** 2.76 ± 1.33 (1-5) **G2:** 3.48 ± 2.02 (1-8)* **G1/BL:** *P* = NS **G2/BL:** *P* < 0.05 **Harms:** NR **Modifiers:** NR

Comments: *Once the treatment group completed the intervention, the program was offered to the wait-list group, so G2 constitutes another follow-up treatment group.

Author: Ben Itzchak et al., 2008 **Country:** Israel **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Israeli Association for Children with Autism **Author industry relationship disclosures:** NR **Design:**	**Intervention:** Autism group: center-based early-intervention program for 45 hrs/week **Assessments:** Cognitive ability: BSID-II for preverbal children, SB-FE for verbal children Autism severity: ADI, ADOS Cognitive assessments done for all participants, ADOS for only those with autism; re-examined after 1 year of intervention Head circumference measurements taken by senior child neurologist **Groups:** **G1:** autism **Ga:** normal cognitive score (IQ > 90) **Gb:** borderline cognitive	**Inclusion criteria:** • Children with autism (G1) **Exclusion criteria:** • See inclusion criteria **Age, months (range):** **G1:** 27.29 (19-35) **G2:** 24.16 (16-31) **Mental age:** NR **Gender, n:** Male: **G1:** 43 Female: **G1:** 1 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In study	**Social skills:** ADOS social interaction, mean ± SD: **G1a:** 14.42 ± 4.43 **G1b:** 16.18 ± 4.19 **G1c:** 21.79 ± 4.64 ADOS play, mean ± SD: **G1a:** 2.71 ± 1.50 **G1b:** 3.61 ± 1.33 **G1c:** 4.78 ± 0.94 **Communication/ language:** ADOS language and communication, mean ± SD: **G1a:** 9.55 ± 2.64 **G1b:** 12.61 ± 3.22 **G1c:** 13.90 ± 5.11 **Repetitive behavior:** ADOS stereotyped behaviors, mean ±	**Social skills:** ADOS social interaction, mean ± SD: **G1a:** 8.44 ± 5.91 **G1b:** 11.72 ± 6.28 **G1c:** 15.94 ± 5.80 **G1/BL:** *P* < 0.001 ADOS play, mean ± SD: **G1a:** 2.14 ± 1.21 **G1b:** 1.94 ± 1.26 **G1c:** 3.22 ± 1.21 **G1/BL:** *P* < 0.001 **Communication/ language:** ADOS language and communication, mean ± SD: **G1a:** 6.86 ± 3.72 **G1b:** 7.82 ± 3.24 **G1c:** 9.58 ± 4.24 **G1/BL:** *P* < 0.001

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Prospective case series **Note:** See related studies: Ben Itzchak et al., 2007{#538}, Zachor et al., 2007{#5652}, Zachor et al., 2009{#3844} (overlap among these not clear)	score (70 < IQ < 89) **Gc:** low cognitive score (50 < IQ < 69) **Provider:** • Child neurologist and multidisciplinary team at regional child development center (G2) • Not specified (G1) **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR Concomitant therapies: NR **N at enrollment:** **G1:** 44 **G1a:** 7 **G1b:** 18 **G1c:** 18 **N at follow-up:** **G1:** 44 **G1a:** 7 **G1b:** 18 **G1c:** 18	**Diagnostic tool/method:** ADI-R and DSM-IV criteria **Diagnostic category, n (%):** Autism: **G1:** 44 (100) PDD-NOS: **G1:** 0 Aspergers: **G1:** 0 Cerebral palsy: **G1:** 0 Global developmental delay: **G1:** 0 **Other characteristics:** NR	SD: **G1a:** 3.71 ± 2.43 **G1b:** 3.87 ± 1.64 **G1c:** 5.65 ± 1.78 **Educational/ cognitive/ academic attainment:** IQ, mean ± SD: **G1:** 74.84 ± 2.57	**Repetitive behavior:** ADOS stereotyped behaviors, mean ± SD: **G1a:** 2.29 ± 1.11 **G1b:** 3.37 ± 1.75 **G1c:** 4.89 ± 1.91 **G1/BL:** *P* < 0.05 **Educational/ cognitive/ academic attainment:** IQ, mean ± SD: **G1:** 89.66 ± 2.69 MANOVA: time (*P* < 0.001), time x group (*P* < 0.05) **Harms:** NR
Ben Itzchak et al., 2008 (continued)				**Modifiers:** Pre- and post-intervention IQ scores inversely related with ADOS scores on language and communication (*P* < 0.05), social interaction (*P* < 0.01), play (*P* < 0.01), and stereotyped behaviors (*P* < 0.01)
Author: Carr et al., 2008 **Country:** UK **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** NR **Funding:** NR	**Intervention:** Six object-and-picture relations using highly preferred reinforcer pictures learned in earlier phases Both groups initially received discrimination teaching at baseline Error correction group: 6 subsequent teaching sessions, 1 per day with max of 2 days between sessions; each session comprised 5 conditional	**Inclusion criteria:** • Children with formal autism diagnosis by a clinical practitioner • Age 3-7 years • At Phase II of the Picture Exchange Communication System (able to make independent exchanges of pictures for items) **Exclusion criteria:** • See inclusion criteria **Age, months:** **G1:** 66	**Educational/ cognitive/ academic attainment:** Number of trials to mastery of conditional discriminations, mean (range): **G1:** 15 (10-40) **G2:** 15.3 (10-60) **G1/G2:** *P* = NS	**Educational/ cognitive/ academic attainment:** Correspondence trial accuracy rates, mean % (range): **G1:** 72.8 (30-97) **G2:** 92.7 (70-100) **G1/G2:** *P* < 0.01 Learning outcome accuracy rates, mean % (range): **G1:** 72.5 (39-100)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Author industry relationship disclosures: NR **Design:** RCT **Note:** See related study Carr et al. 2007{#462}	discrimination trials using standard error correction procedure followed by 5 correspondence checks Error prevention group: 6 subsequent teaching sessions; each session comprised 5 conditional trials using error prevention procedure followed by 5 correspondence checks **Assessments:** Picture Exchange Communication System **Groups:** **G1:** error correction **G2:** error prevention **Provider:** Experimenter **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** Total: 29 **G1:** 14 or 15 (NR) **G2:** 14 or 15 (NR) **N at follow-up:** Total: 29	**G2:** 65 **Mental age, months:** PLS-3 receptive communication: **G1:** 8.4 **G2:** 8.6 PLS-3 expressive communication: **G1:** 8.4 **G2:** 7.6 VABS composite: **G1:** 15 **G2:** 15 **Gender:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** Diagnosis from clinical practitioner **Diagnostic category, n (%):** Autism: 29 (100) **Other characteristics:** NR		**G2:** 91.7 (72-100) **G1/G2:** *P* < 0.03 **Harms:** NR **Modifiers:** NR
Author: Corbett et al., 2008 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** UC Davis MIND Institute **Author industry relationship disclosures:** NR **Design:** RCT, double-blind crossover design	**Intervention:** Tomatis Method: administration of prepared auditory stimulation recordings (2 hours/day filtered music, passed through Electronic Ear (for attenuation and modulation) and audio-vocal feedback; administered in 4 blocks, 3 weeks each for duration followed by break for 18 weeks. The second round (crossover design) for 18 more weeks. Placebo: commercially produced music without active microphone or Electronic Ear **Assessments:** Stanford Binet Intelligence Scale, PPVT-III, EOWVT; context of assessments	**Inclusion criteria:** • DSM-IV diagnosis of autistic disorder corroborated by the ADOS-G and clinical judgment • Able to speak 1-3 words • Had a pointing gesture • Tolerated wearing headphones **Exclusion criteria:** • Previous exposure to auditory stimulation treatments **Age, years (range):** Total: 5.56 (3.5-7.17) **G1:** 5.25 (3.5-7.42) **G2:** 5.93 (4-7.17) **Mental age:** See baseline measures **Gender, n (%):** Male: 9 (82) Female: 2 (18) **Race/ethnicity, n (%):**	**Educational/ cognitive/ academic attainment:** IQ mean, (range): 66.8 (52-83) **Communication/ language:** PPVT-III score, mean ± SD: **G1:** 20.83 ± 28.52 **G2:** 32.20 ± 25.21 EOWVT score, mean ± SD: **G1:** 16.50 ± 21.11 **G2:** 25.20 ± 19.82	**Educational/ cognitive/ academic attainment:** IQ, mean, (range): 62.45 (44-84) **Communication/ language:** PPVT-III score, mean ± SD: Mid-treatment: **G1:** 20 ± 25.76 **G2:** 40.2 ± 26.69 Post-treatment: **G1:** 22.83 ± 29.36 **G2:** 47.2 ± 24.45 ANOVA: group (*P* = NS), time (*P* = 0.03), time X group (*P* = 0.08) EOWVT score, mean ± SD: Mid-treatment: **G1:** 18 ± 18.73

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	not clear **Groups:** **G1:** treatment/placebo **G2:** placebo/treatment **Provider:** Two trained assistants **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies :** NR **N at enrollment:** **G1:** 6 **G2:** 5 **N at follow-up:** **G1:** 6 **G2:** 5	Caucasian: 4 (36) Caucasian/Hispanic: 2(18) Hispanic: 2(18) Caucasian/Native American: 1 (9) Caucasian/Native American/Hispanic: 1 (9) Pacific Islander: 1 (9) **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In study **Diagnostic tool/method:** DSM-IV criteria confirmed by ADOS and clinical judgment **Diagnostic category, n (%):** Autism: 11 (100) **Other characteristics:** NR		**G2:** 29.4 ± 22.65 Post-treatment: **G1:** 21.5 ± 23.3 **G2:** 34.4 ± 25 ANOVA: group (*P* = NS), time (*P* = 0.04), time X group (*P* = 0.63) **Harms:** NR **Modifiers:** NR
Author: Fazlioglu et al., 2008 **Country:** Turkey **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Sensory integration program based on "The Sensory Diet", administered in a specially arranged room at the center, 45 minutes per session, 2 sessions per week for 24 sessions total Control group, matched for age, gender, and level of function, attended regularly scheduled special education classrooms at the center, no sensory integration program **Assessments:** observations (administrator NR) **Groups:** **G1:** experimental **G2:** control group **Provider:** Special educator **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 15	**Inclusion criteria:** • Low functioning children with autism • Attended the Trakya University Training and Research Center for Mentally and Physically Handicapped Children • Ages 7-11 years **Exclusion criteria:** • Previous participation in a sensory integration program • History of epileptic seizures **Age, years (range):** NR (7-11) **Mental age:** NR **Gender, n (%):** Male: **G1:** 12 (80) **G2:** 12 (80) Female: **G1:** 3 (20) **G2:** 3 (20) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** NR **Diagnostic tool/method:** DSM-IV	**Sensory:** Sensory Evaluation for Children with Autism score, mean ± SD: **G1:** 98.2 ± 19.3 **G2:** 95.8 ± 17.0	**Sensory:** Sensory Evaluation for Children with Autism score, mean ± SD: **G1:** 66.5 ± 11.4 **G2:** 97.3 ± 17.8 **G1/G2:** *P* < 0.01 **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	G2: 15 **N at follow-up:** **G1:** 15 **G2:** 15	**Diagnostic category, n (%):** Autism: 30 (100) **Other characteristics:** "majority" could not use language to communicate		
Author: Greenberg et al., 2008 **Country:** US **Practice setting:** Community **Intervention setting:** School **Enrollment period:** September 2006 through August 2007 **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Case series, retrospective	**Intervention:** Early intervention class at CCEI, ABA services provided in environment that combines discrete trial training and natural environment training by delivering learning units across the settings, 10 hours weekly for 44 weeks **Assessments:** Data Decision Analysis Protocol filled out daily by teachers and assistants **Groups:** **G1:** early intervention class at CCEI **Provider:** Teachers **Measure of treatment fidelity reported:** Yes: interobserver agreement ranged between 80% and 100% **Co-interventions held stable during treatment:** No **Concomitant therapies:** Majority of children's programs were supplemented by 10 hours of homebased ABA special instruction **N at enrollment:** **G1:** 24 **N at follow-up:** **G1:** 24	**Inclusion criteria:** NR **Exclusion criteria:** NR **Age, mos. (range):** (23-42) **Mental age:** NR **Gender:** M, n (%): NR F, n (%): NR **Race/ethnicity, n (%):** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** NR **Diagnostic tool/method:** NR **Diagnostic category, n (%):** PDD: 24 (100) **Other characteristics**, %: Severely limited speaker and listener skills, 80 1 child experienced Seizures at the start of CCEI	NR	**Educational/ cognitive/ academic attainment:** Learn Units, weekly: **G1:** (graph) Learn Units presented, total, mean (range): **G1:** 490, 807, 11155 (4413-15281) Learn Units correctly responded to, total, mean (range): **G1:** 315,680, 7175 (2871-10904) Learn Units presented per child per day, across the year mean (range): **G1:** 134 (100-168) Correct Learn Units per child per day, mean (range): **G1:** 86 (60-104) Classwide mean correct & total learn units per day for each child: **G1:** (graph) Total cumulative objectives mastered, n: **G1:** 2561 Average per child objectives

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				mastered, n: **G1:** 107 Objectives met per week, n: **G1:** 58 Cumulative number of objectives met each week: **G1:** (graph) Learn units per objective, mean (range): **G1:** 213 (103-750) Weekly classwide mean learn units to criterion: **G1:** (graph) Students moving to lesser restrictive environments, %: **G1:** 95 **Harms:** NR **Modifiers:** NR
Author: Kasari et al., 2006 Kasari et al., 2008† **Country:** US **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** NR **Funding:** NIH **Author industry relationship disclosures:** NR **Design:**	**Intervention:** Symbolic play or joint attention intervention sessions for 30 minutes daily for 5-6 weeks Combination of adult-directed behavioral drill (approximately 5 minutes) and child-directed milieu teaching approach for approximately 20 minutes ABA and developmental procedures of responsive and interactive methods Semi-structured child-driven floor sessions with environmental adjust-ments to facilitate social and communicative attempts Number of sessions, mean ± SD:	**Inclusion criteria:** • Diagnosis of autism on the ADI-R and ADOS • Age < 5 years old • Accessible for follow-up **Exclusion criteria:** • Seizures • Additional medical diagnoses (e.g., genetic syndromes) • Geographically inaccessible for follow-up visits • Did not plan to stay in the early intervention program for at least 4 weeks **Age, months ± SD:** Study entry: **G1:** 43.2 ± 7.05 **G2:** 42.67 ± 6.93 **G3:** 41.94 ± 4.93	**Communication/ language:** RDLS expressive language score, mean ± SD (range): **G1:** 20.60 ± 6.51 (17.55-23.65) **G2:** 21.43 ± 7.59 (17.97-24.89) **G3:**19.41 ± 7.70 (15.45-23.37) RDLS receptive language score, mean ± SD (range): **G1:** 20.55 ± 7.27 (17.15-23.95) **G2:** 21.00 ± 9.75 (16.56-25.44) **G3:** 17.53 ± 8.70 (13.06-22.00) **Social skills:** ESCS score, mean	**Communication/ language:** RDLS expressive language score, mean ± SD (range): Post-intervention: **G1:** 23.15 ± 6.43 (20.14-26.16) **G2:** 23.67 ± 8.78 (19.67-27.88) **G3:** 21.18 ± 9.11 (16.49-25.86) 12 month follow-up:† **G1:** 35.70 ± 12.57 (29.82-41.59) **G2:** 38.29 ± 15.03 (30.57-46.02) **G3:** 28.06 ± 13.52 (20.86-35.27) RDLS receptive

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
RCT	**G1:** 28.6 ± 15.6 **G2:** 34.7 ± 16.4 **G1/G2:** *P* = NS **Assessments:** MSEL, RDLS, ESCS, and Structured Play Assessment (parent report); parent-child observation (independent assessors) collected pre- and post-intervention and at 6 and 12 months post-intervention follow-up **Groups:** **G1:** joint attention **G2:** symbolic play **G3:** controls **Provider:** Graduate students in education psychology experienced with autistic children **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** NR	Post-intervention: **G1:** 44.68 ± 6.86 **G2:** 44.60 ± 6.61 **G3:** 43.47 ± 5.06 12 month follow-up: **G1:** 58.25 ± 6.86 **G2:** 57.59 ± 6.74 **G3:** 56.63 ± 4.70 **Mental age:** See baseline measures **Gender, n:** Male: **G1:** 15 **G2:** 16 **G3:** 15 Female: **G1:** 5 **G2:** 5 **G3:** 2 **Race/ethnicity, n (%):** White: **G1:** 13 **G2:** 14 **G3:** 10 Minority: **G1:** 3 **G2:** 6 **G3:** 7	± SD: Showing: **G1:** 0.10 ± 0.31 **G2:** 0.52 ± 1.78 **G3:** 0.35 ± 0.61 Child joint attention looks: **G1:** 7.25 ± 6.05 **G2:** 11.9 ± 9.07 **G3:** 8.12 ± 6.75 Pointing: **G1:** 13.15 ± 14.95 **G2:** 9.62 ± 12.81 **G3:** 7.82 ± 11.96 Giving: **G1:** 3.65 ± 3.44 **G2:** 2.52 ± 3.06 **G3:** 3.59 ± 3.45 Responds joint attention: **G1:** 10.50 ± 5.42 **G2:** 11.91 ± 9.07 **G3:** 10.53 ± 6.49	language score, mean ± SD (range): Post-intervention: **G1:** 22.80 ± 6.90 (19.57-26.03) **G2:** 24.12 ± 10.31 (19.43-28.81) **G3:** 18.76 ± 10.55 (13.34-24.19) 12 month follow-up:† **G1:** 31.85 ± 9.21 (27.54-36.16) **G2:** 35.06 ± 11.18 (29.31-40.81) **G3:** 27.31 ± 15.63 (18.99-35.64) **Social Skills:** ESCS score, mean ± SD: Showing: **G1:** 0.70 ± 1.19 **G2:** 1.29 ± 2.65 **G3:** 0.17 ± 0.53 **G1/G2:** *P* = NS **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 ANOVA: time (*P* < 0.05)
Kasari et al., 2006 Kasari et al., 2008† (continued)	**Concomitant therapies:** NR **N at enrollment:** **G1:** 20 **G2:** 21 **G3:** 17 **N at 6 month follow-up:**† **G1:** 20 **G2:** 19 **G3:** 17 **N at 12 month follow-up:**† **G1:** 20 **G2:** 17 **G3:** 16	**SES:** Maternal education, n: High school: **G1:** 0 **G2:** 3 **G3:** 2 Some college: **G1:** 2 **G2:** 4 **G3:** 4 College/professional: **G1:** 18 **G2:** 14 **G3:** 11 Household income: NR **Diagnostic approach:** In study **Diagnostic tool/method:** ADI-R, ADOS **Diagnostic category, n (%):** Autism: 58 (100) **Other characteristics:** NR	Joint attention initiations composite, mean ± SD (range):† **G1:** 3.95 ± 2.33 (2.86-5.04) **G2:** 4.32 ± 3.07 (2.92-5.71) **G3:** 3.29 ± 2.74 (1.88-4.70) Joint attention responses, mean ± SD (range):† **G1:** 10.05 ± 5.42 (7.96-13.04) **G2:** 10.24 ± 5.59 (7.69-12.78) **G3:** 10.52 ± 6.49 (7.19-13.87) Mother-child interaction, mean ± SD: Child joint attention looks: **G1:** 2.45 ± 3.35 **G2:** 2.33 ± 2.67 **G3:** 2.76 ± 4.19	Child joint attention looks: **G1:** 9.55 ± 7.88 **G2:** 12.14 ± 9.30 **G3:** 10.35 ± 9.74 **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = NS ANOVA: time (*P* < 0.05) Pointing: **G1:** 4.65 ± 15.60 **G2:** 9.76 ± 10.21 **G3:** 5.76 ± 7.57 **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = NS ANOVA: time (*P* = NS) Giving: **G1:** 5.10 ± 3.54 **G2:** 3.05 ± 2.27 **G3:** 3.59 ± 2.40 **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = NS ANOVA: time

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
			Pointing: **G1:** 2.35 ± 4.04 **G2:** 2.62 ± 3.47 **G3:** 2.18 ± 3.52 Giving: **G1:** 1.65 ± 2.79 **G2:** 2.09 ± 2.68 **G3:** 1.47 ± 2.21 Showing: **G1:** 1.00 ± 1.34 **G2:** 2.90 ± 7.48 **G3:** 0.53 ± 0.71 Mother-child interaction, seconds ± SD: Child-initiated joint attention: **G1:** 140 ± 109 **G2:** 128 ± 179 **G3:** 229 ± 291 Mother-initiated joint attention: **G1:** 449 ± 191 **G2:** 432 ± 233 **G3:** 382 ± 226	(*P* = NS) Responds joint attention: **G1:** 16.55 ± 6.64 **G2:** 12.04 ± 5.91 **G3:** 9.35 ± 6.00 **G1/G2:** *P* < 0.05 **G1/G3:** *P* < 0.05 **G2/G3:** *P* = NS ANOVA: time (*P* < 0.01), time X treatment (*P* < 0.01) Joint attention initiations composite, mean ± SD (range): Post-intervention: **G1:** 5.23 ± 3.14 (3.76-6.69) **G2:** 4.70 ± 3.40 (3.16-6.25) **G3:** 3.65 ± 2.89 (2.17-5.14)
Kasari et al., 2006 Kasari et al., 2008† (continued)			Mother-child interactions, mean ± SD: Functional types: **G1:** 5.33 ± 4.15 **G2:** 6.45 ± 4.84 **G3:** 5.71 ± 3.87 Symbolic types: **G1:** 1.76 ± 2.77 **G2:** 3.65 ± 4.73 **G3:** 3.12 ± 4.70 Level of play: **G1:** 4.89 ± 2.62 **G2:** 6.14 ± 2.61 **G3:** 5.70 ± 2.83 **Adaptive behavior:** Symbolic play level composite, mean ± SD (range):† **G1:** 6.44 ± 2.03 (5.49-7.39) **G2:** 5.37 ± 2.43 (4.26-6.48) **G3:** 6.18 ± 2.24 (5.02-7.33) Symbolic play types composite, mean ± SD (range): **G1:** 3.83 ± 3.84 (2.03-5.62) **G2:** 2.10 ± 2.54 (0.94-3.25)	12 month follow-up:† **G1:** 6.44 ± 2.89 (5.09-7.79) **G2:** 7.92 ± 4.81 (5.45-10.39) **G3:** 2.91 ± 4.12 (0.71-5.10) **G1/G2:** *P* = NS **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 Joint attention responses, mean ± SD (range): Post-intervention: **G1:** 16.55 ± 6.64 (13.44-19.66) **G2:** 12.05 ± 5.91 (9.36-14.74) **G3:** 9.35 ± 6.00 (6.27-12.44) 12 month follow-up:† **G1:** 10.00 ± 3.58 (8.22-11.78) **G2:** 10.88 ± 4.01 (8.82-12.95) **G3:** 9.30 ± 4.47 (6.10-12.50) **G1/G2:** *P* = NS **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
			G3: 2.91 ± 3.23 (1.25-4.57) Structured play, mean ± SD: Functional types: **G1:** 18.95 ± 8.17 **G2:** 17.85 ± 8.57 **G3:** 20.76 ± 4.75 Symbolic types: **G1:** 2.43 ± 3.09 **G2:** 4.00 ± 5.16 **G3:** 2.71 ± 3.39 Level of play: **G1:** 5.86 ± 2.73 **G2:** 6.75 ± 2.27 **G3:** 6.65 ± 2.45	Mother-child interaction, mean ± SD: Child joint attention looks: **G1:** 3.55 ± 5.38 **G2:** 3.47 ± 3.76 **G3:** 1.53 ± 1.77 **G1/G2:** P = NS **G1/G3:** $P < 0.05$ **G2/G3:** $P < 0.05$ ANOVA: time X treatment ($P < 0.05$)
Kasari et al., 2006 Kasari et al., 2008† (continued)			**Educational/ cognitive/ academic attainment:** Mental age, months ± SD: **G1:** 26.29 ± 8.71 **G2:** 24.55 ± 8.09 **G3:** 21.86 ± 9.26 Non-verbal composite age, months ± SD: **G1:** 28.65 ± 9.03 **G2:** 27.60 ± 6.74 **G3:** 24.34 ± 7.53 Developmental quotient, mean ± SD: **G1:** 58.30 ± 17.18 **G2:** 58.90 ± 18.21 **G3:** 51.98 ± 21.84	Pointing: **G1:** 2.45 ± 3.10 **G2:** 3.71 ± 4.76 **G3:** 4.53 ± 7.00 **G1/G2:** P = NS **G1/G3:** P = NS **G2/G3:** P = NS ANOVA: time (P = NS) Giving: **G1:** 3.25 ± 2.95 **G2:** 1.28 ± 1.71 **G3:** 2.06 ± 3.61 **G1/G2:** $P < 0.05$ **G1/G3:** P = NS **G2/G3:** P = NS ANOVA: time X treatment ($P < 0.05$) Showing: **G1:** 2.65 ± 3.08 **G2:** 2.90 ± 4.25 **G3:** 1.23 ± 2.30 **G1/G2:** $P < 0.05$ **G1/G3:** P = NS **G2/G3:** P = NS ANOVA: time X treatment ($P < 0.05$) Mother-child interaction, child-initiated joint attention, seconds ± SD: Post-intervention: **G1:** 299 ± 237 **G2:** 212 ± 266 **G3:** 128 ± 188 **G1/G2:** P = NS **G1/G3:** $P < 0.05$ **G2/G3:** P = NS

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				ANOVA: treatment (P < 0.05), time X treatment (P < 0.001)
Kasari et al., 2006 Kasari et al., 2008† (continued)				12 month follow-up:† **G1:** 363.55 ± 316.58 (215.39-511.71) **G2:** 309.00 ± 335.70 (136.40-481.60) **G3:** 129.40 ± 228.69 (2.76-256.05) **G1/G2:** P = NS **G1/G3:** P < 0.05 **G2/G3:** P < 0.05 Mother-child interaction, mother-initiated joint attention, seconds ± SD: Post-intervention: **G1:** 420 ± 194 **G2:** 521 ± 236 **G3:** 459 ± 207 **G1/G2:** P = NS **G1/G3:** P = NS **G2/G3:** P = NS ANOVA: time (P = NS) 12 month follow-up:† **G1:** 348.40 ± 259.69 (226.86-469.94) **G2:** 467.24 ± 277.21 (324.71-609.76) **G3:** 533.00 ± 242.12 (398.92-667.08) **G1/G2:** P = NS **G1/G3:** P = NS **G2/G3:** P = NS Mother-child interactions, mean ± SD: Functional types: **G1:** 7.43 ± 3.56 **G2:** 5.95 ± 4.20 **G3:** 5.23 ± 3.31 **G1/G2:** P = NS **G1/G3:** P = NS **G2/G3:** P = NS ANOVA: time

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				(P = NS)
Kasari et al., 2006 Kasari et al., 2008† (continued)				Symbolic types: **G1:** 5.48 ± 7.19 **G2:** 3.70 ± 4.28 **G3:** 2.58 ± 3.62 **G1/G2:** $P < 0.05$ **G1/G3:** P = NS **G2/G3:** $P < 0.05$ ANOVA: treatment ($P < 0.001$), time ($P < 0.001$), time X treatment ($P < 0.001$) Level of play: **G1:** 7.61 ± 2.75 **G2:** 7.47 ± 2.71 **G3:** 5.69 ± 2.42 **G1/G2:** $P < 0.05$ **G1/G3:** P = NS **G2/G3:** $P < 0.05$ ANOVA: treatment ($P < 0.05$), time ($P < 0.001$), time X treatment ($P < 0.001$) **Adaptive Behavior:** Symbolic play level composite, mean ± SD (range):† Post-intervention: **G1:** 7.21 ± 1.76 (6.38-8.04) **G2:** 7.61 ± 2.41 (6.52-8.71) **G3:** 6.05 ± 2.23 (4.91-7.19) 12 month follow-up: **G1:** 8.23 ± 2.46 (7.08-9.38) **G2:** 9.60 ± 1.73 (8.71-10.49) **G3:** 6.75 ± 2.46 (5.44-8.06) **G1/G2:** $P < 0.05$ **G1/G3:** P = NS **G2/G3:** $P < 0.05$
Kasari et al., 2006 Kasari et al., 2008† (continued)				Symbolic play types composite, mean ± SD (range):† Post-intervention: **G1:** 5.00 ± 4.08 (3.09-6.91) **G2:** 5.0 ± 5.38

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				(2.55-7.45) **G3:** 2.85 ± 3.10 (1.26-4.45) 12 month follow-up: **G1:** 9.40 ± 7.58 (5.85-12.94) **G2:** 11.26 ± 7.89 (7.21-15.32) **G3:** 5.34 ± 8.50 (0.81-9.88) **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* < 0.05 Structured play, mean ± SD: Functional types: **G1:** 22.67 ± 6.51 **G2:** 24.00 ± 8.56 **G3:** 21.71 ± 6.82 **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = NS ANOVA: time (*P* < 0.001) Symbolic types: **G1:** 4.52 ± 4.64 **G2:** 6.30 ± 6.65 **G3**: 3.12 ± 3.31 **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* = NS ANOVA: time (*P* < 0.001) Level of play: **G1:** 7.62 ± 2.75 **G2:** 6.95 ± 2.30 **G3:** 6.41 ± 2.60 **G1/G2:** *P* = NS **G1/G3:** *P* = NS **G2/G3:** *P* < 0.05 ANOVA: time X treatment (*P* < 0.05)
Kasari et al., 2006 Kasari et al., 2008† (continued)				**Educational/ cognitive/ academic attainment:** Mental age, 12 month follow-up, months ± SD:† **G1:** 41.82 ± 12.09 **G2:** 40.33 ± 13.24 **G3:** 32.90 ± 14.54 Non-verbal composite age, 12 months follow-up,

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				months ± SD:† **G1:** 47.37 ± 13.77 **G2:** 42.82 ± 14.08 **G3:** 35.87 ± 13.00 **Harms:** NR **Modifiers:** NR
Author: Lopata et al., 2008 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding**: NR **Author industry relationship disclosures:** NR **Design:** Prospective cohort **Note:** See preliminary report of inter-vention, Lopata et al. 2006 ({#2697})	**Intervention:** Manualized social treatment program Participants assigned to one of two performance feedback treatment conditions: response-cost or non-categorical feedback The response-cost group received feedback based on operationally defined behaviors, and the non-categorical feedback group received feedback but there were no predetermined behavioral categories on which feedback was based Each summer the prog-ram was administered for 6 weeks, five days/week for 6 hours each day; there were 4 treatment cycles each day, with each cycle beginning with a 20 minute structured social skills group and ending with a 50 minute therapeutic activity; social treatments were delivered in small groups of 6 children and 3 staff **Assessments:** By treatment staff, teachers, and parents: WISC-IV short form, BASC-PRS, BASC-TRS, Skillstreaming survey, DANVA2, Parent Satisfaction Survey **Groups:** **G1:** non-categorical **G2:** response-cost **Provider:** Psychology and education graduate students **Measure of treatment fidelity reported:**	**Inclusion criteria:** • Formal written diagnosis of AD, autism, or PDD-NOS by a licensed psychologist or psychiatrist • WISC-IV short-form IQ composite > 70 • Index score ≥ 80 on at least one factor of the WISC-IV • Absence of a current significant language delay **Exclusion criteria:** • Current significant language delay **Age, years ± SD:** **G1:** 9.41 ± 2.31 **G2:** 9.6 ± 2.12 **Mental age:** Short-form IQ (WISC-IV), mean ± SD: **G1:** 97.56 ± 13.62 **G2:** 100.87± 17.92 **Gender, n (%):** Male: **G1:** 27 (93.1) **G2:** 23 (92) Female: **G1:** 2 (6.9) **G2:** 2 (8.0) **Race/ethnicity, n (%):** White: **G1:** 26 (89.7) **G2:** 22 (88) African American: **G1:** 1 (2.4) **G2:** 0 Latino: **G1:** 1 (1.9) **G2:** 1 (4) Other: **G1:** 2 (6.9) **G2:** 2 (8) **SES:** Parent education, years ± SD: **G1:** 15.83 ± 2.26	**Social Skills:** BASC social skills score, parent rated, mean ± SD: **G1:** 36.18 ± 7.00 (n=28) **G2:** 36.91 ± 8.81 (n=22) BASC social skills score, teacher rated, mean ± SD: **G1:** 47.38 ± 6.80 (n=28) **G2:** 43.52 ± 8.57 **Adaptive behavior:** BASC adaptive skills score, parent rated, mean ± SD: **G1:** 34.29 ± 7.17 (n=28) **G2:** 35.27 ± 8.69 (n=22) BASC adaptive skills score, teacher rated, mean ± SD: **G1:** 42.63 ± 6.53 (n=28) **G2:** 41.60 ± 6.92 BSI score, parent rated, mean ± SD: **G1:** 65.86 ± 11.50 (n=28) **G2:** 60.91 ± 10.88 (n=22) BSI score, teacher rated, mean ± SD: **G1:** 53.41 ± 9.33 (n=28) **G2:** 53.56 ± 7.70 Skillstreaming survey score, parent report, mean ± SD: **G1:** 104.28 ± 22.84 (n=25) **G2:** 103.15 ± 19.98 (n=20) Skillstreaming survey score, staff report, mean ± SD:	**Social Skills:** BASC social skills score, parent rated, mean ± SD: **G1:** 40.75 ± 8.37 (n=28; d=-0.59) **G2:** 38.59 ± 7.71 **G1+G2/BL:** *P* = 0.002 **G1/G2:** *P* = 0.153 BASC social skills score, teacher rated, mean ± SD: **G1:** 47.84 ± 6.25 (n=28; d=-0.07) **G2:** 46.76 ± 7.97 (d=-0.39) **G1+G2/BL:** *P* = 0.008 **G1/G2:** *P* = 0.067 **Adaptive behavior:** BASC adaptive skills score, parent rated, mean ± SD: **G1:** 37.79 ± 8.01 (n=28; d=0.45) **G2:** 36.05 ± 7.13 (n=22; d=0.1) **G1+G2/BL:** *P* = 0.011 **G1/G2:** *P* = 0.133 BASC adaptive skills score, teacher rated, mean ± SD: **G1:** 43.79 ± 5.89 (n=28; d=0.19) **G2:** 44.20 ± 5.98 (d=0.4) **G1+G2/BL:** *P* = 0.004 **G1/G2:** *P* = 0.291 BSI score, parent rated, mean ± SD: **G1:** 61.32 ± 9.78 (n=28; d=0.43) **G2:** 58.55 ± 11.71 (d=0.21) **G1+G2/BL:** *P* = 0.001

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	Yes	**G2:** 15.30 ± 2.37 Household income: NR	**G1:** 118.59 ± 23.67 **G2:** 118.16 ± 19.52	**G1/G2:** *P* = 0.295
Lopata et al., 2008 (continued)	**Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 29 **G2**: 25 **N at follow-up:** **G1:** 29 **G2:** 25	**Diagnostic approach:** Referral/In-Study assessment **Diagnostic tool/method:** NR **Diagnostic category, n (%):** Autistic disorder: **G1:** 20 (69) **G2:** 16 (64) PDD-NOS: **G1:** 6 (20.7) **G2:** 6 (24) High-functioning autism: **G1:** 3 (10.3) **G2:** 3 (12) **Other characteristics:** NR	**Problem behavior:** BASC atypicality score, parent rated, mean ± SD: **G1:** 62.30 ± 13.06 (n=27) **G2:** 61.95 ± 11.88 (n=22) BASC atypicality score, teacher rated, mean ± SD: **G1:** 57.45 ± 11.64 (n=28) **G2:** 60.50 ± 13.28 BASC withdrawal score, parent rated, mean ± SD: **G1:** 64.61 ± 12.37 (n=28) **G2:** 65.50 ± 10.20 (n=22) BASC withdrawal score, teacher rated, mean ± SD: **G1:** 55.05 ± 10.24 (n=28) **G2:** 60.56 ± 10.27 **Communication/ language:** DANVA2 score, mean ± SD: Child faces: **G1:** 90.83 ± 21.25 (n=18) **G2:** 92.72 ± 17.98 (n=18) Adult faces: **G1:** 102.11 ± 9.68 (n=18) **G2:** 97.56 ± 14.35 (n=18)	BSI score, teacher rated, mean ± SD: **G1:** 56.96 ± 10.10 (n=28; d=0.37) **G2:** 52.52 ± 6.63 (d=0.14) **G1+G2/BL:** *P* = 0.049 **G1/G2:** *P* = 0.003 Skillstreaming survey score, parent report, mean ± SD: Parent report: **G1:**116.04 ± 20.00 (n=25; d=0.55) **G2:**113.60 ± 19.67 (n=20; d=0.53) **G1+G2/BL:** *P* < 0.001 **G1/G2:** *P* = 0.79 Skillstreaming survey score, staff report, mean ± SD: **G1:** 126.88 ± 18.50 (d=0.39) **G2:** 130.42 ± 17.67 (d=0.66) **G1+G2/BL:** *P* < 0.001 **G1/G2:** *P* = 0.395 **Problem behavior:** BASC atypicality score, parent rated, mean ± SD: **G1:** 58.89 ± 8.00 (n=27; d=0.31) **G2:** 59.67 ± 13.81 (n=22; d=0.1) **G1+G2/BL:** *P* = 0.075 **G1/G2:** *P* = 0.52 BASC atypicality score, teacher rated, mean ± SD: **G1:** 61.50 ± 13.72 (n=28; d=-0.32) **G2:** 59.04 ± 14.43 (d=0.11) **G1+G2/BL:** *P* = 0.15 **G1/G2:** *P* = 0.03
Lopata et al., 2008 (continued)				BASC withdrawal score, parent rated, mean ± SD: **G1:** 61.29 ± 12.79

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				(n=28; d=0.26) **G2:** 62.50 ± 9.03 (n=22; d=0.31) **G1+G2/BL:** *P* = 0.004 **G1/G2:** *P* = 0.887 BASC withdrawal score, teacher rated, mean ± SD: **G1:** 55.46 ± 10.11 (n=28; d=0.04) **G2:** 56.56 ± 9.44 (d=0.41) **G1+G2/BL:** *P* = 0.036 **G1/G2:** *P* = 0.028 **Communication/ language:** DANVA2 score, mean ± SD: Child faces: **G1:** 87.11 ± 22.37 (n=18; d=-0.17) **G2:** 89.22 ± 15.16 (n=18; d=-0.21) **G1+G2/BL:** *P* = 0.07 **G1/G2:** *P* = 0.963 Adult faces: **G1:** 101.39 ± 15.55 (n=18; d=-0.06) **G2:** 94.06 ± 13.86 (n=18; d=-0.25) **G1+G2/BL:** *P* = 0.166 **G1/G2:** *P* = 0.521 **Harms:** NR **Modifiers:** See above

**Comments: ***In the outcomes column, d is the Cohen's d effect size estimate for mean differences.

Author: Ludlow et al., 2008 **Country:** UK **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** NR **Funding:**	**Intervention:** Three experiments to assess therapeutic benefits of colored overlays; participants selected the best color and side (matt or gloss) for clarity over text and as favorite over a blank sheet of paper Experiment 1 tested the rate of reading with and without colored overlays. Experiment 2 compared the rate of reading with	**Inclusion criteria:** • Diagnosis of ASD • Recruited from schools for children with moderate learning difficulties with autism units **Exclusion criteria:** • See inclusion criteria **Age, years ± SD (range):** **G1:** 12.3 ± 2.1 (9-15.83) **G2:** 14.8 ± 8.1 (14.1-15.83) **G3:** 12.3 ± 2.2 (9-15.83) **Mental age:** IQ score (Raven's	**Communication /language:** BPVS score, mean ± SD: **G1:** 64.5 ± 11.2 **G2:** 59.6 ± 5.3 **G3:** NR	**Communication/ language:** **Experiment 1:** Symptoms of visual stress, mean ± SD: **G1a:** 0.06 ± 0.24 **G1c:** 0.39 ± 0.78 **G1a/G1c:** *P* < 0.05 Words read per minute, mean ± SD: **G1a:** 96.9 ± 33.7 **G1c:** 83.2 ± 32.3 **G1a/G1c:** *P* < 0.001 **Experiment 2:** Words read per

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
NR **Author industry relationship disclosures:** 1 of 3 British Medical Research Council (royalties for intuitive overlays) **Design:** Prospective case series	overlays chosen for clarity vs. favorite color. Experiment 3 detected changes in visual stimuli with and without colored overlays in children with high and low functioning ability. **Assessments:** BPVS, rate of reading test, symptoms of visual stress (out of five) **Groups:** **G1:** Experiment 1 **G2:** Experiment 2 **G3:** Experiment 3 **Ga:** colored overlay, chosen for clarity **Gb:** colored overlay, chosen as favorite **Gc:** no colored overlay **Provider:** NR **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:*** **G1:** 18 **G2:** 16 **G3:** 26	matrices), mean ± SD: **G1:** NR **G2:** 67.0 ± 5.3 **G3:** 75.8 ± 16.2 **Gender, n (%):** Male: **G1:** 18 (100) **G2:** 12 (75) **G3:** NR Female: **G1:** 0 **G2:** 4 (25) **G3:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** NR **Diagnostic category, n (%):** ASD: **G1:** 18 (100) **G2:** 16 (100) **G3:** 26 (100) **Other characteristics:** NR		minute, mean ± SD: **G2a:** 72.3 ± 29.2 **G2b:** 65.4 ± 29.7 **G2c:** 57.8 ± 36.8 **G2a/G2c:** $P < 0.05$ **G2b/G2c:** $P < 0.05$ **G2a/G2b:** $P < 0.05$ **Experiment 3:** Accuracy (out of 30) in sample matching task, mean ± SD: **G3a:** 26.8 ± 4.4 **G3c:** 26.4 ± 3.9 **G3a/G3c:** P = NS Time taken to complete sample matching task, seconds ± SD: **G3a:** 112.9 ± 57.0 **G3c:** 135.7 ± 60.1 **G3a/G3c:** $P < 0.05$ **Harms:** NR **Modifiers:** Experiment 3: There were no significant differences between low functioning and high functioning children with ASD. There was also no significant correlation between age or Raven's matrices scores and time taken with or without overlays.
Ludlow et al., 2008 (continued)	**N at follow-up:*** **G1:** 18 **G2:** 16 **G3:** 26			

Comments: *None of the partipants in Experiment 2 participated in Experiment 1 or 3, but 13 of the participants from Experiment 1 also participated in Experiment 3.

Author:	Intervention:	Inclusion criteria:	Overall ratings:	Overall ratings:
Meguid et al., 2008 **Country:** Egypt **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:**	Efalex supplement (blend of high DHA fish oil and evening primrose oil containing both omega 3 and 6 fatty acids as well as vitamin E) Children with autism (G1) received 2 capsules twice per day for 3 months; the controls (G2) were healthy and received no treatment or placebo	• Autism based on DSM-IV criteria and CARS scores • Good physical health • Not currently taking medications or essential fatty acid supplements during study • Agree not to make changes in treatments for autism (medical, nutritional, behavioral,	CARS score, mean ± SD: **G1:** 39.5 ± 3.86 **Medical:** PUFA levels, mean ± SD: Linolenic: **G1:** 0.86 ± 0.44 **G2:** 3.2 ± 0.72 **G1/G2:** $P < 0.0001$ DHA: **G1:** 0.95 ± 0.2	CARS score, mean ± SD: **G1:** 32.7 ± 3.37 **G1/BL:** $P <$ 0.0001 **Medical:** PUFA levels, mean ± SD: Linolenic: **G1:** 1.76 ± 0.56 **G1/BL:** $P <$ 0.0001

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Non-randomized controlled trial	**Assessments:** Blood levels of free PUFAs estimated from dried blood spot using tandem mass spectrometry; CARS at baseline and follow-up (3 months after treatment) **Groups:** **G1:** children with autism **G2:** healthy children, same age and gender **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** NR **Concomitant therapies:** None **N at enrollment:** **G1:** 30 (28 families) **G2:** 30 **N at follow-up:** **G1:** 30 **G2:** NA	dietary) during the three months of the study Exclusion criteria: • See inclusion criteria **Age, yrs (range):** NR (3-11) **Mental age:** NR **Gender, n (%):** Male: 18 (60) Female: 12 (40) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral Department of Children with Special Needs **Diagnostic tool/method:** DSM-IV and CARS **Diagnostic category, n (%):** Autism: 30 (100) **Other characteristics:** NR	**G2:** 2.85 ± 0.65 **G1/G2:** *P* < 0.0001 Linoleic: **G1:** 1.75 ± 0.46 **G2:** 2.77 ± 0.64 **G1/G2:** *P* < 0.0001 Arachidonic: **G1:** 2.5 ± 0.5 **G2:** 4.65 ± 0.5 **G1/G2:** *P* < 0.0001 AA/DHA: **G1:** 2.77 ± 0.84 **G2:** 1.71 ± 0.4 **G1/G2:** *P* < 0.0001	DHA: **G1:** 1.69 ± 0.42 **G1/BL:** *P* < 0.0001 Linoleic: **G1:** 2.32 ± 0.41 **G1/BL:** *P* < 0.0001 Arachidonic: **G1:** 3.23 ± 0.49 **G1/BL:** *P* < 0.0001 AA/DHA: **G1:** 2.01 ± 0.53 **G1/BL:** *P* < 0.0001 **Harms:** NR **Modifiers:** Correlation between CARS and baseline PUFA level, no significant improvement in autistic behavior (n=10): Linolenic: -0.471 (*P* > 0.05) DHA: -0.670 (*P* < 0.05) Linoleic: -0.118 (*P* > 0.05) AA: 0.115 (*P* > 0.05)
Meguid et al., 2008 (continued)				Correlation between CARS and post-treatment PUFA level, no significant improvement in autistic behavior (n=10): Linolenic: 0.395 (*P* > 0.05) DHA: -0.541 (*P* > 0.05) Linoleic: -0.287 (*P* > 0.05) AA: 0.262 (*P* > 0.05)
Author: Nickels et al., 2008 **Country:** US	**Intervention:** Population-based study of stimulant medication use in treatment of autism symptoms	**Inclusion criteria:** • Research identified autism • Resident of Olmsted County, MN upon	**Overall measures:** Medication use, n (%): Psychopharmacologic treatment:	**Overall measures:** Duration of treatment, years ± SD (range): **G1:** 4.0 ± 3.9

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Practice setting: Academic **Intervention setting:** Clinic **Enrollment period:** January 1976 to December 1997 **Funding:** Grant from Mr. and Mrs. David and Elaine Dana **Author industry relationship disclosures:** NR **Design:** Retrospective case series	**Assessments:** Detailed chart review to abstract treatment information Episode of treatment: period of time subject treated with specific medication at specific dose, converted to methylphenidate equivalent units (MEUs) **Groups:** **G1:** stimulant medication **G2:** other treatment **Ga:** male **Gb:** female **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** NR **Concomitant therapies:** NR **N at enrollment:** Total: 124 **G1:** 65 **N at follow-up:** NA	meeting DSM criteria • IQ or DQ ≥ 35 • Age 21 and younger **Exclusion criteria:** • Diagnosis of Rett disorder, CDD, or schizophrenia prior to fulfilling DSM-IV criteria for autism **Age, onset of stimulant treatment, years (range):** **G1:** 7.9 ± 2.9 (3.4-14.5) **G1a:** 7.0 ± 2.5 (3.4-14.2) **G1b:** 10.8 ± 2.4 (6.7-14.5) **G1a/G1b:** *P* < 0.001 **Mental age:** NR **Gender, n (%):** Male: Total: 95 (76.6) **G1:** 50 (76.9) Female: Total: 29 (23.4) **G1:** 15 (23.1) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** NR **Diagnostic tool/method:** Review of records noting any reference to autism symptoms as per an autism glossary developed from 182 children given diagnoses of autism in the medical diagnosis index at the Mayo Clinic. School and medical records of children with ≥ 2 symptoms noted were reviewed and all noted symptoms were evaluated using DSM-IV criteria	82/124 (66) Psychostimulants: 65/124 (52) Number of stimulants used, n (%): One: **G1:** 32 (49) Two: **G1:** 19 (29) Three: **G1:** 14 (22) Total episodes of psychostimulant treatment, n: **G1:** 398 Episodes of psychostimulant treatment, median per child (range): **G1:** 5 (1-21) Type of stimulant used, n (%): Methylphenidate: **G1:** 52 (80) **G1a:** 41 (82) **G1b:** 11 (73) Dextroamphetamine: **G1:** 34 (52) **G1a:** 29 (58) **G1b:** 5 (33) Mixed amphetamine salts: **G1:** 13 (20) **G1a:** 11 (22) **G1b:** 2 (13) Pemoline: **G1:** 11 (17) **G1a:** 9 (18) **G1b:** 2 (13) Methamphetamine: **G1:** 2 (3) **G1a:** 2 (4) **G1b:** 0	(0.003-14.1) **G1a:** 4.5 ± 4.0 (0.008-14.1) **G1b:** 2.3 ± 2.8 (0.003-6.9) **G1a/G1b:** *P* = 0.03 Average daily dose, mg MEUs ± SD (range): **G1:** 27.3 ± 7.8 (2.5-75.2) **G1a:** 25.4 ± 15.3 (2.5-67.3) **G1b:** 34.1 ± 24.0 (5-75.2) Favorable response, n (%): **G1:** 276/398 (69) **G1a:** 235/345 (68) **G1b:** 41/53 (77) **G1a/G1b:** *P* = 0.33 Favorable response by stimulant episodes, n (%): Methylphenidate: 135/195 (69) Dextroamphetamine: 105/143 (73) Mixed amphetamine salts: 24/41 (59) Pemoline: 11/16 (69) Methamphetamine: 1/3 (33) **Harms:** Experienced at least one side effect, n (%): **G1:** 43/65 (66) **G1a:** 36/50 (72) **G1b:** 7/15 (47) **G1a/G1b:** *P* = 0.069
Nickels et al., 2008 (continued)		**Diagnostic category, n (%):** Autism: 124 (100) **Other characteristics:** Comorbid diagnoses, n (%):* Speech/language: Total: 96 (77) Epilepsy: Total: 17 (14) Cognitive impairment (IQ/DQ < 70):		Side effects by stimulant episodes, n (%): Total: 67/398 (16.8) Methylphenidate: 31/195 (16) Dextroamphetamine: 24/143 (17) Mixed amphetamine salts: 7/41 (17)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
		Total: 68 (61)		Pemoline: 4/16 (25) Methamphetamine: 1/3 (33) Methylphenidate side effects, n (# episodes): Tics: 4 (4) Appetite changes: 5 (6) Sleep disturbances: 6 (6) Headaches: 2 (2) Irritability/anxious-ness/worsening of behavior: 9 (10) Sedation/lethargy/ sleepiness: 3 (4) Other: 2 (2) Dextroampheta-mine side effects, n (# episodes): Tics: 2 (3) Appetite changes: 3 (5) Sleep disturbance: 4 (6) Irritability/anxious-ness/worsening behavior: 10 (10) Sedation/lethargy/ sleepiness: 1 (1) Other: 1 (1) Unknown: 1 (1)
Nickels et al., 2008 (continued)				Mixed ampheta-mine salts side effects, n (# episodes): Tics: 1 (2) Sleep disturbances: 2 (2) Irritability/anxious-ness/worsening behavior: 3 (3) Other: 2 (3) Pemoline side effects, n (# episodes): Tics: 1 (1) GI complaints/ stomach ache: 1 (1) Other: 2 (2) Methamphetamine side effects, n (# episodes): Tics: 1 (1)

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				Modifiers: No significant difference in rate of favorable response by type of stimulant used. No association between type of stimulant used and occurrence of side effects
Author: Osborne et al., 2008 **Country:** UK **Practice setting:** Academic **Intervention setting:** Home, school **Enrollment period:** 2003 to 2005 **Funding:** South East Regional Special Education Needs Partnership **Author industry relationship disclosures:** NR **Design:** Prospective cohort	**Intervention:** Teaching interventions: reinforcement (ABA-like with 1:1 in-home antecedent-behavior-conseuquence discrete trial training, with reinforcement), nursery (classes of 6-8 children with postgrad-trained teacher, plus 2-3 learning support assistants; some TEACCH methodology), speech/language, and parent training (on what is ASD and how to manage behaviors) Intervention types, n (%): Reinforcement: 49 (75) Nursery: 36 (55) Speech/language: 31 (48) Parent training: 11 (17) Reinforcement: 49 (75) Nursery: 36 (55) Number of interventions, n (%): 1: 21 (32) 2: 27 (42) 3: 16 (25) 4: 1 (1) Hours of intervention by type, mean ± SD (range):* Reinforcement: 13.5 ± 10.7 (1-35) Nursery: 8.1 ± 5.5 (1-23) Speech/language: 1.2 ± 0.7 (1-3) Parent training: 4.2 ± 2.3 (1-10) Total intervention hours/ week: mean ± SD (range): 15.6 ± 9.2 (2-40) **Groups:** **G1:** low intensity (< 15.6 hours/week) intervention **G2:** high intensity (> 15.6	**Inclusion criteria:** • Age 2.6-4.0 years • At the start of their first teaching intervention • Independent prior ASD diagnosis from specialist pediatrician • Initial referral from a general medical practitioner • Statement of special education needs related to ASD from local education authorities **Exclusion criteria:** • See inclusion criteria **Age, years (range):** NR (2.6-4.0) **Mental age:** See developmental age in baseline measures **Gender, n (%):** Male: 59 (90.1) Female: 6 (9.9) **Race/ethnicity:** NR **SES:** Maternal education, %: Secondary (16 yrs): 8 Tertiary (18 yrs): 33 Degree: 59 Postgraduate: 0 Paternal education, %: Secondary (16 yrs): 17 Tertiary (18 yrs): 17 Degree: 33 Postgraduate: 33 Maternal occupation, %: Unskilled/laborer: 33 Skilled/technical: 8 Managerial: 8 Unemployed/career houseworker: 50 Paternal occupation, %: Unskilled/laborer: 8 Skilled/technical: 17	**Overall ratings:** GARS score, mean ± SD: **G1a:** 90.7 ± 19.8 **G1b:** 95.8 ± 11.8 **G2a:** 90.7 ± 13.7 **G2b:** 90.6 ± 19.0 **G1a/G1b/G2a/G2b:** *P* = NS **Adaptive behavior:** VABS score, mean ± SD: **G1a:** 55.6 ± 4.7 **G1b:** 56.6 ± 6.2 **G2a:** 57.0 ± 6.6 **G2b:** 58.6 ± 11.0 **G1a/G1b/G2a/G2b:** *P* = NS VABS develop-mental age, months ± SD: **G1a:** 18.1 ± 3.6 **G1b:** 17.4 ± 6.7 **G2a:** 18.1 ± 5.4 **G2b:** 20.7 ± 13.6 **G1a/G1b/G2a/G2b:** *P* = NS **Educational/ cognitive/ academic attainment:** PEP-R score, mean ± SD: **G1a:** 51.3 ± 11.9 **G1b:** 53.7 ± 22.1 **G2a:** 54.0 ± 12.2 **G2b:** 57.2 ± 20.2 **G1a/G1b/G2a/G2b:** *P* = NS PEP-R develop-mental age, months ± SD: **G1a:** 21.7 ± 6.3 **G1b:** 21.9 ± 11.8 **G2a:** 21.9 ± 6.0 **G2b:** 25.2 ± 16.1	**Adaptive behavior:** VABS score, 9-10 months, mean change ± SD: **G1a:** NR** **G1b:** NR** **G2a:** NR** **G2b:** NR** **G1a/G1b:** *P* = NS **G2a/G2b:** *P* < 0.05 **G1a/G2a:** *P* < 0.05 **G1b/G2b:** *P* = NS VABS develop-mental age, 9-10 months, months ± SD: **G1a:** NR** **G1b:** NR** **G2a:** NR** **G2b:** NR** **G1a/G1b:** *P* = NS **G2a/G2b:** *P* = NS **G1a/G2a:** *P* = NS **G1b/G2b:** *P* = NS **Educational/ cognitive/ academic attainment:** PEP-R score, 9-10 months, mean change ± SD: **G1a:** NR** **G1b:** NR** **G2a:** NR** **G2b:** NR** **G1a/G1b:** *P* = NS **G2a/G2b:** *P* = NS **G1a/G2a:** *P* < 0.05 **G1b/G2b:** *P* = NS

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	hours/week) intervention **Ga:** parenting stress (self-reported) below median **Gb:** parenting stress (self-reported) above median	Managerial: 75 Unemployed/career houseworker: 0	**G1a/G1b/G2a/G2b:** *P* = NS	
Osborne et al., 2008 (continued)	**Provider:** Teachers, tutors (2-9, mean 4.2 ± 1.6), and/or parents **Assessment:** • Autism severity by GARS • Intellectual functioning by PEP-R • Educational achievement by BAS-2 • Adaptive behavior and social functioning by VABS • Self-report parental stress by QRS-F • All testing conducted by an educational psychologist blind to intervention **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** No **Concomitant therapies, %:** Dietary interventions: 60 Fringe crystal treatment: 1.5 **N at enrollment:** Total: 65 **G1a:** 25 **G1b:** 20 **G2a:** 9 **G2b:** 11 **N at follow-up:** Total: 65 **G1a:** 25 **G1b:** 20 **G2a:** 9 **G2b:** 11	Marital status,%: Married: 83 Separated/divorced: 17 Household income: NR **Diagnostic approach:** Referral from specialized pediatrician based on clinical judgment, often with psychometric data In study confirmation **Diagnostic tool/method:** GARS **Diagnostic category, n (%):** Autism: 65 (100) **Other characteristics: NR**	BAS-II score, mean ± SD: **G1a:** 53.4 ± 9.1 **G1b:** 56.8 ± 14.0 **G2a:** 57.7 ± 19.0 **G2b:** 59.3 ± 20.7 **G1a/G1b/G2a/G2b:** *P* = NS BAS-II developmental age, months ± SD: **G1a:** 22.5 ± 5.5 **G1b:** 23.2 ± 9.7 **G2a:** 23.9 ± 11.2 **G2b:** 27.0 ± 18.4 **G1a/G1b/G2a/G2b:** *P* = NS **Parenting Stress:** QRS score, mean ± SD: **G1a:** 23.4 ± 5.3 **G1b:** 33.3 ± 4.7 **G2a:** 25.1 ± 4.4 **G2b:** 32.5 ± 4.1	PEP-R developmental age, 9-10 months, months ± SD: **G1a:** NR** **G1b:** NR** **G2a:** NR** **G2b:** NR** **G1a/G1b:** *P* = NS **G2a/G2b:** *P* = NS **G1a/G2a:** *P* < 0.05 **G1b/G2b:** *P* = NS BAS-II score, 9-10 months, mean change ± SD: **G1a:** NR** **G1b:** NR** **G2a:** NR** **G2b:** NR** **G1a/G1b:** *P* = NS **G2a/G2b:** *P* < 0.05 **G1a/G2a:** *P* < 0.01 **G1b/G2b:** *P* = NS BAS-II developmental age, 9-10 months, months ± SD: **G1a:** NR** **G1b:** NR** **G2a:** NR** **G2b:** NR** **G1a/G1b:** *P* = NS **G2a/G2b:** *P* < 0.001 **G1a/G2a:** *P* < 0.001 **G1b/G2b:** *P* = NS **Harms:** NR **Modifiers:** Baseline QRS score was not associated with intervention intensity.
Osborne et al., 2008 (continued)				MANOVAs showed a significant effect of intervention

Evidence Table. Therapies for children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
				intensity (*P* < 0.05), stress (*P* < 0.05), and stress X intensity (*P* < 0.05) for both standard scores and develop-mental age.

Comments: * Means and standard deviations reported only within children who received the specified treatment
** Data only illustrated graphically.

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Owens et al., 2008 **Country:** UK **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** NR **Funding:** Medical Research Council **Author industry relationship disclosures:** NR **Design:** Non-randomized Control Trial	**Intervention:** LEGO Therapy and SULP (Social Use of Language Programme) One hour of group therapy per week for 18 weeks (over 5.5 months) LEGO: Collaborative LEGO play with projects divided into different roles, facilitated by adult super-visor SULP: direct teaching based on stories, activities, and games using stories, adult models, and children practicing to learn social and communication skills **Assessments:** Initial: Wechsler IQ, GARS, Spence Children's Anxiety Scale, Conner's ADHD and CDC. Outcome: VABS (socialization, communication and maladaptive behavior domains), GARS, parent satisfaction and child enjoyment, direct observation on school playground (examiner unblinded to group) **Groups:** **G1:** LEGO **G2:** SULP **G3:** controls* **Provider:** First author (trained in LEGO therapy by Dr. LeGoff) with under-graduate volunteers who attended a one day training supervised by the first author **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR	**Inclusion criteria:** • Current diagnosis of HFA, Aspergers, ASD, or autism by a clinical psychologist, psychia-trist, or pediatrician • 6-11 years old • IQ > 70 • Met cutoff on SCQ or ADI-R • Able to speak on phrases • Currently receiving no other behavioral intervention or social skills groups • Attending mainstream education or an inclusion unit in a mainstream school • No additional diagnoses of psychiatric disorders **Exclusion Criteria:** • See inclusion criteria **Age, months ± SD:** **G1:** 99.13 ± 20.14 **G2:** 97.33 ± 22.33 **G3:** 105.81 ± 16.05 **Mental age, mean ± SD:** WASI FSIQ: **G1:** 113.93 ±16.97 **G2:** 106.87 ± 17.15 **G3:** 108 ± 14.48 WASI VIQ: **G1:** 110.4 ± 16.24 **G2:** 100.62 ± 22.62 **G3:** 105 ± 15.61 GARS AQ: **G1:** 81.75 ± 16.39 **G2:** 86.27 ± 13.53 **G3:** 93.19 ± 18.23 **Gender, n (%):** Male: **G1:** 16 (100) **G2:** 14 (93) **G3:** 16 (100) Female: **G1:** 0 **G2:** 1 (7) **G3:** 0 **Race/ethnicity:** NR	**Overall ratings:** GARS social interaction score, mean ± SD: **G1:** 7.94 ± 2.70 **G2:** 8.60 ± 2.97 **G3:** 8.75 ± 2.91 **Social skills:** Frequency of self-initiated social interactions, 10 minute playground observation, mean ± SD:** **G1:** 9.09 ± 5.49 **G2:** 8.40 ± 6.34 Duration of self-initiated social interactions, 10 minute playground observation, mean ± SD:** **G1:** 4.77 ± 2.25 **G2:** 4.96 ± 2.30 **Adaptive behavior:** VABS socialization score, mean ± SD: **G1:** 70.56 ± 12.13 **G2:** 63.73 ± 11.63 **G3:** 67.19 ± 11.51 VABS communi-cation score, mean ± SD **G1:** 87.25 ± 14.89 **G2:** 74.13 ± 18.47 **G3:** 82.5 ± 23.94 VABS maladaptive behaviors score, mean ± SD **G1:** 17.75± 9.43 **G2:** 19.31 ± 7.89 **G3:** 23.19 ± 6.15	**Overall ratings:** GARS social interaction score, mean ± SD: **G1:** 7.44 ± 2.20 **G2:** 9.27 ± 2.66 **G3:** 9.75 ± 3.36 **G1/BL:** P = NS **G2/BL:** P = NS **G3/BL:** P = NS **G1/G2:** $P < 0.05$ **G1/G3:** $P < 0.05$ **G2/G3:** P = NS **Social skills:** Frequency of self-initiated social interactions, 10 minute playground observation, mean ± SD:** **G1:** 8.81 ± 7.32 **G2:** 7.20 ± 5.67 Duration of self-initiated social interactions, 10 minute playground observation, mean ± SD:** **G1:** 6.66 ± 3.54 **G2:** 5.80 ± 2.30 **G1/BL:** $P < 0.05$ **G2/BL:** P = NS **G1/G2:** P = NS **Adaptive behavior:** VABS socialize-tion score, mean ± SD **G1:** 75.94 ± 14.86 **G2:** 71.33 ± 12.63 **G3:** 69.69 ± 13.23 **G1/BL:** P = NS **G2/BL:** $P < 0.05$ **G3/BL:** P = NS **G1/G2:** P = NS **G1/G3:** P = NS **G2/G3:** P = NS

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Owens et al., 2008 (continued)	**Concomitant therapies, n (%):** **G1:** Speech and language: **G1:** 3 (19) **G2:** 4 (27) **G3:** 7 (44) OT: **G1:** 0 **G2:** 0 **G3:** 4 (25) GF/CF diet: **G1:** 1 (6) **G2:** 0 **G3:** 1 (6) **N at enrollment:** **G1:** 16 (in 5 groups) **G2:** 15 (in 5 groups) **G3:** 16 **N at follow-up:** **G1:** 16 **G2:** 15 **G3:** 16	**SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral, diagnosis was confirmed in study **Diagnostic tool/method:** ADI-R for G1 and G2; SCQ for G3 **Diagnostic category, n (%):** High functioning autism: **G1:** 5 (31) **G2:** 1 (7) **G3:** 2 (13) Aspergers: **G1:** 8 (50) **G2:** 8 (53) **G3:** 11 (69) ASD: **G1:** 2 (13) **G2:** 4 (27) **G3:** 2 (13) Autism: **G1:** 1 (6) **G2:** 2 (13) **G3:** 1 (6) **Other characteristics:** Educational support, n (%): Part-time TA: **G1:** 4 (25) **G2:** 4 (27) **G3:** 8 (50) Full time TA: **G1:** 7 (44) **G2:** 4 (27) **G3:** 2 (12.5) Inclusion unit: **G1:** 1 (6) **G2:** 3 (20) G3: **2 (12.5)**		VABS communication score, mean ± SD **G1:** 91.88 ± 18.83 **G2:** 83.13 ± 16.34 **G3:** 76.06 ± 17.17 **G1/BL:** P = NS **G2/BL:** $P < 0.01$ **G3/BL:** P = NS **G1/G2:** P = NS **G1/G3:** P = NS **G2/G3:** P = NS VABS maladaptive behaviors score, mean ± SD **G1:** 13.81 ± 5.23 **G2:** 16.69 ± 5.79 **G3:** 22.75 ± 5.52 **G1/BL:** $P < 0.05$ **G2/BL:** P = NS **G3/BL:** P = NS **G1/G2:** P = NS **G1/G3:** $P < 0.05$ **G2/G3:** $P < 0.05$ **Harms:** NR **Modifiers:** NR

Comments: *Participants initially only recruited for G1 and G2; G3 participants were recruited at a later date as part of another study and asked if their data could be used for this study in a no intervention control group sample.
**In an unspecified subset of 21 of the 31 children in groups G1 and G2.

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Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Perry et al., 2008 **Country:** Canada **Practice setting:** Academic **Intervention setting:** home, clinic, or child care center **Enrollment period:** NR Program data: 2000-2006 **Funding:** Ontario Ministry of Children and Youth Services **Author industry relationship disclosures:** NR **Design:** Retrospective case series	**Intervention:** Ontario IBI, 20 to 40 hours a week throughout the year in a variety of settings (home, center, and integrated child care) using structured behavioral teaching based on the principles of applied behavior analysis duration ranged from 4 to 47 months (mean 18 months) **Assessments:** CARS, VABS, and cognitive (most commonly used: MSEL, BSID, WPPSI, SB-FE) "typically conducted by assessment staff of the central agency"(p.627). Seven categories of progress/outcomes were generated based on all available information including developmental rates, VABS ABC, cognitive standard scores, and CARS. **Groups:** **G1:** IBI **G1a:** higher functioning (VABS ABC ≥ 60) **G1b:** intermediate functioning (VABS ABC between 50 and 59) **G1c:** lower functioning (VABS ABC ≤ 49) **Provider:** Instructor-therapists (virtually all had a college or university level education and all received same initial IBI training) who were supervised by Senior Therapists (had a Master's degree and/or were Board Certified Behavior Analysts) **Measure of treatment fidelity reported:** No	**Inclusion criteria:** • entry assessment within 3 months of entry • another assessment (usually at exit) • diagnosis of autism or a disorder toward the severe end of the autism spectrum **Exclusion criteria:** • see inclusion criteria **Age, mean/yrs (range in months):** 4.5 (20-86) **Mental age, n, mean/months ± SD (range):** (Combined scores from MSEL, BSID, WPPSI, and SB:FE) **G1:** 151, 22.92 ± 10.96 (3-60) **G1a:** 44, 28.24 ± 11.46 **G1b:** 66, 21.51 ± 10.61 **G1c:** 33, 17.64 ± 6.84 $P < 0.001$ **Gender, n (%):** M: 276 (83) F: 56 (17) **Race/ethnicity, n (%):** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** DSM-IV **Diagnostic category, n (%):** Autism 194 (58) PDD-NOS 46 (14) ASD/PDD 92 (28) **Other characteristics:** NR	**Overall ratings:** CARS, n, mean ± SD: **G1:** 275, 36.09 ± 5.09 **G1a:** 68, 33.48 ± 4.35 **G1b:** 105, 35.71 ± 4.43 **G1c:** 79, 38.91 ± 5.37 CARS symptom severity, n: Not quite autism range: 24 Mild/moderate autism range: 145 Severe autism range: 106 VABS/ABC, n, mean age equivalent ± SD: **G1:** 279, 16.81 ± 6.46 **G1a:** 72, 21.80 ± 7.96 **G1b:** 115, 16.16 ± 5.25 **G1c:** 9, 13.73 ± 3.73 VABS/ABC, n, mean standard score ± SD: **G1:** 274, 54.77 ± 9.24 **G1a:** 70, 66.90 ± 6.76 **G1b:** 116, 54.55 ± 3.00 **G1c:** 86, 45.65 ± 3.30	**Overall ratings:** CARS, n, mean ± SD: **G1:** 275, 31.26 ± 5.31 $P < 0.001$ **G1a:** 68, 26.99 ± 4.93 $P < 0.001$ **G1b:** 105, 31.62 ± 4.14 $P < 0.001$ **G1c:** 79, 34.85 ± 4.61 $P < 0.001$ main effect of time: $P < 0.001$ reported reductions ($P < 0.001$) on each individual items of the CARS (with the exception of item XIV ($P = 0.055$)) CARS symptom severity changes, n (%): Non-autism remained non-autism: 19 (79) Non-autism to mild/moderate: 5 (21) Mild moderate to non-autism: 59 (41) Mild/moderate remained mild/moderate: 76 (52) Mild/moderate to severe: 10 (7) Severe to non-autism: 16 (15) Severe to mild/moderate: 63 (59) Severe remained severe: 27 (26) Children initially scoring in autism range changed to milder category: 138 (50)

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Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Perry et al., 2008 (continued)	**Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 332 **G1a:** 78 **G1b:** 126 **G1c:** 96 **N at follow-up:** **G1:** 332 **G1a:** 78 **G1b:** 126 **G1c:** 96		**Social skills:** VABS Socialization domain, n, mean age equivalent ± SD: **G1:** 279, 13.71 ± 6.34 **G1a:** 72, 18.60 ± 7.62 **G1b:** 115, 13.15 ± 5.37 **G1c:** 91, 10.56 ± 3.50 VABS Socialization domain, n, mean standard score ± SD: **G1:** 274, 56.69 ± 7.82 **G1a:** 70, 66.10 ± 8.68 **G1b:** 116, 55.49 ± 3.66 **G1c:** 86, 50.83 ± 2.47 **Communication/ language:** VABS Communication domain, n, mean age equivalent ± SD: **G1:** 281, 15.65 ± 8.86 **G1a:** 72, 22.29 ± 12.01 **G1b:** 115, 14.33 ± 6.24 **G1c:** 92, 12.18 ± 5.54 VABS Communication domain, n, mean standard score ± SD: **G1:** 273, 53.92 ± 11.34 **G1a:** 70, 68.23 ± 11.09 **G1b:** 116, 52.47 ± 4.30 **G1c:** 85, 44.51 ± 4.54	VABS/ABC, n, mean age equivalent ± SD: **G1:** 279, 29.71 ± 14.21 *P* < 0.001 **G1a:** 72, 43.70 ± 14.48 *P* < 0.001 **G1b:** 115, 28.12 ± 10.83 *P* < 0.001 **G1c:** 91, 20.83 ± 8.20 *P* < 0.001 main effect of time *P* < 0.001 VABS/ABC, n, mean standard score ± SD: **G1:** 274, 56.26 ± 16.20 *P* = 0.02 **G1a:** 70, 75.79 ± 14.47 *P* < 0.001 **G1b:** 116, 54.28 ± 9.42 *P* = NS **G1c:** 86, 43.69 ± 7.32 *P* = 0.007 main effect of time *P* < 0.001 **Categories of progress/ outcome, n (%):** Average functioning: **G1:** 32 (10.8) **G1a:** 25 (32.5) **G1b:** 5 (4.2) **G1c:** 0 Substantial improvement: **G1:** 43 (14.5) **G1a:** 19 (24.7) **G1b:** 16 (13.4) **G1c:** 6 (6.5)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Perry et al., 2008 (continued)			**Adaptive behavior:** VABS Daily Living Skills domain, n, mean age equivalent ± SD: **G1:** 282, 20.90 ± 6.70 **G1a:** 73, 24.19 ± 8.25 **G1b:** 115, 20.99 ± 6.16 **G1c:** 92, 18.29 ± 4.58 VABS Daily Living Skills domain, n, mean standard score ± SD: **G1:** 274, 53.84 ± 12.10 **G1a:** 70, 66.36 ± 9.24 **G1b:** 116, 55.68 ± 5.24 **G1c:** 86, 41.99 ± 7.73 **Motor skills:** VABS Motor domain, n, mean age equivalent ± SD: **G1:** 167, 27.45 ± 7.59 **G1a:** 58, 28.71 ± 7.02 **G1b:** 69, 26.87 ± 7.60 **G1c:** 40, 26.63 ± 8.28 VABS Motor domain, n, mean standard score ± SD: **G1:** 138, 66.33 ± 13.95 **G1a:** 52, 76.94 ± 12.41 **G1b:** 66, 61.92 ± 10.10 **G1c:** 20, 53.30 ± 9.29	Clinically significant improvement: **G1:** 90 (30.4) **G1a:** 18 (23.4) **G1b:** 43 (36.1) **G1c:** 28 (30.4) Less autistic: **G1:** 31 (10.5) **G1a:** 4 (5.2) **G1b:** 11(9.2) **G1c:** 14 (15.2) Minimal improvement: **G1:** 25 (8.4) **G1a:** 4 (5.2) **G1b:** 7 (5.9) **G1c:** 14 (15.2) No change: **G1:** 55 (18.6) **G1a:** 5 (6.5) **G1b:** 27 (22.7) **G1c:** 22 (23.9) Worse: **G1:** 20 (6.8) **G1a:** 2 (2.6) **G1b:** 10 (8.4) **G1c:** 8 (8.7) *P* < 0.001 **Social skills:** VABS Socialization domain, n, mean age equivalent ± SD: **G1:** 279, 24.28 ± 13.59 *P* < 0.001 **G1a:** 72, 36.65 ± 14.99 *P* < 0.001 **G1b:** 115, 22.58 ± 10.72 *P* < 0.001 **G1c:** 91, 16.79 ± 7.89 *P* < 0.001 main effect of time *P* < 0.001

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Perry et al., 2008 (continued)			**Educational/ cognitive/ academic attainment:** FS IQ, n, mean ± SD: **G1:** 127, 47.42 ± 19.47 **G1a:** 40, 62.05 ± 15.99 **G1b:** 56, 43.44 ± 17.28 **G1c:** 26, 31.08 ± 9.90 Rate of developmental score, n, mean ± SD: **G1:** 278, 0.32 ± 0.12) **G1a:** 72, 0.47 ± 0.12 **G1b:** 114, 0.31 ± 0.06 **G1c:** 91, 0.22 ± 0.06	VABS Socialization domain, n, mean standard score ± SD: **G1:** 274, 58.91 ± 12.07 *P* < 0.001 **G1a:** 70, 72.11 ± 13.11 *P* = 0.001 **G1b:** 116, 56.82 ± 7.69 *P* = NS **G1c:** 86, 51.63 ± 4.87 *P* = NS main effect of time *P* < 0.001 **Communication/ language:** VABS Communication domain, n, mean age equivalent ± SD: **G1:** 281, 32.12 ± 19.94 *P* < 0.001 **G1a:** 72, 52.31 ± 19.09 *P* < 0.001 **G1b:** 115, 29.26 ± 15.85 *P* < 0.001 **G1c:** 92, 20.30 ± 11.95 *P* < 0.001 main effect of time *P* < 0.001
Perry et al., 2008 (continued)				VABS Communication domain, n, mean standard score ± SD: **G1:** 273, 59.13 ± 2216 *P* < 0.001 **G1a:** 70, 86.00 ± 20.45 *P* < 0.001 **G1b:** 116, 55.14 ± 14.09 *P* < 0.022 **G1c:** 85, 43.09 ± 8.60

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Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				P = NS main effect for time *P* < 0.001 **Adaptive behavior:** VABS Daily Living Skills domain, n, mean age equivalent ± SD: **G1:** 282, 32.60 ± 12.43 *P* < 0.001 **G1a:** 73, 42.21 ± 14.77 *P* < 0.001 **G1b:** 115, 32.50 ± 9.68 *P* < 0.001 **G1c:** 92, 25.24 ± 7.52 *P* < 0.001 main effect of time *P* < 0.001
Perry et al., 2008 (continued)				VABS Daily Living Skills domain, n, mean standard score ± SD: **G1:** 274, 50.68 ± 17.89 *P* < 0.001 **G1a:** 70, 69.26 ± 16.62 *P* = NS **G1b:** 116, 50.89 ± 10.74 *P* < 0.001 **G1c:** 86, 36.00 ± 11.03 *P* < 0.001 main effect of time *P* < 0.001 **Motor skills:** VABS Motor domain, n, mean age equivalent ± SD: **G1:** 167, 43.52 ± 14.51 *P* < 0.001 **G1a:** 58, 50.98 ± 13.10 *P* < 0.001 **G1b:** 69, 42.12 ± 12.89 *P* < 0.001

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G1c: 40, 35.13 ± 14.04 $P < 0.001$ main effect of time $P < 0.001$ VABS Motor domain, n, mean standard score ± SD: **G1:** 138, 68.47 ± 20.56 P = NS **G1a:** 52, 82.31 ± 18.10 **G1b:** 66, 62.08 ± 17.78 **G1c:** 20, 53.60 ± 13.72 main effect of time P = NS
Perry et al., 2008 (continued)				**Educational/ cognitive/ academic attainment:** Mental age (Combined scores from MSEL, BSID, WPPSI, and SB-FE) mean/months ± SD: **G1:** 127, 41.40 ± 17.33 $P < 0.001$ **G1a:** 40, 54.77 ± 12.65 $P < 0.001$ **G1b:** 55, 38.40 ± 15.46 $P < 0.001$ **G1c:** 26, 25.56 ± 11.64 $P = 0.002$ main effect of time $P < 0.001$ Mental age changes, n (%): Gain of more than 12 months: 77 (61) Gain of 24 months or greater: 40 (32) Reduction of more than 12 months: 1 (0.8) Remained within

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				12 month of intake level: 48 (38) FS IQ mean ± SD: **G1:** 127, 59.28 ± 27.34 *P* < 0.001 **G1a:** 40, 82.67 ± 21.12 *P* < 0.001 **G1b:** 56, 53.74 ± 22.52 *P* < 0.001 **G1c:** 26, 33.08 ± 15.44 *P* = NS main effect for time *P* < 0.001
Perry et al., 2008 (continued)				IQ changes, n (%): Increased by 15 points or more: 49 (39) Increased by 30 points or more: 22 (17) Decreased by 15 or more points: 3 (2) Remained within 15 points of initial score: 75 (59) Rate of developmental score, n, mean ± SD: **G1:** 278, 0.77 ± 0.76 *P* < 0.001 **G1a:** 72, 1.16 ± 0.95 *P* < 0.001 **G1b:** 114, 0.66 ± 0.59 *P* < 0.001 **G1c:** 91, 0.59 ± 0.69 *P* < 0.001 main effect of time *P* < 0.001 Developmental rate at or above typical development, n

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				(%): **G1a:** 38 (53) **G1b:** 34 (30) **G1c**: 14 (15) **Harms:** NR **Modifiers:** CARS: group x time interaction: *P* = 0.004 FSIQ: group x time interaction: *P* < 0.001
Perry et al., 2008 (continued)				MA: group x time interaction: *P* < 0.001 VABS Communication age equivalent, standard scores: group x time interaction: *P* < 0.001, *P* < 0.001 VABS Daily Living age equivalent, standard score: group x time interaction: *P* < 0.001, *P* < 0.001 VABS Socialization age equivalent, standard score group x time interaction: *P* < 0.001, *P* < 0.001 VABS Motor age equivalent, standard score group x time interaction: *P* < 0.001, *P* = NS VABS/ABC age equivalent, standard score

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				group x time interaction: *P* < 0.001, *P* < 0.001. Developmental rate, group x time interaction: *P* = 0.006

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Author: Probst and Leppert, 2008 **Country:** Germany **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Case series, prospective	**Intervention:** Teacher training in ASD symptoms, causes, assessment, treatment as well as educational skills focusing on antecedent interventions, methods of structured teaching and use of visual supports Three training sessions in two groups of 5 teachers each; one month between each session (months 1-3) Following group trainings, teachers had individual training sessions in the classroom for 6 months (months 4-9) Number of individual training sessions ± SD: 6 ± 1.25 Duration of individual training sessions, minutes ± SD: 30 ± 13 **Assessments:** Classroom Child Behavior Symptoms Questionnaire (CCBSQ) developed by authors, administered at baseline and the end of month 9 **Groups:** **G1:** teacher training **Provider:** 10 teachers (8 female) aged 42.0 ± 13.4 in two special education schools; each teacher had one child with ASD in a classroom of 8 ± 1.2 total children with MR. Teachers were trained by a graduate student who had competed a 5-day intensive TEACCH-training program **Measure of treatment fidelity reported:** No	**Inclusion criteria:** • Met DSM-IV criteria for autism **Exclusion criteria:** • See Inclusion Criteria **Age, years ± SD:** 10.0 ± 2.1 **Mental age:** NR **Gender, n (%):** Male: 7 (70) Female: 3 (30) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** Previous diagnosis of autism, as per school records; DSM-IV, CARS **Diagnostic category, n (%):** Autism: 10 (100) Severe Autism: 6 (66) Moderate Autism: 3 (33) Mild Autism: 1 (10) **Other characteristics, n (%):** Moderate or severe MR: 9 (90) Verbal language use: Never or seldom: 6 (60) Sometimes: 3 (30) Often: 1 (10)	**Overall ratings:** CARS score, mean ± SD: **G1:** 39.0 ± 7.0 **Educational/ cognitive/ academic attainment:** CCBSQ score, mean ± SD: **G1:** 106.4 ± 15.5	**Educational/ cognitive/ academic attainment:** CCBSQ score, month 9, mean ± SD: **G1:** 100.8 ± 16.7 **G1/BL:** $P < 0.05$ **Harms:** NR **Modifiers:** NR
Probst and Leppert, 2008 (continued)	**Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 10			

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	N at follow-up: **G1:** 10			
Author: Silva et al., 2008 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic and home **Enrollment period:** 2006 **Funding:** Spirit Mountain community fund **Author industry relationship disclosures:** NR **Design:** Case series, prospective **Note:** See related paper Silva et al., 2007 {#302}	**Intervention:** Qigong sensory training (QST) massage movements; 21 visits over 5 months, plus 15 minutes daily at home by parent QST trainers were recruited from the education service district and local health professionals. QST training consisted of skill-based curriculum and 50 hrs of didactic and experiential material. Trainers were observed by the PI delivering the 5 month intervention to two children. **Assessments:** VABS, Sensory Profile, Autism Behavior Checklist conducted by third party evaluators; parent-completed questionnaire RE observations of child's behaviors **Groups:** **G1:** QST **Provider:** Professionals trained in QST, n: OT: 5 Autism specialist: 3 Teacher/educator: 2 OT assistant: 1 Instructional assistant: 1 Nurse: 1 Chiropractor: 1 Social worker: 1 **Treatment manual followed:** NR **Defined protocol followed:** Yes **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR	**Inclusion criteria:** • < 6 years old • Diagnosis of autism • Enrolled in early intervention services • No complicating medical diagnoses or medication (chelation agents) **Inclusion criteria for QST trainers:** • Minimum 3 years experience working with children with autism • Healthy and energetic (self assessment) • Not on medications for chronic health conditions **Age, months ± SD (range):** 56.3 ± 12.5 (31-84) **Mental age:** NR **Gender, n (%):** Male: 21 (81) Female: 5 (19) **Race/ethnicity:** NR **SES:** NR **Diagnostic approach:** Referral Children were recruited who were receiving autism services from the education service district **Diagnostic tool/method:** NR **Diagnostic category, n (%):** Autism: 26 (100) **Other characteristics:** NR	**Social skills:** VABS score, mean ± SD: Socialization: **G1:** 70.9 ± 13.0 **Communication/ language:** VABS Communication: **G1:** 68.5 ± 15.0 **Adaptive behavior:** VABS Composite: **G1:** 68.6 ± 12.2 VABS Daily living skills: **G1:** 73.3 ± 18.5 **Motor skills:** VABS Motor skills: **G1:** 73.5 ± 12.0 **Sensory:** Sensory profile score, mean ± SD: Total: **G1:** 21.0 ± 11.8 Processing: **G1:** 6.2 ± 3.7 Modulation: **G1:** 4.6 ± 3.3 Behavioral response: **G1:** 3.4 ± 1.9 **Autism Behavior Checklist score, mean ± SD:** **G1:** 66.0 ± 25.1	**Problem behavior:** Autism Behavior Checklist score, mean ± SD: **G1:** 41.9 ± 22.1 *P* = 0.00005 **Social skills:** VABS socialization score, mean ± SD: **G1:** 79.8 ± 13.9 *P* = 0.003 **Communication/ language:** VABS communication score, mean ± SD: **G1:** 77.6 ± 16.9 *P* = 0.0003 **Adaptive behavior:** VABS composite score, mean ± SD: **G1:** 77.7 ± 14.5 *P* = 0.00009 VABS daily living score, mean ± SD: **G1:** 82.7 ± 17.8 *P* = 0.003 **Motor skills:** VABS motor skills score, mean ± SD: **G1:** 81.0 ± 11.4 *P* = 0.003 **Sensory:** Sensory profile total score, mean ± SD: **G1:** 14.5 ± 10.7 *P* = 0.0003 Sensory processing score, mean ± SD: **G1:** 4.1 ± 3.4 *P* = 0.002
Silva et al., 2008 (continued)	**Concomitant therapies:** NR **N at enrollment:**			Sensory modulation score, mean ± SD:

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	G1: 26 **N at follow-up:** **G1:** 26			**G1:** 3.2 ± 2.7 *P* = 0.003 Sensory behavioral response score, mean ± SD: **G1:** 2.8 ± 1.6 *P* = NS **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Solomon et al., 2008 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Children's Miracle Network **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Parent Child Interaction Therapy Phase 1: Child directed interaction, initially clinician led, then parents coached until reached mastery criteria (occurred within 8 sessions for all participants) Phase 2: Parent directed interaction, all parents completed within 6 sessions. Mean length of total treatment: 12.7 sessions (one family relocated in middle of CDI) **Assessments:** Parent rated ECBI, BASC, PSI-SF; DPICS affect coding done in free play session (G1 only) **Groups:** **G1:** intervention **G2:** control (waiting list) **Provider:** Five therapists (3 trained in PCIT with master trainers: shadowing and practicing at least 6 mos; 2 trained in team working with trained therapists) **Measure of treatment fidelity reported:** Regular team coding meetings during study, but no formal treatment fidelity measure taken **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 10 **G2:** 9 **N at follow-up:** **G1:** 10 **G2:** 9	**Inclusion criteria:** • Met DSM-IV-TR criteria for autistic disorder, aspergers disorder, or PDD-NOS • Met cutoffs for ASD on ADOS • Met cutoffs for autism on ADI-R • Clinically significant externalizing behavior problems on BASC externalizing behavior scale OR exceed threshold on ECBI intensity scale **Exclusion criteria:** • FSIQ < 70 on WASI • Not enough receptive or expressive language abilities to participate in language intensive intervention **Age, mean/yrs (range):** **G1:** 8.2 ± 1.7 (6.0-10.8) **G2:** 8.1 ± 2.2 (5.3-12.1) **Mental age:** WASI FSIQ, mean ± SD: **G1:** 100.11 ± 19.2 (83-135) **G2:** 93.4 ± 16.8 (79-125) WASI VIQ, mean ± SD: **G1:** 97.7 ± 18.4 (73-138) **G2:** 90.4 ± 20.3 (75-133) WASI PIQ, mean ± SD: **G1:** 102.2 ± 21.6 (82-138) **G2:** 94.7 ± 9.3 (84-110) **Gender, n (%):** Male: 19 (100) Female: 0 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral, with diagnosis **Diagnostic tool/method:** ADOS and ADI-R in study DSM-IV-TR	**Overall ratings:** ADOS score, mean ± SD (range): **G1:** 13.1 ± 4.3 (8-22) **G2:** 11.3 ± 3.6 (7-19) **Problem behavior:** ECBI intensity score, mean ± SD: **G1:** 67.0 ± 5.64 **G2:** 65.67 ± 8.80 ECBI problem score, mean ± SD: **G1:** 62.90 ± 6.30 **G2:** 66.78 ± 8.51 BASC externalizing score, mean ± SD: **G1:** 71.1 ± 8.2 **G2:** 76.6 ± 14.9 BASC aggression score, mean ± SD: **G1:** 63.90 ± 10.58 **G2:** 70.33 ± 14.21 BASC hyperactivity score, mean ± SD: **G1:** 74.30 ± 8.29 **G2:** 80.56 ± 13.95 BASC attention score, mean ± SD: **G1:** 72.80 ±6.13 **G2:** 70.89 ± 10.46 BASC conduct score, mean ± SD: **G1:** 67.40 ± 8.63 **G2:** 67.00 ± 14.03 **Social skills:** BASC adaptability score, mean ± SD: **G1:** 23.90 ± 7.91 **G2:** 28.44 ± 6.48 BASC social skills score, mean ± SD: **G1:** 30.20 ± 3.77 **G2:** 35.00 ± 10.52 BASC leadership score, mean ± SD: **G1:** 36.20 ± 4.02 **G2:** 33.89 ± 6.07	**Problem behavior:** ECBI intensity score, mean ± SD: **G1:** 59.70 ± 4.95 **G2:** 62.22 ± 9.77 **G1/BL:** *P* = NS **G2/BL:** *P* = NS **G1/G2:** *P* = 0.462 ECBI problem score, mean ± SD: **G1:** 52.00 ± 6.52 **G2:** 63.00 ± 7.31 **G1/BL:** *P* = 0.015 **G2/BL:** *P* = NS **G1/G2:** *P* = 0.007 BASC aggression score, mean ± SD: **G1:** 59.00 ± 6.25 **G2:** 67.78 ± 14.60 **G1/BL:** *P* = NS **G2/BL:** *P* = NS **G1/G2:** *P* = 0.516 BASC hyperactivity score, mean ± SD: **G1:** 68.70 ± 11.68 **G2:** 80.56 ± 8.31 **G1/BL:** *P* = NS **G2/BL:** *P* = NS **G1/G2:** *P* = 0.055 BASC attention score, mean ± SD: **G1:** 65.80 ±8.77 **G2:** 70.67 ± 10.92 **G1/BL:** *P* = NS **G2/BL:** *P* = NS **G1/G2:** *P* = 0.062 BASC conduct score, mean ± SD: **G1:** 59.90 ± 8.01 **G2:** 66.00 ± 10.44 **G1/BL:** *P* = NS **G2/BL:** *P* = NS **G1/G2:** *P* = 0.059
Solomon et al., 2008 (continued)		**Diagnostic category:** Autism: **G1:** 4 **G2:** 4 PDD-NOS: **G1 :** 0	BASC depression score, mean ± SD: **G1:** 60.00 ± 9.57 **G2:** 72.33 ±15.68 BASC atypicality score, mean ± SD:	**Social skills:** BASC adaptability score, mean ± SD: **G1:** 32.40 ± 10.23 **G2:** 27.33 ± 10.38

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
		G2: 3 Aspergers: **G1:** 6 **G2:** 2 **Other characteristics:** NR	**G1:** 75.50 ±14.25 **G2:** 72.33 ± 21.09 DPICS affect code score, mean ± SD: Shared positive affect: **G1:** 1.5 ± 1.8 (0-5) Parent positive affect: **G1:** 4.2 ± 2.5 (1-9) Child positive affect: **G1:** 4.8 ± 4.2 (0-12) Lag sequential: **G1:** 1.2 ± 1.6 (0-4)	**G1/BL:** *P* = 0.002 **G2/BL:** *P* = NS **G1/G2:** *P* = 0.035 BASC social skills score, mean ± SD: **G1:** 37.40 ± 5.80 **G2:** 37.33 ± 6.91 **G1/BL:** *P* = NS **G2/BL:** *P* = NS **G1/G2:** *P* = 0.16 BASC leadership score, mean ± SD: **G1:** 38.10 ± 6.15 **G2:** 37.56 ± 4.72 **G1/BL:** *P* = NS **G2/BL:** *P* = NS **G1/G2:** *P* = 0.79 BASC depression score, mean ± SD: **G1:** 53.60 ± 7.25 **G2:** 65.11 ± 13.91 **G1/BL:** *P* = NS **G2/BL:** *P* = NS **G1/G2:** *P* = 0.089 BASC atypicality score, mean ± SD: **G1:** 69.10 ± 20.51 **G2:** 78.33 ± 17.11 **G1/BL:** *P* = NS **G2/BL:** *P* = NS **G1/G2:** *P* = 0.048 DPICS affect code score, mean ± SD: Shared positive affect: **G1:** 5.3 ± 5.2 **G1/BL:** *P* < 0.05 Parent positive affect: **G1:** 10.4 ± 5.7 **G1/BL:** *P* < 0.01
Solomon et al., 2008 (continued)				Child positive affect: **G1:** 7.3 ± 6.3 **G1/BL:** *P* < 0.1 Lag sequential: **G1:** 4.7 ± 4.9 **G1/BL:** *P* < 0.05 **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Tyminski et al., 2008 **Country:** US **Practice setting:** Community **Intervention setting:** School and home **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Group psychotherapy, for an average 14 months for 2 groups of 6 and 3 groups of 5 **Assessment:** Social skills at home assessed by VABS and at school by the Social Skills Checklist; baseline social development by teachers Follow-up assessment of all study measures at 4 months to 3 years after start of study therapy **Groups:** **G1:** group psychotherapy **Provider:** Therapists **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 39 (100) **N at follow-up:** **G1:** 27 (69)	**Inclusion criteria:** • Diagnosis of DSM-IV criteria for PDD • Capacity for verbal communication • No history of verbal aggression towards peers **Exclusion criteria:** • See inclusion criteria **Age, years (range):** **G1:** 9.2 (5-16) **Mental age:** NR **Gender, n (%):** Male: 33 (85) Female: 6 (15) **Race/ethnicity, n (%):** White: 12 (31) Asian: 12 (31) Hispanic: 9 (23) African American: 2 (5) Multiracial: 4 (10) **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** DSM-IV **Diagnostic category, n (%):** Autism: 15 (38) PDD-NOS: 21 (54) Aspergers: 3 (8) **Other characteristics:** Theory of Mind: NR	**Social skills:** VABS socialization, developmental age, months ± SD (range): **G1:** 33 ± 15.3 (13-86) Correlation between VABS and baseline measures: Age at intake: 0.38 ($P < 0.05$) Theory of Mind: 0.35 ($P < 0.05$) Social Skills Checklist score, mean ± SD (range): **G1:** 2.5 ± 0.8 (1.4-4.7) Correlation between SSC score and baseline measures: Age: 0.29 ($P < 0.10$)	**Social skills:** VABS socialization, developmental age, months ± SD (range): **G1:** 46 ± 18.2 (17-90) **G1/BL:** $P < 0.001$ Correlation between follow-up VABS and other measures: Theory of Mind: 0.49 ($P < 0.01$) Baseline VABS: 0.74 ($P < 0.0001$) Duration of therapy: -0.44 ($P < 0.01$) Social Skills Checklist score, mean ± SD (range): **G1:** 2.9 ± 0.7 (1.2-4.0) **G1/BL:** $P < 0.01$ Correlation between follow-up SSC score and other measures: Baseline SSC: 0.54 ($P < 0.001$) Correlation between change in SSC score and other measures: Age at intake: -0.32 ($P < 0.10$) **Harms:** NR **Modifiers:** Age at intake, theory of mind, and duration of therapy

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: RUPP, 2007 **Country:** US **Practice setting:** Specialty treatment center **Intervention setting:** Clinic and home **Enrollment period:** NR **Funding:** NIH **Author industry relationship disclosures:** NR **Design:** Case series	**Intervention:** 11 parent education sessions covering prevention strategies, schedules, reinforcement, planned ignoring, compliance training, functional communication techniques, teaching techniques, and generalization; up to 4 optional sessions including time-out, contingency contracting, imitation training, and crisis management implemented at clinician discretion Mean parental adherence score for 11 mandatory sessions: 80 **Assessments:** Either WISC-III, MSEL, or LIPS-R, depending on the child's cognitive functioning; Slosson Intelligence Test Parent(s) seen weekly for 75-90 minute parent training visits until week 14, and then for a home visit (week 17) and booster sessions (weeks 18, 20, and 22); initial home visit conducted between the week 2 and 3 parent training sessions Repeated measures collected at regular time points during the parent training program (base-line, weekly through week 8, monthly at weeks 12, 16, and 20, and study end-point at week 24): PTA, HSQ, ABC, CGI-I, VABS, PSI **Groups:** **G1:** parent training **Provider:** Parent training administered by therapists	**Inclusion criteria:** • Age 4-13 years • On stable medication for significant behavior problems (stable = on same medication dose for ≥ 4 weeks with no planned dosage changes for 6 months) • At least one parent available for training • Met clinical DSM-IV criteria for Autistic Disorder, Asperger's Disorder, or PDD-NOS • CGI-S score of 3-5 at baseline **Exclusion criteria:** • IQ < 35 or mental age <18 months **Age, years ± SD:** 7.7 ± 2.6 **Mental age:** IQ, mean ± SD: 55.9 ± 22.3 **Gender, n:** Male: 14 Female: 3 **Race/ethnicity, %:**** White: 88 African American: 12 Asian: 6 Hispanic: 12 **SES:** Maternal education: NR Household income, %: < $20,000: 12 $20,001-$40,000: 18 $40,001-$60,000: 47 $60,001-$90,000: 23 **Diagnostic approach:** In Study **Diagnostic tool/method:** diagnosis using DSM-IV criteria made by experi-enced clinicians at each study site by interview and direct observation; diagnosis corroborated by ADI-R	**Communication/ language:** ABLLS raw score, mean ± SD: **G1:** 133.4 ± 64.2 **Problem behavior:** ABC score, mean ± SD: Irritability: **G1:** 24.3 ± 9.3 Stereotypic behavior: **G1:** 8.8 ± 5.7 Lethargy/social withdrawal: **G1:** 9.5 ± 8.2 Hyperactivity/ noncompliance: **G1:** 27.4 ± 9.5 Inappropriate speech: **G1:** 3.8 ± 3.6 PSI score, mean ± SD: **G1:** 114.1 ± 18 **Adaptive behavior:** VABS daily living skills score, mean ± SD: Raw score: **G1:** 119.9 ± 62.4 Standard score: **G1:** 38.3 ± 16.4 Age equivalency: **G1:** 35.7 ± 18.2	**Overall ratings:** CGI-I rating, %: Very much improved/much improved: 53 Minimal improvement: 30 No change: 6 Parent rating of target behaviors improved, highly satisfied: 100 **Communication/ language:** ABLLS raw score, week 24, mean ± SD: **G1:** 159 ± 56.4 **G1/BL:** *P* < 0.001 % change = 19.2 **Problem behavior:** ABC score, week 24, mean ± SD: Irritability: **G1:** 16.1 ± 9.5 33.8% reduction from BL **G1/BL:** *P* < 0.01 Stereotypic behavior: **G1:** NR **G1/BL:** *P* = NS Lethargy/social withdrawal: **G1:** NR **G1/BL:** *P* = NS Hyperactivity/ noncompliance: **G1:** 21.7 ± 10.2 20.6% reduction from BL **G1/BL:** *P* < 0.05 Inappropriate speech: **G1:** NR **G1/BL:** *P* = NS
RUPP, 2007 (continued)	**Frequency of contact during study:** Parent(s) seen weekly until week 14; home visit at week 17, booster	**Diagnostic category, n:** Autism: 11 PDD-NOS: 3 Aspergers: 2 **Other characteristics,%:**		PSI score, week 24, mean ± SD: **G1:** 98.3 ± 17.7 13.9% reduction from BL

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	sessions at weeks 18, 20, and 22; home visit between weeks 2 and 3 **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** Yes **Concomitant therapies, %:** Taking medication: 100 Enrolled in special education: 65 **N at enrollment:** **G1:** 17 **N at follow-up:** **G1:** 14*	Living in 2-parent house-hold: 88 Living in a parental home: 100		**G1/BL:** $P < 0.05$ **Adaptive behavior:** VABS daily living skills score, week 24, mean ± SD: Raw score: **G1:** 146.7 ± 68.5 % change = 22.3 **G1/BL:** $P < 0.01$ Standard score: **G1:** 45.2 ± 18.2 % change = 18 **G1/BL:** P = NS Age equivalency: **G1:** 42.4 ± 22.2 % change = 18.7 **G1/BL:** $P < 0.01$ **Harms:** NR **Modifiers:** At 24 weeks: Correlation between adaptive behavior & improvement in the HSQ was r = 0.28

Comments: *Reasons for study withdrawal: medication changes (1), medical problems (1), and parental unavailability (1).
**18% selected more than one race category

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Baker-Ericzén et al., 2007 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** 1999 to 2003 **Funding:** NIH **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Pivotal Response Training (PRT): 12-week parent education program in which trained therapists taught parents strategies for increasing motivation Families met individually with therapist for 1 hour/week for 12 weeks **Provider:** Therapists conducting parent education (trained in PRT through graduate studies or a train-the-trainer model with supervising psychologist; also trained in use of manual to teach techniques to parents) and master's level developmental specialists or doctoral-level clinical psychologists with experience with children with ASD **Assessments:** VABS administered by therapist with parent at first and last treatment session **Groups:** **G1:** PRT **Ga:** males **Gb:** females **Measure of treatment fidelity reported:** Yes, but not after initial training **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 269 **N at follow-up:** **G1:** 158	**Inclusion criteria:** • Child with diagnosis of autistic disorder or PDD-NOS by DSM-IV **Exclusion criteria:** • See inclusion criteria **Age, months (range):** 49.36 (24-113) Age grouping, %: ≤ 3 years: 55 4-5 years: 35 ≥ 6 years: 10 **Mental age:** NR **Gender, %:** Male: 83 Female: 17 **Race/ethnicity, %:** Hispanic: 35.4 White: 27.4 Asian/Pacific Islander: 19.5 African American: 4 Native American: 2.7 Unknown/other: 10.6 **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** DSM-IV; not confirmed in study **Diagnostic category, n (%):** Autism/PDD-NOS: 158 (100) **Other characteristics:** NR	**Social skills:** VABS socialization score, mean ± SD: **G1a:** 59.65 ± 9.22 (n=136) **G1b:** 62.82 ± 10.47 (n=28) **G1a/G1b:** P = NS **Communication/ language:** VABS communication score, mean ± SD: **G1a:** 58.93 ± 12.72 (n=136) **G1b:** 64.46 ± 13.87 (n=28) **G1a/G1b:** P = NS **Motor skills:** VABS motor skills score, mean ± SD: **G1:** NR* **Adaptive behavior:** VABS composite score, mean ± SD: **G1a:** 54.50 ± 10.38 (n=128) **G1b:** 59.50 ± 10.81 (n=28) **G1a/G1b:** $P < 0.05$ VABS daily living skills score, mean ± SD: **G1a:** 56.54 ± 12.15 (n=135) **G1b:** 63.43 ± 12.23 (n=28) **G1a/G1b:** P = NS	**Social skills:** VABS socialization score, mean ± SD: **G1a:** 63.63 ± 11.70 (n=136) **G1b:** 67.82 ± 15.95 (n=28) **G1a/BL:** $P < 0.001$ **G1a/BL:** $P < 0.01$ **G1/BL:** $P < 0.001$ **Communication/ language:** VABS communication score, mean ± SD: **G1a:** 63.61 ± 15.56 (n=136) **G1b:** 66.96 ± 15.44 (n=28) **G1a/BL:** $P < 0.001$ **G1a/BL:** P = NS **G1/BL:** $P < 0.001$ **Motor skills:** VABS motor skills score, mean ± SD: **G1:** NR* **G1/BL:** $P < 0.001$ **Adaptive behavior:** VABS composite score, mean ± SD: **G1a:** 58.84 ± 12.32 (n=128) **G1b:** 64.75 ± 16.33 (n=28) **G1a/BL:** $P < 0.001$ **G1a/BL:** $P < 0.01$ **G1/BL:** $P < 0.001$
Baker-Ericzén et al., 2007 (continued)				VABS daily living skills score, mean ± SD: **G1a:** 59.66 ± 12.74 (n=135) **G1b:** 66.36 ± 13.27 (n=28) **G1a/BL:** $P < 0.001$

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G1a/BL: *P* < 0.01 **G1/BL:** *P* < 0.001 **Harms:** NR **Modifiers:** Significant effect for age with younger children (≤ 3 years) showing most improvement on the VABS composite score (*P* < 0.001) and older children (≥ 6 years) showing the least improvement (*P* < 0.01). No significant differences in domain scores by race at baseline.

Comments: *The VABS motor skills score was only calculated for children under the age of 6 and is not reported.

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Bauminger et al., 2007 **Country:** Israel **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** NR **Funding:** Israel Foundation Trustees **Author industry relationship disclosures:** NR **Design:** Retrospective case series **Note:** See related study with 11 overlapping participants, Bauminger et al., 2007{#422}	**Intervention:** Group-centered social multimodal Cognitive Behavioral-Ecological intervention: within teacher-led small groups of peers that included 2 typical peers and between 1 and 3 high functioning children with ASD. The research coordinator supported each teacher once monthly. Duration: 7 months Group lesson included teaching process to set “definitions and rules” for participants and practice process that allowed rehearsal of learned skills Social skills training consisted of 50 lessons focusing on group behavior and practicing behavior, covering: • Instruction in prerequisite concepts for group involvement • Affective education focusing mainly on higher processes of emotional understanding • Group conversation skills • Cooperative skills • Double message issues **Assessments:** Observed direct and indirect treatment effects on social cognitive capabilities, children’s change in overt cooperative skills within and outside the group. All measures administered once before and once after treatment. **Groups:** **G1:** individual intervention **Ga:** original group **Gb:** newly recruited	**Inclusion criteria:** • Diagnosis of ASD from prior assessment by licensed psychologists using DSM-IV **Exclusion criteria:** • See inclusion criteria **Age, months ± SD:** **G1a:** 105.4 ± 7.24 **G1b:** 110.78 ± 15.06 **Mental age:** Verbal IQ, mean ± SD: **G1a:** 104.09 ± 14.28 **G1b:** 110.62 ± 14.44 **G1a/G1b:** *P* = NS PIQ, mean ± SD: **G1a:** 109.73 ± 9.12 **G1b:** 116.92 ± 16.44 **G1a/G1b:** *P* = NS Full IQ, mean ± SD: **G1a:** 108.09 ± 8.62 **G1b:** 115.08 ± 13.68 **G1a/G1b:** *P* = NS **Gender, n:** Male: **G1a:** 10 **G1b:** 14 Female: **G1a:** 1 **G1b:** 1 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referred from prior assessment by psychologists, diagnosis verified In Study **Diagnostic tool/method:** DSM-IV, ADI-R **Diagnostic category, n:** High functioning autism: **G1a:** 7 **G1b:** 10 Aspergers: **G1a:** 4 **G1b:** 5	**Social Skills:** Specific companionship behaviors, mean ± SD: Mutual planning: **G1:** 1.69 ± 0.73 Cooperation: **G1:** 2.08 ± 1.16 Eye contact: **G1:** 2.50 ± 0.76 Negotiation: **G1:** 1.15 ± 0.36 Sharing: **G1:** 2.00 ± 0.93 Positive interaction, social behaviors, mean ± SD: Group: **G1a:** 8.27 ± 10.01 **G1b:** 9.86 ± 8.82 **G1a/G1b:** *P* = NS Dydactic: **G1a:** 25.45 ± 23.98 **G1b:** 34.86 ± 27.73 **G1a/G1b:** *P* = NS Low-level interaction, social behaviors, mean ± SD: Group: **G1a:** 14.09 ± 7.1 **G1b:** 10.73 ± 8.14 **G1a/G1b:** *P* = NS Dydactic: **G1a:** 15.36 ± 10.26 **G1b:** 21.00 ± 15.40 **G1a/G1b:** *P* = NS Negative interaction, social behaviors, mean ± SD: Group: **G1a:** 0.91 ± 1.22 **G1b:** 0.6 ± 1.12 **G1a/G1b:** *P* = NS Dydactic: **G1a:** 5.09 ± 5.32 **G1b:** 2.26 ± 2.21 **G1a/G1b:** *P* = NS	**Social skills:** Specific companionship behaviors, mean ± SD: Mutual planning: **G1:** 2.19 ± 0.84 **G1/BL:** *P* < 0.01 Cooperation: **G1:** 3.58 ± 1.39 **G1/BL:** *P* < 0.001 Eye contact: **G1:** 2.65 ± 1.12 **G1/BL:** *P* = NS Negotiation: **G1:** 1.23 ± 0.65 **G1/BL:** *P* = NS Sharing: **G1:** 2.58 ± 1.20 **G1/BL:** *P* < 0.05 Positive interaction, social behaviors, mean ± SD: Group: **G1a:** 4.36 ± 6.75 **G1b:** 14.26 ± 16.48 Dydactic: **G1a:** 29.45 ± 9.67 **G1b:** 27.73 ± 18.01 Low-level interaction, social behaviors, mean ± SD: Group: **G1a:** 14.36 ± 4.41 **G1b:** 11.86 ± 7.33 Dyadic: **G1a:** 11.09 ± 5.50 **G1b:** 14.86 ± 10.02 Negative interaction, social behaviors, mean ± SD: Group: **G1a:** 1 ± 1.34 **G1b:** 0.87 ± 1.41
Bauminger et al., 2007 (continued)	**Provider:** Special education teacher **Measure of treatment fidelity reported:** NR	**Other characteristics:** ADI social score, mean ± SD: **G1a:** 17.45 ± 3.90 **G1b:** 17.64 ± 3.62	Problem solving initiation behavior, mean ± SD: **G1a:** 4.72 ± 2.41 **G1b:** 4.33 ± 2.52	Dydactic: **G1a:** 6.09 ± 4.82 **G1b:** 2.46 ± 3.90 ANOVA: social behavior type

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	Co-interventions held stable during treatment: NR **Concomitant therapies:** NR **N at enrollment:** **G1a:** 11 **G1b:** 15 **N at follow-up:** **G1a:** 11 **G1b:** 15	**G1a/G1b:** *P* = NS ADI communication score, mean ± SD: **G1a:** 13.27 ± 4.88 **G1b:** 13.71 ± 4.28 **G1a/G1b:** *P* = NS ADI behavior score, mean ± SD: **G1a:** 5.00 ± 1.34 **G1b:** 5.79 ± 1.52 G1a/G1b: ***P* = NS**	Number of social solutions, mean ± SD: **G1a:** 55.71 ± 17.80 **G1b:** 47.25 ± 17.74 TOM strange stories, mean ± SD: Comprehension: **G1a:** 4.45 ± 1.03 **G1b:** 4.13 ± 0.91 Justification: **G1a:** 3.63 ± 2.46 **G1b:** 4.2 ± 3.02 Executive function, mean ± SD: Number of sorts performed: **G1a:** 9.18 ± 2.18 **G1b:** 8.13 ± 4.27 Strategies generated: **G1a:** 9.18 ± 2.52 **G1b:** 8 ± 4.05 Strategies recognized: **G1a:** 9 ± 3.13 **G1b:** 7.40 ± 3.92 **Emotional understanding:** Recognition of emotion, mean ± SD: Basic: **G1a:** 10.90 ± 1.86 **G1b:** 11.60 ± 2.16 Complex: **G1a:** 11.18 ± 2.08 **G1b:** 10.46 ± 3.22 Relevancy of explanation, mean ± SD: Basic: **G1a:** 6.90 ± 1.04 **G1b:** 6.53 ± 1.76 Complex: **G1a:** 7.00 ± 0.77 **G1b:** 6.33 ± 1.45	(group/didactic; P < 0.001), group (newly recruited/ original; P < 0.05) Problem solving initiation behavior, mean ± SD: **G1a:** 6.54 ± 4.03 **G1b:** 5.80 ± 2.33 **G1/BL:** *P* < 0.01 Number of social solutions, mean ± SD: **G1a:** 58.60 ± 23.74 **G1b:** 59.32 ± 13.99 **G1/BL:** *P* < 0.05 TOM strange stories, mean ± SD: Comprehension: **G1a:** 4.09 ± 1.37 **G1b:** 4.26 ± 0.45 **G1/BL:** *P* = NS Justification: **G1a:** 4.18 ± 2.35 **G1b:** 5.40 ± 2.35 **G1/BL:** *P* < 0.01 Executive function, mean ± SD: Number of sorts performed: **G1a:** 10.45 ± 2.84 **G1b:** 9.46 ± 2.94 **G1/BL:** *P* < 0.001 Strategies generated: **G1a:** 10.63 ± 2.84 **G1b:** 9.46 ± 2.92 **G1/BL:** *P* < 0.05 Strategies recognized: **G1a:** 10.27 ± 3.19 **G1b:** 7.80 ± 2.47 **G1/BL:** *P* < 0.05
Bauminger et al., 2007 (continued)			Definition accuracy, mean ± SD: Basic: **G1a:** 1.09 ± 1.51 **G1b:** 1.06 ± 1.33 Complex: **G1a:** 2.36 ± 2.01 **G1b:** 2.80 ± 2.56 Overall: **G1a:** 3.45 ± 3.41 **G1b:** 3.86 ± 3.64	**Emotional understanding:** Recognition of emotion, mean ± SD: Basic: **G1a:** 13.81 ± 2.27 **G1b:** 12.66 ± 2.59 **G1/BL:** *P* = 0.056 Complex: **G1a:** 12.27 ± 2.10

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
			Number of emotions described, mean ± SD: Basic: **G1a:** 3.45 ± 0.08 **G1b:** 3.40 ± 0.91 Complex: **G1a:** 4.18 ± 2.56 **G1b:** 4.27 ± 2.43 Overall: **G1a:** 8.54 ± 4.22 **G1b:** 7.66 ± 2.79 Audience awareness, mean ± SD: Basic: **G1a:** 4.15 ± 1.85 **G1b:** 5.31 ± 1.31 Complex: **G1a:** 9.56 ± 5.84 **G1b:** 9.58 ± 3.61 Overall: **G1a:** 13.71 ± 6.77 **G1b:** 14.89 ± 4.04	**G1b:** 13.20 ± 2.07 **G1/BL:** *P* = 0.056 Relevancy of explanation, mean ± SD: Basic: **G1a:** 7.81 ± 0.60 **G1b:** 7.46 ± 1.18 **G1/BL:** *P* = 0.056 Complex: **G1a:**7.45 ± 0.82 **G1b:**7.20 ± 0.94 **G1/BL:** *P* < 0.01 Definition accuracy, mean ± SD: Basic: **G1a:** 1.81 ± 1.40 **G1b:** 1.73 ± 1.33 **G1/BL:** *P* < 0.01 Complex: **G1a:** 4.63 ± 2.57 **G1b:** 3.80 ± 2.33 **G1/BL:** *P* = 0.056 Overall: **G1a:** 6.34 ± 3.61 **G1b:** 5.53 ± 3.29 **G1/BL:** *P* = 0.056 Number of emotions described, mean ± SD: Basic: **G1a:** 3.72 ± 0.05 **G1b:** 3.60 ± 0.63 **G1/BL:** *P* = NS Complex: **G1a:** 5.18 ± 2.13 **G1b:** 5.33 ± 2.16 **G1/BL:** *P* < 0.05
Bauminger et al., 2007 (continued)				Overall: **G1a:** 8.90 ± 2.30 **G1b:** 8.93 ± 2.43 **G1/BL:** *P* = NS Audience awareness, mean ± SD: Basic: **G1a:** 4.75 ± 2.03 **G1b:** 5.62 ± 1.47 **G1/BL:** *P* = NS Complex: **G1a:** 12.71 ± 2.33 **G1b:** 11.38 ± 3.15 **G1/BL:** *P* < 0.05 Overall: **G1a:** 17.47 ± 4.01 **G1b:** 17.00 ± 3.73 **G1/BL:** *P* < 0.05 **Harms:**

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Bauminger et al., 2007 **Country:** Israel **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** NR **Funding:** Israel Foundation Trustees **Author industry relationship disclosures:** NR **Design:** Retrospective case series **Note:** See related study with 11 overlapping participants, Bauminger et al., 2007{#422}	**Intervention:** Group-centered social multimodal Cognitive Behavioral-Ecological intervention: within teacher-led small groups of peers that included 2 typical peers and between 1 and 3 high functioning children with ASD. The research coordinator supported each teacher once monthly. Duration: 7 months Group lesson included teaching process to set "definitions and rules" for participants and practice process that allowed rehearsal of learned skills Social skills training consisted of 50 lessons focusing on group behavior and practicing behavior, covering: • Instruction in prerequisite concepts for group involvement • Affective education focusing mainly on higher processes of emotional understanding • Group conversation skills • Cooperative skills • Double message issues **Assessments:** Observed direct and indirect treatment effects on social cognitive capabilities, children's change in overt cooperative skills within and outside the group. All measures administered once before and once after treatment. **Groups:** **G1:** individual intervention **Ga:** original group **Gb:** newly recruited	**Inclusion criteria:** • Diagnosis of ASD from prior assessment by licensed psychologists using DSM-IV **Exclusion criteria:** • See inclusion criteria **Age, months ± SD:** **G1a:** 105.4 ± 7.24 **G1b:** 110.78 ± 15.06 **Mental age:** Verbal IQ, mean ± SD: **G1a:** 104.09 ± 14.28 **G1b:** 110.62 ± 14.44 **G1a/G1b:** *P* = NS PIQ, mean ± SD: **G1a:** 109.73 ± 9.12 **G1b:** 116.92 ± 16.44 **G1a/G1b:** *P* = NS Full IQ, mean ± SD: **G1a:** 108.09 ± 8.62 **G1b:** 115.08 ± 13.68 **G1a/G1b:** *P* = NS **Gender, n:** Male: **G1a:** 10 **G1b:** 14 Female: **G1a:** 1 **G1b:** 1 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referred from prior assessment by psychologists, diagnosis verified In Study **Diagnostic tool/method:** DSM-IV, ADI-R **Diagnostic category, n:** High functioning autism: **G1a:** 7 **G1b:** 10 Aspergers: **G1a:** 4 **G1b:** 5	**Social Skills:** Specific companionship behaviors, mean ± SD: Mutual planning: **G1:** 1.69 ± 0.73 Cooperation: **G1:** 2.08 ± 1.16 Eye contact: **G1:** 2.50 ± 0.76 Negotiation: **G1:** 1.15 ± 0.36 Sharing: **G1:** 2.00 ± 0.93 Positive interaction, social behaviors, mean ± SD: Group: **G1a:** 8.27 ± 10.01 **G1b:** 9.86 ± 8.82 **G1a/G1b:** *P* = NS Dydactic: **G1a:** 25.45 ± 23.98 **G1b:** 34.86 ± 27.73 **G1a/G1b:** *P* = NS Low-level interaction, social behaviors, mean ± SD: Group: **G1a:** 14.09 ± 7.1 **G1b:** 10.73 ± 8.14 **G1a/G1b:** *P* = NS Dydactic: **G1a:** 15.36 ± 10.26 **G1b:** 21.00 ± 15.40 **G1a/G1b:** *P* = NS Negative interaction, social behaviors, mean ± SD: Group: **G1a:** 0.91 ± 1.22 **G1b:** 0.6 ± 1.12 **G1a/G1b:** *P* = NS Dydactic: **G1a:** 5.09 ± 5.32 **G1b:** 2.26 ± 2.21 **G1a/G1b:** *P* = NS	**Social skills:** Specific companionship behaviors, mean ± SD: Mutual planning: **G1:** 2.19 ± 0.84 **G1/BL:** *P* < 0.01 Cooperation: **G1:** 3.58 ± 1.39 **G1/BL:** *P* < 0.001 Eye contact: **G1:** 2.65 ± 1.12 **G1/BL:** *P* = NS Negotiation: **G1:** 1.23 ± 0.65 **G1/BL:** *P* = NS Sharing: **G1:** 2.58 ± 1.20 **G1/BL:** *P* < 0.05 Positive interaction, social behaviors, mean ± SD: Group: **G1a:** 4.36 ± 6.75 **G1b:** 14.26 ± 16.48 Dydactic: **G1a:** 29.45 ± 9.67 **G1b:** 27.73 ± 18.01 Low-level interaction, social behaviors, mean ± SD: Group: **G1a:** 14.36 ± 4.41 **G1b:** 11.86 ± 7.33 Dyadic: **G1a:** 11.09 ± 5.50 **G1b:** 14.86 ± 10.02 Negative interaction, social behaviors, mean ± SD: Group: **G1a:** 1 ± 1.34 **G1b:** 0.87 ± 1.41
Bauminger et al., 2007 (continued)	**Provider:** Special education teacher **Measure of treatment fidelity reported:** NR	**Other characteristics:** ADI social score, mean ± SD: **G1a:** 17.45 ± 3.90 **G1b:** 17.64 ± 3.62	Problem solving initiation behavior, mean ± SD: **G1a:** 4.72 ± 2.41 **G1b:** 4.33 ± 2.52	Dydactic: **G1a:** 6.09 ± 4.82 **G1b:** 2.46 ± 3.90 ANOVA: social behavior type

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	Co-interventions held stable during treatment: NR **Concomitant therapies:** NR **N at enrollment:** **G1a:** 11 **G1b:** 15 **N at follow-up:** **G1a:** 11 **G1b:** 15	**G1a/G1b:** *P* = NS ADI communication score, mean ± SD: **G1a:** 13.27 ± 4.88 **G1b:** 13.71 ± 4.28 **G1a/G1b:** *P* = NS ADI behavior score, mean ± SD: **G1a:** 5.00 ± 1.34 **G1b:** 5.79 ± 1.52 G1a/G1b: ***P* = NS**	Number of social solutions, mean ± SD: **G1a:** 55.71 ± 17.80 **G1b:** 47.25 ± 17.74 TOM strange stories, mean ± SD: Comprehension: **G1a:** 4.45 ± 1.03 **G1b:** 4.13 ± 0.91 Justification: **G1a:** 3.63 ± 2.46 **G1b:** 4.2 ± 3.02 Executive function, mean ± SD: Number of sorts performed: **G1a:** 9.18 ± 2.18 **G1b:** 8.13 ± 4.27 Strategies generated: **G1a:** 9.18 ± 2.52 **G1b:** 8 ± 4.05 Strategies recognized: **G1a:** 9 ± 3.13 **G1b:** 7.40 ± 3.92 **Emotional understanding:** Recognition of emotion, mean ± SD: Basic: **G1a:** 10.90 ± 1.86 **G1b:** 11.60 ± 2.16 Complex: **G1a:** 11.18 ± 2.08 **G1b:** 10.46 ± 3.22 Relevancy of explanation, mean ± SD: Basic: **G1a:** 6.90 ± 1.04 **G1b:** 6.53 ± 1.76 Complex: **G1a:** 7.00 ± 0.77 **G1b:** 6.33 ± 1.45	(group/didactic; P < 0.001), group (newly recruited/ original; P < 0.05) Problem solving initiation behavior, mean ± SD: **G1a:** 6.54 ± 4.03 **G1b:** 5.80 ± 2.33 **G1/BL:** *P* < 0.01 Number of social solutions, mean ± SD: **G1a:** 58.60 ± 23.74 **G1b:** 59.32 ± 13.99 **G1/BL:** *P* < 0.05 TOM strange stories, mean ± SD: Comprehension: **G1a:** 4.09 ± 1.37 **G1b:** 4.26 ± 0.45 **G1/BL:** *P* = NS Justification: **G1a:** 4.18 ± 2.35 **G1b:** 5.40 ± 2.35 **G1/BL:** *P* < 0.01 Executive function, mean ± SD: Number of sorts performed: **G1a:** 10.45 ± 2.84 **G1b:** 9.46 ± 2.94 **G1/BL:** *P* < 0.001 Strategies generated: **G1a:** 10.63 ± 2.84 **G1b:** 9.46 ± 2.92 **G1/BL:** *P* < 0.05 Strategies recognized: **G1a:** 10.27 ± 3.19 **G1b:** 7.80 ± 2.47 **G1/BL:** *P* < 0.05
Bauminger et al., 2007 (continued)			Definition accuracy, mean ± SD: Basic: **G1a:** 1.09 ± 1.51 **G1b:** 1.06 ± 1.33 Complex: **G1a:** 2.36 ± 2.01 **G1b:** 2.80 ± 2.56 Overall: **G1a:** 3.45 ± 3.41 **G1b:** 3.86 ± 3.64	**Emotional understanding:** Recognition of emotion, mean ± SD: Basic: **G1a:** 13.81 ± 2.27 **G1b:** 12.66 ± 2.59 **G1/BL:** *P* = 0.056 Complex: **G1a:** 12.27 ± 2.10

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
			Number of emotions described, mean ± SD: Basic: **G1a:** 3.45 ± 0.08 **G1b:** 3.40 ± 0.91 Complex: **G1a:** 4.18 ± 2.56 **G1b:** 4.27 ± 2.43 Overall: **G1a:** 8.54 ± 4.22 **G1b:** 7.66 ± 2.79 Audience awareness, mean ± SD: Basic: **G1a:** 4.15 ± 1.85 **G1b:** 5.31 ± 1.31 Complex: **G1a:** 9.56 ± 5.84 **G1b:** 9.58 ± 3.61 Overall: **G1a:** 13.71 ± 6.77 **G1b:** 14.89 ± 4.04	**G1b:** 13.20 ± 2.07 **G1/BL:** *P* = 0.056 Relevancy of explanation, mean ± SD: Basic: **G1a:** 7.81 ± 0.60 **G1b:** 7.46 ± 1.18 **G1/BL:** *P* = 0.056 Complex: **G1a:**7.45 ± 0.82 **G1b:**7.20 ± 0.94 **G1/BL:** *P* < 0.01 Definition accuracy, mean ± SD: Basic: **G1a:** 1.81 ± 1.40 **G1b:** 1.73 ± 1.33 **G1/BL:** *P* < 0.01 Complex: **G1a:** 4.63 ± 2.57 **G1b:** 3.80 ± 2.33 **G1/BL:** *P* = 0.056 Overall: **G1a:** 6.34 ± 3.61 **G1b:** 5.53 ± 3.29 **G1/BL:** *P* = 0.056 Number of emotions described, mean ± SD: Basic: **G1a:** 3.72 ± 0.05 **G1b:** 3.60 ± 0.63 **G1/BL:** *P* = NS Complex: **G1a:** 5.18 ± 2.13 **G1b:** 5.33 ± 2.16 **G1/BL:** *P* < 0.05
Bauminger et al., 2007 (continued)				Overall: **G1a:** 8.90 ± 2.30 **G1b:** 8.93 ± 2.43 **G1/BL:** *P* = NS Audience awareness, mean ± SD: Basic: **G1a:** 4.75 ± 2.03 **G1b:** 5.62 ± 1.47 **G1/BL:** *P* = NS Complex: **G1a:** 12.71 ± 2.33 **G1b:** 11.38 ± 3.15 **G1/BL:** *P* < 0.05 Overall: **G1a:** 17.47 ± 4.01 **G1b:** 17.00 ± 3.73 **G1/BL:** *P* < 0.05 **Harms:**

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Ben Itzchak and Zachor, 2007 **Country:** Israel **Practice setting:** Academic **Intervention setting:** Clinic and home **Enrollment period:** NR **Funding:** Israeli Ministry of Education **Author industry relationship disclosures:** NR **Design:** Prospective case series **Note:** See related studies: Ben Itzchak et al., 2007, Zachor et al., 2007, Zachor et al., 2009 (overlap among these not clear)	**Intervention:** Center-based ABA program with one-on-one therapy with behavioral therapists for at least 35 hours/week and behavioral methods used at home by parents **Assessments:** Pre- and post-treatment (1 year): ADI-R, ADOS, BSID-II, Stanford-Binet Intelligence Scale, 4th ed. Developmental-behavioral scales, all administered by therapists and scores provided by blinded raters **Groups:** **G1:** intervention **Ga:** low-IQ (50-70) at baseline **Gb:** high-IQ (71-103) at baseline **Gc:** score ≥ 16 on ADOS-module I reciprocal-social interaction (low social) **Gd:** score < 16 on ADOS-module I reciprocal-social interaction (high social) **Provider:** Planning and supervision by trained behavior analyst; provided by skilled behavioral therapists and by parents **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 25 **G1a:** 12 **G1b:** 12 **G1c:** 12 **G1d:** 12 **N at follow-up:** **G1:** 25	**Inclusion criteria:** • Age < 32 months • Diagnosed with autism **Exclusion criteria:** • Certain comorbidities (e.g., seizure disorder; genetic syndromes) **Age, mean months (range):** 26.6 (20-32) **Mental age:** NR **Gender, n (%):** Male: 23 (92) Female: 2 (8) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** ADI-R, ADOS protocols, and DSM-IV criteria for autism assessed by an independent clinician **Diagnostic category, n (%):** Autism: 25 (100) PDD-NOS: 0 Aspergers: 0 **Other characteristics, n (%):** Expressive vocabulary < 10 words, n: 24 Expressive vocabulary: two-word utterances, n: 1	**Social skills:** Play skills score, mean ± SD: **G1:** 0.92 ± 1.19 **G1a:** 0.33 ± 0.89 **G1b:** 1.33 ± 1.15 **G1c:** 0.67 ± 1.15 **G1d:** 1.25 ± 1.21 **Communication/ language:** Imitation score, mean ± SD: **G1:** 2.36 ± 2.61 **G1a:** 0.91 ± 1.73 **G1b:** 3.42 ± 2.54 **G1c:** 1.08 ± 1.72 **G1d:** 3.83 ± 2.69 Receptive language score, mean ± SD: **G1:** 1.64 ± 1.87 **G1a:** 0.67 ± 1.15 **G1b:** 2.42 ± 2.02 **G1c:** 1.00 ± 1.28 **G1d:** 2.41 ± 2.15 Expressive language, mean ± SD: **G1:** 0.76 ±1.69 **G1a:** 0.83 ± 0.28 **G1b:** 1.25 ± 2.22 **G1c:** 0.25 ± 0.45 **G1d:** 1.33 ± 2.31 Nonverbal skills, mean ± SD: **G1:** 0.80 ± 0.76 **G1a:** 0.42 ± 0.51 **G1b:** 1.08 ± 0.79 **G1c:** 0.58 ± 0.51 **G1d:** 1.08 ± 0.90 **Repetitive behavior:** Stereotyped behaviors, mean ± SD: **G1:** 6.48 ± 3.23 **G1a:** 7.58 ± 2.97 **G1b:** 5.92 ± 2.91 **G1c:** 7.58 ± 2.27 **G1d:** 5.42 ± 3.87	**Social skills:** Play skills score, mean ± SD: **G1:** 3.16 ± 1.62 **G1a:** 2.08 ± 1.44 **G1b:** 4.17 ± 1.11 **G1c:** 2.33 ± 1.37 **G1d:** 4.00 ± 1.53 **G1/BL:** $P < 0.001$ **G1a/BL:** $P < 0.001$ **G1b/BL:** $P < 0.001$ **G1c/BL:** $P < 0.001$ **G1d/BL:** $P < 0.001$ **G1a/G1b:** $P = 0.07$ **G1c/G1d:** P = NS **Communication/ language:** Imitation score, mean ± SD: **G1:** 8.00 ± 1.44 **G1a:** 7.08 ± 1.62 **G1b:** 8.83 ± 0.39 **G1c:** 7.50 ± 1.44 **G1d:** 8.41 ± 2.62 **G1/BL:** $P < 0.001$ **G1a/BL:** $P < 0.001$ **G1b/BL:** $P < 0.001$ **G1c/BL:** $P < 0.001$ **G1d/BL:** $P < 0.001$ **G1a/G1b:** $P < 0.01$ **G1c/G1d:** $P < 0.05$
Ben Itzchak and Zachor, 2007 (continued)			**Educational/ cognitive/ academic attainment:** IQ, mean ± SD: **G1:** 70.67 ± 17.01	Receptive language, mean ± SD: **G1:** 6.28 ± 2.34 **G1a:** 4.75 ± 2.26 **G1b:** 7.58 ± 1.31

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
			G1a: 61.00 ± 12.10 **G1b:** 80.45 ± 15.15	**G1c:** 4.91 ± 2.19 **G1d:** 7.58 ± 1.78 **G1/BL:** *P* < 0.001 **G1a/BL:** *P* < 0.001 **G1b/BL:** *P* < 0.001 **G1c/BL:** *P* < 0.001 **G1d/BL:** *P* < 0.001 **G1a/G1b:** *P* < 0.05 **G1c/G1d:** *P* = NS Expressive language, mean ± SD: **G1:** 5.84 ± 3.69 **G1a:** 3.67 ± 3.14 **G1b:** 7.67 ± 3.08 **G1c:** 3.50 ± 3.12 **G1d:** 7.92 ± 2.91 **G1/BL:** *P* < 0.001 **G1a/BL:** *P* < 0.001 **G1b/BL:** *P* < 0.001 **G1c/BL:** *P* < 0.001 **G1d/BL:** *P* < 0.001 **G1a/G1b:** *P* = NS **G1c/G1d:** *P* = 0.09
Ben Itzchak and Zachor, 2007 (continued)				Nonverbal skills, mean ± SD: **G1:** 2.00 ± 0.76 **G1a:** 1.50 ± 0.52 **G1b:** 2.42 ± 0.67 **G1c:** 1.58 ± 0.51 **G1d:** 2.42 ± 0.79 **G1/BL:** *P* < 0.001 **G1a/BL:** *P* < 0.001 **G1b/BL:** *P* < 0.001 **G1c/BL:** *P* < 0.001 **G1d/BL:** *P* < 0.001 **G1a/G1b:** *P* = NS **G1c/G1d:** *P* = NS **Repetitive behavior:** Stereotyped behaviors, mean ± SD:

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G1: 3.36 ± 2.62 **G1a:** 4.33 ± 2.50 **G1b:** 2.67 ± 2.50 **G1c:** 4.75 ± 2.26 **G1d:** 2.08 ± 2.42 **G1/BL:** *P* < 0.001 **G1a/BL:** *P* < 0.001 **G1b/BL:** *P* < 0.001 **G1c/BL:** *P* < 0.001 **G1d/BL:** *P* < 0.001 **G1a/G1b:** *P* = NS **G1c/G1d:** *P* = NS **Educational/ cognitive/ academic attainment:** IQ, mean ± SD: **G1:** 87.90 ± 16.56 **G1c:** 76.82 ± 17.32 **G1d:** 96.50 ± 10.45 **G1/BL:** *P* < 0.001 **G1c/BL:** *P* < 0.001 **G1d/BL:** *P* < 0.001 **G1c/G1d:** *P* = NS
Ben Itzchak and Zachor, 2007 (continued)				**Harms:** NR **Modifiers:** Post-intervention scores for G1b were significantly greater than G1a on imitation (*P* < 0.01) and receptive language (*P* < 0.05). Post-intervention scores for G1d were significantly greater than G1c on imitation (*P* < 0.05). Higher IQ scores correlated with fewer deficits in social interaction as measured by ADOS (*P* < 0.01), ADOS-language and communica-

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				tion scores (*P* = 0.09)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Carr and Felce, 2007 **Country:** UK **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** NR **Funding:** Healthcare Foundation (formerly PPP Foundation) **Author industry relationship disclosures:** NR **Design:** Non randomized controlled trial **Note:** See related study Carr et al., 2007 ({#165})	**Intervention:** PECS intervention: 15 hours of PECS teaching over 5 weeks; 3-4 PECS teaching days/week with a total of 1 hour teaching delivered over 2-3 sessions on each PECS teaching day Controls had two 2 hour observations separated by a 5 week interval without PECS teaching **Assessments:** VABS and PLS-3UK at baseline; observation instrument to record communication interactions between children and teachers 6 weeks before, during the week prior and during the week following teaching **Groups:** **G1:** PECS **G2:** controls **Provider:** 2 researchers trained to deliver PECS teaching **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 24 **G2:** 17 **N at follow-up:** **G1:** 24 **G2:** 17	**Inclusion criteria:** • Age 3-7 years • Previous diagnosis of autism from a clinical practitioner, verified through their classroom teachers from the child's Statement of Special Educational Needs • Attending special education classrooms or units for autism • Received no previous PECS teaching beyond Phase I (G1) • Within 50 miles from the researchers' base and child's school agreed to participate (G1) • No PECS teaching anytime (G2) • Outside the 50 mile limit (G2) **Exclusion criteria:** • See Inclusion criteria **Age, months:** **G1:** 65 **G2:** 69 **Mental age:** NR **Gender:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** Previous diagnosis of autism from a clinical practitioner **Diagnostic category, n (%):** Autism: 41 (100) PDD-NOS: NR Aspergers: NR **Other characteristics:** NR	**Overall ratings:** VABS score, developmental age, months: Daily living skills: **G1:** 16.5 **G2:** 15.9 Social interaction: **G1:** 12.0 **G2:** 12.5 Composite: **G1:** 14.7 **G2:** 14.8 PLS-3UK developmental age, months: Receptive: **G1:** 7.8 **G2:** 8.6 Expressive: **G1:** 7.4 **G2:** 9.8 Composite: **G1:** 7.7 **G2:** 9.4 **Communication/ language:** Child-to-adult total initiations, mean: **G1:** 11.1 **G2:** 12.6 Child-to-adult total initiations, 6 weeks before intervention, mean: **G1:** 9.9 Child-to-adult linguistic initiations: **G1:** 0.7 **G2:** 2 Adult response, mean %: **G1:** 67.10 **G2:** 78.35 Child-to-adult linguistic initiations, 6 weeks before intervention, mean: **G1:** 0.4	**Communication/ language:** Child-to-adult total initiations, mean: **G1:** 61.4 **G2:** 10 **G1/BL:** *P* < 0.001 **G2/BL:** *P* = NS **G1/G2:** *P* < 0.00003 Child-to-adult linguistic initiations, mean: **G1:** 50.8 **G2:** 1.3 **G1/BL:** *P* < 0.001 **G2/BL:** *P* = NS **G1/G2:** *P* < 0.00003 Adult responses, mean %: **G1:** 96.7 **G2:** 76.94 **G1/BL:** *P* < 0.01 **G2/BL:** *P* = NS **G1/G2:** *P* < 0.003 Adult-to-child initiations with opportunity for child response: **G1:** 44.7 **G2:** 59.5 **G1/BL:** *P* < 0.05 **G2/BL:** *P* = NS **G1/G2:** *P* = NS Child response, mean %: **G1:** 66.80 **G2:** 58.40 **G1/BL:** *P* < 0.03 **G2/BL:** *P* = NS **G1/G2:** *P* < 0.01 Adult-to-child initiations with no opportunity for child response, mean: **G1:** 13.3 **G2:** 21.1 **G1/BL:** *P* < 0.005 **G2/BL:** *P* = NS **G1/G2:** *P* = 0.0495
Carr and Felce, 2007 (continued)			Adult response, mean %: **G1:** 76.30 Adult-to-child	**Harms:** NR **Modifiers:** NR

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Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
			initiations with opportunity for child response: **G1:** 43.4 **G2:** 51 Child response, mean %: **G1:** 51.30 **G2:** 59.60 Adult-to-child initiations with opportunity for child response, 6 weeks before intervention, mean: **G1:** 48.5 Child response, mean %: **G1:** 53.30 Adult-to-child initiations with no opportunity for child response: **G1:** 24.9 **G2:** 18.9 Adult-to-child initiations with no opportunity for child response, mean: **G1:** 23.1	

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Chalfant et al., 2007 **Country:** Australia **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** CBT based on "cool kids" (Lyneham, Abbott, Wignall, & Rapee, 2003) consisted of recognition of anxious feelings and reactions to anxiety, cognitive restructuring strategies, coping self-talk, exposure to feared stimuli, and relapse prevention; 2-hr weekly sessions for 9 weeks, and three monthly booster sessions totaling 12 sessions **Groups:** **G1:** CBT **G2:** Wait-list control **Provider:** • Clinical psychologist **Assessment:** Multi-modal and multi-person assessment Self report: RCMAS, SCAS, CATS Parent-report: SCAS, SDQ Teacher report: SDQ **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 32 **G2:** 19 **N at follow-up:** **G1:** 28 **G2:** 19	**Inclusion criteria:** • Met criteria for an anxiety Disorder beyond their ASD symptoms. • Children with frequent , irrational fears and avoidant behaviors **Exclusion criteria:** • Intellectual delay • Physical disability • Currently taking anti-anxiety or anti-depressant medication • Those presenting with marked externalizing difficulties (e.g. Conduct Disorder or Oppositional Defiant Disorder) or whose parents were experiencing acute marital breakdown **Age, mean/years ± SD:** G1 and G2 combined: 10.8 ± 1.35 Range: 8-13 years **Mental age:** NR **Gender:** G1 and G2 combined M, n (%): 35 (74) F, n (%): 12 (26) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** **In Study (method):** Independent diagnosis; confirmed during baseline Referral (method): **Community health centers, mental health professionals, medical practitioners, and parents**	**Commonly occurring comoribidities:** Child Report: Children's Automatic Thoughts Scale (internalizing), mean ± SD: **G1:** 43.82 ± 22.91 **G2:** 54.58 ± 14.8 Revised Children's Manifest Anxiety Scale, mean ± SD: **G1:** 15.86 ± 3.33 **G2:** 17.58 ± 4.10 Spence Children's Anxiety Scale, mean ± SD: **G1:** 43.57 ± 12.74 **G2:** 42.26 ± 8.53 Children's Automatic Thoughts Scale (hostile intent), mean ± SD: **G1:** 14.75 ± 8.61 **G2:** 11.21 ± 5.67 Parent Report: Spence Children's Anxiety Scale – Parent report, mean ± SD: **G1:** 44.96 ± 13.7 **G2:** 46.79 ± 10.95 Strengths and difficulties questionnaire – Parent report (emotional) , mean ± SD: **G1:** 7.25 ± 1.88 **G2:** 7.37 ± 2.48 Strengths and difficulties questionnaire – Parent report (externalizing) , mean ± SD: **G1:** 6.96 ± 4.29 **G2:** 5.95 ± 5.23	**Commonly occurring co-morbidities:** Child Report: Children's Automatic Thoughts Scale (internalizing), mean ± SD: **G1:** 10.39 ± 5.56 **G2:** 51 ± 11.87 Revised Children's Manifest Anxiety Scale, mean ± SD: **G1:** 4.93 ± 2.55 **G2:** 16.74 ± 4.63 Spence Children's Anxiety Scale, mean ± SD: **G1:** 13.79 ± 10.96 **G2:** 41.37 ± 9.09 Children's Automatic Thoughts Scale (hostile intent), mean ± SD: **G1:** 9.54 ± 5.64 **G2:** 11.37 ± 5.25 Parent Report: Spence Children's Anxiety Scale – Parent report, mean ± SD: **G1:** 13.96 ± 5.11 **G2:** 44.16 ± 9.04 Strengths and difficulties questionnaire – Parent report (emotional) , mean ± SD: **G1:** 2.75 ± 1.38 **G2:** 8.21 ± 1.03
Chalfant et al., 2007 (continued)		**Diagnostic tool / method:** Diagnosed by pediatrician,	Teacher report: Strengths and	Strengths and difficulties

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Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
		Psychiatrists or psychologists **Diagnostic category, n (%):** G1 and G2 combined High Functioning Autistic Disorder: 13 (28) Asperger's Disorder: 34 (72) **Other characteristics**, n (%)**:** G1 and G2 combined SAD: 8 (17) GAD: 14 (30) SP: 20 (43) SpP: 3 (6) PD: 2 (4) ADHD: 13 (28) **G1, %:** SAD: 18 GAD: 32 SP: 43 SpP: 4 PD: 4 **G2, %:** SAD: 16 GAD: 26 SP: 42 SpP: 11 **PD: 5**	difficulties questionnaire – Teacher report (emotional) , mean ± SD: **G1:** 5.61± 1.99 **G2:** 6.32 ± 2.14 Strengths and difficulties questionnaire – Teacher report (externalizing) , mean ± SD: **G1:** 5.79 ± 4.52 **G2:** 4.79 ± 4.65 Number of anxiety disorder diagnoses between G1 & G2 at pre- treatment: G1 vs. G2 NS, P>0.05 No significant difference elicited between G1 & G2 for any of the child/parent or teacher reported measures (*P* > 0.05)	questionnaire – Parent report (externalizing) , mean ± SD: **G1:** 3.82 ± 3.12 **G2:** 6.32 ± 4.92 Teacher report: Strengths and difficulties questionnaire – Teacher report (emotional) , mean ± SD: **G1:** 2.39 ± 1.45 **G2:** 6.89 ± 1.82 Strengths and difficulties questionnaire – Teacher report (externalizing) , mean ± SD: **G1:** 2.75 ± 2.32 **G2:** 4.89 ± 4.58 Comparisons: **Number of anxiety disorder diagnoses** between G1 & G2 at pre-post treatment: Time effect: F=73.66 *P* < 0.001 Time X group: F=63.79 *P* < 0.001 Within G1 Pre vs. post F=10.41 *P* < 0.01 Within G2 Pre vs. Post *P* > 0.05 Within Post trt G1 vs. G2 t=5.07 *P* < 0.01
Chalfant et al., 2007 (continued)				**Child report measures:**

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				CATS Internalising: Time effect: F=37.58 *P* < 0.005 Time X group: F=24.45 *P* < 0.005 Within G1 Pre vs. post t=7.85 *P* < 0.01 Within G2 Pre vs. Post ns *P* > 0.05 Within Post trt G1 vs. G2 t=15.78 *P* < 0.01 **RCMAS**: Time effect: F=96.89, *P* < 0.005 Time X group: F=71.15 *P* < 0.005 Within G1 Pre vs. post t=14.88 *P* < 0.01 Within G2 Pre vs. Post Ns, P>0.05 Within Post trt G1 vs. G2: t=11.25 *P* < 0.01 **SCAS:** Time effect**:** F=58.13 *P* < 0.005
Chalfant et al., 2007 (continued)				Time X group: F=51.54 *P* < 0.005 Within G1

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				Pre vs. post t=10.91 *P* < 0.01 Within G2 Pre vs. Post NS *P* > 0.05 Within Post trt G1 vs. G2 t=9.05 *P* < 0.01 **CATS-Hostile:** NS **Parent-Report measures comparison:** **SCAS-P:** Time effect: F=74.26 *P* < 0.005 Time X group: F=52.84 *P* < 0.005 Within G1 Pre vs. post t=11.48 *P* < 0.01 Within Post trt G1 vs. G2 t=14.61 *P* < 0.01 **SDQ-Emotional:** Time effect: F=25.48 *P* < 0.005 Time X group: F=54.34 *P* < 0.005 Within G1 Pre vs. post t=10.28 *P* < 0.01
Chalfant et al., 2007 (continued)				Within Post tx G1 vs. G2 t=14.69 *P* < 0.01

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Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				SDQ-Externalizing: Time effect: F=10.06 *P* < 0.005 Time X group: F=16.11 *P* < 0.005 Within G1 Pre vs. post t=5.23 *P* < 0.01 Within Post trt G1 vs. G2 NS **Teacher-rated measures:** **SDQ Emotional:** Time effect: F=13.85 *P* < 0.005 Time X group: F=28.70 *P* < 0.005 Within G1 Pre vs. post t=8.25 *P* < 0.01 Within Post trt G1 vs. G2 t=9.42 *P* < 0.01 **SDQ-Externalizing:** Time effect: F=10.86 *P* < 0.005 Time X group: F=12.48 *P* < 0.005
Chalfant et al., 2007 (continued)				Within G1 Pre vs. post t=4.997 *P* < 0.01 Within Post trt G1 vs. G2

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				NS Within G2 (pre vs. post treatment) none of the parent and teacher rated measures were significant (*P* > 0.05) **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Coben et al., 2007 **Country:** US **Practice setting:** Private practice **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** Neurorehabilitation and Neuropsychological services (2) **Design:** Non randomized controlled trial	**Intervention:** Assessment-guided neurofeedback for at least 20 sessions **Assessments:** Diagnostic interview with parents to ascertain core behavioral, cognitive, and social/emotional issues of concern Before and after treatment: ATEC, GADS, GARS, BRIEF, PIC-2, Quantitative EEG analysis, and infrared imaging **Groups:** **G1:** intervention **G2:** waitlist group **Provider:** NR **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** Yes (no new treatments undertaken by study participants) **Concomitant therapies, n (%):** One medication: **G1:** 8 (22) **G2:** 2 (12) Two medications: **G1:** 5 (14) **G2:** 1 (8) Three medications: **G1:** 2 (5) **G2:** 1 (8) **N at enrollment:** **G1:** 38 **G2:** 12 **N at follow-up:** **G1:** 37 **G2:** 12	**Inclusion criteria:** • Diagnosed ASD **Exclusion criteria:** • See inclusion criteria **Age, years (range):** **G1:** 8.92 (3.92-14.66) **G2:** 8.19 (5.83-10.92) **Mental age:** NR **Gender, n (%):** Male: **G1:** 31 (84) **G2:** 10 (83) Female: **G1:** 6 (16) **G2:** 2 (17) **Race/ethnicity, n (%):** White: **G1:** 36 (97) **G2:** 12 (100) Asian: **G1:** 1 (3) **G2:** 0 **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study/Referral **Diagnostic tool/method:** NR **Diagnostic category, n (%):** Autism: **G1:** 7 (18.9) **G2:** NR PDD-NOS: **G1:** 21 (56.8) **G2:** NR Aspergers: **G1:** 5 (13.5) **G2:** NR Childhood disintegrative disorder: **G1:** 4 (10.8) **G2:** NR **Other characteristics, n (%):** Right handed: **G1:** 27 (73) **G2:** 9 (75)	**Overall ratings:** ATEC total score, mean: **G1:** 46.1 GADS ADQ score, mean: **G1:** 83.852 BRIEF GEC score, mean: **G1:** 71.700 PIC-2 TOTC score, mean: **G1:** 71.250 **Medical:** Neuropsychological testing, mean composite score: Attention: **G1:** -1.859 Visual perception: **G1:** -2.483 Executive: **G1:** -1.818 Language: **G1:** -1.928 **Medical:** IR imaging, first session, minimum thermal reading, mean: **G1:** 93.523 IR imaging, first session, range of thermal degrees: **G1:** 4.032	**Overall ratings:** ATEC total score, mean: **G1:** 27.733 **G1/BL:** $P < 0.000$ GADS ADQ score, mean: **G1:** 72.519 **G1/BL:** $P < 0.001$ BRIEF GEC score, mean: **G1:** 64.767 **G1/BL:** $P < 0.003$ PIC-2 TOTC score, mean: **G1:** 64.250 **G1/BL:** $P < 0.006$ **Medical:** Neuropsychological testing, mean composite score: Attention: **G1:** -0.571 **G1/BL:** $P < 0.000$ Visual perception: **G1:** -1.584 **G1/BL:** $P < 0.000$ Executive: **G1:** -0.783 **G1/BL:** $P < 0.001$ Language: **G1:** -0.798 **G1/BL:** $P = 0.000$ **Medical:** IR imaging, 20th session, minimum thermal reading, mean: **G1:** 94.368 **G1/BL:** $P = 0.043$ IR imaging, 20th session, range of thermal degrees: **G1:** 3.574 **G1/BL:** $P = 0.050$ Parent judgment of treatment outcome, n (%): Improved symptoms: **G1:** 33 (89) **G2:** 2 (17)
Coben et al., 2007 (continued)		Left handed: **G1:** 5 (14) **G2:** 2 (17) Mixed handedness:		No change: **G1:** 4 (11) **G2:** 10 (83) **G1/G2:** P = 0.000

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
		G1: 5 (14) **G2:** 1 (8) ATEC score, mean (range): **G1:** 45.16 (12-100) **G2:** 45.23 (26-72)		**Harms:** No reports of worsening symptoms (benefit to harm ratio 89:1) **Modifiers:** Ruled out confounding for baseline severity of ASD, age, and number of medications**.**

Comments: *The numbers in this paper are extremely difficult to read; data extraction may be incorrect.

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Dosman et al., 2007 **Country:** Canada **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Oral iron supplement: 6 mg elemental iron/kg/ day; if it was anticipated that oral preparations would not be accepted by the child, iron Sprinkles (Supple-Forte) were offered: two 30 mg sachets/day Average duration of treatment was 7.2 weeks (range 4-8 weeks) **Assessments:** Prior to baseline and at post-treatment, parents completed SDSC (26 items), Periodic Leg Movements during Sleep scale (6 items), 3 day Food Record, Nutritional Supplement Log, and irritability measure (developed by authors based on CGIS) Baseline and post treatment growth measures and blood samples were taken for serum ferritin and transferrin receptor, mean corpuscular volume, hemoglobin, albumin, and vitamin B_{12} in the child **Groups:** **G1:** iron intervention **Ga:** preschool age (less than 6 years old) **G1a:** school age (6 or more years old) **Gi:** ferritin < 10 µg post-treatment **Gii:** ferritin > 10 µg post-treatment **Gc:** children on SSRI or stimulant medication (and completed SDSC) **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** NR	**Inclusion criteria:** • Child had had ferritin measured previously as part of routine diagnostic assessment from autism at The Hospital for Sick Children's tertiary level Child Development Centre **Exclusion criteria:** • Currently receiving iron supplement **Age, years (range):** **G1:** 6.5 (2.67-10.75) **Mental age:** NR **Gender, n:** Male: 27/33 Female: 6/33 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** NR **Diagnostic tool/method:** ADI-R, ADOS, and clinical evaluation **Diagnostic category:** NR	**Commonly occurring co-morbidities:** CGIS irritability, mean: **G1:** 1.19 (n=32) **Medical:** SDSC restless sleep score (1-5), mean ± SD: **G1:** 3.7 ± 1.450 (n=32) **G1c:** 3.4 ± 1.60 SDSC restless sleep, abnormal, %: **G1:** 77 SDSC delayed sleep onset, n (%): **G1:** 14/31 (44) **G1c**: 5/8 (62.5) Periodic Leg Movements during Sleep, children with mean score > 0.33, n (%): **G1:** 14/32 (44) Dietary iron intake, median mg/day (range): **G1a:** 13.7 (4-39) **G1b:** 17.85 (7-43) Insufficient dietary iron intake, %: **G1a:** 69 **G1b:** 35 Ferritin, mean µg/L (range): **G1:** 15.72 (4.2-39.0) Low ferritin (< 10 µg/L), n: **G1a:** 6 **G1b:** 2 **G1a/G1b:** P = NS Albumin below normal levels, n: **G1:** 0/32 Vitamin B_{12} below normal levels, n: **G1:** 0/32	**Commonly occurring co-morbidities: :** CGIS irritability, mean: **G1:** 1.0 (n=32) **G1/BL:** P = NS **Medical:** SDSC restless sleep score, showing improvement, n (%): **G1:** 7/24 (29) **G1/BL:** P = 0.04 SDSC delayed sleep onset, n (%): **G1:** 11/31 (35) **G1/BL:** P = NS Periodic Leg Movements during Sleep, children with mean score > 0.33, n (%): **G1:** 12/32 (38) **G1/BL:** P = NS Dietary iron intake, median mg/day (range): **G1:** NR **G1/BL:** P = 0.32 Ferritin, mean µg/L (range): **G1:** 28.8 (6.6-103) **G1/BL:** P < 0.001 Low ferritin (<10 µg/L), n: **G1a:** 3 **G1b:** 0 **G1/BL:** P = NS Albumin, below normal levels n: **G1:** NR Vitamin B_{12}, below normal levels, n: **G1:** 2/32

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Dosman et al., 2007 (continued)	**Concomitant therapies:** NR **N at enrollment:** **G1:** 43 **G1a:** 16 **G1ai:** NR **G1aii:** NR **G1b:** 17 **G1c:** 8 **N at follow-up:** **G1:** 33 **G1a:** 16 **G1ai:** NR **G1aii:** NR **G1b:** 17 **G1c:** NR	**Other characteristics, n (%):** Any gastrointestinal symptom: 28/43 (65) Constipation: 14/43 (33) Loose stools: 14/43 (33) Failure to thrive, abdominal distension and pain, excessive gas: 16/43 (37) Seizures: 9/43 (21) Gluten and/or casein-free diet: 11/43 (26) SSRI: 7/43 (16) Melatonin: 3/43 (7) Antiepileptic: 4/43 (9) Stimulant: 2/43 (5) Antihistamine: 3/43 (7) Vitamin supplement: 14/43 (33) Nutritional supplement: 7/43 (16) Ferritin < 50 µg/L: 43/43 (100) Iron supplementation, n: Iron suspension: 23/33 Sprinkles: 10/33 Gastrointestinal symptoms, n (%): 23/33 (76) Number of gastrointenstinal symptoms, mean: **G1:** 1.9 **G1ai:** 3.3 G1aii: **0.8**	Mean corpuscular volume, fl ± SD: **G1:** 80.8 ± 3.79 Children with mean corpuscular volume < 80 fl, n (%): **G1:** 14/33 (42) Hemoglobin, mean gm/L ± SD: **G1:** 125.6 ± 7.00 Children with serum concentration of hemoglobin < 110 gm/L (2-4 year olds) or < 120 gm/L (5-10 year olds), %: **G1:** 3/33 (9) Transferrin receptor, mean µg/mL ± SD (range): **G1:** 5.43 ± 1.49 (3.46-9.94) (n=25) Children with serum transferrin receptor > 8.3 µg/mL, n (%): **G1:** 1/25 (4)	Mean corpuscular volume, mean change fl (SE): **G1:** 1.02 (0.30) **G1/BL:** P = 0.002 Children with mean corpuscular volume < 80 fl, n (%): **G1:** 8/33 (24) Hemoglobin, mean change gm/L (SE): **G1:** 2.42 (1.06) **G1/BL:** P = 0.029 Children with serum concentration of hemoglobin < 110 gm/L (2-4 year olds) or < 120 gm/L (5-10 year olds), %: **G1:** 1/33 (3) Transferrin receptor, mean change µg/mL (SE): **G1:** 0.06 (0.24) **G1/BL:** P = NS Children with serum transferrin receptor > 8.3 µg/mL, n (%): **G1:** 1/25 (4) **Harms:** Withdrew due to AEs, n: 2/43 Treatment-related AEs, n (%): Any symptom: 13/33 (39) Gastrointestinal symptom: 9/33 (27) Constipation: 4/33 (12) Loose stools: 6/33 (18) Abdominal pain: 1/33 (3) Decreased appetite: 1/33 (3)
Dosman et al., 2007 (continued)				Stained teeth: 2/33 (6) Increased night waking: 1/33 (3)

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				Decreased sleep: 1/33 (3) Decreased attention, aggression: 1/33 (3) Enuresis: 1/33 (3) **Modifiers:** No correlation between ferritin and ADI or ADOS scores except for children aged 4-8 (inverse relationship between ferritin and ADOS-communication domain; *P* = 0.009) No consistent relationship found between dietary iron intake and ferritin

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Eikeseth et al., 2002 Eikeseth et al., 2007† **Country:** Norway **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** November 1995 to November 1998 **Funding:** NIH† **Author industry relationship disclosures:** NR **Design:** Non randomized controlled trial	**Intervention:** Behavioral treatment: Lovaas treatment excluding aversive contingencies; progression from simple to complex tasks such as imitating verbal and nonverbal behavior, labeling objects, identifying actions, and abstract concepts. Progression to answering questions, conversing and making friends with peers. Also emphasized play and social skills. Based on operant conditioning principles such as shaping, chaining, discrimination training, and contingency management. Progressed from discrete trial to generalizing skills. Eclectic treatment: best practices, including TEACCH, sensory-motor therapies, and ABA Treatment hours, mean ± SD (range): **G1:** 28 ± 5.76 (20-35) **G2:** 29.08 ± 8.05 (20-41) **Assessments:** ADI-R administered by independent child clinical psychologist prior to study Weekly, 2-hour meetings with child, primary caregiver, therapists, supervisor, and director; treatment program was modified based on data collected during the preceding week	**Inclusion criteria:** • Age 4-7 years at intake • Diagnosed with autism according to ADI-R administered by child clinical psychologist and clinical interview • Diagnosis established less than 6 months prior to study entrance for all participants • Deviation IQ of 50 or above on WPPSI-R or ratio IQ of 50 or above on BSID-R • No major medical conditions **Exclusion criteria:** • See inclusion criteria **Age, months ± SD:** **G1:** 66.31 ± 11.31 **G2:** 65 ± 10.95 **Mental age:** See IQ scores in baseline measures **Gender, n (%):** Male: **G1:** 8 (62) **G2:** 11 (92) Female: **G1:** 5 (38) **G2:** 1 (8) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** ADI-R and clinical interview conducted by clinical psychologist independent of the investigation **Diagnostic category, n (%):** Autism: 25 (100) **Other characteristics:** NR	**Educational/ cognitive:** IQ, mean ± SD: **G1:** 61.92 ± 11.31 **G2:** 65.17 ± 14.97 PIQ, mean ± SD: **G1:** 77.54 ± 30.21 **G2:** 81.83 ± 21.05 **Communication/ language:** Language status, mean ± SD: Comprehension: **G1:** 49.03 ± 16.42 **G2:** 50.38 ± 15.46 Expressive: **G1:** 45.12 ± 13.44 **G2:** 51.24 ± 19.24 Total: **G1:** 51.83 ± 17.42 **G2:** 60.00 ± 24.22 VABS communication score, mean ± SD: **G1:** 58.23 ± 9.21 **G2:** 63.17 ± 16.11 **Adaptive behavior:** VABS daily living score, mean ± SD: **G1:** 56.92 ± 9.8 **G2:** 57.00 ± 15.92 VABS composite score, mean ± SD: **G1:** 55.77 ± 8.96 **G2:** 60.00 ± 13.2 **Social skills:*** VABS socialization score, mean ± SD: **G1:** 59.92 ± 7.19 **G2:** 62.17 ± 10.32	**Educational/ cognitive:** IQ, mean ± SD: 1 year: **G1:** 79.08 ± 18.09 **G2:** 69.5 ± 18.38 **G1/G2:** $P < 0.01$ 8 years:† **G1:** 86.9 ± 25 **G2:** 71.9 ± 28.4 **G1/G2:** $P < 0.05$ PIQ, 1 year, mean ± SD: **G1:** 95 ± 16.91 **G2:** 90.17 ± 19.97 **Communication/ language:** Language status, 1 year, mean ± SD: Comprehension: **G1:** 58.47 ± 17.11 **G2:** 47.55 ± 17.25 **G1/G2:** $P < 0.05$ Expressive: **G1:** 67.39 ± 17.81 **G2:** 49 ± 18.69 **G1/G2:** $P < 0.05$ Total: **G1:** 76.85 ± 26.67 **G2:** 61.58 ± 24.34 **G1/G2:** $P < 0.05$ VABS communication score, mean ± SD: 1 year: **G1:** 73.93 ± 16.55 **G2:** 61.58 ± 13.37 **G1/G2:** $P < 0.01$ 8 years:† **G1:** 78.5 ± 22.3 **G2:** 56 ± 16.3 **G1/G2:** $P < 0.01$ **Adaptive behavior:** VABS daily living score, mean ± SD: 1 year: **G1:** 66.15 ± 16.55 **G2:** 62.5 ± 10.97
Eikeseth et al., 2002 Eikeseth et al., 2007† (continued)	Child assessed at intake and 1 year after treatment began (follow-up conducted by licensed psychologist or examiner with Master's in Special			8 years:† **G1:** 66.1 ± 18.1 **G2:** 50.4 ± 20.2 **G1/G2:** $P < 0.05$ VABS composite score, mean ±

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	Education and license to administer tests); standardized tests of intelligence (WPPSI-R or WISC-R), visual-spatial skills (Merrill-Palmer Scale of Mental Tests), language (Reynell Developmental Language Scales), and adaptive functioning (VABS) **Groups:** **G1:** behavioral **G2:** eclectic **Provider:** • One or more aides • Special education teacher **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** Yes **Concomitant therapies:** NR **N at enrollment:** **G1:** 13 **G2:** 12 **N at follow-up:** **G1:** 13 **G2:** 12			SD: 1 year: **G1:** 67 ± 16.3 **G2:** 60.17 ± 11.69 **G1/G2:** *P* < 0.05 8 years:† **G1:** 67.9 ± 17.1 **G2:** 49.5 ± 13 **G1/G2:** *P* < 0.01 **Social Skills:** VABS socialize-tion score, mean ± SD: 1 year: **G1:** 69.92 ± 17.26 **G2:** 70.67 ± 13.66 8 years:† **G1:** 72.2 ± 14.4 **G2:** 58.1 ± 9.6 **G1/G2:** *P* < 0.01 VABS maladap-tive behavior score, mean ± SD: 1 year: **G1:** 4.29 ± 2.89 **G2:** 7.25 ± 2.99 **G1/G2:** *P* < 0.05 8 years:† **G1:** 6.3 ± 4.1 **G2:** 11 ± 5.8 **G1/G2:** *P* < 0.05 **Problem behavior:** Achenbach Child Behavior Check-list, 8 years, mean ± SD:† Withdrawn: **G1:** 59.4 ± 6.3 **G2:** 61.4 ± 5.3 Somatic: **G1:** 55 ± 7 **G2:** 58 ± 9.6
Eikeseth et al., 2002 Eikeseth et al., 2007† (continued)				Anxious/depress-sed: **G1:** 57.8 ± 6.1 **G2:** 57.1 ± 7.1 Social: **G1:** 62.3 ± 6.3 **G2:** 67.2 ± 4.9 **G1/G2:** *P* < 0.05 Thought: **G1:** 68.1 ± 9.6 **G2:** 68.5 ± 7 Attention: **G1:** 59 ± 5.4

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Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G2: 62.1 ± 6.1 Delinquent: **G1:** 56 ± 5.2 **G2:** 59 ± 3.8 Aggressive: **G1:** 57.3 ± 4.5 **G2:** 63.7 ± 4.6 **G1/G2:** *P* < 0.01 **Harms:** NR **Modifiers:** **G1:** intake IQ correlated with change in language at one year follow-up (r = 0.59; P < 0.05) intake PIQ correlated with change in PIQ at one-year follow-up (r = -0.84; P < 0.01); intake VABS correlated with change in PIQ at one year follow-up (r = -0.60; P < 0.05).
Eikeseth et al., 2002 Eikeseth et al., 2007† (continued)				**G2:** age at intake correlated with change in VABS at one year follow-up (r = -0.65; P < 0.05) and change in VABS communication at eight-year follow-up (r = -0.64; P < 0.05);† intake PIQ correlated with change in IQ at one-year follow-up (r = 0.67; P < 0.05), intake VABS daily living and socialization correlated with change in IQ at eight-year follow-up (r = 0.58; P < 0.05),† VABS composite correlated with change in IQ at eight-year follow-up (r = 0.63; P < 0.05).†

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Comments: *VABS maladaptive not given at baseline because it is normed for children 5 years and older.				

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Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Gabriels et al., 2001 and 2007 **Country:** US **Practice setting:** Academic **Intervention setting:** home, school, clinic **Enrollment period:** NR **Funding:** Agency/NR **Author industry relationship disclosures:** NR **Design:** 2001: Retrospective cohort with some prospective data collection 2007:Prospective case series	**Intervention:** Combination of variety of treatments (e.g., TEACCH, LEAP or DENVER Model) from community providers over a period of 37 months (1st follow up) or 5 years (2nd follow-up) **Assessments:** 2001: Assessment records were requested, photocopied, placed in the participant's file, and reviewed upon completion of testing Participants, with parent(s) present, completed testing in up to 3 sessions; MSEL, PLS-III, & during 3rd session, subtests of Woodcock-Johnson Revised Tests of Achievement and ADOS-G Participants were evaluated by a team of study evaluators, consisting of a psychology postdoctoral fellow, a psychology intern, and a speech-language clinical fellow 2007: Leiter International Performance Scale-Revised (LIPS-R), VABS, CCIF, Expressive One-Word Picture Vocabulary Test-Revised (EOWPVT-R), and PPVT-III	**Inclusion criteria:** • Current diagnosis of autistic disorder or PDD-NOS • At least 22 months post-diagnosis • Available standardized intellectual and/or language functioning scores at time of diagnosis **Exclusion criteria:** • History of traumatic brain injury • History of seizure disorder, fragile X, or other known genetic or biologic problems No additional psychiatric disorders **Age at diagnosis, mean months ± SD (range):** 30.6 ± 7.27 (20-47) **Age at 1st follow-up, mean months ± SD (range):** 68.7 ± 10.11 (44-88) G1a: 69±9.3 G1b: 68±11.5 **Mean age at 2nd follow-up:** 11.42 Age at 2nd follow-up, mean years ± SD: **G1c:** 10.69 ± 0.72 **G1d:** 10.88 ± 0.74 **Mental age:** NR **Gender, n:** M: 12 (10 at 2nd follow-up) F: 5 (4 at 2nd follow-up) **Race/ethnicity, n:** Anglo: 14 (at 1st and 2nd follow-up) African American/Native American: 1 Hispanic: 1 Asian: 1 (1 non-Anglo ethnicity at 2nd follow-up) **SES:** Maternal education: NR	**Educational/ cognitive/ academic attainment:** Cognitive quotient at diagnosis (n=16), mean ± SD (range): 57.81 ± 25.88 (25.00-128.00) **G1a:** 68.50 ± 30.78 **G1b:** 47.12 ± 15.06 **Communication/ language:** Language quotient at diagnosis (n=15), mean ± SD (range): 42.46 ± 16.11 (5.00-72.00) **G1a** (n=7): 47.42 ± 12.48 **G1b:** 28.12 ± 18.43	**Social skills:** VABS Socialization at 1st follow-up, mean ± SD: **G1c:** 64.75 ± 16.97 **G1d:** 38.50 ± 11.54 VABS Socialization at 2nd follow-up, mean ± SD: **G1c:** 84.38 ± 10.97 **G1d:** 39.33 ± 11.98 VABS Socialization age equivalent at 2nd follow-up, mean years ± SD: **G1c:** 5.54 ± 1.72 **G1d:** 1.78 ± 0.86 **Communication/ language:** Language quotient at 1st follow-up, mean ± SD (range): 57.64 ± 31.96 (16.00-119.00) **G1a:** 82.11 ± 22.23 (significant increase compared with baseline, *P* = 0.01) **G1b:** 30.12 ± 11.61 EOWPT standard score at 2nd follow-up, mean± SD: **G1c:** 112.13 ± 9.09 **G1d:** 59.83 ± 11.84 (t(12) = 9.38, P < 0.001, G1c vs. G1d)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Gabriels et al., 2001 and 2007 (continued)	**Groups:** **G1a:** children with developmental IQ ≥64 at 1st follow-up **G1b:** children with developmental IQ ≤ 48 at 1st follow-up **G1c:** children with nonverbal intelligence (NVIQ) ≥ 97 at 2nd follow-up **G1d:** children with NVIQ score ≤ 56 at 2nd follow-up **Provider:** Community providers; details not reported **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** Yes Therapies at 1st follow-up (parent report data), n: Structured home program: **G1a:** 5 **G1b:** 5 Private speech therapy: **G1a:** 9 **G1b:** 7 Private occupational therapy: **G1a:** 5 **G1b:** 5 Current public special education classroom: **G1a:** 5 **G1b:** 6 Current public integrated classroom with special education services: **G1a:** 3 **G1b:** 2 Current public integrated classroom (no special education services): **G1a:** 1 **G1b:** 0 Social tutoring: **G1a:** 1 **G1b:** 0	Household income: NR Hollingshead at 1st follow-up, mean ± SD (range): 56.25 ± 10.68 (27.00-66.00) **G1a:** 54.88 ±12.6040 **G1b:** 57.75 ± 8.61 Hollingshead at 2nd follow-up, mean ± SD: **G1c:** 58.63 ± 4.17 **G1d:** 56.00 ± 8.07 **Diagnostic approach:** In Study **Diagnostic tool/method:** Initial diagnosis by clinic multidisciplinary team including a psychiatrist or psychologist with extensive experience in diagnosing early childhood autism; children re-diagnosed at time of first follow-up study using ADOS-G **Diagnostic category at 1st follow-up, n:** Autism: 15 PDD-NOS: 2 **Diagnostic category at 2nd follow-up, n:** Autism: 12 PDD-NOS: 2 **Other characteristics:** Age began treatment, mean months ± SD: **G1a:** 33 ± 8.7 **G1b:** 31 ± 5.9 Total hours of treatment per month at 1st follow-up, mean ± SD: **G1a:** 103.22 ± 66.33 **G1b:** 76.25 ± 48.10 Mean school-based treatment hours/week ± SD at 2nd follow-up: **G1c:** 31.2 ± 3.8 **G1d:** 33.8 ± 2.1		PPVT-III standard score at 2nd follow-up, mean ± SD: **G1c:** 101.50 ± 12.62 **G1d:** 46.83 ± 16.74 (t(12) = 6.99, P < 0.001, G1c vs. G1d) VABS Communication score at 1st follow-up, mean ± SD: **G1c:** 92.63 ± 13.16 **G1d:** 37.17 ± 19.94 VABS Communication score at 2nd follow-up, mean ± SD: **G1c:** 115.50 ± 7.93 **G1d:** 49.83 ± 27.12 VABS Communication age-equivalent at 2nd follow-up, mean years ± SD: **G1c:** 8.49 ± 2.56 **G1d:** 2.46 ± 1.62 **Adaptive behavior:** Adaptive quotient at 1st follow-up, mean ± SD **G1a:** 80.77 ± 14.28 **G1b:** 37.75 ± 16.26 *P* ≥ 0.01
Gabriels et al., 2001 and 2007	Vision therapy: **G1a:** 2	Mean private treatment hours/week ± SD at 2nd		VABS standard composite score

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(continued)	**G1b:** 1 Music therapy: **G1a:** 1* **G1b:** 1 Cranio-sacral: **G1a:** 1* **G1b:** 0 Kinesiology: **G1a:** 1* **G1b:** 0 Homeopathy: **G1a:** 1* **G1b:** 0 Horseback riding therapy: **G1a:** 1* **G1b:** 0 Sensory learning therapy: **G1a:** 1* **G1b:** 0 *same child received all these therapies; additional details on treatment overlap not reported School-based therapies at 2nd follow-up (parent report data), n: Special education class only: **G1c:** 0 **G1d:** 1 Integrated class (no special education): **G1c:** 7 **G1d:** 0 Mixed (special education and integrated classes): **G1c:** 1 **G1d:** 5 Speech therapy: **G1c:** 4 **G1d:** 5 Occupational therapy: **G1c:** 2 **G1d:** 4 1:1 paraprofessional: **G1c:** 3 **G1d:** 3 Music therapy: **G1c:** 0 **G1d:** 1 Social skills group: **G1c:** 3 **G1d:** 1	follow-up: **G1c:** 1.7 ± 2.4 **G1d:** 1.8 ± 3.2		at 2nd follow-up, mean ± SD: **G1c:** 67.38 ± 16.24 **G1d:** 27.67 ± 9.35 (F(1,12) = 33.67, *P* < 0.001, G1c vs. G1d) VABS raw composite, 1st follow-up, mean ± SD: **G1c:** 238.25 ± 46.89 **G1d:** 127.00 ± 50.32 (*P* < 0.001, G1c vs. G1d) VABS raw composite, 2nd follow-up, mean ± SD: **G1c:** 300.75 ± 45.30 **G1d:** 128.00 ± 34.19 (P < 0.001, G1c vs. G1d) VABS Daily Living at 1st follow-up, mean ± SD: **G1c:** 80.13 ± 20.21 **G1d:** 51.33 ± 21.18 VABS Daily Living at 2nd follow-up, mean ± SD: **G1c:** 109.25 ± 37.91 **G1d:** 63.83 ± 24.31 VABS Daily Living age equivalent at 2nd follow-up, mean/years ± SD **G1c**: 7.77 ± 2.65 **G1d:** 3.35 ± 1.46
Gabriels et al., 2001 and 2007 (continued)	**Private therapies at 2nd follow-up (parent report data), n:**			**Educational/ cognitive/ academic**

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	Home trainer: **G1c:** 1 **G1d:** 1 Speech therapy: G1c: 0 G1d: 2 Occupational therapy: G1c: 0 G1d: 1 Social tutoring/group: G1c: 2 G1d: 1 Family therapy: G1c: 2 G1d: 0 Parent support group: G1c: 1 G1d: 1 Respite care: G1c: 0 G1d: 5 **N at enrollment:** 17 **N at 1st follow-up (at least 22 months post-diagnosis):** 17 **G1a:** 9 **G1b:** 8 **N at 2nd follow-up:** 14 **G1c:** 8 **G1d:** 6			**attainment:** Cognitive quotient at 1st follow-up, mean ± SD (range): 62.94 ± 30.79 (25.00-126.00) **G1a:** 87.11 ± 20.50 **G1b:** 35.75 ± 9.51 (G1b significant decrease compared with baseline, p=.03) G1a vs. G1b: $P < 0.01$ Academic quotient at 1st follow-up, mean ± SD: **G1a:** 113.11 ± 30.58 **G1b:** 66.38 ± 18.86 $P \leq 0.01$ Non-Verbal IQ at 2nd follow-up, mean ± SD **G1c:** 110.13 ± 18.47 **G1d:** 43.17 ± 10.59 Non-Verbal IQ > adaptive ability **G1c:** t(14) = 4.92, P < 0.001; **G1d:** t(10) = 2.69, P = 0.02 Within G1c: Age equivalent score for Socialization < communication subscale score (mean diff = 2.86, $P = 0.006$)
Gabriels et al., 2001 and 2007 (continued)				Within G1d: Daily Living age equivalent score > communication subscale (mean diff = 0.89, $P = 0.004$)

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				Harms: NR **Modifiers:** Correlations between the number and intensity of individual, group, and total treatment hours and outcomes at 1st follow-up were all nonsignificant (*P* > 0.05) Initial development IQ scores correlated significantly with 1st follow-up developmental IQ scores (r = 0.70, *P* < 0.01), language scores (r= 0.69, *P* < 0.01) academic scores (r = 0.74, *P* < 0.01) and adaptive functioning (r =0.57, *P* = 0.02) Initial language scores were not significantly correlated with 1st follow-up outcome measures (*P* > 0.05) Finance and business strains significantly greater in G1b vs. G1a (F (1,14) = 6.27, *P* = 0.025)
Gabriels et al., 2001 and 2007 (continued)				Trend toward significant difference (*P* = 0.06) between G1a and G1b regarding extended family social support , mean ± SD:

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				G1a: 9.22 ± 3.30) **G1b:** 11.62 ± 0.52 Change in developmental IQ over time: Significant interaction overall :F (1,15) = 17.26 , *P* < 0.01 G1a showed significant increase in Developmental IQ from time 1 to 1st follow up (F = 10.46, *P* = 0.01) G1b showed significant decrease in developmental IQ (F = 7.02, *P* =0.03) At 1st follow-up, developmental IQ scores significantly different from each other (F = 48.51, *P* < 0.01)

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Author: Gulsrud et al., 2007 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period**: NR **Funding:** NIH **Author industry relationship disclosures:** NR **Design:** RCT **Note:** See related study Wong 2007{#3875}, Kasari 2008{#184}, Kasari 2006{#540}, and Jahromi 2009{#3615}	**Intervention:** Joint attention or symbolic play intervention, administered during 5-8 week preschool program for 6 hours daily **Groups:** **G1:** joint attention **G2:** symbolic play **Provider:** NR **Assessments:** Auditory-visual and auditory probes presented at the beginning, middle and end of the treatment phase; responses: eye gaze, affect, non-verbal gestures, verbalization **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 20 **G2:** 20 **N at follow-up:** **G1:** 17 **G2:** 18	**Inclusion criteria:** • Preschool children from an existing intervention study for preschool children diagnosed with ASD **Exclusion criteria:** • Seizures • Sensory or physical disorders • Comorbidity with any other psychological disorder or disease • Children not given the study's novel probe activation at the 3 study time points due to scheduling conflicts **Age, months ± SD:** **G1:** 42.65 ± 7.13 **G2:** 43.11 ± 6.93 **Age range (months):** Total: 33-54 **Mental age, months ± SD:** **G1:** 25.74 ± 9.00 **G2:** 26.64 ± 7.90 **Gender, n:** Male: **G1:** 13 **G2:** 15 Female: **G1:** 4 **G2:** 3 **Race/ethnicity, n:** White: **G1:** 12 **G2:** 14 Minority: **G1:** 5 **G2:** 4 **SES:** Maternal education, n: Completed high school: **G1:** 0 **G2:** 2 Some college/technical: **G1:** 2 **G2:** 2 College/professional training: **G1:** 15 **G2:** 14	**Communication/ language:** Probe acknow-ledgement, %: **G1:** 47 **G2:** 66 Verbalizations, mean ± SD: **G1:** 0.30 ± 0.26 **G2:** 0.67 ± 0.26 Non-verbal gestures, mean ± SD: **G1:** 0.05 ± 0.06 **G2:** 0.05 ± 0.06 Ability to engage in coordinated joint looks during probe activation, % **G1:** 35.7 **G2:** 50	**Communication/ language:** Probe acknow-ledgement, %: **G1:** 88.2 **G2:** 55.6 **G1/G2:** *P* < 0.05 Probe acknow-ledgement changes, %: No change: **G1:** 58.5 **G2:** 55.6 Increase: **G1:** 41.2 **G2:** 16.7 **G1/G2:** *P* < 0.05 Verbalizations, mean ± SD: **G1:** 2.5 ± 0.80 **G2:** 1.3 ± 0.78 **G1/G2:** *P* = NS Non-verbal gestures, mean ± SD: **G1:** 0.60 ± 0.30 **G2:** 0.83 ± 0.30 **G1/G2:** *P* = NS Ability to engage in coordinated joint looks during probe activation, % **G1:** 76.5 **G2:** 38.9 **G1/G2:** *P* < 0.05 **Harms:** NR
Gulsrud et al., 2007 (continued)		Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** Referral diagnosis		**Modifiers:** Significant group difference in the duration of coordinated joint

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		validated using ADI-R and ADOS **Diagnostic category, n (%):** ASD: 35 (100) **Other characteristics**: Receptive language age, months ± SD: **G1:** 20.50 ± 8.00 **G2:** 22.28 ± 9.40 Expressive language age, months ± SD: **G1:** 20.60 ± 7.20 G2: 22.22 ± 7.60		looks during probe activation: G1 engaged for longer periods of time across 3 time points compared to G2 (*P* < 0.05); G2 made no increase or decrease in the duration of coordinated joint looks (only graphically represented)

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Author: Gutstein et al., 2007 **Country:** US **Practice setting:** Specialty treatment center **Intervention setting:** Clinic **Enrollment period:** January 2000 to May 2003 **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Retrospective case series	**Intervention:** Relationship Development Intervention (RDI): parents are trained in 6 days of workshops in RDI components to learn how to provide opportunities for their children to respond in more flexible, thoughtful ways to novel, challenging, and increasingly unpredictable settings and problems **Assessments:** ADOS, ADI-R, flexibility interview (10 items related to child's ability to adapt to change and transition), and educational placement **Groups:** **G1:** RDI training **Provider:** Parents **Duration, median months in RDI (range) :** 41.5 (33-79) **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 16 **N at follow-up:** **G1:** 16	**Inclusion criteria:** • An interval of at least 30 months between initial and follow-up testing • Previous diagnosis of autism, Asperger's syndrome, or PDD-NOS • Participation in the RDI protocol • Age at time of RDI initiation 20-96 months • Pretreatment IQ ≥ 70 **Exclusion criteria:** • See inclusion criteria **Age, months ± SD (range):** 60.50 ± 20.43 (20-94) **Mental age:** IQ, mean ± SD (range): 90.50 ± 13.23 (70-118) **Gender, n (%):** Male: 15 (94) Female: 1 (6) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** NR **Diagnostic category, n (%):** Autism: 5 (31) Asperger's syndrome: 7 (44) PDD-NOS: 4 (25) **Other characteristics, n (%):** Language delays: 8 (50) ADHD: 5 (31) Bipolar disorder: 1 (6) Food allergies: 1 (6)	**Overall ratings:** ADOS rating, n (%): Autism: 10/12 (83) Autism spectrum: 2/12 (17) Non-autism: 0 **Communication/ language:** ADOS communication score mean ± SD (range): **G1:** 5.92 ± 1.975 (2-10) ADOS social interaction score mean ± SD (range): **G1:** 9.58 ± 2.968 (3-13) ADI-R communication + language score, mean (range): **G1:** 10.6 (7.9-14.3) Age appropriate flexibility, %: Unexpected change to familiar routines: 12.5 Unexpected omission of a routine activity: 18.8 Changes to activities without preparation: 25 Anticipating an event and encountering another: 31.3 Unexpected actions by familiar people: 25 Interruption during a highly favored activity: 6.3 Stopping a task before it is finished: 12.5 Planning for things that might go wrong: 0	**Overall ratings:** ADOS rating, n (%): Autism: 0 Autism spectrum: 6/16 (38) Non-autism: 10/16 (63) **Communication/ language:** ADOS communication score, mean ± SD (range): **G1:** 2.67 ± 0.99 (0-4) **G1/BL:** *P* < 0.0001 ADOS social interaction score mean ± SD: (range): **G1:** 4.17 ± 2.44 (0-9) **G1/BL:** *P* < 0.004 ADI-R communication + language score, mean (range): **G1:** 2.4 (0-5.7) **G1/BL:** *P* < 0.0001 Age appropriate flexibility, %: Unexpected change to familiar routines: 81.3 Unexpected omission of a routine activity: 87.5 Changes to activities without preparation: 81.3 Anticipating an event and encountering another: 75 Unexpected actions by familiar people: 75 Interruption during a highly favored activity: 68.8
Gutstein et al., 2007 (continued)			Adapting when original plans don't work out: 18.8	Stopping a task before it is finished: 68.8

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
			Using familiar objects in a novel way: 12.5 Educational Placement, %: Special education: 57.1 Partial mainstream: 28.6 Mainstream with pullout: 7.1 Mainstream: 7.1 Home school: 0	Planning for things that might go wrong: 43.8 Adapting when original plans don't work out: 75 Using familiar objects in a novel way: 56.3 Educational Placement, %: Special education: 12.5 Partial main-stream: 18.8 Mainstream with pullout: 31.3 Mainstream: 31.3 Home school: 6.3 **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Howlin et al., 2007 **Country:** UK **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** None **Design:** RCT, not masked	**Intervention:** PECS: 2-day workshop (13 hours) for teachers plus 6 half day school-based trainings sessions with expert consultants over 5 months **Assessments:** ADOS-G, BPVT and EOWPVT administered by researchers in school setting **Groups:** 18 classrooms (from 15 schools) were random-ized into 6 classes per group **G1:** immediate treatment **G2:** delayed treatment (recieved PECS 2 terms after study entry) **G3:** no treatment **Provider:** • Teachers trained to teach PECS • PECS consultants **Measure of treatment fidelity reported:** No **Measure of observer reliability reported:** Yes **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 30 **G2:** 29 **G3:** 29 **N at follow-up:*** **G1:** 25 **G2:** 30 **G3:** 28	**Inclusion criteria:** • Formal clinical autism diagnosis and meet criteria for autism or ASD (ADOS-G) • Little or no functional language • No evidence of sensory impairment • Age 4-11 years • Not using PECS beyond Phase 1 • Each class was required to have a minimum of 3 children who met the above criteria **Exclusion criteria:** • See inclusion criteria **Age, months ± SD (range):** **G1:** 73.1 ± 15.8 (47.3-106.3) **G2:** 86.6 ± 12.7 (62-113.5) **G3:** 85.6 ± 13.6 (61-122.1) **Mental age:** NR **Gender, n (%):** Male: **G1:** 21 (81) **G2:** 27 (90) **G3:** 25 (89) Female: **G1:** 5 (19) **G2:** 3 (10) **G3:** 3 (11) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral; diagnosis confirmed in study **Diagnostic tool/method:** ADOS-G **Diagnostic category, n (%):** Autism: 75 (89) ASD: 9 (11)	**Communication/ language:** ADOS language impairment score, mean ± SD: **G1:** 2.7 ± 1.4 **G2:** 3.4 ± 0.8 **G3:** 2.5 ± 1.5 **G1/G2:** $P < 0.05$ **G1/G3:** P = NS **G2/G3:** $P < 0.05$ Non-verbal mental age equivalent/ chronological age x 100, mean ± SD: **G1:** 25.9 ± 11.4 **G2:** 22.7 ± 8.2 **G3:** 27.3 ± 10.2 ADOS total algorithm scores, mean ± SD: **G1:** 16.4 ± 2.7 **G2:** 16.9 ± 2.9 **G3:** 15.3 ± 3.2	**Overall ratings:** Rate of initiations, more likely to be in higher initiation rate category, pre- to post-treatment, OR (95% CI): **G1+G2/G3:** 2.73 (1.22-6.08) Rate of initiations, children moved up one or more categories, pre- to post-treatment, %: **G1+G2:** 51.8 **G3:** 25.0 No change: **G1+G2:** 28.6 **G3:** 35.7 Moved down one or more categories: **G1+G2:** 19.6 **G3:** 39.3 Rate of initiations, more likely to be in higher initiation rate category, post-treatment to 10 month follow-up, OR (95% CI): **G1/G3:** 1.08 (0.30-3.90) **Communication/ Language:** Rate of speech, pre- to post-treatment, OR (95% CI): **G1+G2/G3:** 1.10 (0.46-2.62) ADOS-G communication scores, pre- to post-treatment, OR (95% CI): **G1+G2/G3:** 0.52 (0 .24-1.12)
Howlin et al., 2007 (continued)		Other characteristics: NR		ADOS-G reciprocal social interaction scores, pre- to post-treatment,

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				OR (95% CI): **G1+G2/G3:** 0.55 (0.25-1.19) ADOS-G reciprocal social interaction scores, post-treatment to 10 month follow-up, OR (95% CI): **G1/G3:** 0.28 (0.09-0.89) EOWPVT, pre- to post-treatment, OR (95% CI): **G1+G2/G3:** 1.01 (0.89-1.15) BPVS, pre- to post-treatment, OR (95% CI): **G1+G2/G3:** 1.54 (0.52-4.54) **Harms:** NR **Modifiers:** NR

Comments: *For G1, one class withdrew after randomization: the number of children at baseline assessment and post-treatment assessment was 26, and at follow-up assessment was 25; for G2, one girl entered a class a year into the study; for G3, one girl failed to met the criteria for ASD.

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Keen et al., 2007 **Country:** Australia **Practice setting:** Academic **Intervention setting:** Clinic, Home **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Case series, prospective **Note:** For more details on the Stronger Families Project intervention, see Rodger et al., 2004	**Intervention:** Stronger Families Project Intervention: A two day parent workshop, followed by 10 sessions of individual home-based early intervention, using a social-pragmatic approach emphasizing functional use of communication skills in natural and semi-structured interactions; 6 week intervention **Assessments:** Scales of Independent Behavior, CSBS administered by observer in clinic. Parents completed parental stress and component measures. **Groups:** **G1:** intervention **Provider:** NR **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 16 **N at follow-up:** **G1:** 16	**Inclusion criteria:** • Recruited from community health, hospital, and education-based early intervention services • Clinical diagnosis of autism based on DSM-IV criteria **Exclusion criteria:** • See inclusion criteria **Age, months ± SD (range):** 38.06 ± 5.49 (25-47) **Mental age:** NR **Gender, n (%):** Male: 14 (87) Female: 2 (13) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** DSM-IV **Diagnostic category:** NR **Other characteristics:** NR	**Language/ communication:** CSBS score, median (range): Total: **G1:** 74.5 (65-126) Social: **G1:** 4 (3-11) Speech: **G1:** 9 (3-17) Symbolic: **G1:** 5.5 (3-13) CSBS caregiver questionnaire score, median (range): Total: **G1:** 84.5 (65-100) Social: **G1:** 4 (3-7) Speech: **G1:** 10 (3-17) Symbolic: **G1:** 7.5 (3-10)	**Language/ communication:** CSBS score, median (range): Total: **G1:** 75 (65-135) **G1/BL:** $P = 0.1$ Social: **G1:** 5 (3-15) **G1/BL:** $P = 0.122$ Speech: **G1:** 8.5 (3-17) **G1/BL:** $P = 0.194$ Symbolic: **G1:** 6.5 (3-17) **G1/BL:** $P = 0.203$ CSBS caregiver questionnaire score, median (range): Total: **G1:** 90 (70-103) **G1/BL:** $P = 0.007$ Social: **G1:** 5.5 (3-9) **G1/BL:** $P = 0.017$ Speech: **G1:** 10.5 (7-17) **G1/BL:** $P = 0.044$ Symbolic: **G1:** 7 (5-11) **G1/BL:** $P = 0.007$ **Harms:** NR **Modifiers:** No significant relationships found between child/parent variables and change in behavior sample scores

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Kroeger et al., 2007 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Xavier University Mentoring and Project Chair Award, Autism Society of Greater Cincinnati Student Researcher Grant **Design:** RCT	**Intervention:** In both interventions (direct teaching and play activities), the child participates for a total of 15 hours in 15 group sessions, which include: • Beginning and ending circle times • Visual schedules during each session to transition activities • 2:1 student to facilitator ratio • Secondary (social) reinforcement for prosocial behaviors • Behavior management for inappropriate behaviors • Introduction of identical toys and materials commensurate with the video modeling curriculum In the direct teaching intervention, children participated in the video modeling curriculum and received primary (edible) rein-forcement during the course of the video modeling In the play activities intervention, children engaged in supervised free play during the middle portion of the session instead of video modeling **Assessments:** Parent satisfaction survey; Social Interaction Observation Code videotape data **Groups:** **G1:** direct teaching **G2:** play activities **Provider:** Group supervisor and facilitators	**Inclusion criteria:** • 4-6 years old • Diagnosed with Autistic disorder **Exclusion criteria:** • Other autism spectrum disorders (i.e. Asperger's disorder, Rett's disorder, childhood disintegrative disorder, and pervasive developmental disorder, NOS) **Age, months ± SD:** **G1:** 65.00 ± 12.25 **G2:** 61.42 ± 9.15 **Mental age:** NR **Gender, n:** Male: **G1:** 9 **G2:** 11 Female: **G1:** 4 **G2:** 1 **Race/ethnicity, n:** Caucasian: **G1:** 9 **G2:** 12 African American: **G1:** 4 **G2:** 0 **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** By developmental pediatrician following routine multidisciplinary assessment: parent and a variety of autism and developmental standar-dized assessments conducted by corre-sponding professionals **Diagnostic category, n (%):** Autism: 25 (100)	**Social skills:** Number of initiating behaviors: **G1:** NR* **G2:** NR* **G1/G2:** *P* = NS Number of respon-ding behaviors: **G1:** NR* **G2:** NR* **G1/G2:** *P* = NS Number of inter-acting behaviors: **G1:** NR* **G2:** NR* **G1/G2:** *P* = NS	**Overall:** Parent satis-faction rating, mean: **G1:** 5.69 **G2:** 5.67 **G1/G2:** *P* = NS **Social skills:** Number of initiating behaviors: **G1:** NR* **G2:** NR* ANOVA: time (P = 0.001), treatment (0.020) η^2 = 0.215 Number of responding behaviors: **G1:** NR* **G2:** NR* ANOVA: time (P = 0.005), treatment (P = 0.003) η^2 = 0.328 Number of inter-acting behaviors: **G1:** NR* **G2:** NR* ANOVA: time (P = 0.002), treatment (P = 0.006); η^2 = 0.288 **Harms:** NR **Modifiers:** NR
Kroeger et al., 2007 (continued)	**Mean # of sessions attended:** **G1:** 14.08 **G2:** 14.42 **Measure of treatment fidelity reported:**	**Other characteristics:** GARS score, mean ± SD: **G1:** 92.15 ± 15.24 **G2:** 92.58 ± 9.66 **G1/G2:** *P* = NS Non-verbal		

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 14 **G2:** 13 **N at follow-up:** **G1:** 13 **G2:** 12	**G1:** 2 **G2:** 2		

Comments: *Data only illustrated graphically

Author: Magiati et al., 2007 **Country:** UK **Practice setting:** Academic **Intervention setting:** Community **Enrollment period:** July 1998 to July 2002 **Funding:** Local educational authorities **Author industry relationship disclosures:** None **Design:** Prospective cohort	**Intervention:** Early Intensive Behavioral Intervention: children received 1:1 home teaching using discrete trial techniques and Verbal Behavior; 27 families attended an initial workshop of 1-3 days Nursery: eclectic intervention, emphasizing structure, visual cues, individualized teaching, and contact with families (most commonly reported TEACCH, PECS, Makatan, and SPELL) Duration of treatment, months ± SD (range): **G1:** 25.5 ± 1.04 (23-27) **G2:** 26.0 ± 1.5 (23-27) Total hours of intervention, mean ± SD: **G1:** 3,415 ± 444 **G2:** 2,266 ± 533 Hours of intervention per week, mean ± SD (range): First week: **G1:** 32.4 ± 6.4 (18-40) **G2:** 25.6 ± 6.4 (15-30) **G1/G2:** *P* < 0.001 Last week: **G1:** 33.2 ± 3.5 (26-40) **G2:** 27.4 ± 4.2 (19-30) **G1/G2:** *P* < 0.001 **Assessments:** BSID, WPPSI, MPS, VABS, BPVS-II, Word Picture Vocabulary Test-Revised, Symbolic Play Test-II, Test of Pretend Play, administered at home or school by	**Inclusion criteria:** • Age 22-54 months • Independent professional diagnosis of autism/ASD confirmed by ADI-R • No major medical diagnoses • English main language at home • Living within 3 hours of London • Enrolled in either EIBI home-based program or specialist autism-specific school-based nursery provision for a minimum of 15 hours per week • Receiving no other intensive treatment **Exclusion criteria:** • See inclusion criteria **Age, months ± SD:** **G1:** 38 ± 7.2 **G2:** 42.5 ± 7.8 **Mental age, mean ± SD (range):** See baseline measures **Gender, n (%):** Male: **G1:** 27 (96.4) **G2:** 12 (75) Female: **G1:** 1 (3.6) **G2:** 4 (25) **Race/ethnicity, n (%):** White: **G1:** 21 (47) **G2:** 11 (69) Mixed: **G1:** 4 (9)	**Overall measures:** VABS composite, standard score, mean ± SD (range): **G1:** 59.6 ± 6.2 (50-72) (n=26) **G2:** 55.4 ± 5.4 (47-64) (n=14) **G1/G2:** *P* = 0.04 ADI-R total algorithm score, mean ± SD (range): **G1:** 36.4 ± 6.7 (18-46) (n=26) **G2:** 40 ± 6.9 (18-46) (n=15) **G1/G2:** *P* = NS **Educational/ cognitive/ academic attainment:** Mental age, months ± SD (range): **G1:** 31.4 ± 11.1 (5-55) **G2:** 29.1 ± 13.1 (9-48) **G1/G2:** *P* = NS IQ, mean ± SD (range): **G1:** 83 ± 27.9 (16-138) **G2:** 65.2 ± 26.9 (27-112) **G1/G2:** *P* = 0.04 Symbolic play test score, developmental age, months ± SD (range): **G1:** 18.8 ± 8 (12-36) (n=27) **G2:** 19.2 ± 8.6 (12-34)	**Overall measures:** VABS composite, age equivalent, months ± SD (range): **G1:** 32.6 ± 10.2 (19-58) **G2:** 26.1 ± 12.4 (11-48) **G1/G2:** *P* = NS VABS composite, standard score, mean ± SD (range): **G1:** 57.5 ± 10.1 (41-79) **G2:** 48.6 ± 10.7 (35-72) **G1/G2:** *P* = NS ADI-R total algorithm score, mean ± SD (range): **G1:** 30.7 ± 8.8 (13-40) (n=26) **G2:** 34.9 ± 9.9 (11-48) **G1/G2:** *P* = NS **Educational/ cognitive/ academic attainment:** Mental age, months ± SD (range): **G1:** 49.2 ± 9.8 (29-70) **G2:** 44.7 ± 14.1 (17-67) (n=15) **G1/G2:** *P* = NS IQ, mean ± SD (range): **G1:** 78.4 ± 17.6

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	investigators at baseline and follow-up **Groups:** **G1:** EIBI **G2:** nursery	**G2:** 0 Asian/Asian British: **G1:** 2 (45) **G2:** 2 (13) Black/Black British: **G1:** 1 (2) **G2:** 3 (19)	**G1/G2:** *P* = NS BPVS score, mean ± SD (range): **G1:** 4.9 ± 9.1 (0-32) **G2:** 2.9 ± 7.7 (0-27) **G1/G2:** *P* = NS	(43-129) **G2:** 65.3 ± 18 (30-94) (n=15) **G1/G2:** *P* = NS

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Magiati et al., 2007 (continued)	**Provider:** EIBI provider, n (%): Supervisor and consultant: 14 (50) Supervisor: 7 (25) Consultant: 3 (11) Senior therapist: 2 (7) One-two parents trained as a therapist: 23 (82) Nursery provider, n (%): Teachers: 16 (100) **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies, n:** Special Dietary: G1: 21 G2: 6 G1/G2: P = 0.01 Other biological interventions: G1: 17 G2: 3 G1/G2: P = 0.01 Extra-curricular educational interventions: G1: 2 G2: 7 G1/G2: P < 0.01 Other alternative treatments: G1: 8 G2: 2 G1/G2: P = 0.18 **N at enrollment:** G1: 28 G2: 16 **N at follow-up:** G1: 28 G2: 16	SES: Parental education, n: Higher (degree or above): G1: 18 G2: 7 Lower (A-levels or below): G1: 5 G2: 8 No information: G1: 5 G2: 1 Family SEC, n: Higher (categories 1–3): G1: 23 G2: 9 Lower (categories 4–9): G1: 4 G2: 6 No information: G1: 1 G2: 1 Diagnostic approach: **In Study** **Diagnostic tool/method: ADI-R** Diagnostic category, n (%): Autism: G1: 19 (43) G2: 13 (81) ASD: G1: 9 (20) G2: 3 (19) Other characteristics: NR	Communication/ language: EOWPVT-R score, mean ± SD (range): G1: 2.2 ± 7.8 (0-39) G2: 1.7 ± 3.7 (0-12) G1/G2: P = NS VABS communication, age equivalent, months ± SD (range): G1: 14.4 ± 5.2 (8-28) (n=26) G2: 13.1 ± 4.5 (8-26) (n=14) G1/G2: P = NS VABS communication, standard score, mean ± SD (range): G1: 60 ± 7.4 (50-78) (n=26) G2: 55.8 ± 6.8 (47-74) (n=14) G1/G2: P = NS Adaptive behavior: VABS daily living, age equivalent, months ± SD (range): G1: 19 ± 6.1 (11-39) (n=26) G2: 20 ± 3.9 (15-27) (n=14) G1/G2: P = NS VABS daily living, standard score, mean ± SD (range): G1: 63 ± 7.4 (55-89) (n=26) G2: 61.4 ± 4.9 (52-69) (n=14) G1/G2: P = NS Social skills: VABS socialization, age equivalent, months ± SD (range): G1: 13 ± 4.4 (6-24) (n=26) G2: 11.1 ± 3.4 (6-20) (n=14) G1/G2: P = NS	Symbolic play test score, developmental age, months ± SD (range): G1: 29.2 ± 12.7 (12-65) G2: 28.8 ± 13 (12-61) (n=15) G1/G2: P = NS BPVS score, mean ± SD (range): G1: 20.8 ± 20.8 (0-68) (n=27) G2: 13.2 ± 17.8 (0-52) (n=15) G1/G2: P = NS Communication/ language: EOWPVT-R score, mean ± SD (range): G1: 13 ± 17.3 (0-59) (n=27) G2: 10.2 ± 13.7 (0-38) (n=15) G1/G2: P = NS VABS communication, age equivalent, months ± SD (range): G1: 29.6 ± 17.2 (12-70) G2: 23.6 ± 16.8 (11-67) G1/G2: P = NS VABS communication, standard score, mean ± SD (range): G1: 61.2 ± 17.6 (41-106) G2: 51.6 ± 14.8 (37-87) G1/G2: P = NS
Magiati et al., 2007 (continued)			VABS socialization, standard score, mean ± SD (range): G1: 60.3 ± 6 (51-76) (n=26)	Adaptive behavior: VABS daily living, age equivalent, months ± SD

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
			G2: 56.6 ± 4.8 (52-67) (n=14) G1/G2: P = 0.05 VABS composite, age equivalent, months ± SD (range): G1: 18.6 ± 5.4 (12-32) (n=26) G2: 17.3 ± 3.9 (12-26) (n=14) G1/G2: P = NS	(range): G1: 32.4 ± 8.2 (20-55) G2: 29.4 ± 9.7 (17-49) G1/G2: P = NS VABS daily living, standard score, mean (SD); range: G1: 58.6 ± 8.4 (38-78) G2: 49.6 ± 12.4 (28-73) G1/G2: P = 0.06 Social skills: VABS socialization, age equivalent, months ± SD (range): G1: 25.1 ± 11.8 (12-61) G2: 20.2 ± 14 (7-53) G1/G2: P = NS VABS socialization, standard score, mean ± SD (range): G1: 61.8 ± 10.4 (41-90) G2: 56.7 ± 10.3 (47-82) G1/G2: P = NS Harms: NR
Magiati et al., 2007 (continued)				Modifiers: Progress after 2 years was best predicted by baseline IQ (P < 0.001) and baseline PBVS score (P < 0.01); VABS and ADI-R total scores also contributed to the model (P < 0.05)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Shea et al., 2004 Pandina et al., 2007† **Country:** Canada **Practice setting:** Academic, tertiary care hospital, pharmaceutical company, contract research organization **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Janssen-Ortho, Inc., Canada; Johnson & Johnson Pharmaceutical Research and Development **Author industry relationship disclosures:** 1 of 7 Janssen-Ortho (1) 5 of 5† Janssen (4) Janssen-Ortho (1) **Design:** RCT	**Intervention:** Risperidone oral solution 1.0 mg/mL once daily in the morning at 0.01 mg/kg/day on treatment days 1-2, increased to 0.02 mg/kg/day on day 3. Depending on response at day 8, could be increased in increments up to 0.02 mg/kg/day. Thereafter adjusted at investigator's discretion weekly in increments ≤ 0.02 mg/kg/day up to max allowable dosage of 0.06 mg/kg/day. Duration: days (range): **G1:** 52.7 (2-62) **G2:** 49.6 (7-63) Planned: 8 weeks **Assessments:** CGI-S completed at intake by investigator ESRS, VAS-MS (most troublesome symptom) CGI-C by investigator weekly ABC, N-CBRF (parent version) completed weekly by parent with investigator guidance **Groups:** **G1:** risperidone oral solution **G2:** placebo oral solution **Ga:** diagnosis of autism **Co-interventions held stable during treatment:** Yes **Frequency of contact during study:** Weekly for 8 weeks **Concomitant therapies:** At least one concomitant medication, n (%): **G1:** 36 (90) **G2:** 26 (66.7) Medication, %: Analgesics: **G1:** 37.5 **G2:** 17.9	**Inclusion criteria:** • Physically healthy outpatients • Ages 5-12 years • DSM-IV Axis 1 diagnosis of PDD • CARS total score ≥ 30 with or without mental retardation **Exclusion criteria:** • Schizophrenia • Other psychotic disorders • Clinically relevant non-neurologic disease • Clinical significant laboratory abnormalities • Seizure disorder for which they were receiving one or more anticonvulsants or had a seizure within 3 months • History of hypersensitivity to neuroleptics, tardive dyskinesia, narcoleptic malignant syndrome, drug or alcohol abuse, or HIV infection • Used risperidone in the last 3 months, previously unresponsive or intolerant to risperidone • Using a prohibited medication (including antipsychotics other than study medication, antidepressants, lithium, α_2-antagonists, clonidine, guanfacine, cholinesterase inhibitors, psychostimulants, and naltrexone) **Age, years ± SD (range):** **G1:** 7.6 ± 2.3 (5-12) **G1a:** 7.4 ± 2.4 (NR)† **G2:** 7.3 ± 2.3 (5-12) **G2a:** 7.1 ± 2.1 (NR)†	**Problem behavior:** ABC score, mean ± SD: Irritability: **G1:** 18.9 ± 8.8 **G1a:** 20.6 ± 8.1 (n=24)† **G2:** 21.2 ± 9.7 **G2a:** 21.6 ± 10.2† Lethargy: **G1:** 13.7 ± 7.0 **G1a:** 14 ± 6.8 (n=26)† **G2:** 14.3 ± 8.2 **G2a:** 13 ± 8.6† Stereotypic behavior: **G1:** 7.9 ± 5.0 **G1a:** 8.4 ± 5.8 (n=25)† **G2:** 8.1 ± 5.6 **G2a:** 9.4 ± 5.5† Hyperactivity/non-compliance: **G1:** 27.3 ± 9.7 **G1a:** 29.2 ± 9.5 (n=25)† **G2:** 30.9 ± 8.8 **G2a:** 33.6 ± 6.8 (n=27)† Inappropriate speech: **G1:** 4.6 ± 3.4 **G1a:** 4.5 ± 3.7 (n=26)† **G2:** 4.8 ± 3.7 **G2a:** 4.5 ± 3.7† N-CBRF score, parent rated, mean ± SD: Adaptive/social:† **G1a:** 3.8 ± 2.3 (n=26) **G2a:** 3.9 ± 2 Compliant/Calm:† **G1a:** 6.8 ± 2.7 (n=25) **G2a:** 6.2 ± 2.4 (n=26)	**Problem behavior:** ABC score, mean change ± SD: Irritability: **G1:** -12.1 ± 5.8 **G2:** -6.5 ± 8.4 **G1/G2:** $P \leq 0.001$ Lethargy: **G1:** -8.6 ± 5.9 **G2:** -5.7 ± 6.9 **G1/G2:** $P \leq 0.01$ Stereotypic Behavior: **G1:** -4.3 ± 3.8 **G2:** -2.4 ± 4.0 **G1/G2:** $P \leq 0.05$ Hyperactivity/ noncompliance: **G1:** -14.9 ± 6.7 **G2:** -7.4 ± 9.7 **G1/G2:** $P \leq 0.001$ Inappropriate speech: **G1:** -2.6 ± 2.6 **G2:** -1.6 ± 3.0 **G1/G2:** $P \leq 0.05$ ABC score, mean ± SD: Irritability:† **G1a:** 7.2 ± 5.9 (n=24) **G2a:** 14.1 ± 11.3 **G1a/G2a:** P = 0.002 Lethargy: **G1a:** 4.7 ± 4.4 (n=26) **G2a:** 8.2 ± 8.9 **G1a/G2a:** P = 0.020 Stereotypic Behavior: **G1a:** 3.9 ± 4.2 (n=25) **G2a:** 6.9 ± 6.9 **G1a/G2a:** P = 0.053
Shea et al., 2004 (continued)	Cough and cold preparations: **G1:** 25 **G2:** 10.3 Antibiotics:	**Mental age:** IQ score, n (%): ≥ 85, normal: **G1:** 3/31 (9.7) **G1a:** 0†	Conduct problem: **G1:** 16.8 ± 9.4 **G1a:** 17.2 ± 8 (n=26)† **G2:** 23.3 ± 12.0	Hyperactivity/ noncompliance: **G1a:** 13.3 ± 8.7 (n=25) **G2a:** 26.4 ± 12.8

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	G1: 12.5 **G2:** 12.8 Anti-asthmatics: **G1:** 15 **G2:** 10 Sedative/hypnotics: **G1:** 27.5 **G2:** 23.1 Anticholinergics: **G1:** 7.5 **G2:** 2.6 **N at enrollment:** **G1:** 40 **G1a:** 27 **G2:** 39 **G2a:** 28 **N at follow-up:** **G1:** 39 **G1a:** 25 **G2:** 38 **G2a:** 24	**G2:** 11/35 (31.4) **G2a:** 6/24 (25)† 71-84, borderline: **G1:** 6/31 (19.4) **G2:** 4/35 (11.4) 50-70, mild: **G1:** 12/31 (38.7) **G2:** 8/35 (22.9) 35-49, moderate: **G1:** 10/31 (32.3) **G2:** 12/35 (34.3) IQ, mean ± SD:† **G1a:** 50.8 ± 19.8 **G2a:** 60.1 ± 26.9 **Gender, n (%):** Male: **G1:** 29 (72.5) **G1a:** 19 (70)† **G2:** 32 (82.1) **G2a:** 24 (86)† Female: **G1:** 11 (27.5) **G1a:** 8 (30)† **G2:** 7 (17.9) **G2a:** 4 (14)† **Race/ethnicity, n (%):** **G1:** White: **G1:** 27 (67.5) **G1a:** 16 (59)† **G2:** 28 (71.8) **G2a:** 18 (64)† Black: **G1:** 6 (15.0) **G1a:** 4 (15)† **G2:** 6 (15.4) **G2a:** 6 (21)† Other: **G1:** 7 (17.5) **G1a:** 7 (26)† **G2:** 5 (12.8) **G2a:** 4 (14)† **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study	**G2a:** 21.5 ± 10.7† Hyperactive: **G1:** 17.2 ± 5.8 **G1a:** 17.7 ± 5.6 (n=25)† **G2:** 18.9 ± 5.3 **G2a:** 19.6 ± 5.2† Insecure/anxious: **G1:** 8.7 ± 8.1 **G1a:** 6.3 ± 6.7 (n=26)† **G2:** 10.6 ± 7.6 **G2a:** 8.7 ± 6.7† Overly sensitive: **G1:** 6.9 ± 3.4 **G1a:** 6.7 ± 3.4 (n=26)† **G2:** 7.4 ± 3.5 **G2a:** 6.6 ± 3.4† Self-injury/ stereotypic: **G1:** 4.2 ± 4.2 **G1a:** 4.5 ± 4.4 (n=26)† **G2:** 3.5 ± 4.2 **G2a:** 4.1 ± 4.4† Self-isolated/ ritualistic: **G1:** 7.5 ± 4.1 **G1a:** 7.3 ± 4 (n=26)† **G2:** 8.2 ± 4.5 **G2a:** 7.8 ± 4.2† VAS-MS, mean ± SD: **G1:** 81.0 ± 13.3 **G2:** 84.8 ± 14.1 VAS-MS score by symptom, mean ± SD:† Aggression: **G1a:** 86 ± 14.5 (n=7) **G2a:** 88.3 ± 9 (n=7)	(n=27) **G1a/G2a:** *P* = 0.001 Inappropriate speech: **G1a:** 1.9 ± 2.2 (n=26) **G2a:** 3.1 ± 3.5 **G1a/G2a:** *P* = 0.058 N-CBRF score, parent rated, mean change ± SD: Conduct problem: **G1:** -10.4 ± 7.4 **G2:** -6.6 ± 9.5 **G1/G2:** *P* ≤ 0.001 Hyperactive: **G1:** -8.1 ± 4.6 **G2:** -5.6 ± 6.6 **G1/G2:** *P* ≤ 0.05 Insecure/anxious: **G1:** -4.6 ± 6.5 **G2:** -3.5 ± 5.5 **G1/G2:** *P* ≤ 0.05 Overly sensitive: **G1:** -3.8 ± 2.8 **G2:** -2.7 ± 3.2 **G1/G2:** *P* ≤ 0.05 Self-injurious/ stereotypic: **G1:** -2.6 ± 3.3 **G2:** -1.3 ± 2.8 **G1/G2:** *P* = NS Self-isolated/ ritualistic: **G1:** -4.8 ± 3.9 **G2:** -3.6 ± 4.6 **G1/G2:** *P* = NS
Shea et al., 2004 (continued)		**Diagnostic tool/method:** DSM-IV **Diagnostic category, n (%):** Autism: **G1:** 27 (67.5) **G2:** 28 (71.8) Asperger: **G1:** 5 (12.5) **G2:** 7 (17.9)	Defiance/ disobedience: **G1a:** 75 ± 47 (n=7) **G2a:** 84.8 ± 19.6 (n=7) Hyperactivity: **G1a:** 68.7 ± 28.6 (n=7) **G2a:** 96.3 ± 4.2	N-CBRF score, parent rated, mean ± SD:† Adaptive/social: **G1a:** 5.3 ± 2.4 (n=26) **G2a:** 4.3 ± 2.4 **G1a/G2a:** *P* = 0.072 Compliant/calm:

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
		Childhood disintegrative disorder: **G1:** 1 (2.5) **G2:** 0 PDD-NOS: **G1:** 7 (17.5) **G2:** 4 (10.3) **Other characteristics:** Weight, kg ± SD: **G1:** 31.2 ± 14.5 **G2:** 27.6 ± 8.6 VABS composite score, mean ± SE: **G1:** 46.6 ± 13.1 **G1a:** 44.6 ± 13.8† **G2:** 52.2 ± 19.8 **G2a:** 46.7 ± 19.7† CARS score, mean ± SE: **G1:** 38.9 ± 5.3 **G1a:** 40.1 ± 5.4† **G2:** 39.1 ± 6.7 **G2a:** 50.9 ± 6.6† CARS score, n (%): 31-36, mild/moderate: **G1:** 17 (42.5) **G2:** 18 (46.2) 37-60, severe: **G1:** 23 (57.5) **G2:** 21 (53.8)	(n=7) Obsessive/ repetitive: **G1a:** 86.3 ± 19.4 (n=7) **G2a:** 98 ± 0 (n=7) Tantrums/negative mood: **G1a:** 80.8 ± 10.1 (n=7) **G2a:** 81.2 ± 13.9 (n=7) **Medical:** Pulse, mean bpm ± SD: **G1:** 90.2 ± 12.0 **G2:** 95.0 ± 13.7 Diastolic BP, mean mm Hg ± SD: **G1:** 68.1 ± 9.8 **G2:** 67.8 ± 10.3 Systolic BP, mean mm Hg ± SD: **G1:** 99.8 ± 9.6 **G2:** 100.4 ± 10.5 Weight, mean kg ± SD: **G1:** 31.2 ± 14.5 **G2:** 27.5 ± 8.7	**G1a:** 8.7 ± 3.3 (n=25) **G2a:** 6.9 ± 2.9 (n=26) **G1a/G2a:** *P* = 0.072 Conduct problem: **G1a:** 6.5 ± 5.7 (n=26) **G2a:** 15.5 ± 11.9 **G1a/G2a:** *P* = 0.005 Hyperactive: **G1a:** 9.4 ± 5.4 (n=25) **G2a:** 14.9 ± 8.4 **G1a/G2a:** *P* = 0.021 Insecure/anxious: **G1a:** 3.2 ± 4.3 (n=26) **G2a:** 5.4 ± 4.8 **G1a/G2a:** *P* = NS Overly sensitive: **G1a:** 2.8 ± 2.3 (n=26) **G2a:** 4.3 ± 3.3 **G1a/G2a:** *P* = 0.029 Self-injury/ stereotypic: **G1a:** 2.2 ± 3.1 (n=26) **G2a:** 2.8 ± 3.9 **G1a/G2a:** *P* = NS Self-isolated/ ritualistic: **G1a:** 2.4 ± 2.5 (n=26) **G2a:** 4.5 ± 5.5 **G1a/G2a:** *P* = 0.078
Shea et al., 2004 (continued)				VAS-MS, mean change ± SD: **G1:** -38.4 ± 28.9 **G2:** -26.2 ± 29.2 **G1/G2:** *P* ≤ 0.05 VAS-MS score by symptom, mean ± SD:† Aggression: **G1a:** 22.3 ± 20 (n=7) **G2a:** 63.4 ± 37.3 (n=8) **G1a/G2a:** *P* = 0.056

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				Defiance/ disobedience: **G1a:** 60 ± 12.1 (n=4) **G2a:** 65.2 ± 25 (n=5) **G1a/G2a:** *P* = NS Hyperactivity: **G1a:** 39.7 ± 19.7 (n=3) **G2a:** 80.5 ± 14.2 (n=4) **G1a/G2a:** *P* = 0.04 Obsessive/ repetitive: **G1a:** 70 ± 16.8 (n=3) **G2a:** 48 ± 63.4 (n=2) **G1a/G2a:** *P* = NS Tantrums/ negative mood: **G1a:** 28 ± 20.9 (n=6) **G2a:** 43.4 ± 28.8 (n=5) **G1a/G2a:** *P* = NS **Medical:** Pulse, mean change bpm ± SD: **G1:** 8.9 ± 13.9 **G2:** -0.6 ± 13.1 **G1/G2:** *P* ≤ 0.01
Shea et al., 2004 (continued)				Diastolic BP, mean change mm Hg ± SD: **G1:** 0.7 ± 9.1 **G2:** -0.7 ± 8.8 **G1/G2:** *P* = NS Systolic BP, mean change mm Hg ± SD: **G1:** 4.0 ± 10.4 **G2:** -0.7 ± 10.7 **G1/G2:** *P* ≤ 0.01 Weight, mean change kg ± SD: **G1:** 2.7 ± 2.0 **G2:** 1.0 ± 1.6 **G1/G2:** *P* ≤ 0.001 **Harms, n (%):** Any event: **G1:** 40 (100) **G2:** 31 (79.5) Somnolence:

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G1: 29 (72.5) **G2:** 3 (7.7) Upper respiratory tract infection: **G1:** 15 (37.5) **G2:** 6 (15.4) Rhinitis: **G1:** 11 (27.5) **G2:** 4 (10.3) Increased appetite: **G1:** 9 (22.5) **G2:** 4 (10.3) Abdominal pain: **G1:** 8 (20.0) **G2:** 3 (7.7) Fever: **G1:** 8 (20) **G2:** 7 (17.9) Insomnia: **G1:** 6 (15.0) **G2:** 6 (15.4) Vomiting: **G1:** 6 (15.0) **G2:** 6 (15.4) Coughing: **G1:** 6 (15.0) **G2:** 4 (10.3) Headache: **G1:** 5 (12.5) **G2:** 2 (5.1)
Shea et al., 2004 (continued)				Constipation: **G1:** 5 (12.5) **G2:** 1 (2.6) Apathy: **G1:** 5 (12.5) **G2:** 0 Tachycardia: **G1:** 5 (12.5) **G2:** 0 Influenza-like symptoms: **G1:** 4 (10.0) **G2:** 2 (5.1) Anorexia: **G1:** 4 (10.0) **G2:** 1 (2.6) Fatigue: **G1:** 4 (10.0) **G2:** 1 (2.6) Saliva increased: **G1:** 4 (10) **G2:** 1 (2.6) Weight increase: **G1:** 4 (10) **G2:** 1 (2.6) Tremor:

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G1: 4 (10) **G2:** 0 **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Reed et al., 2007 **Country:** UK **Practice setting:** Academic **Intervention setting:** Home **Enrollment period:** NR **Funding:** South East Region Special Education Needs Partnership **Author industry relationship disclosures:** NR **Design:** Non randomized controlled trial	**Intervention:** High-intensity ABA vs. low-intensity ABA High-intensity intervention offered home-based mostly 1:1 training between 20-40 hours per week (mean 30.4 hours); approaches included: • Lovaas (discrete-trial reinforcement-based) • Verbal behavior (discrete-trial focused on developmental of verbal responses) • CABAS-based (combination of ABA technologies, stresses importance of learn-units) Each session lasted 2-3 hours. Low-intensity intervention offered training between 10-20 hours per week (mean 12.6 hours) using similar procedures as described in high-intensity intervention with up to four 3-hour home based direct 1:1 teaching sessions each week. **Assessments:** Blinded educational psychologist administered BAS and PEP-R. Parent completed VABS and GARS measures pre- and post-treatment (9-10 months) **Groups:** **G1:** high-intensity **G2:** low-intensity **Ga:** Lovaas **Gb:** verbal behavior **Gc:** CABAS	**Inclusion criteria:** • Age 2.5-4 years at start of study • At start of intervention • Received no other major interventions during the assessment period • Diagnosed with ASD **Exclusion criteria:** • See inclusion criteria **Age, months ± SD:** **G1:** 42.9 ± 14.8 **G1a:** 47.5 ± 13.5 **G1b:** 38.0 ± 9.9 **G1c:** 44.2 ± 20.5 **G2:** 40.8 ± 5.6 **Mental age:** See baseline measures **Gender, n (%):** Male: **G1:** 14 (100) **G2:** 13 (100) Female: **G1:** 0 **G2:** 0 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** NR **Diagnostic tool/method:** NR **Diagnostic category:** NR **Other characteristics:** NR	**Overall ratings:** GARS autism quotient, mean ± SD: **G1:** 89.1 ± 14.7 **G1a:** 93.0 ± 19.9 **G1b:** 87.6 ± 11.1 **G1c:** 87.4 ± 16.1 **G2:** 95.1 ± 11.6 **Adaptive Behavior:** VABS composite score, mean ± SD: **G1:** 59.3 ± 10.1 **G1a:** 59.8 ± 16.7 **G1b:** 58.2 ± 6.5 **G1c:** 60.0 ± 8.6 **G2:** 56.5 ± 4.4 **Educational/ cognitive/ academic attainment:** PEP-R overall score, mean ± SD: **G1:** 57.2 ± 17.8 **G1a:** 58.0 ± 30.7 **G1b:** 50.2 ± 7.7 **G1c:** 63.6 ± 12.4 **G2:** 49.3 ± 13.2 BAS cognitive ability score, mean ± SD: **G1:** 60.1 ± 22.4 **G1a:** 72.0 ± 30.6 **G1b:** 48.0 ± 4.6 **G1c:** 62.8 ± 23.9 **G2:** 52.4 ± 9.9	**Overall ratings:** GARS autism quotient, mean change ± SD: **G1:** -2.2 ± 7.8 **G2:** 1.6; ± 6.2 **G1/BL:** *P* = NS **G2/BL:** *P* = NS **G1/G2:** *P* = NS **Adaptive behavior:** VABS composite score, mean change (ES**): **G1:** NR* **G1a:** NR* (0.03) **G1b:** NR* (0.18) **G1c:** NR* (0.53) **G2:** NR* **G1/BL:** *P* = NS **G1a/BL:** *P* = NS **G1b/BL:** *P* = NS **G1c/BL:** *P* = NS **G2/BL:** *P* = NS **G1/G2:** *P* = NS **G1a/G1b/G1c:** *P* = NS **Educational/ cognitive/ academic attainment:** PEP-R overall score, mean change (ES**): **G1:** NR* **G1a:** NR* (0.91) **G1b:** NR* (0.82) **G1c:** NR* (1.11) **G2:** NR* **G1/BL:** *P* < 0.01 **G1a/BL:** *P* < 0.05 **G1b/BL:** *P* = NS **G1c/BL:** *P* < 0.05 **G2/BL:** *P* = NS **G1/G2:** *P* = NS **G1a/G1b/G1c:** *P* < 0.05
Reed et al., 2007 (continued)	**Provider:** High-intensity programs were supervised by tutors trained in the approach who provided supervision on average of once every two weeks; low intensity was provided by trained assistants **Measure of treatment**			BAS cognitive ability score, mean change (ES**): **G1:** NR* **G1a:** NR* (0.58) **G1b:** NR* (3.74) **G1c:** NR* (3.74) **G2:** NR* **G1/BL:** *P* < 0.01

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	fidelity reported: No **Co-interventions held stable during treatment:** Yes **Concomitant therapies:** NR **N at enrollment:** **G1:** 14 **G1a:** 4 **G1b:** 5 **G1c:** 5 **G2:** 13 **N at follow-up:** **G1:** 14 **G1a:** 4 **G1b:** 5 **G1c:** 5 **G2:** 13			**G1a/BL:** P = NS **G1b/BL:** P = NS **G1c/BL:** $P < 0.01$ **G2/BL:** $P < 0.05$ **G1/G2:** $P < 0.01$ **G1a/G1b/G1c:** P = NS **Harms:** NR **Modifiers:** Increases in hours/week of intervention were associated with decreases in mean-outcome gains for G1*

Comments: *data only illustrated graphically
**Effect sizes were calculated by dividing the change score by the original standard deviation of the sample

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Reed et al., 2007 **Country:** UK **Practice setting:** Community **Intervention setting:** Home or school **Enrollment period:** 2002 to 2004 **Funding:** South East Regional Special Educational Needs Partnership **Author industry relationship disclosures:** NR **Design:** Retrospective cohort Note: see related study, Reed et al. 2010	**Intervention:** Applied Behavioral Analysis (ABA): 1:1 interaction for 2 to 3 hrs, approx 8 to 14 tasks or drills per session; programs used an antecedent (question/ task), behavior (response) sometimes prompted if necessary, and consequence procedure; programs included Lovaas, verbal behavior, CABAS; all ABA programs overseen by either BCBA or CABAS-certified qualification Frequency: mean 30.4 hours per week (range 20-40) of intervention Special Nursery: group interaction for 2 to 3 hrs; a session would start and end with six to eight children in a group with the teacher at the front; individual tasks organized into highly structured method as outlined by the TEACCH methodology Frequency: mean 12.7 hours per week (range 3-23) of intervention Portage: supervisor visits the parents once every 1 to 2 weeks, and parents and caregivers are shown how to apply this system during these visits; 1:1 situation targeting several skills/week; 40 to 60 min/day, scheduled when the parent believes the child will be at his or her most receptive; children are taught new skills through the use of questions and tasks, prompts, and rewards Frequency: mean 8.5 hours per week (range 2-15) of intervention	**Inclusion criteria:** • Age 2.5 to 4 years old • Beginning their first teaching intervention • Independent diagnosis of ASD made by specialist pediatrician following initial referral from a general medical practitioner **Exclusion criteria:** • Receiving other major intervention during the assessment period **Age, months (range):** **G1:** 40 (32-47) **G2:** 43 (41-48) **G3:** 38 (30-45) **Mental age:** NR **Gender, n (%):** Male: **G1:** 11 (92) **G2:** 18 (90) **G3:** NR Female: **G1:** 1 (8) **G2:** 2 (10) **G3:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** GARS, CRS-R **Diagnostic category, n (%):** Autism: 48 (100) **Other characteristics:** NR	**Overall ratings:** GARS total score, mean ± SD: **G1:** 90.5 ± 13.9 **G2:** 96.8 ± 10.4 **G3:** 91.3 ± 14.3 PEP-R total score, mean ± SD: **G1:** 55.6 ± 13.8 **G2:** 51.9 ± 20.1 **G3:** 53.3 ± 16.1 BAS II total score, mean ± SD: **G1:** 56.8 ± 16.6 **G2:** 57.8 ± 12.8 **G3:** 53.4 ± 10.9 **Repetitive behaviors:** GARS stereotyped behaviors score, mean ± SD: **G1:** 8.1 ± 2.8 **G2:** 9.3 ± 2.3 **G3:** 8.9 ± 3.1 **Communication/ language:** GARS communication score, mean ± SD: **G1:** 1.6 ± 3.3 **G2:** 5.9 ± 5.6 **G3:** 0.4 ± 1.8 **Social skills:** GARS social interaction score, mean ± SD: **G1:** 7.4 ± 2.7 **G2:** 9.1 ± 2.8 **G3:** 8.3 ± 2.9 GARS developmental disturbance score, mean ± SD: **G1:** 9.2 ± 2.3 **G2:** 9.6 ± 1.9 **G3:** 9.2 ± 1.8 PEP-R imitation score, mean ± SD: **G1:** 45.5 ± 30.9 **G2:** 52.9 ± 30.3 **G3:** 39.4 ± 22.1	**Overall ratings:** GARS total score, mean change ± SD: **G1:** -2.0 ± 8.4 **G2:** 0.5 ± 9.3 **G3:** 1.5 ± 5.9 **G1/G2/G3:** *P* = NS PEP-R total score, mean change ± SD: **G1:** 13.6 ± 12.7 **G2:** 10.2 ± 13.6 **G3:** 1.6 ± 11.2 **G1/G2:** *P* = NS* **G1/G3:** *P* < 0.05* **G2/G3:** *P* = NS* BAS II total score, mean change ± SD: **G1:** 17.8 ± 15.0 **G2:** 7.9 ± 8.6 **G3:** 6.6 ± 9.1 **G1/G2:** *P* < 0.05* **G1/G3:** *P* < 0.05* **G2/G3:** *P* = NS* **Social skills:** GARS social interaction score, mean change ± SD: **G1:** -0.4 ± 1.6 **G2:** -0.6 ± 2.5 **G3:** 0.1 ± 1.1 **G1/BL:** *P* = NS* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS* VABS socialization score, mean change ± SD: **G1:** 4.0 ± 7.3 **G2:** 5.0 ± 8.8 **G3:** -0.3 ± 3.9 **G1/BL:** *P* = NS* **G2/BL:** *P* < 0.05 **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS*

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Reed et al., 2007 (continued)	**Assessments:** Initial and follow-up assessment handled by senior educational psychologist **Groups:** **G1:** ABA **G2:** special nursery **G3:** portage **Provider:** **G1:** either board certified behavior analyst or master teaching-level CABAS qualifications **G2:** trained teacher **G3:** parents with supervision by trained provider **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 12 **G2:** 20 **G3:** 16 **N at follow-up:** **G1:** 12 **G2:** 20 **G3:** 16		PEP-R perception score, mean ± SD: **G1:** 78.2 ± 24.6 **G2:** 80.4 ± 45.6 **G3:** 74.8 ± 31.3 VABS socialization score, mean ± SD: **G1:** 62.1 ± 9.3 **G2:** 62.1 ± 9.3 **G3:** 61.0 ± 5.8 **Motor Skills:** PEP-R fine motor score, mean ± SD: **G1:** 71.5 ± 18.7 **G2:** 59.9 ± 21.0 **G3:** 65.0 ± 19.9 PEP-R gross motor score, mean ± SD: **G1:** 60.3 ± 17.5 **G2:** 67.2 ± 28.2 **G3:** 68.3 ± 20.2 PEP-R hand-eye coordination score, mean ± SD: **G1:** 64.8 ± 21.7 **G2:** 66.0 ± 31.3 **G3:** 64.7 ± 28.0 VABS motor skills score, mean ± SD: **G1:** 73.8 ± 16.6 **G2:** 73.8 ± 16.6 **G3:** 70.9 ± 11.1 **Educational/ cognitive academic attainment:** PEP-R cognitive score, mean ± SD: **G1:** 40.7 ± 23.2 **G2:** 42.5 ± 20.2 **G3:** 38.3 ± 17.6 **Communication/ language:** PEP-R verbal score, mean ± SD: **G1:** 41.9 ± 22.6 **G2:** 43.8 ± 23.8 **G3:** 42.6 ± 15.9	**Communication/ language:** GARS communication score, mean ± SD: **G1:** 3.8 ± 5.5 **G2:** -1.3 ± 5.8 **G3:** 1.2 ± 3.1 **G1/BL:** *P* = NS* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS* PEP-R verbal score, mean change ± SD: **G1:** 19.8 ± 24.5 **G2:** 11.5 ± 15.3 **G3:** 31 ± 17.7 **G1/BL:** *P* < 0.05* **G2/BL:** *P* < 0.01* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS* BAS II verbal comprehension score, mean change ± SD: **G1:** 9.5 ± 14.3 **G2:** 1.8 ± 4.1 **G3:** 0.7 ± 3.4 **G1/BL:** *P* < 0.05* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* < 0.05* **G1/G3:** *P* < 0.05* **G2/G3:** *P* = NS* BAS II picture matching score, mean change ± SD: **G1:** 8.6 ± 8.8 **G2:** 7.9 ± 10.9 **G3:** 6.9 ± 7.6 **G1/BL:** *P* < 0.05* **G2/BL:** *P* < 0.01* **G3/BL:** *P* < 0.01* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS*
Reed et al., 2007 (continued)			BAS II verbal comprehension score, mean ± SD: **G1:** 23.3 ± 6.8 **G2:** 23.3 ± 6.8	BAS II naming score, mean change ± SD: **G1:** 13.2 ± 11.9 **G2:** 2.7 ± 4.0

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
			G3: 21.7 ± 4.3 BAS II picture matching score, mean ± SD: **G1:** 33.8 ± 13.3 **G2:** 33.8 ± 13.3 **G3:** 28.8 ± 8.0 BAS II naming score, mean ± SD: **G1:** 22.4 ± 8.3 **G2:** 22.4 ± 8.4 **G3:** 22.3 ± 6.3 BAS II early number skills score, mean ± SD: **G1:** 26.3 ± 5.3 **G2:** 26.3 ± 5.3 **G3:** 26.1 ± 7.8 VABS communication score, mean ± SD: **G1:** 57.1 ± 7.6 **G2:** 57.1 ± 7.6 **G3:** 57.1 ± 4.9 **Adaptive behavior:** VABS total score, mean ± SD: **G1:** 58.2 ± 8.0 **G2:** 53.0 ± 4.6 **G3:** 58.6 ± 6.0 VABS daily living skills score, mean ± SD: **G1:** 61.6 ± 6.7 **G2:** 61.6 ± 6.9 **G3:** 64.6 ± 6.2 **Problem behavior:** CRS-R score, mean ± SD: Oppositional: **G1:** 62.1 ± 9.9 **G2:** 70.4 ± 13.0 **G3:** 68.3 ± 6.1 Cognitive: **G1:** 72.4 ± 19.4 **G2:** 78.9 ± 10.9 **G3:** 74.9 ± 13.6	**G3:** 1.7 ± 4.6 **G1/BL:** *P* < 0.01* **G2/BL:** *P* < 0.01* **G3/BL:** *P* = NS* **G1/G2:** *P* < 0.05* **G1/G3:** *P* < 0.05* **G2/G3:** *P* = NS* BAS II early number skills score, mean change ± SD: **G1:** 8.6 ± 9.6 **G2:** 4.3 ± 7.6 **G3:** 1.8 ± 8.6 **G1/BL:** *P* < 0.01* **G2/BL:** *P* < 0.01* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS* VABS communication score, mean ± SD: **G1:** 7.0 ± 11.6 **G2:** 3.1 ± 6.4 **G3:** -2.3 ± 4.1 **G1/BL:** *P* = NS* **G2/BL:** *P* < 0.05* **G3/BL:** *P* < 0.05* **G1/G2:** *P* = NS* **G1/G3:** *P* < 0.05* **G2/G3:** *P* = NS* PEP-R imitation score, mean change ± SD: **G1:** 31.0 ± 22.8 **G2:** 8.2 ± 21.2 **G3:** 10.1 ± 23.6 **G1/BL:** *P* < 0.01* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* < 0.05* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS*
Reed et al., 2007 (continued)			Hyperactivity: **G1:** 63.2 ± 8.2 **G2:** 68.6 ± 9.9 **G3:** 68.4 ± 6.3 ADHD: **G1:** 64.6 ± 7.2 **G2:** 69.0 ± 9.3 **G3:** 66.9 ± 7.1	PEP-R perception score, mean change ± SD: **G1:** 21.6 ± 20.1 **G2:** 0.8 ± 34.6 **G3:** 1.9 ± 20.8 **G1/BL:** *P* < 0.01* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS*

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G1/G3: *P* = NS* **G2/G3:** *P* = NS* **Repetitive behavior:** GARS stereotyped behaviors score, mean change ± SD: **G1:** -1.0 ± 1.5 **G2:** 0.3 ± 2.1 **G3:** 0.1 ± 2.5 **G1/BL:** *P* = NS* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS* **Problem behavior:** CRS-R score, mean change ± SD: Oppositional: **G1:** -0.8 ± 10.1 **G2:** -10.7 ± 11.4 **G3:** -9.9 ± 6.3 **G1/BL:** *P* = NS* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* < 0.05* **G1/G3:** *P* < 0.05* **G2/G3:** *P* = NS* Cognitive: **G1:** -10.4 ± 26.6 **G2:** -16.1 ± 14.1 **G3:** 0.4 ± 13.2 **G1/BL:** *P* = NS* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* < 0.05*
Reed et al., 2007 (continued)				Hyperactivity: **G1:** -7.0 ± 7.1 **G2:** -6.5 ± 8.5 **G3:** -4.8 ± 6.4 **G1/BL:** *P* = NS* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS* **Adaptive behavior:** VABS total score, mean change ±

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				SD: **G1:** 2.9 ± 6.5 **G2:** 3.3 ± 6.3 **G3:** -1.4 ± 4.0 **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* < 0.05* VABS daily living skills score, mean change ± SD: **G1:** 2.7± 6.2 **G2:** 3.1± 8.6 **G3:** -1.5 ± 6.6 **G1/BL:** *P* = NS* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS* **Commonly occurring co-morbidities:** CRS-R ADHD score, mean change ± SD: **G1:** -6.9 ± 8.0 **G2:** -6.7 ± 6.2 **G3:** -3.8 ± 7.1 **G1/BL:** *P* = NS* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS*
Reed et al., 2007 (continued)				**Motor skills:** PEP-R fine motor score, mean change ± SD: **G1:** 3.8 ± 19.5 **G2:** 3.7 ± 13.1 **G3:** -1.1 ± 15.1 **G1/BL:** *P* = NS* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS* PEP-R gross motor score, mean change ± SD: **G1:** 30.8 ± 25.0 **G2:** 13.3 ± 19.7 **G3:** 11.0 ± 26.0 **G1/BL:** *P* < 0.01* **G2/BL:** *P* < 0.01* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS*

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G1/G3: *P* = NS* **G2/G3:** *P* = NS* PEP-R hand-eye coordination score, mean change ± SD: **G1:** 12.4 ± 16.4 **G2:** 5.0 ± 21.9 **G3:** -0.9 ± 18.9 **G1/BL:** *P* < 0.05* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS* VABS motor skills score, mean change ± SD: **G1:** -2.0 ± 11.6 **G2:** 3.2 ± 10.7 **G3:** -0.9 ± 10.3 **G1/BL:** *P* = NS* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS*
Reed et al., 2007 (continued)				**Educational/ cognitive/ academic attainment:** GARS develop-mental disturbance score, mean change ± SD: **G1:** 0 ± 1.1 **G2:** -0.2 ± 1.2 **G3:** 0.5 ± 1.5 **G1/BL:** *P* = NS* **G2/BL:** *P* = NS* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS* PEP-R cognitive score, mean change ± SD: **G1:** 18.6 ± 17.4 **G2:** 13.9 ± 16.0 **G3:** 5.9 ± 14.3 **G1/BL:** *P* < 0.01* **G2/BL:** *P* < 0.01* **G3/BL:** *P* = NS* **G1/G2:** *P* = NS* **G1/G3:** *P* = NS* **G2/G3:** *P* = NS* **Harms:**

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				NR **Modifiers:** Age at intake

Comments: *ANCOVA with age and baseline GARS total score as covariates.

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Remington et al., 2007 **Country:** UK **Practice setting:** Academic **Intervention setting:** Home, school, clinic **Enrollment period:** NR **Funding:** UK Health Foundation **Author industry relationship disclosures:** NR **Design:** Cohort, prospective	**Intervention:** Home-based early intervention for two years, 25.6 ± 4.8 hours/week (range 18.4-34.0 hours); one-on-one intervention provided by parents and 3-5 trained tutors; programs used discrete trial training and incorporated generalization procedures (specific programming individualized for each child), participants were identified based on parent preference for EIBI (funded either publicly n=13 or purchased privately n=10) Controls had local education authorities' standard treatment for two years; in general not intensive or delivered one-to-one **Assessments:** Performance-based tests administered at family home, parents mailed questionnaires, telephone interviews using VABS approximately 1 week prior to the children's 60 minute assessment visits at 3 time points (baseline, 1 and 2 year follow-up); ADI administered by first author, ESCS, BSID or Stanford Binet, and RDLS were administered by a Master's level psychometrician **Groups:** **G1:** EIBI intervention **G2:** treatment as usual through public funds **Provider:** Parents and trained tutors, supervised by more experienced behavior analysts, in some cases a consultant with PhD experience in behavior analysis	**Inclusion criteria:** • Autism diagnosis from ADI-R • Previously diagnosed with autism by an independent clinician, or suspected autism diagnosis • Age 30-42 months at enrollment • Children lived in the family home **Exclusion criteria:** • Other chronic or serious medical conditions that would interfere with consistency of intervention **Age, months ± SD:** **G1:** 35.7 ± 4.0 **G2:** 38.4 ± 4.4 **G1/G2:** *P* < 0.05 **Mental age:** See baseline measures **Gender:** NR **Race/ethnicity:** NR **SES:** University education, maternal, n (%): **G1:** 10/23 (43) **G2:** 4/21 (19) Household income: NR Mother working, n (%): Full time: **G1:** 0 **G2:** 0 Part time: **G1:** 7 (30.4) **G2:** 7 (33.3) Fathers (living in the family home) working, n (%): Full time: **G1:** 19/20 (95) **G2:** 17/20 (85) Part time: **G1:** 0 **G2:** 1/20 (5) **Diagnostic approach:** Referral	**Overall ratings:** DBC total score, mean ± SD: Maternal report: **G1:** 50.26 ± 22.75 **G2:** 67.81 ± 18.77 Paternal report: **G1:** 46.67 ± 22.15 **G2:** 57.57 ± 15.67 DBC autism score, mean ± SD: Maternal report: **G1:** 22.22 ± 9.54 **G2:** 31.14 ± 9.22 Paternal report: **G1:** 22.33 ± 9.92 **G2:** 26.29 ± 8.90 ASQ score, mean ± SD: Maternal report: **G1:** 19.26 ± 4.93 **G2:** 21.14 ± 5.47 Paternal report: **G1:** 20.88 ± 4.54 **G2:** 21.07 ± 6.41 **Social skills:** NCBRF positive social behavior score, mean ± SD: Maternal report: **G1:** 10.57 ± 4.24 **G2:** 9.29 ± 3.47 Paternal report: **G1:** 8.94 ± 3.47 **G2:** 8.73 ± 3.67 **Communication/ language:** ESCS joint attention score, mean ± SD: Initiating: **G1:** 3.33 ± 4.40 **G2:** 3.63 ± 4.92 Responding: **G1:** 5.29 ± 3.62 **G2:** 5.94 ± 3.91 Reynell verbal comprehension score obtained, n: **G1:** 4 **G2:** 3 **G1/G2:** *P* = NS	**Overall ratings:** DBC total score, mean ± SD: Maternal report: **G1:** 44.70 ± 24.20 **G2:** 60.62 ± 24.72 Paternal report: **G1:** 45.19 ± 20.94 **G2:** 55.20 ± 19.44 DBC autism score, mean ± SD: Maternal report: **G1:** 18.91 ± 10.29 **G2:** 26.76 ± 11.21 Paternal report: **G1:** 19.50 ± 8.80 **G2:** 24.00 ± 11.60 ASQ score, mean ± SD: Maternal report: **G1:** 15.96 ± 5.63 **G2:** 19.29 ± 7.22 Paternal report: **G1:** 19.88 ± 6.16 **G2:** 19.47 ± 7.46 **Social skills:** NCBRF positive social behavior score, mean ± SD: Maternal report: **G1:** 15.30 ± 4.69 **G2:** 11.86 ± 4.84 **G1/G2:** *P* = 0.004 Paternal report: **G1:** 12.60 ± 4.06 **G2:** 11.20 ± 5.19 **G1/G2:** *P* = 0.053 **Communication/ language:** ESCS joint attention score, mean ± SD: Initiating: **G1:** 11.76 ± 9.41 **G2:** 11.19 ± 13.86 **G1/G2:** *P* = NS Responding: **G1:** 11.29 ± 3.47 **G2:** 10.06 ± 4.99 **G1/G2:** *P* < 0.05

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Remington et al., 2007 (continued)	**Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** Yes **Concomitant therapies, n (%):** Baseline: Speech therapy: **G1:** 15 (65) **G2:** 12 (57) Dietary intervention: **G1:** 11 (48) **G2:** 3 (14) Prescription medications: **G1:** 1 (4) **G2:** 1 (5) Vitamin injection or high-dose vitamins: **G1:** 6 (26) **G2:** 0 Homeopathic intervention: **G1:** 5 (22) **G2:** 5 (24) 12 month follow-up: In mainstream school: **G1:** 13 (57) **G2:** 6 (48) Special needs school: **G1:** 0 **G2:** 9 (43) Mixed school: **G1:** 0 **G2:** 2 (10) TEACHH principles in school settings: **G1:** 2 (9) **G2:** 8 (38) PECS: **G1:** NR **G2:** 14 (67) Sign language/Makaton: **G1:** NR **G2:** 5 (24) Speech therapy: **G1:** 5 (22) **G2:** 14 (67) Dietary intervention: **G1:** 14 (61) **G2:** 4 (19) Prescription medications: **G1:** 4 (17) **G2:** 5 (24)	**Diagnostic tool/method:** ADI-R **Diagnostic category, n (%):** Autism : 44 (100) PDD-NOS: NR Aspergers: NR **Other characteristics: NR**	Reynell expressive language score obtained, n: **G1:** 2 **G2:** 1 **G1/G2:** P = NS **Adaptive behavior:** VABS score, mean ± SD: Composite: **G1:** 114.78 ± 26.89 **G2:** 113.57 ± 29.78 Communication: **G1:** 23.52 ± 11.35 **G2:** 21.62 ± 10.81 Daily living skills: **G1:** 24.13 ± 7.49 **G2:** 25.43 ± 10.56 Social skills: **G1:** 29.57 ± 6.65 **G2:** 28.29 ± 7.48 Motor skills: **G1:** 37.57 ± 6.37 **G2:** 38.24 ± 7.06 **Educational/ cognitive/ academic attainment:** IQ, Bayley and SB-IV, mean ± SD: **G1:** 61.43 ± 16.43 **G2:** 62.33 ± 16.64 Mental age, months ± SD: **G1:** 22.04 ± 6.89 **G2:** 23.71 ± 6.00	Reynell verbal comprehension score obtained, n: **G1:** 21 **G2:** 11 **G1/G2:** P < 0.005 Reynell expressive language score obtained, n: **G1:** 21 **G2:** 10 **G1/G2:** P < 0.005 **Adaptive behavior:** VABS score, mean ± SD: Composite: **G1:** 202.83 ± 61.98 **G2:** 182.86 ± 58.89 Communication: **G1:** 54.74 ± 24.43 **G2:** 46.00 ± 24.51 Daily living skills: **G1:** 50.22 ± 16.46 **G2:** 44.67 ± 16.99 **G1/G2:** P < 0.05 Social skills: **G1:** 43.52 ± 15.94 **G2:** 41.48 ± 14.52 Motor skills: **G1:** 54.35 ± 9.12 **G2:** 50.71 ± 8.21 **G1/G2:** P < 0.05 **Educational/ cognitive/ academic attainment:** IQ, Bayley and SB-IV, mean ± SD: **G1:** 73.48 ± 27.28 **G2:** 60.14 ± 27.76 **G1/G2:** P < 0.01 Mental age, months ± SD: **G1:** 44.39 ± 16.39 **G2:** 38.00 ± 17.44 **G1/G2:** P < 0.01
Remington et al., 2007 (continued)	Vitamin injection or high-dose vitamins: **G1:** 10 (44)			**Harms:** NR **Modifiers:**

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	G2: 1 (5) Homeopathic intervention: **G1:** 2 (9) **G2:** 1 (5) 24 month follow-up: In mainstream school: **G1:** 17 (74) **G2:** 10 (48) Special needs school: **G1:** 5 (22) **G2:** 11 (52) TEACHH principles in school settings: **G1:** 3 (13) **G2:** 11 (52) PECS: **G1:** NR **G2:** 16 (76) Sign language/Makaton: **G1:** NR **G2:** 10 (48) Speech therapy: **G1:** 6 (26) **G2:** 10 (48) Dietary intervention: **G1:** 12 (52) **G2:** 6 (29) Prescription medications: **G1:** 1 (4) **G2:** 4 (19) Vitamin injection or high-dose vitamins: **G1:** 7 (30) **G2:** 1 (5) Homeopathic intervention: **G1:** 1 (4) **G2:** 1 (5) **N at enrollment:** **G1:** 23 **G2:** 21 **N at follow-up:** **G1:** 23 **G2:** 21			In G1, 6 improved most on IQ tests (more than 23.94 points) vs. 6 whose IQ scores decreased: improved IQ associated with higher IQ, higher MA, higher VBS composite, communication, and social skills scores, lower vineland motor skills scores, more behavior problems on both maternal and paternal DBC, more autism symptoms on DBC, fewer intervention hours in year two

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Rickards et al., 2007 **Country:** Australia **Practice setting:** Academic **Intervention setting:** Clinic (child development and early intervention center) **Enrollment period:** May 2000 to December 2003 **Funding:** Murdoch Children's Research Institute and the Jack Brockhoff Foundation **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Home-based program: 1 of 2 specialist preschool teachers visited each family weekly for 1-1.5 hours for 12 months. Time was spent discussing protocols developed at the centers, and developing new goals and strategies as needed. Included parent training and adapting home environment for the needs of the child. Addressed daily living skills, how to respond to behavior, how to provide choices. Center-based program: children in both the home-based program and control groups participated in one of two center-based programs. This consisted of 5 hours spread over two weekly sessions and included an individualized program for each child determined by the child's developmental level, learning style, and interests. Training techniques included chaining, variety, repetition, sequencing, and reward systems. The major principle was to learn through play; communication systems (PECS), behavior modification techniques, speech and OT were provided as needed. **Assessments:** Baseline and 13 months (mean for both groups). Cognitive development either by BSID-II or by WPPSI-R Adaptive behavior by VABS parent interview Bayley Behavior Rating Scale by psychologist	**Inclusion criteria:** • Delays in two or more areas of development based on play observations, parental interview, and information supplied by referring agency **Exclusion criteria:** • Diagnosis of cerebral palsy • Families with inadequate English language skills **Age, months ± SD:** **G1:** 44.6 ± 6.1 **G2:** 43.1 ± 6.5 **Mental age:** NR **Gender, n (%):** Male: **G1:** 24 (80) **G2:** 23 (79) Female: **G1:** 6 (20) **G2:** 6 (21) **Race/ethnicity:** NR **SES:** Maternal education < 12 years, n (%): **G1:** 14 (48.3) **G2:** 14 (50) Social status, Daniel Scale score, n (%): High (1-4): **G1:** 9 (30) **G2:** 11 (37.9) Low (4.1-7.0): **G1:** 21 (70) **G2:** 18 (62.1) **Diagnostic approach:** In Study **Diagnostic tool/method:** DSM-IV or ADI-R & ADOS **Diagnostic category, n (%):** ASD: **G1:** 18 (60) **G2:** 21 (72.4) Developmental delay: **G1:** 7 (23.3) **G2:** 2 (6.9)	**Educational/ cognitive/ academic attainment:** IQ score, mean ± SD: **G1:** 60.2 ± 20 **G1a:** 55.7 ± 22.1 **G1b:** 67 ± 14.4 **G2:** 60.6 ± 21.8 **G2a:** 52.9 ± 18.3 **G2b:** 80.8 ± 17.4 **G1/G2:** *P* = NS **Problem behavior:** Behavior Rating Scale score, mean ± SD **G1:** 98 ± 17.1 (n=29) **G2:** 98.3 ± 13.4 (n=28) **G1/G2:** *P* = NS Behavior Screening Questionnaire, mean ± SD: **G1:** 11.3 ± 4.9 **G2:** 9.6 ± 4.4 (n=28) **G1/G2:** *P* = NS Preschool Behavior Checklist score, mean ± SD: **G1:** 19.2 ± 10.4 (n=27) **G1a:** 22.1 ± 11 (n=16) **G1b:** 15 ± 8.2 (n=11) **G2:** 17.4 ± 10.8 (n=26) **G2a:** 22 ± 9.7 (n=18) **G2b:** 7.1 ± 3.4 (n=8) **G1/G2:** *P* = NS **Adaptive behavior:** VABS composite score, mean ± SD: **G1:** 61.2 ± 18.8 **G2:** 55 ± 14.6 (n=28) **G1/G2:** *P* = NS	**Educational/ cognitive/ academic attainment:** IQ score, mean ± SD: **G1:** 64.9 ± 22.2 **G1a:** 57.2 ± 21.9 **G1b:** 76.4 ± 17.9 **G2:** 57.1 ± 22.4 **G2a:** 48.6 ± 17.5 **G2b:** 79.4 ± 18.8 **G1+G2/BL:** *P* = NS **G1/G2:** *P* = 0.007 **G1a/BL:** *P* = NS **G1b/BL:** *P* = NS **G2a/BL:** *P* = NS **G2b/BL:** *P* = NS **G1a/G2a:** *P* = 0.09 **G1b/G2b:** *P* = 0.08 Change in IQ, n: Improved: **G1:** 12 **G2:** 3 No change: **G1:** 10 **G2:** 16 Deteriorated: **G1:** 8 **G2:** 10 No change: **G1:** 10 **G2:** 16 **G1/G2:** *P* = 0.03 **Problem behavior:** Behavior Rating Scale score, mean ± SD **G1:** 105.8 ± 13.2 (n=29) **G2:** 100.8 ± 11.2 (n=28) **G1+G2/BL:** *P* = 0.01 **G1/G2:** *P* = NS
Rickards et al., 2007 (continued)	Behavior Screening Questionnaire competed by parents Preschool Behavior	Language delay: **G1:** 5 (16.7) **G2:** 6 (20.7) **Other characteristics:**		Behavior Screening Questionnaire, mean ± SD:

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	Checklist completed by teachers QRS-F stress and family scales completed by parents/caregivers **Groups:** **G1:** home-based program **G2:** controls **Ga:** autism **Gb:** developmental and language delay **Provider:** Multidisciplinary team including psychologist, teacher and parent **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** Yes **Concomitant therapies, n (%):** Speech therapy: **G1:** 6 (20) **G2:** 10 (34.5) **N at enrollment:** **G1:** 30 **G1a:** 18 **G1b:** 12 **G2:** 29 **G2a:** 21 **G2b:** 8 **N at follow-up:** **G1:** 30 **G2:** 29	NR		**G1:** 8 ± 5.1 **G2:** 8.1 ± 3.8 (n=28) **G1+G2/BL:** *P* = 0.0004 **G1/G2:** *P* = NS Preschool Behavior Checklist score, mean ± SD: **G1:** 12 ± 8.5 (n=27) **G1a:** 13.7 ± 8.3 (n=16) **G1b:** 9.6 ± 8.6 (n=11) **G2:** 17.7 ± 8.2 (n=26) **G2a:** 21.2 ± 6.7 (n=18) **G2b:** 10 ± 5.6 (n=8) **G1+G2/BL:** *P* = 0.0014 **G1/G2:** *P* = 0.007 **G1a/BL:** *P* = 0.02 **G1b/BL:** *P* = NS **G2a/BL:** *P* = NS **G2b/BL:** *P* = NS **G1a/G2a:** *P* = 0.054 **G1b/G2b:** *P* = 0.02 Change in PBCL: Improved: **G1:** 14 **G2:** 8 No change: **G1:** 9 **G2:** 12 Deteriorated: **G1:** 4 **G2:** 7 **G1/G2:** *P* = NS Changed from severe behavior problem classification to normal range, n: **G1:** 11/18 **G2:** 1/17
Rickards et al., 2007 (continued)				**Adaptive behavior:** VABS composite score, mean ± SD: **G1:** 64.3 ± 20.4

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G2: 59.2 ± 19.7 (n=28) **G1+G2/BL:** *P* = 0.01 **G1/G2:** *P* = NS **Harms:** NR **Modifiers:** No girl in G1 showed any improvement in either IQ/PBCL; in G2, only 1 improved on IQ and 2 improved on PBCL. Boys IQ improved (*P* = 0.003) and PBCL improved (*P* = 0.03) Improvement in IQ significantly associated in G1 with low SES status (*P* = 0.04), age < 42 months (*P* = 0.001), and family stress QRS-F >160 (*P* = 0.02). Improvement in PBCL significantly associated with age < 42 months (*P* = 0.04) in G1 but not in G2.

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Silva et al., 2007 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic and home **Enrollment period:** August 2005 **Funding:** Spirit Mountain community fund & Brigid Kildare **Author industry relationship disclosures:** NR **Design:** RCT with continuation **Note:** See related papers Silva et al., 2008, 2009 {#58:#5051}	**Intervention:** Qigong Massage movements (Cignolini methodology) Treatment given twice weekly for two 5 week periods with 5 weeks in-between by trained practitioner; parent administers the same treatment at least once daily for 5 months Children stratified into 3 groups according to Battele Developmental Inventory cognitive scores then randomly assigned to treatment and control within each cognitive group All children attended pre-school classrooms 2-4 times/week for 2 hours at the Willamette Education Service District **Assessments:** Principal author provided initial evaluation of child, including administering Batelle Developmental Inventory Blinded examiners administered VABS and ABC tests and parents completed a sensory profile questionnaire pre- and post-treatment; exit interview with parents administered post-treatment. Several treatment visits and the exit interview were videotaped. **Groups:** **G1:** Cignolini method **G2:** controls **Provider:** Parent and trained practitioner **Measure of treatment fidelity reported:** NR	**Inclusion criteria:** • Formal diagnosis of uncomplicated autism according to DSM-IV • Age up to 6 years • Parental commitment to give massage every day for 5 months and get the child to the clinic to get prescription from the doctor 20 times • Willingness of the parent not to try any new treatments while in this study **Exclusion criteria:** • Children with other neurological conditions such as seizures • Chronic medication **Age, years (range):** 4.83 (3-6) **Mental age:** NR **Gender, n (%):** Male: 13 (86.7) Female: 2 (13.3) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In study **Diagnostic tool/method:** DSM-IV by medical specialists **Diagnostic category, n (%):** Autism: 15 (100) **Other characteristics:** NR	**Social skills:** VABS socialization, score, mean: **G1:** 29.8 **G2:** 24.7 **Communication/ language:** VABS receptive language score, mean: **G1:** 33.8 **G2:** 23.6 VABS expressive language score, mean: **G1:** 31.5 **G2:** 24.4 **Adaptive behavior:** ABC score, mean: **G1:** 71.3 **G2:** 87.7 VABS daily living skills, mean: **G1:** 28.8 **G2:** 24.1 **Motor skills:** VABS gross motor skills score, mean: **G1:** 37.5 **G2:** 33.4 VABS fine motor skills, mean: **G1:** 36 **G2:** 29 **Sensory:** Sensory profile score, mean: Total (items A-N): **G1:** 16.2 **G2:** 15.7 Processing (items A-F): **G1:** 7.2 **G2:** 7.1 Modulation (items G-K): **G1:** 5.3 **G2:** 5	**Social skills:** VABS socialization, score, mean change: **G1:** 10 **G2:** 4.7 **G1/G2:** $P = 0.04$ **Communication/ language:** VABS receptive language score, mean change: **G1:** 8.3 **G2:** 10.6 **G1/G2:** *P* = NS VABS expressive language score, mean change: **G1:** 8.9 **G2:** 6.7 **G1/G2:** *P* = NS **Adaptive behavior:** ABC score, mean change: **G1:** -13.3 **G2:** -24.3 **G1/G2:** *P* = NS VABS daily living skills, mean change: **G1:** 9.8 **G2:** 0.9 **G1/G2:** $P = 0.02$ **Motor skills:** VABS gross motor skills score, mean change: **G1:** 6.5 **G2:** 0.9 **G1/G2:** *P* = NS VABS fine motor skills, mean change: **G1:** 8.8 **G2:** 7.6 **G1/G2:** *P* = NS
Silva et al., 2007 (continued)	**Co-interventions held stable during treatment:** See inclusion criteria **Concomitant therapies, n (%):**		Behavioral/emotional abnormality (items L-N): **G1:** 3.6 **G2:** 3.6	**Sensory:** Sensory profile score, mean change: Total (items A-N):

Evidence Table. Therapies for children with ASD

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	Speech therapy: 4/15 (26) **N at enrollment:** **G1:** 8 **G2:** 7 **N at follow-up:** **G1:** 13* **G2:** 7		Factor scale (factors 1-8): **G1:** 8.5 **G2:** 8.7	**G1:** -5.4 **G2:** 2.7 **G1/G2:** $P = 0.01$ Processing (items A-F): **G1:** -2.4 **G2:** 1 **G1/G2:** $P = 0.01$ Modulation (items G-K): **G1:** -1.9 **G2:** 1 **G1/G2:** $P = 0.02$ Behavioral/emotional abnormality (items L-N): **G1:** -1.1 **G2:** 0.7 **G1/G2:** $P = 0.02$ Factor scale (factors 1-8): **G1:** -3.1 **G2:** 1.4 **G1/G2:** $P = 0.02$ **Medical:** Improvement in bowel and sleep abnormalities, n: **G1:** 8/8 **G2:** 0 **Harms:** NR **Modifiers:** NR

Comments: *The authors state that because the treatment was beneficial, after the RCT phase the 7 controls were offered the treatment. One child could not participate because of his mother's severe health problems, and one child began treatment but moved from the area after completing only 9 weeks. The pre- and post-treatment measures of 5 controls in the continuation phase are included in the baseline and outcome measures reported (the authors do not report the measures separately for the original treatment group and continuation group).
** The authors do not report standard deviations or standard errors, but do report the Kruskal Wallace H statistic.

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Sofronoff et al., 2007 **Country:** Australia **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Apex Autism Trust Foundation **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Cognitive Behavior Therapy for Anger Management, sessions included exploration of different feelings, methods for "fixing" the feelings, relaxation techniques, recruiting help to restore positive feelings, and social stories; 2 hours per week for 6 weeks **Assessments:** Therapists assessed children individually with WISC; child completed anger measures (Dylan, What makes me angry); parents completed Children's Inventory of Anger **Groups:** **G1:** intervention **G2:** waitlist control **Provider:** Postgraduate students from clinical psychology program trained in the technique in a one-day workshop **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 24 **G2:** 21 **N at follow-up:** **G1:** 24 **G2:** 21	**Inclusion criteria:** • Primary diagnosis of Asperger syndrome from a pediatrician and interview with parents based on DSM-IV criteria and CAST **Exclusion criteria:** • See inclusion criteria **Age, years ± SD (range):** **G1:** 10.79 ± 1.12 (9.8-13.6) **G2:** 10.77 ± 0.87 (10.1-13.0) **Mental age:** IQ (WISC-III), mean ± SD (range): **G1:** 105.24 ± 22.3 (95-132) **G2:** 108.7 ± 21.6 (101-127) **Gender, n (%):** Male: **G1:** 23 (96) **G2:** 20 (95) Female: **G1:** 1 (4) **G2:** 1 (5) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral and in-study confirmation **Diagnostic tool/method:** Semi-structured interview and CAST based on DSM-IV criteria **Diagnostic category, n (%):** Asperger's: 45 (100) **Other characteristics, n (%):** ADHD diagnosis: **G1:** 11 (46) **G2:** 9 (43)	**Problem behavior:** Children's Inventory of Anger score, mean: Total: **G1:** 108.7 **G2:** 109.1 Frustration: **G1:** 28.6 **G2:** 28.9 Physical aggression: **G1:** 25.1 **G2:** 24.1 Peer relationships: **G1:** 23.8 **G2:** 24.4 Authority relationships: **G1:** 29 **G2:** 28 Parent monitoring of instances of anger, mean ± SD: **G1:** 8.7 ± 4.4 **G2:** 7.6 ± 4.3 Parent monitoring of anger management, mean ± SD:* Parent confidence: **G1:** 4.3 ± 2.2 **G2:** 4.9 ± 2 Child confidence: **G1:** 2.7 ± 1.7 **G2:** 2.9 ± 2	**Problem behavior:** Children's Inventory of Anger score, mean: Total: Post-treatment: **G1:** 100.7 **G2:** 108.1 **G1/BL:** *P* < 0.0001 **G2/BL:** *P* = NS 6 week follow-up: **G1:** 97.4 **G2:** 108.1 **G1/BL:** *P* < 0.001 **G2/BL:** *P* = NS Frustration: Post-treatment: **G1:** 26.1 **G2:** 28.4 **G1/BL:** *P* < 0.0001 **G2/BL:** *P* = NS 6 week follow-up: **G1:** 24.7 **G2:** 28.4 **G1/BL:** *P* < 0.0001 **G2/BL:** *P* = NS Physical aggression: Post-treatment: **G1:** 25.2 **G2:** 23.0 **G1/BL:** *P* = NS **G2/BL:** *P* = NS 6 week follow-up: **G1:** 25.4 **G2:** 28.6 **G1/BL:** *P* = NS **G2/BL:** *P* = NS Peer relationships: Post-treatment: **G1:** 22.3 **G2:** 23.4 **G1/BL:** *P* < 0.05 **G2/BL:** *P* = NS

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Sofronoff et al., 2007 (continued)				6 week follow-up: **G1:** 21.7 **G2:** 23.4 **G1/BL:** *P* < 0.05 **G2/BL:** *P* = NS Authority relationships: Post-treatment: **G1:** 26.7 **G2:** 28.3 **G1/BL:** *P* < 0.0001 **G2/BL:** *P* = NS **G1/G2:** *P* < 0.02 6 week follow-up: **G1:** 25.7 **G2:** 28.3 **G1/BL:** *P* < 0.05 **G2/BL:** *P* = NS Parent monitoring of instances of anger, mean ± SD: Post-treatment: **G1:** 3.7 ± 3.9 **G2:** 7.9 ± 5.1 **G1/BL:** *P* < 0.0001 **G2/BL:** *P* = NS **G1/G2:** *P* < 0.005 6-week follow-up: **G1:** 3.2 ± 3.9 **G2:** 7.9 ± 5.1 **G1/BL:** *P* < 0.0001 **G2/BL:** *P* = NS Parent monitoring of anger management, mean ± SD:* Parent confidence: Post-treatment: **G1:** 6 ± 1.6 **G2:** 5.2 ± 2.1 **G1/BL:** *P* < 0.001 **G2/BL:** *P* = NS 6-week follow-up: **G1:** 6.1 ± 1.9 **G2:** 5.2 ± 2.1 **G1/BL:** *P* < 0.001 **G2/BL:** *P* = NS
Sofronoff et al., 2007 (continued)				Child confidence Post-treatment: **G1:** 4.1 ± 1.7 **G2:** 2.9 ± 2.2 **G1/BL:** *P* <

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				0.0001 **G2/BL:** *P* = NS 6-week follow-up: **G1:** 5.2 ± 1.9 **G2:** 2.9 ± 2.2 **G1/BL:** *P* < 0.0001 **G2/BL:** *P* = NS **G1/G2:** *P* < 0.0001 **Harms:** NR **Modifiers:** NR

Comments: *scale of 1-10: 1 not confident at all, 10 extremely confident

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Solomon et al., 2007 **Country:** US **Practice setting:** Academic **Intervention setting:** Home **Enrollment period:** October 2000 to February 2002 **Funding:** Fee for service and foundation grant **Author industry relationship disclosures:** NR **Design:** Case series, prospective	**Intervention:** PLAY parent training program: trained consultants visit home monthly for 3-4 hours to teach parents intensive 1:1 play-based services (modeling, coaching, video assessment, written objectives). Parents attended 1 day workshop by lead author on play-based DIR methods. **Assessments:** FEAS, clinical rating by home consultant at baseline and 1 year, family log of PLAY hours at home, and client satisfaction survey Videotaped assessments and half-day/month home visits **Groups:** **G1:** PLAY intervention **Provider:** Three trained home consultants: one MSW and two recreational therapists **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies, n (%):** Early intervention (under age 3, about 2 hours/wk): 12 (18) Special education preschool programs (age 3 and older): 56 (82) **N at enrollment:** **G1:** 74 **N at follow-up:** **G1:** 68	**Inclusion criteria:** • Diagnosis of autistic disorder, PDD-NOS/ Asperger syndrome according to DSM-IV criteria • Between 18 months and 6 years old at time of diagnosis **Exclusion criteria:** • Live more than 60 miles from Ann Arbor, MI • Participation in other intensive intervention more than 10 hrs/week with 1:1 or 1:2 teacher to pupil ratio • Severe medical disability **Age, years (SE) (range):** 3.7 (0.2) (2-7) **Mental age:** NR **Gender, n (%):** Male: 51 (75) Female: 17 (25) **Race/ethnicity, n (%):** White: 65 (96) African-American: 3 (4) **SES:** Parents with bachelor's degrees or above, %: 70 (approximately) Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** DSM-IV **Diagnostic category, n:** Severe autism: 10 Moderate autism: 22 Mild Autism: 18 PDD-NOS: 14 Aspergers: 3 Down's syndrome: 1 Seizure disorders: 2 **Other characteristics:** Mother's age, mean (range): 37 (28-49) Father's age, mean (range): 38 (27-53)	**Emotional:** FEAS score, caregivers, mean: **G1:** 86 FEAS score, children, mean: **G1:** 38 Scaled FEAS score, children, mean: **G1:** 3.6 Clinical rating, mean: **G1:** 2.5	**Emotional:** FEAS score, caregivers, mean: **G1:** 86 **G1/BL:** *P* = NS FEAS score, children, mean: **G1:** 45 **G1/BL:** *P* ≤ 0.0001 Scaled FEAS score, children, mean: **G1:** 4.5 **G1/BL:** *P* ≤ 0.0001 Clinical rating, mean: **G1:** 4.2 **G1/BL:** *P* ≤ 0.0001 Good to very good functional development progress, %:* FEAS scores: 45.5 Clinical rating: 85.3 Family survey result, n: Very satisfied: 35/50 Somewhat satisfied: 10/50 Unsatisfied: 5/50 **Harms:** NR **Modifiers:** No significant relationship found between initial ASD severity and FEAS total or scaled scores. Marginal association between hours/week of intervention and lower scaled FEAS scores (*P* = 0.09).
Solomon et al., 2007 (continued)		Married, %: 91 Number of siblings, mean (range): 0.75 (0-3)		

Comments: *Clinicians over-rated improvements compared to FEAS scores.

Author:	Intervention:	Inclusion criteria:	Overall ratings:	Overall ratings:

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Tsang et al., 2007 **Country:** China **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** NR **Funding:** Providence Foundation Limited; Committee on Conference and Research Grants, The University of Hong Kong; Research Grants Council of the Hong Kong Special Administrative Region **Author industry relationship disclosures:** NR **Design:** Prospective cohort	Chinese version of TEACCH for 12 months, 7 hours/day, 5 days/week vs. varied non-TEACCH full-time training, 5 days/ week **Assessments:** CPEP-R, Merrill Palmer Scale and HKBABS administered; context NR **Groups:** **G1:** TEACCH training **G2:** varied non-TEACCH **Provider:** NR **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** Yes **Concomitant therapies:** Individualized or group treatment by speech, occupational or physiotherapist as needed; numbers NR **N at enrollment:** **G1:** 18 **G2:** 16 **N at 6 month follow-up:** **G1:** 18 **G2:** 16 **N at 12 month follow-up:** **G1:** 18 **G2:** 2	• Formally diagnosed with PDD including autistic disorder and PDD-NOS by DSM-IV • No prior exposure to structured teaching, TEACCH • Randomly selected from preschool children with autism studying at Heep Hong Society (G1) • Recruited from Preschool Parents' Association & Child Assessment Centres of the Department of Health (G2) **Exclusion criteria:** • See inclusion criteria **Age, years ± SD (range):** **G1:** 4.06 ± 0.53 (3-5) **G2:** 4.05 ± 0.73 (3-5) **Mental age:** See baseline measures **Gender, n (%):** Male: **G1:** 17 (94.4) **G2:** 12 (75) Female: **G1:** 1 (5.6) **G2:** 4 (25) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** See inclusion criteria **Diagnostic tool/method:** DSM-IV **Diagnostic category:** See inclusion creteria **Other characteristics:** IQ, mean ± SD: **G1:** 59.97 ± 11.10 **G2:** 74.22 ± 18.06	Merrill-Palmer raw score, mean ± SD: **G1:** 29.22 ± 15.98 **G2:** 49.62 ± 28.02 Merrill-Palmer mental age, mean ± SD: **G1:** 28.11 ± 6.21 **G2:** 36.06 ± 10.94 HKBABS sum of standard scores, mean ± SD: **G1:** 231.11 ± 22.99 **G2:** 290.69 ± 444.73 **Educational/ cognitive/ academic attainment:** CPEP-R score, mean ± SD: Cognitive performance: **G1:** 5.22 ± 2.65 **G2:** 10.50 ± 7.47 Cognitive verbal: **G1:** 1.11 ± 1.28 **G2:** 8.44 ± 7.55 Developmental scale total: **G1:** 45.44 ± 13.67 **G2:** 75.62 ± 32.03 **Social skills:** HKBABS total score, mean ± SD: Socialization: **G1:** 27.06 ± 8.33 **G2:** 48.81 ± 15.98 **Communication/ language:** CPEP-R score, mean ± SD: Imitation: **G1:** 4.22 ± 3.10 **G2:** 8.19 ± 6.58 Perception: **G1:** 7.28 ± 2.56 **G2:** 8.88 ± 4.48	Merrill-Palmer raw scores, mean ± SD: 6 months: **G1:** 40.78 ± 16.79 **G2:** 59.75 ± 22.14 **G1/BL:** P ≤ 0.001 **G2/BL:** P ≤ 0.001 **G1/G2:** P = NS* ANOVA: time (P ≤ 0.001) 12 months: **G1:** 48.00 ± 19.55 **G1/6M:** ≤ 0.01 ANOVA: time (P ≤ 0.001) Merrill-Palmer mental age, mean ± SD: 6 months: **G1:** 32.78 ± 6.30 **G2:** 40.12 ± 8.64 **G1/BL:** P ≤ 0.001 **G2/BL:** P ≤ 0.001 **G1/G2:** P = NS* 12 months: **G1:** 35.44 ± 7.38 **G1/6M:** P ≤ 0.01 ANOVA: time (P ≤ 0.001)CPEP-R score, mean ± SD: HKBABS sum of standard scores, mean ± SD: 6 months: **G1:** 226.39 ± 31.38 **G2:** 315.19 ± 60.00 **G1/BL:** P = NS **G2/BL:** P ≤ 0.01 **G1/G2:** P ≤ 0.05* 12 months: **G1:** 232.28 ± 31.86 **G1/6M:** P = NS ANOVA: time (P ≤ NS)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Tsang et al., 2007 (continued)		Ratio of mental retardation: limited intelligence or above: **G1:** 14:4 **G2:** 7:9	HKBABS total score, mean ± SD: Communication: **G1:** 20.56 ± 9.40 **G2:** 66.62 ± 30.92 **Adaptive behavior:** HKBABS total score, mean ± SD: Daily living skills: **G1:** 42.33 ± 12.89 **G2:** 62.62 ± 24.42 **Motor skills:** CPEP-R score, mean ± SD: Fine motor: **G1:** 8.89 ± 1.97 **G2:** 9.50 ± 4.87 Gross motor: **G1:** 13.22 ± 2.88 **G2:** 12.87 ± 5.51 Eye-hand coordination: **G1:** 5.50 ± 2.20 **G2:** 7.06 ± 4.65 HKBABS total score, mean ± SD: Motor skills: **G1:** 49.89 ± 11.86 **G2:** 61.50 ± 12.20	**Educational/ cognitive/ academic attainment:** Cognitive performance: 6 months: **G1:** 7.00 ± 3.16 **G2:** 13.19 ± 8.96 **G1/BL:** P ≤ 0.01 **G2/BL:** P = NS **G1/G2:** P = NS* 12 months: **G1:** 8.28 ± 4.04 **G1/6M:** P = NS ANOVA: time (P ≤ 0.001) Cognitive verbal: 6 months: **G1:** 3.50 ± 3.15 **G2:** 11.12 ± 8.27 **G1/BL:** P ≤ 0.001 **G2/BL:** P = NS **G1/G2:** P = NS* 12 months: **G1:** 5.00 ± 4.42 **G1/6M:** P ≤ 0.01 ANOVA: time (P ≤ 0.001) Developmental scale total: 6 months: **G1:** 56.89 ± 15.66 **G2:** 87.25 ± 30.68 **G1/BL:** P ≤ 0.001 **G2/BL:** P ≤ 0.001 **G1/G2:** P = NS* 12 months: **G1:** 62.39 ± 17.80 **G1/6M:** P ≤ 0.05 ANOVA: time (P ≤ 0.001) **Social skills:** HKBABS total score, mean ± SD: Socialization: 6 months: **G1:** 29.61 ± 8.26 **G2:** 58.44 ± 19.10 **G1/BL:** P = NS **G2/BL:** P ≤ 0.01 **G1/G2:** P = NS*
Tsang et al., 2007 (continued)				12 months: **G1:** 35.33 ± 12.09 **G1/6M:** P ≤ 0.01 ANOVA: time

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				(P ≤ 0.001) **Communication/ language:** CPEP-R score, mean ± SD: Imitation: 6 months: **G1:** 6.50 ± 3.48 **G2:** 9.37 ± 6.43 **G1/BL:** P ≤ 0.001 **G2/BL:** P = NS **G1/G2:** P = NS* 12 months: **G1:** 7.22 ± 3.87 **G1/6M:** P = NS ANOVA: time (P ≤ 0.001) Perception: 6 months: **G1:** 8.89 ± 2.54 **G2:** 8.62 ± 5.52 **G1/BL:** P ≤ 0.001 **G2/BL:** P = NS **G1/G2:** P ≤ 0.05* 12 months: **G1:** 9.39 ± 2.59 **G1/6M:** P = NS ANOVA: time (P ≤ 0.001) HKBABS total score, mean ± SD: Communication: 6 months: **G1:** 28.56 ± 12.37 **G2:** 83.25 ± 34.42 **G1/BL:** P ≤ 0.01 **G2/BL:** P ≤ 0.001 **G1/G2:** P = NS* 12 months: **G1:** 40.11 ± 20.47 **G1/6M:** P ≤ 0.01 ANOVA: time (P ≤ 0.001)
Tsang et al., 2007 (continued)				**Adaptive behavior:** HKBABS total score, mean ± SD: Daily living skills: 6 months: **G1:** 46.67 ± 12.31 **G2:** 79.00 ± 23.45 **G1/BL:** P ≤ 0.05 **G2/BL:** P ≤ 0.001 **G1/G2:** P ≤ 0.001*

Evidence Table. Therapies for children with ASD

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				12 months: **G1:** 58.56 ± 18.62 **G1/6M:** P ≤ 0.001 ANOVA: time (P ≤ 0.001) **Motor skills:** CPEP-R score, mean ± SD: Fine motor: 6 months: **G1:** 10.67 ± 1.61 **G2:** 9.69 ± 5.61 **G1/BL:** P ≤ 0.001 **G2/BL:** P = NS **G1/G2:** P ≤ 0.01* 12 months: **G1:** 10.67 ± 1.61 **G1/6M:** P = NS ANOVA: time (P ≤ 0.001) Gross motor: 6 months: **G1:** 14.44 ± 2.33 **G2:** 12.62 ± 7.09 **G1/BL:** P ≤ 0.01 **G2/BL:** P = NS **G1/G2:** P ≤ 0.05* 12 months: **G1:** 14.44 ± 2.38 **G1/6M:** P = NS ANOVA: time (P ≤ 0.05) Eye-hand coordination: 6 months: **G1:** 6.50 ± 2.50 **G2:** 9.44 ± 5.81 **G1/BL:** P ≤ 0.05 **G2/BL:** P = NS **G1/G2:** P = NS*
Tsang et al., 2007 (continued)				12 months: **G1:** 7.39 ± 3.05 **G1/6M:** P ≤ 0.05 ANOVA: time (P ≤ 0.001) HKBABS total score, mean ± SD: Motor skills: 6 months: **G1:** 53.94 ± 10.78 **G2:** 65.62 ± 12.02 **G1/BL:** P ≤ 0.05 **G2/BL:** P ≤ 0.001 **G1/G2:** P = NS* 12 months: **G1:** 59.11 ± 10.05

Evidence Table. Therapies for children with ASD

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				G1/6M: P ≤ 0.001 ANOVA: time (P ≤ 0.001) **Harms:** NR **Modifiers:** NR

Comments: *after controlling for age, IQ and baseline scores

Author: Vorgraft et al., 2007 **Country:** Israel Practice **setting:** Academic **Intervention setting:** Residential and home **Enrollment period:** 1997 to 1999 **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Case series, retropective	**Intervention:** Mifne treatment: family attends a residential treatment facility for 3 weeks; therapy is provided together and separately for each family member, followed by intensive home care for 6-18 months, and a gradual integration into nursery. Reciprocal play therapy attempts to gradually introduce social interactions to the child by using the child's lead. **Assessments:** Assessments by trained raters of videotapes of child in home and clinic (Mifne) settings CARS, SBRS **Groups:** **G1:** Mifne treatment **Ga:** baseline CARS total score ≤ 27 **Gb:** baseline CARS total score ≥ 28 **Provider:** OT, physiotherapists, psychologists, social workers, and speech therapists trained for 1.5 years and accredited **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 23 **G1a:** 14 **G1b:** 9 **N at follow-up:** **G1:** 23	**Inclusion criteria:** • Children with PDD treated at the Mifne Institute for whom full documentation was available • DSM-IV diagnosis by consultant child and adolescent psychiatrists • Diagnosis confirmation by two senior clinicians on the study team after chart review **Exclusion criteria:** • See inclusion criteria **Age, months ± SD (range):** 42.8 ± 11.4 (38-49) **Mental age:** NR **Gender, n (%):** Male: 15 (65) Female: 8 (35) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In study **Diagnostic tool/method**: Based on DSM-IV **Diagnostic category, n (%):** Autistic disorder: 14 (61) PDD-NOS: 9 (39) **Other characteristics, n (%):** Intellectual impairment: 2 (9) Specific developmental language disorder: 1 (4)	**Overall ratings:** CARS score, home video, mean ± SD: Total: **G1:** 27.7 ± 6.1 Emotional response: **G1:** 2 ± 0.8 Fearful and nervous response: **G1:** 1.8 ± 0.0 Overall impression: **G1:** 2.9 ± 0.7 CARS score, Mifne video, mean ± SD: Total: **G1:** 29.7 ± 7.1 Emotional response: **G1:** 2.4 ± 0.7 Fearful and nervous response: **G1:** 1.6 ± 0.9 Overall impression: **G1:** 2.7 ± 0.7 SBRS score, home video, mean ± SD: Total: **G1:** 46 ± 8.1 Awareness of others' emotional states: **G1:** 3.3 ± 0.7 Mutuality: **G1:** 3.7 ± 0.5 Overall impression: **G1:** 3 ± 0.8 SBRS score, Mifne video, mean ± SD: Total: **G1:** 48.5 ± 7.9 Awareness of others' emotional states: **G1:** 3.5 ± 0.6 Joint positive emotional experiences: **G1:** 3.4 ± 0.7	**Overall ratings:** CARS score, home video, mean ± SD: Total: **G1:** 24.5 ± 5.3 **G1/BL:** *P* = NS Emotional response: **G1:** 1.8 ± 0.8 **G1/BL:** *P* < 0.05 Fearful and nervous response: **G1:** 1 ± 0.0 **G1/BL:** *P* < 0.05 Overall impression: **G1:** 2.5 ± 0.8 **G1/BL:** *P* < 0.05 CARS total score, home video, mean change ± SD: **G1a:** -0.27 ± 3.6 **G1b:** 7.56 ± 7.8 **G1a/BL:** *P* = NS **G2a/BL:** *P* < 0.05 CARS score, Mifne video, mean ± SD: Total: **G1:** 26.7 ± 6 **G1/BL:** *P* < 0.01 Emotional response: **G1:** 2 ± 0.4 **G1/BL:** *P* < 0.05 Fearful and nervous response: **G1:** 1.1 ± 0.3 **G1/BL:** *P* < 0.05 Overall impression: **G1:** 1.7 ± 0.5 **G1/BL:** *P* < 0.05 CARS total score, Mifne video, mean change ± SD:

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G1a: 0.25 ± 4.8 **G1b:** 5.82 ± 6.3 **G1a/BL:** *P* = NS **G2a/BL:** *P* < 0.01

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Vorgraft et al., 2007 (continued)			Emotional availability: **G1:** 3.1 ± 0.9 Reactions to social initiative: **G1:** 3.1 ± 0.8 Overall impression **G1:** 3 ± 0.9	SBRS score, home video, mean ± SD: Total: **G1:** 41.2 ± 7.6 **G1/BL:** *P* < 0.01 Awareness of others' emotional states: **G1:** 2.8 ± 0.9 **G1/BL:** *P* < 0.05 Mutuality: **G1:** 3.1 ± 0.7 **G1/BL:** *P* < 0.05 Overall impression: **G1:** 2.5 ± 0.8 **G1/BL:** *P* < 0.05 SBRS score, home video, mean change ± SD: **G1a:** 1.27 ± 4.8 **G1b:** 9.11 ± 8.3 **G1a/BL:** *P* = NS **G2a/BL:** *P* < 0.01 SBRS score, Mifne video, mean ± SD: Total: **G1:** 44 ± 1.4 **G1/BL:** *P* < 0.01 Awareness of others' emotional states: **G1:** 3 ± 0.8 **G1/BL:** *P* < 0.05 Joint positive emotional experiences: **G1:** 2.8 ± 0.7 **G1/BL:** *P* < 0.05 Emotional availability: **G1:** 2.5 ± 0.7 **G1/BL:** *P* < 0.05 Reactions to social initiative: **G1:** 2.4 ± 0.7 **G1/BL:** *P* < 0.05
Vorgraft et al., 2007 (continued)				Overall impression: **G1:** 2.4 ± 0.7 **G1/BL:** *P* < 0.05 SBRS score, Mifne video, mean change ± SD:

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G1a: 2.92 ± 8.4 **G1b:** 6.27 ± 7.3 **G1a/BL:** *P* = NS **G2a/BL:** *P* < 0.05 **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Wong et al., 2007 **Country:** US **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective case series **Note:** See related study Gulsrud et al. 2007{#2578}, Jahromi et a. 2009{#3615}, Kasari et al. 2008{#184}, and Kasari et al. 2006{#540}	**Intervention:** Targeted intervention for play skills focused on improving functional and symbolic play skills; targeted intervention for joint attention skills. Both interventions occurred daily for 30 minutes by trained interventionist: starting with Naturalistic I conditions at the table for approximately 5-8 minutes, followed by Naturalistic II floor conditions for approximately 20-25 minutes **Assessments:** Before start of treatment: MSEL, RDLS, SPA, ESCSA, M-CIA **Groups:** **G1:** play skills **G2:** joint attention **Provider:** Trained interventionist **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 21 **G2:** 20 **N at follow-up:** **G1:** 21 **G2:** 20	**Inclusion criteria:** • Preschool-aged children with autism in early intervention program • Staying in preschool program > 1 month and not involved in other educational programs **Exclusion criteria**: • Seizures • On medication • Associated sensory or physical disorders • Comorbidity with other syndromes or diseases **Age, months ± SD:** **G1:** 42.67 ± 6.92 **G2:** 43.2 ± 7.05 **Mental age, months ± SD:** **G1:** 24.55 ± 8.09 **G2:** 26.29 ± 8.71 **Gender, n (%):** Male: **G1:** 16 (76) **G2:** 15 (75) Female: **G1:** 5 (24) **G2:** 5 (25) **Race/ethnicity, n (%):** Caucasian: **G1:** 16 (76) **G2:** 16 (80) Hispanic: **G1:** 1 (5) **G2:** 0 Asian: **G1:** 2 (10) **G2:** 1 (5) Other: **G1:** 2 (10) **G2:** 3 (15) **SES:** Maternal education, n (%): High school: **G1:** 3 (14) **G2:** 0 Some college: **G1:** 3 (14) **G2:** 2 (10) Special training after high school: **G1:** 1 (5) **G2:** 0	**Communication/ language:** Developmental quotient, mean ± SD: **G1:** 58.90 ± 18.21 **G2:** 58.30 ± 17.18 Reynell developmental language age, months ± SD: Receptive language **G1:** 21.00 ± 9.75 **G2:** 20.55 ± 7.27 Expressive language: **G1:** 21.43 ± 7.59 **G2:** 20.60 ± 6.51	**Educational/ cognitive/ academic attainment:** Days to performance mastery, mean: Naturalistic I conditions: **G1:** 3.24 **G2:** 5.32 **G1/G2:** $P < 0.05$ Naturalistic II conditions: **G1:** 5.2 **G2:** 6.3 **G1/G2:** P = NS **Harms:** NR **Modifiers:** Children with higher mental, receptive and expressive language age reached mastery criteria in fewer days ($P < 0.05$) Significant interaction effect between teaching method and child's developmental quotient ($P = 0.02$) for Naturalistic II conditions. Significant interaction between teaching method & skill domain ($F = 5.04$, $P = 0.03$). G1 showed mastery in significantly fewer days than G2 in the Naturalistic I teaching environment.
Wong et al., 2007 (continued)		Completed college: **G1:** 8 (38) **G2:** 12 (60) Graduate/professional		

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
		training: **G1:** 6 (29) **G2:** 6 (30) Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** ADI-R, ADOS **Diagnostic category, n (%):** Autism: 41 (100) **Other characteristics:** NR		

Comments: Most data is presented in graphs and figures rather than tables.

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Zachor et al., 2007 **Country:** Israel **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Israeli Ministry of Education **Author industry relationship disclosures:** NR **Design:** Prospective cohort **Note:** See related studies: Ben Itzchak et al. 2007, Zachor et al. 2007, Zachor et al. 2009, Ben Itzchak et al. 2007; the overlap among these is not clear	**Intervention:** Participants received either applied behavioral or eclectic treatment. Behavioral was 1-to-1 individualized treatment for 35 hrs/week addressing various skills such as imitation, receptive and expressive language, joint attention, non-verbal communication, pre-academic skills, play, fine motor skills and adaptive living skills. Eclectic was small-group activities supervised by special education teacher, individual therapy with various therapists (i.e., speech and language, occupational and music therapies, and structured cognitive teaching; each provided 2 hr of individual, 1 hr of group therapy, and 1 hr of consultation to the team), and also included parent training to address problem behaviors. **Assessments:** Autism severity: ADI, ADOS Cognitive ability: BSID-II (pre-verbal children), SB-FE **Groups:** **G1:** behavioral **G2:** eclectic **Provider:** Special education teacher, speech and language therapists, occupational therapists, music therapists, behavior analysts **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR	**Inclusion criteria:** • Met DSM-IV criteria for Autism/PDD-NOS **Exclusion criteria:** • Identified medical abnormalities, such as seizures, hearing deficiencies **Age, months (range):** **G1:** 27.7 (22-34) **G2:** 28.8 (23-33) **Mental age:** NR **Gender, n (%):** Male: **G1:** 19 (95) **G2:** 18 (95) Female: **G1:** 1 (5) **G2:** 1 (5) **Race/ethnicity, n (%):** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** ADI **Diagnostic category, n (%):** Autism: **G1:** 19 (95) **G2:** 18 (95) ASD: **G1:** 1 (5) **G2:** 1 (5) **Other characteristics:** NR	**Social skills:** ADOS reciprocal social interaction score, mean ± SD: **G1:** 17.9 ± 6.2 **G2:** 16.3 ± 5.2 **Communication/ language:** ADOS language and communication score, mean ± SD: **G1:** 13.8 ± 4.3 **G2:** 11.8 ± 4.3	**Overall ratings:** ASD diagnostic category, n (%): Autism: **G1:** 11 (55) **G2:** 15 (79) ASD: **G1:** 5 (25) **G2:** 4 (21) Off spectrum: **G1:** 4 (20) **G2:** 0 **G1/G2:** $P < 0.05$ **Social skills:** ADOS reciprocal social interaction score, mean ± SD: **G1:** 11.1 ± 6.7 **G2:** 13.3 ± 4.8 **G1/BL:** $P < 0.001$ **G2/BL:** $P < 0.05$ **G1/G2:** $P = 0.07$ **Communication/ language:** ADOS language and communication score, mean ± SD: **G1:** 7.2 ± 4.1 **G2:** 9.7 ± 3 **G1/BL:** $P < 0.001$ **G2/BL:** $P = 0.07$ **G1/G2:** $P < 0.01$ **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Zachor et al., 2007 (continued)	**Concomitant therapies:** NR **N at enrollment:** **G1:** 20 **G2:** 19 **N at follow-up:** **G1:** 20 **G2:** 19			

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Cohen et al., 2006 **Country:** US **Practice setting:** Community **Intervention setting:** Home and school **Enrollment period:** 1995 to 2000 **Funding:** Valley Mountain Regional Center (Stockton, CA) and the child's Special Education Local Planning Area residence **Author industry relationship disclosures:** NR **Design:** Prospective cohort	**Intervention:** 35-40 hours/week of Early Intensive Behavioral treatment (EIBT) based on Lovaas' UCLA treatment model for 47 weeks/year over 3 years Intervention protocol consisted of in-home 1:1 instruction, peer play training and regular education classroom inclusion At one year into EIBT, the distribution of hours were: • Home instruction for 26-31 hours • Peer play for 3-5 hours • Pre-school for 6-9 hours Comparison group: children meeting criteria for EIBT and whose parents chose other services; controls received services from local public schools. **Assessments:** ADI by certified examiner at baseline; independent licensed psychologist administered standardized behavior observation, parent interview, and developmental tests, including the BSID-R, Merrill-Palmer Scale of Mental Tests, RDLS, and VABS at baseline and annual follow-up **Groups:** **G1:** EIBT **G2:** comparison group **Provider:** Staff and parents **Measure of treatment fidelity reported:** NR **Co-interventions held stable during treatment:** NR	**Inclusion criteria:** • Primary diagnosis of autistic disorder/PDD-NOS based on an evaluation by an independent licensed psychologist and confirmed by ADI-R • Pre-treatment IQ > 35 on the BSID-R • Age 18-42 months at diagnosis and under 48 months at treatment onset • No severe medical limitation or illness including motor or sensory deficits that would preclude a child from participating in 30 hours per week of treatment • Residence within 60 km of the treatment agency • No more than 400 hours of behavioral intervention prior to intake • Parents agreed to participate actively in parent training and generalization and to have an adult present during home intervention hours **Exclusion criteria:** • See inclusion criteria **Age, years ± SD:** **G1:** 30.2 ± 5.8 **G2:** 33.2 ± 3.7 **Mental age:** See baseline measures **Gender, n (%):** Male: **G1:** 18 (85.7) **G2:** 17 (81) Female: **G1:** 3 (14.3) **G2:** 4 (19) **Race/ethnicity:** NR	**Educational/ cognitive/ academic/ attainment:** IQ, mean ± SD: **G1:** 61.6 ± 16.4 **G2:** 59.4 ± 14.7 Merrill-Palmer Scale of Mental Tests score, mean ± SD: **G1:** 82.4 ± 17.3 **G2:** 73.4 ± 11.9 **Communication/ language:** RDLS score, mean ± SD: Comprehension: **G1:** 51.7 ± 15.2 **G2:** 52.7 ± 15.1 Expressive language: **G1:** 52.9 ± 14.5 **G2:** 52.8 ± 14.4 VABS communication score, mean ± SD: **G1:** 69.4 ± 11.8 **G2:** 65.0 ± 6.8 **Adaptive behavior:** VABS score, mean ± SD: Composite: **G1:** 69.8 ± 8.1 **G2:** 70.6 ± 9.6 Daily living skills: **G1:** 73.2 ± 9.2 **G2:** 72.7 ± 12.5 **Social skills:** VABS socialization score, mean ± SD: **G1:** 70.3 ± 10.9 **G2:** 75.1 ± 13.0	**Educational/ cognitive/ academic attainment:** IQ, year 3, mean: **G1:** 87 **G2:** 73 (n=19) **G1/G2:** *P* < 0.05 Children in the average range, n: **G1:** 12 **G2:** 7 **G1/G2:** *P* = NS Regular education classroom placement, year 3, n: **G1:** 17/21* **G2:** 1/21 **G1/G2:** *P* = 0.001 Merrill-Palmer Scale of Mental Tests score, mean change: **G1:** 13 **G2:** 13 (n=16) **G1/G2:** *P* = NS **Communication/ language:** RDLS language comprehension score, mean: **G1:** 72 **G2:** 62 (n=19) **G1/G2:** *P* = 0.06 Children in the average range, n: **G1:** 8 **G2:** 4 **G1/G2:** *P* = NS RDLS expressive language score, mean: **G1:** 78 (n=20) **G2:** 66 (n=19) **G1/G2:** *P* = 0.13 Children in the average range, n: **G1:** 9 **G2:** 6 **G1/G2:** *P* = NS
Cohen et al., 2006 (continued)	**Concomitant therapies:** NR **N at enrollment:** **G1:** 21 **G2:** 21	**SES:** Maternal education, years ± SD: **G1:** 15.3 ± 2.9 **G2:** 13.1 ± 1.6		VABS communication score, mean ± SD: **G1:** NR*** **G2:** NR***

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	N at follow-up: **G1:** 21 **G2:** 21	**G1/G2:** *P* < 0.05 Paternal education, years ± SD: **G1:** 15.8 ± 2.9 **G2:** 11.8 ± 2.3 **G1/G2:** *P* < 0.05 Household income: NR Two parent household, n (%): **G1:** 21 (100) **G2:** 14 (67) **G1/G2:** *P* < 0.05 **Diagnostic approach:** Referral **Diagnostic tool/method:** DSM-IV, ADI-R **Diagnostic category, n (%):** Autism: **G1:** 20 (95.2) **G2:** 15 (71.4) PDD-NOS: **G1:** 1 (4.8) **G2:** 6 (28.6) Aspergers: **G1:** NR **G2:** NR **G1/G2:** *P* < 0.05 **Other characteristics:** NR		**G1/G2:** *P* < 0.05 **Adaptive Behavior:** VABS composite score, mean change: **G1:** 9 (n=20) **G2:** -4 (n=20) **G1/G2:** *P* < 0.01 Children in the average range, n: **G1:** 8 **G2:** 3 **G1/G2:** *P* = 0.10 VABS daily living skills score, mean: **G1:** NR*** **G2:** NR*** **G1/G2:** *P* < 0.05 **Social skills:** VABS socialization score, mean: **G1:** NR*** **G2:** NR*** **G1/G2:** *P* < 0.10 **Harms:** NR **Modifiers:** NR

Comments: *The difference between groups for change in IQ score was no longer significant when father's education was added as a covariate.
**6 children were fully included without assistance, 4 were fading the shadow, and 7 required full shadows.
***data only illustrated graphically.

Author: Eldevik et al., 2006 **Country:** Norway **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** 1993 to 2001 **Funding Agency:** Akershus University Hospital; Helge Morset Fond, Norway; NFBU; Norwegian Red Cross & Stiftelsen	**Intervention:** Low intensity behavioral intervention vs. eclectic treatment Low intensity behavioral intervention was approximately 12 hours/week ABA based on UCLA model behavior therapy for a period of 2 years Eclectic treatment includes at least 2 of the following intervention types: alternative communication, ABA, total communication sensory motor therapies, programs based on the principles of TEACCH Duration of treatment, months ± SD (range): **G1:** 20.3 ± 5.3 (13-28)	**Inclusion criteria:** • Diagnosis of autism and mental retardation by ICD-10 from a licensed psychologist and/or a medical doctor • Age < 6 years at start of treatment • Treatment record indicating 10-20 hours/week of one-to-one treatment • Assessments of intellectual functioning, adaptive behavior and language conducted pretreatment and after two years of treatment **Exclusion criteria:** • Medical conditions that could interfere with treatment, such as uncontrollable epilepsy	**Educational/ cognitive/ academic attainment:** Intellectual functioning (BSID-II, WISC-R, WPPSI-R, SB) ratio score, mean ± SD: **G1:** 41.0 ± 15.2 **G2:** 47.2 ± 14.7 Merrill Palmer nonverbal intelligence score, mean ± SD: **G1:** 68.2 ± 28.3 (n=8) **G2:** 72.0 ± 22.1 Language comprehension (RDLS or PEP-R) ratio score, mean ± SD:	**Educational/ cognitive/ academic attainment:** Intellectual functioning (BSID-II, WISC-R, WPPSI-R, SB) ratio score, mean ± SD: **G1:** 49.2 ± 16.6 **G2:** 44.3 ± 18.9 **G1/G2:** *P* < 0.001 Merrill Palmer non-verbal intelligence score, mean ± SD: **G1:** 76.9 ± 27.2 (n=8) **G2:** 61.5 ± 24.5 **G1/G2:** *P* = NS Language comprehension

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
SOR **Author industry relationship disclosures:** NR **Design:** Retrospective cohort	**G2:** 21.4 ± 6.4 (14-30) **Assessments:** ADI-R at baseline; BSID-II, WPPSI-R, WISC-R, RDLS, PEP-R, VABS, MPS, pathology checklist (1=symptom present, 0=absent) conducted at intake and after 2 years of treatment Supervisors completed retrospective question-naire about the type of treatment or special education each child's program was based on 6 months to 3 years after the rest of the post-treatment assessments **Groups:** **G1:** low-intensity behavioral therapy **G2:** eclectic treatment **Provider:** • Teachers, parents, individual aides, case supervisors • Licensed psychologists	or major motor delays **Age, months ± SD (range):** **G1:** 53 ± 9.5 (36-68) **G2:** 49 ± 16.9 (21-69) **Mental age:** IQ score, mean: 41 **Gender, n:** Male: **G1:** 10 **G2:** 14 Female: **G1:** 3 **G2:** 1 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** ADI-R, clinical judgment by independent professional **Diagnostic category, n:** Autism: 26 PDD-NOS: NR Aspergers: NR	**G1:** 37.3 ± 11.7 **G2:** 44.0 ± 17.7 Expressive language (RDLS or PEP-R) ratio score, mean ± SD: **G1:** 33.8 ±10.6 **G2:** 41.6 ±15.4 **Adaptive behavior:** VABS score, mean ± SD: Composite: **G1:** 52.5 ± 3.9 **G2:** 52.5 ± 9.6 Communication: **G1:** 54.1 ± 7.0 **G2:** 54.7 ± 10.0 Daily living skills: **G1:** 56.7 ± 6.0 **G2:** 54.5 ± 15.2 Socialization: **G1:** 53.7 ± 3.7 **G2:** 59.3 ± 7.8 **Problem behavior:** Pathology checklist score, mean ± SD: No words: **G1:** 0.4 ± 0.5 **G2:** 0.5 ± 0.5	(RDLS or PEP-R) ratio score, mean ± SD: **G1:** 44.3 ± 17.8 **G2:** 33.2 ± 24.7 **G1/G2:** $P < 0.05$ Expressive language (RDLS or PEP-R) ratio score, mean ± SD: **G1:** 44.8 ± 19.2 **G2:** 34.1 ± 26.2 **G1/G2:** $P < 0.05$ **Adaptive behavior:** VABS score, mean ± SD: Composite: **G1:** 52.4 ± 9.2 **G2:** 47.7 ± 10.2 **G1/G2:** P = NS Communication: **G1:** 58.8 ± 12.8 **G2:** 50.2 ± 9.4 **G1/G2:** $P < 0.01$ Daily living skills: **G1:** 53.7 ± 9.9 **G2:** 47.2 ± 14.6 **G1/G2:** P = NS

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Eldevik et al., 2006 (continued)	**Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 13 **G2:** 15 **N at follow-up:** **G1:** 13 **G2:** 13	**Other characteristics:** Therapists per child, range: **G1:** 2-4 **G2:** 2-4	Affectionate: **G1:** 0.9 ± 0.3 **G2:** 0.7 ± 0.5 Toy play: **G1:** 0.8 ± 0.4 **G2:** 0.9 ± 0.4 Peer play: **G1:** 1.0 ± 0.0 **G2:** 0.9 ± 0.4 Stereotypies: **G1:** 1.0 ± 0.0 **G2:** 0.9 ± 0.3 Temper tantrums: **G1:** 0.4 ± 0.5 **G2:** 0.5 ± 0.5 Toilet trained: **G1:** 0.8 ± 0.4 **G2:** 0.6 ± 0.5 Sum pathology: **G1:** 5.3 ± 1.1 **G2:** 4.9 ± 1.6	Socialization: **G1:** 56.2 ± 5.2 **G2:** 57.9 ± 12.1 **G1/G2:** P = NS **Problem behavior:** Pathology checklist score, mean change ± SD: No words: **G1:** -0.3 ± 0.5 **G2:** -0.1 ± 0.3 **G1/G2:** P = NS Affectionate: **G1:** -0.7 ± 0.4 **G2:** -0.2 ± 0.4 **G1/G2:** P < 0.001 Toy play: **G1:** -0.6 ± 0.5 **G2:** -0.3 ± 0.4 **G1/G2:** P < 0.01 Peer play: **G1:** -0.4 ± 0.5 **G2:** 0.0 ± 0.0 **G1/G2:** P < 0.01 Stereotypies: **G1:** -0.1 ± 0.3 **G2:** 0.0 ± 0.0 **G1/G2:** P = NS Temper tantrums : **G1:** -0.3 ± 0.5 **G2:** 0.0 ± 0.5 **G1/G2:** P = NS Toilet trained: **G1:** -0.6 ± 0.5 **G2:** -0.2 ± 0.4 **G1/G2:** P < 0.05 Sum pathology: **G1:** -3.1 ± 1.2 **G2:** -0.7 ± 1.3 **G1/G2:** P < 0.001 **Harms:** NR **Modifiers:** Age associated with intellectual functioning in the eclectic treatment group

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Gevers et al., 2006 **Country:** Netherlands **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Theory of Mind (TOM) to the child, with an average duration of 7 months Social-cognition training to the parents (5 monthly sessions) **Assessments:** Multidisciplinary assessment by a specialized team and parent report TOM Test and VABS assessed prior to training and within 4 weeks after completion of treatment **Groups:** **G1:** TOM and social cognition training **Provider:** Special team **Measure of treatment fidelity reported:** NR **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 18 **N at follow-up:** **G1:** 18	**Inclusion criteria:** • Met DSM-IV criteria for PDD-NOS • WISC-R Verbal IQ > 85 with average intelligence **Exclusion criteria:** • See inclusion criteria **Age years (range):** 8-11 **Mental age:** WISC-R Verbal IQ, mean ± SD: 97.1 ± 14.9 WISC-R Verbal IQ > 85, n (%): 18 (100) **Gender, n (%):** Male: 13 (72.2) Female: 5 (27.8) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** DSM-IV for PDD-NOS **Diagnostic category, n (%):** Autism: NR PDD-NOS: 18 (100) Aspergers: NR **Other characteristics:** NR	**Social skills:** TOM Test score, mean ± SD: Total: **G1:** 52.8 ± 7.8 Perception/ imitation: **G1:** 6.6 ± 1.5 Emotion recognition: **G1:** 5.0 ± 0.0 Pretense: **G1:** 4.1 ± 1.3 Distinction physical-mental: **G1:** 2.8 ± 0.6 TOM 1: **G1:** 18.4 ± 2.4 First order belief: **G1:** 24.3 ± 4.9 False belief: **G1:** 2.6 ± 0.6 TOM 2: **G1:** 27.0 ± 4.8 Second order belief: **G1:** 0.6 ± 0.5 Irony/humor: **G1:** 6.9 ± 2.2 TOM 3: **G1:** 7.7 ± 2.4 **Adaptive behavior:** VABS socialization subdomain score, developmental quotient, mean ± SD: Interpersonal relationships: **G1:** 0.36 ± 0.09 Play/leisure: **G1:** 0.39 ± 0.10 Social skills: **G1:** 0.51 ± 0.13	**Social Skills:** TOM Test score, mean ± SD: Total: **G1:** 62.7 ± 5.2 **G1/BL:** *P* = 0.000 Perception/ imitation: **G1:** 8.2 ± 1.2 **G1/BL:** *P* = 0.000 Emotion recognition: **G1:** 4.9 ± 0.2 **G1/BL:** *P* = NS Pretense: **G1:** 4.8 ± 0.5 **G1/BL:** *P* = 0.039 Distinction physical-mental: **G1:** 2.9 ± 0.2 **G1/BL:** *P* = NS TOM 1: **G1:** 20.9 ± 1.2 **G1/BL:** *P* = 0.000 First order belief: **G1:** 29.6 ± 2.6 **G1/BL:** *P* = 0.001 False belief: **G1:** 2.7 ± 0.6 **G1/BL:** *P* = NS TOM 2: **G1:** 32.3 ± 3.0 **G1/BL:** *P* = 0.001 Second order belief: **G1:** 0.8 ± 0.4 **G1/BL:** *P* = NS Irony/humor: **G1:** 8.7 ± 1.6 **G1/BL:** *P* = 0.002 TOM 3: **G1:** 9.5 ± 1.9 **G1/BL:** *P* = 0.001
Gevers et al., 2006 (continued)				**Adaptive Behavior:** VABS socialization subdomain score, developmental quotient, mean ± SD: Interpersonal relationships: **G1:** 0.42 ± 0.14 **G1/BL:** *P* = 0.021 Play/leisure: **G1:** 0.47 ± 0.10

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G1/BL: P = 0.013 Social skills: **G1:** 0.61 ± 0.15 **G1/BL:** P = 0.000 **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Heimann et al., 2006 **Country:** Norway **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Meltzer Foundation, University of Bergen **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Imitation interaction vs. contingent, non-imitative interaction **Assessments:** PEP-R subscales for imitation, perception, cognitive performance and cognitive verbal administered 4-8 weeks before treatment and again after treatment Social interest composite score created from coding scheme of Nadel et al. 2000 adapted to measure social behaviors in still-face and free play phases **Duration:** Four 3-minute phases of still face procedure, intervention, still-face, and free play initially conducted then repeated after 30-60 minute break Frequency: four-phase procedure conducted twice in one session **Groups:** **G1:** imitation interaction **G2:** contingent interaction **Provider:** NR **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NA **Concomitant therapies, n:** Imitation training: **G1:** 0 **G2:** 2 **N at enrollment:** **G1:** 10 **G2:** 10 **N at follow-up:** **G1:** 10 **G2:** 10	**Inclusion criteria:** • Non-verbal children with autism spectrum disorder by ICD-10 criteria **Exclusion criteria:** • See inclusion criteria **Age, years (range):** 6.42 (4.33, 12.75) **Age, months ± SD:** **G1:** 87.0 ± 32.5 **G2:** 67.4 ± 10.1 **Mental age, years ± SD (range):** 2.08 ± 1.0 (1-4.42) Developmental age, months ± SD: PEP-R: **G1:** 23.2 ± 10.4 **G2:** 27.5 ± 13.5 Perceptual age: **G1:** 27.8 ± 14.0 **G2:** 35.5 ± 20.5 Cognitive non-verbal: **G1:** 22.1 ± 9.3 **G2:** 24.6 ± 13.5 Cognitive verbal: **G1:** 23.9 ± 9.6 **G2:** 23.7 ± 11.1 Imitation age: **G1:** 19.1 ± 12.4 **G2:** 26.3 ± 13.5 Language age (PEP), mean ± SD: **G1:** 23.0 ± 8.9 **G2:** 24.2 ± 12.0 **Gender, n (%):** Male: 19 (95) Female: 1 (5) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral	**Social skills:** Proportion of time displaying social interest, still-face phases, %: **G1:** NR* **G2:** NR* **G1/G2:** *P* = NS Proportion of time displaying social interest, free play phases, %: **G1:** NR* **G2:** NR* **G1/G2:** *P* = NS PEP-R imitation subscale score, mean ± SD: **G1:** 19.1 ± 12.4 **G2:** 26.3 ± 13.6 **G1/G2:** *P* = NS	**Social skills:** Proportion of time displaying social interest, still-face phases, % ± SD: **G1:** 35.23 ± 31.01 **G2:** 12.90 ± 14.59 **G1/BL:** *P* < 0.05 **G2/BL:** *P* = NS **G1/G2:** *P* < 0.05 Proportion of time displaying social interest, free play phases, % ± SD: **G1:** 33.7 ± 14.6 **G2:** 21.5 ± 11.8 **G1/BL:** *P* < 0.05 **G2/BL:** *P* = NS **G1/G2:** *P* < 0.05 PEP-R imitation subscale score, mean change ± SD: **G1:** 6.5 ± 9.6 **G2:** -0.6 ± 2.8 **G1/BL:** *P* < 0.05 **G2/BL:** *P* = NS **G1/G2:** *P* < 0.01 **Harms:** NR **Modifiers:** NR
Heimann et al., 2006 (continued)		**Diagnostic tool/method:** NR **Diagnostic category, n (%):** Autism: 20 (100) **Other characteristics:** NR		

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Comments: *Data only illustrated graphically.				

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Henry et al., 2006 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic (neuro-developmental) **Enrollment period:** July 2001 to January 2004 **Funding:** NR **Author industry relationship disclosures:** None **Design:** Retrospective case series	**Intervention:** Subjects treated with an SSRI:* SSRI, n (%): Sertraline: 31 (34.8) Citalopram: 25 (28.1) Paroxetine: 15 (16.9) Fluvoxamine: 10 (11.2) Fluoxetine: 6 (6.7) Escitalopram: 2 (2.2) Mean dose, mg (SE): Sertraline: 46.7 (47.54) Citalopram:10.42 (6.77) Paroxetine: 10.67 (4.95) Fluvoxamine: 40.28 (33.53) Fluoxetine: 18.33 (14.50) Escitalopram:11.25 (12.37) Treatment duration was 7.8 ± 7.6 months **Assessments:** Diagnosis using DSM-IV, parental interview, child exam, record review by trained child and adolescent psychiatrists SCI-I and CGI-S scales completed by reviewers **Groups:** **G1:** PDD subjects treated with SSRIs **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** NA **Concomitant therapies, n :** Alpha-2 agonists: 22 Psychostimulants: 20 Atypical antipsychotics: 15 Mood stabilizers: 3 Atomoxetine: 6 Gabapentin: 3 Bupropion: 2 Buspirone: 2 Lorazepam: 1 Phenytoin: 1 Levothyroxine: 1	**Inclusion criteria:** • Age 18 or younger • DSM-IV diagnosis of autism, Asperger disorder or PDD-NOS • Subjects treated with an SSRI **Exclusion criteria:** • See inclusion criteria **Age, years ± SD (range):** 8.6 ± 3.4 (3-18) **Mental age:** NR **Gender, n (%):** Male: 80 (90) Female: 9 (10) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** DSM-IV-chart review **Diagnostic category, n (%):** Autism: 50 (56) PDD-NOS: 33 (37) Aspergers: 6 (7) **Other characteristics:** Comorbid Diagnoses, n: ADHD-NOS: 5 Mental retardation: 4 Anxiety disorder NOS: 3 Mood disorder NOS: 3 Oppositional-defiant disorder: 3 Adjustment disorder: 1 PTSD: 1 Cleft lip: 1 Central hypomyleination: 1 Complex II mitochondrial disorder: 1 Seizure disorder: 1 Hypotonia/hypermobility: 1 Lead poisoning: 1	**Overall ratings:** CGI-S score, mean ± SD: **G1:** 4.55 ± 0.71	**Overall ratings:** CGI-I score, mean ± SD: **G1:** 2.93 ± 1.11 Trial outcome, n (%): Much or very much improved: 40/89 (44.9) Worsened: 9/89 (10.1) Failed trial due to AEs or lack of efficacy: 28/89 (31.5) Lost to outside follow-up: 16/89 (18) Drop out, reason unknown: 3/89 (3.4) Response rate by SSRI, %: Sertraline: 55 Citalopram: 44 Paroxetine: 53 Fluvoxamine: 30 Fluoxetine: 0 Escitalopram: 50 (*P* = 0.19) Response rate by indication, %: Anxiety: 48 Perseverations: 44 Aggression: 45 Depressed mood: 60 (*P* = 0.86) Response rate by diagnosis, %: Autism: 46 Asperger disorder: 33 PDD-NOS: 46 (*P* = 0.84) Response rate by family history, % (*P*-value for correlation with positive outcome): PDDs: 72 (*P* = 0.011)**

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Henry et al., 2006 (continued)	**N at enrollment:** **G1:** 89 **N at follow-up:** **G1:** 89	Indications, n: Anxiety: 61 Perseverations: 59 Aggression: 31 Depressed mood: 5 Family history, n: PDDs: 18 Bipolar disorder: 12 Depression: 36 Mood disorder NOS: 2 Obsessive-compulsive Disorder: 10 Panic disorder: 5 Anxiety NOS: 14 Posttraumatic stress disorder: 1 Phobia: 1 Tic disorder: 2 Schizophrenia: 6 Psychosis NOS: 2 Mental retardation: 3 Learning disabililty: 7 Attention-deficit/ hyperactivity disorder: 18 Substance abuse: 12		Bipolar disorder: 33 (*P* = 0.364) Depression: 44 (*P* = 0.874) Mood disorder NOS: 0 (*P* = 0.192) Obsessive-compulsive disorder: 30 (*P* = 0.297) Panic disorder: 60 (*P* = 0.501) Anxiety NOS: 43 (*P* = 0.831) PSD: 0 (*P* = 0.359) Phobia: 100 (*P* = 0.271) Tic disorder: 100 (*P* = 0.117) Schizophrenia: 67 (*P* = 0.28) Psychosis NOS: 100 (*P* = 0.117) Mental retardation: 100 (*P* = 0.108) Learning disabililty: 57 (*P* = 0.517) Attention-deficit/ hyperactivity disorder: 44 (*P* = 0.923) Substance abuse: 25 (*P* = 0.126)
Henry et al., 2006 (continued)				**Harms:** Activation side effects, n (%): Total: 48 (53.9) Agitation: 31 (34.8) Aggression: 9 (10.1) Increased impulsivity: 9 (10.1) Increased distractibility: 6 (6.7) Increased hyperactivity: 9 (10.1) Insomnia: 11 (12.4) Euphoria: 1 (1.1)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				Other side effects, n (%): Diarrhea: 4 (4.5) Decreased appetite: 3 (3.4) Constipation: 3 (3.4) Headaches: 1 (1.1) Tics: 1 (1.1) Stomach upset: 1 (1.1) Increased stereotypy: 1 (1.1) Increased perseverations: 1 (1.1) Increased anxiety: 1 (1.1) Psychosis: 1 (1.1) Yawning: 1 (1.1) Pica: 1 (1.1) Weight gain: 1 (1.1) Priapism: 1 (1.1)
Henry et al., 2006 (continued)				**Modifiers:** 75% of subjects with family history of bipolar disorder have activation side effects (*P* = 0.13; RR = 2.50, 95%CI: 0.73-8.62) No association between age and activation side effects observed

Comments: *For subjects treated with more than one SSRI during this period, only the first trial was analyzed in order to have all the SSRI trials reference separate subjects, keeping the trials independent.
** RR = 3.12, 95% CI: 1.216-8.005

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Jung et al., 2006 **Country:** South Korea **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Korea Research Foundation Grant **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** SIT (based on the virtual reality tangible interaction system, with three components: coordination ability measurement, social skill training, and sensory integration); 10 sessions, length NR **Assessments:** VCAA (a measuring program for visuomotor coordination ability, levels controlled by the therapist, breaking virtual balloons with a real stick, reaction accuracy, movement of the stick, and average reaction time), SST (social skills training) reaction time, measured at each of 10 sessions **Groups:** **G1:** SIT intervention **G2:** healthy controls **Provider:** Therapist **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 12 **G2:** 20 **N at follow-up:** **G1:** 11 **G2:** 20	**Inclusion criteria:** **G1:** • Ages 5-6 years • Met DSM-IV criteria for autism • Recruited from out-patient unit at Children's Hospital in Seoul **G2:** • Unrelated healthy children • Recruited from a kindergarten belonging to a university in Seoul **Exclusion criteria:** • See inclusion criteria **Age, range (years):** **G1:** 6 **G2:** 5-6 **Mental age, mean IQ:** **G1:** 64 **G2:** NR **Gender, n (%):** Male: **G1:** 10 (83.3) **G2:** NR Female: **G1:** 2 (16.6) **G2:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** DSM-IV **Diagnostic category, n (%):** Autism: **G1:** 12 (100) PDD-NOS: **G1:** 0 Aspergers: **G1:** 0	**Sensory:** VCAA reaction time, mean: **G1:** NR* VCAA reaction accuracy, mean: **G1:** NR* VCAA stick movement, mean: **G1:** NR* **Social Skills:** SST reaction time, stopping balloon, mean: **G1:** NR* SST reaction time, moving balloon, mean: **G1:** NR* SST reaction time, reading mind, mean: **G1:** NR	**Sensory:** VCAA reaction time, mean: **G1:** NR* **G2:** NR* **G1/BL:** P = NS **G1/G2:** P < 0.01 (healthy children had lower reaction times) VCAA reaction accuracy, mean: **G1:** NR* **G2:** NR* **G1/BL:** P = NS **G1/G2:** P = NS VCAA average reaction accuracy by sound stimulus, range: **G1:** 51.9-60.2 VCAA stick movement, mean: **G1:** NR* **G2:** NR* **G1/BL:** P = NS **G1/G2:** P < 0.01 (healthy children moved the stick more) **Social Skills:** SST reaction time, stopping balloon, mean ± SD: **G1:** 21.1 ± 10.9 **G2:** 17.6 ± 3.1 **G1/BL:** P < 0.05 (reaction time decreased) **G1/G2:** P = NS SST reaction time, moving balloon, mean ± SD: **G1:** 15.8 ± 5.1 **G2:** 13.8 ± 3.1 **G1/BL:** P = 0.08 (reaction time decreased) **G1/G2:** P = NS

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Jung et al., 2006 (continued)		**Other characteristics:** SMS index, mean: **G1:** 73 **G2:** NR		SST reaction time, reading mind, mean ± SD: **G1:** 19.3 ± 9.7 **G2:** 17.3 ± 4.8 **G1/BL:** P = NS **G1/G2:** P = NS **Harms:** NR **Modifiers:** Boredom; authors report increased preference for unrepeated stimuli such as running as sessions progressed

Comments: *Data only illustrated graphically

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Legoff and Sherman, 2006 **Country:** US **Practice setting:** Private multi-disciplinary autism disorders clinic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** None **Design:** Retrospective cohort	**Intervention:** LEGO intervention vs. comparable (in form and intensity) individual and group therapy on a weekly basis without LEGO materials LEGO-based interactive play groups met on a weekly basis for 90 minutes and engaged in collaborative LEGO building activities and other projects **Groups:** **G1:** LEGO intervention **G2:** control group, **Ga:** autistic disorder **Gb:** Asperger/PDD-NOS **Provider:** Therapist **Measure of treatment fidelity reported:** NR **Co-interventions held stable during treatment:** NR **Concomitant therapies, hrs/week, mean ± SD:** Individual therapy: **G1:** 1.18 ± 0.43 **G2:** 1.30 ± 0.75 **G1/G2:** *P* = NS Group therapy: **G1:** 1.59 ± 0.35 **G2:** 1.61 ± 0.39 **G1/G2:** *P* = NS Family therapy: **G1:** 0.82 ± 0.66 **G2:** 1.05 ± 0.67 **G1/G2:** *P* = NS Therapeutic aide: **G1:** 11.93 ± 13.40 **G2:** 12.07 ± 15.13 **G1/G2:** *P* = NS Speech-language therapy: **G1:** 1.29 ± 0.41 **G2:** 1.35 ± 0.54 **G1/G2:** *P* = NS	**Inclusion criteria:** **G1:** • Participated in both individual and group sessions continuously for at least 3 years • Initial and follow-up assessment data were available **G2:** • Had two complete triannual assessments • Matched the LEGO therapy subjects on subject and treatment variables **Exclusion criteria:** • Participants who started on a new psychiatric medication or changed medications (other than minor changes in dosage) during the 3 year treatment interval **Age, years ± SD:** **G1:** 9.3 ± 1.6 **G2:** 10.1 ± 1.4 **Mental age:** See educational/cognitive/ academic attainment **Gender, n (%):** Male: **G1:** 49 (81.7) **G2:** 47 (82.5) Female: **G1:** 11 (18.3) **G2:** 10 (17.5) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral	**Social skills:** VABS socialization score, mean ± SD: **G1:** 62.27 ± 13.43 **G2:** 59.95 ± 16.48 GARS social interaction, mean ± SD: **G1:** 11.53 ± 1.75 **G2:** 11.00 ± 1.72 **Communication/ language:** VIQ, mean ± SD: **G1:** 82.0 ± 21.6 **G2:** 83.3 ± 18.8 VABS communication score, mean ± SD: **G1:** 67.2 ± 17.4 **G2:** 65.4 ± 19.2 **Educational/ cognitive/ academic attainment:** PIQ, mean ± SD: **G1:** 90.7 ± 17.5 **G2:** 89.3 ± 18.7 Wechsler FSIQ, mean ± SD: **G1:** 84.6 ± 16.6 **G2:** 85.7 ± 17.9	**Social skills:** VABS socialization score, mean change ± SD: **G1:** 20.68 ± 10.32 **G1a:** 21.45 ± 10.05 **G1b:** 19.91 ± 10.30 **G2:** 10.77 ± 10.97 **G2a:** 11.96 ± 11.08 **G2b:** 9.58 ± 10.88 ANOVA: time (P < 0.001), treatment P < 0.01), interaction (G1/BL > G2/BL; P < 0.05) GARS social interaction score, mean change ± SD: **G1:** -3.60 ± 1.38 G1a: -3.82 ± 1.56 G1b: -3.43 ± 1.26 **G2:** -2.30 ± 1.45 G2a: -2.29 ± 1.42 G2b: -2.32 ± 1.55 ANOVA: time (P < 0.001), treatment P < 0.001), interaction (**G1/**BL > G2/BL; P < 0.01) **Communication/ language:** VIQ, mean ± SD: **G1:** 86.3 ± 16.9 **G2:** 79.9 ± 19.0 VABS communication score, mean ± SD: **G1:** 75.0 ± 11.4 **G2:** 70.5 ± 16.9 **Educational/ cognitive/ academic attainment:** Wechsler FSIQ, mean ± SD: **G1:** 90.6 ± 15.8 **G2:** 87.1 ± 18.8

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Legoff and Sherman, 2006 (continued)	Occupational therapy: **G1:** 1.24 ± 0.89 **G2:** 1.19 ± 0.88 **G1/G2:** *P* = NS Physical therapy: **G1:** 0.21 ± 1.17 **G2:** 0.57 ± 1.31 **G1/G2:** *P* = NS Psychiatric medications, n (%): Antipsychotics: **G1:** 14 (23.3) **G2:** 15 (26.3) **G1/G2:** *P* = NS Psychostimulants: **G1:** 18 (30.0) **G2:** 17 (29.8) **G1/G2:** *P* = NS SSRI: **G1:** 9 (15.0) **G2:** 8 (14.0) **G1/G2:** *P* = NS **N at enrollment:** **G1:** 60 **G1a:** 26 **G1b:** 34 **G2:** 57 **G2a:** 24 **G2b:** 33 **N at follow-up:** **G1:** 60 **G1a:** 26 **G1b:** 34 **G2:** 57 **G2a:** 24 **G2b:** 33	**Diagnostic tool/method:** Diagnosis made on basis of comprehensive evaluations by a pediatric neuropsychologist, a child psychiatrist, a child psychologist, and a speech pathologist, all of whom were specialists in autism spectrum disorders **Diagnostic category, n (%):** Autism: **G1:** 26 (43.3) **G2:** 24 (42.1) Asperger's: **G1:** 27 (45.0) **G2:** 28 (49.1) PDD-NOS: **G1:** 7 (11.7) **G2:** PDD-NOS: 5 (8.7) **Other characteristics, n (%):** Diagnosis, axis II: No diagnosis: **G1:** 41 (68.3) **G2:** 39 (68.4) Mild MR: **G1:** 16 (26.7) **G2:** 15 (26.3) Moderate MR: **G1:** 2 (3.3) **G2:** 3 (5.3) MR unspecified: **G1:** 1 (1.7) **G2:** 0 (0.0)		PIQ, mean ± SD: **G1:** 99.3 ± 16.8 **G2:** 90.3 ± 18.1 **Harms:** NR **Modifiers:** No main effect or interaction effect for diagnostic group (G1a, G1b, G2a, G2b) for VABS-SD or GARS-SI In the autistic disorder group, GARS-SI outcome was significantly correlated with initial VABS-CD and VIQ scores (*P* < 0.05) and this relationship was found in both the LEGO and comparison groups Communication ability (measured by the VABS-CD and VIQ) was significantly correlated with outcome on the VABS-CD for both LEGO (*P* < 0.02) and comparison participants (*P* < 0.01)
Legoff and Sherman, 2006 (continued)				Regression analyses of VABS-CD and VIQ predicting VABS-SD difference scores: **G1+G2:** *P* < 0.01 **G1:** *P* < 0.001 **G2:** *P* < 0.004 **Ga:** *P* = NS **Gb:** *P* < 0.001 **G1a:** *P* < 0.021 **G1b:** *P* < 0.019 **G2a:** *P* = NS. **G2b:** *P* < 0.004 Regression analyses of VABS-CD and

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				VIQ predicting GARS-SI difference scores: **G1+G2:** *P* = NS **G1:** *P* = NS **G2:** *P* = NS **Ga:** *P* < 0.021 **Gb:** *P* = NS **G1a:** *P* = NS **G1b:** *P* = NS **G2a:** *P* = NS **G2b:** *P* = NS

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Lopata et al., 2006 **Country:** US **Practice setting:** Academic **Intervention setting:** NR **Enrollment period:** Summer 2003 to Summer 2004 **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective case series with a randomized component (2003 participants were all assigned to G1; 2004 participants age-matched and randomized) **Note:** See follow-up study Lopata et al. 2008 ({#216}), years 3-4 of intervention	**Intervention:** Summer treatment sessions consisting of social skills alone or social skills plus behavioral treatment in groups of 4-6 children with 3 staff members Duration: 6 weeks Frequency: 5 days/week, 6 hours/day **Assessments:** BASC-PRS conducted immediately prior to beginning of program and at completion of treatment; BASC-TRS conducted on day 8 of program and at completion of treatment **Groups:** **G1:** social skills plus behavioral treatment **G2:** social skills only **Provider:** Undergraduate and graduate psychology and education students who received and verified training prior to program **Measure of treatment fidelity reported:** Yes* **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** G1: 12 **G2:** 9 **N at follow-up:** G1: 12 **G2:** 9	**Inclusion criteria:** • Children diagnosed with Aspergers • Completion of three-stage screening process to confirm diagnosis **Exclusion criteria:** • See inclusion criteria **Age, years ± SD (range):** 10.05 ± 2.13 (6-13) **Mental age:** NR **Gender, n (%):** Male: 21 (100) Female: 0 **Race/ethnicity, n (%):** White: 20 (95.24) Hispanic: 1 (4.76) **SES:** Maternal education: NR Household income, n (%): \$25,000-\$35,000: 1/15 (6.7) \$35,001-\$50,000: 2/15 (13.3) \$50,001-\$70,000: 1/15 (6.7) \$70,001-\$95,000: 7/15 (46.7) > \$95,000: 4/15 (26.7) **Diagnostic approach:** Confirmation of diagnosis consisted of documentation of formal Aspergers diagnosis from a licensed psychiatrist, physician, or psychologists, submission of prior testing and evaluation records, and formal assessment of cognitive and social-emotional domain **Diagnostic tool/method:** NR **Diagnostic category, n (%):** Autism: 0 (0) PDD-NOS: 0 (0) Aspergers: 21 (100)	**Social skills:** BASC social skills score, parent-rated, mean ± SD: **G1:** 40.27 ± 9.51 (n=11) **G2:** 40.63 ± 4.31 (n=8) BASC social skills score, teacher-rated, mean ± SD: **G1:** 46.58 ± 7.15 **G2:** 44.78 ± 5.63 **Problem behavior:** BASC atypicality score, parent-rated, mean ± SD: **G1:** 77.27 ± 17.07 (n=11) **G2:** 66.25 ± 14.67 (n=8) BASC atypicality score, teacher-rated, mean ± SD: **G1:** 52.75 ± 6.77 **G2:** 48.67 ± 8.19 **Adaptive behavior:** BASC adaptability score, parent-rated, mean ± SD: **G1:** 30.25 ± 10.08 (n=8) **G2:** 36.83 ± 5.53 (n=6) BASC adaptability score, teacher-rated, mean ± SD: **G1:** 46.56 ± 8.35 (n=9) **G2:** 43.88 ± 9.14 (n=8)	**Social Skills:** BASC social skills score, parent-rated, mean ± SD: **G1:** 43.82 ± 11.21 (n=11) **G2:** 41.88 ± 4.97 (n=8) **G1+G2/BL:** *P* = 0.048 BASC social skills score, teacher-rated, mean ± SD: **G1:** 49.33 ± 7.11 **G2:** 48.89 ± 5.33 **G1+G2/BL:** *P* = 0.019 **Problem behavior:** BASC atypicality score, parent-rated, mean ± SD: **G1:** 69.00 ± 15.28 (n=11); **G2:** 61.13 ± 12.89 (n=8) **G1+G2/BL:** *P* = 0.001 BASC atypicality score, teacher-rated, mean ± SD: **G1:** 54.58 ± 9.39 **G2:** 52.67 ± 11.43 **G1+G2/BL:** *P* = 0.031 **Adaptive Behavior:** BASC adaptability score, parent-rated, mean ± SD: **G1:** 35.63 ± 9.53 (n=8) **G2:** 42.83 ± 6.15 (n=6) **G1+G2/BL:** *P* = 0.009
Lopata et al., 2006 (continued)		**Other characteristics:** NR		BASC adaptability score, teacher-rated, mean ± SD: **G1:** 43.00 ± 4.56 (n=9) **G2:** 43.00 ± 4.38 (n=8) **G1+G2/BL:** *P* =

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				0.151 **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Ludlow et al., 2006 **Country:** UK **Practice setting:** Academic **Intervention setting:** NR **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Colored overlays; participants selected the best color and side (matt or gloss) for clarity over text Frequency/duration: Single session **Assessments:** BPVS, City University Color Vision Test (max = 16), Ishihara Color Test (max = 38) **Groups:** **G1:** Autistic children **Ga:** colored overlay, chosen for clarity **Gb:** no colored overlay **Provider:** NR **Measure of treatment fidelity reported:** NR **Co-interventions held stable during treatment:** Yes **Concomitant therapies:** NR **N at enrollment:** **G1:** 19 **N at follow-up:** **G1:** 19	**Inclusion criteria:** • Attend a school in which a formal diagnosis of autism is necessary **Exclusion criteria:** • See inclusion criteria **Age, mean/yrs (range):** **G1:** 11.10 ± 2.23 (8.3,15.1) **Mental age:** NR **Gender:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** NR **Diagnostic category, n (%):** Autism: 19 (100) **Other characteristics:** NR	**Communication/ language:** BPVS score, mean ± SD: **G1:** 64.32 ± 10.91 **Sensory:** City University Color Test score, mean ± SD: **G1:** 15.9 ± 0.33 Ishihara Color Test score, mean ± SD: **G1:** 36.7 ± 1.04	**Sensory:** Words read per minute, mean: **G1a:** NR* **G1b:** NR* **G1a/G1b:** $P <$ 0.004 **Educational/ cognitive/ academic attainment:** Percentage improvement reading with colored overlays, n (%): Less than 5%: **G1:** 4 (21) 5-10%: **G1:** 3 (16) 11-20%: **G1:** 6 (31) 21-30%: **G1:** 0 31-40%: **G1:** 4 (21) 41-50%: **G1:** 2 (10) **Harms:** NR **Modifiers:** The correlation between verbal IQ measured via BPVS and degree of improvement using overlay was not significant

Comments: *Data only illustrated graphically.

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Mousain-Bosc et al., 2006 **Country:** France **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Sanofi-Aventis **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Mg-vitamin B6 regimen: (6 mg/kg/day Mg, 0.6 mg/kg/d vitamin B6) for an average of 8 ± 5 months (range 2-40 months) **Assessments:** Symptoms and symptom groups of PDD from the DSM-IV evaluated by the physician after discussion with parents and teachers Biological parameters measured at first clinic visit of child then after 2 months of treatment; subsequent evaluations depended on the frequency of visits. Children were followed over a period of about 24 months **Groups:** **G1:** Mg-B6 therapy **Co-interventions held stable during treatment:** Yes **Frequency of contact during study:** NR **Concomitant therapies, n (%):** **G1:** 0 **N at enrollment:** **G1:** 33 **N at follow-up:** **G1:** 33	**Inclusion criteria:** • Clinical symptoms of PDD as described in DSM-IV (G1) **Exclusion criteria:** See inclusion criteria **Age, years ± SD (range):** **G1:** 4 ± 2 (1-10) **Mental age:** NR **Gender, n:** Male: **G1:** 21 Female: **G1:** 12 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** DSM-IV **Diagnostic category, n (%):** PDD: **G1:** 33 (100) **Other characteristics:** NR	**Social skills:** DSM-IV visual contact score, mean ± SD: **G1:** 3.33 ± 0.89 DSM-IV visual contact score > 3, n: **G1:** 26 DSM-IV connection with equals score, mean ± SD: **G1:** 3.12 ± 0.74 DSM-IV connection with equals score > 3, n: **G1:** 28 DSM-IV delight partition score, mean ± SD: **G1:** 3.03 ± 0.81 DSM-IV delight partition score > 3, n: **G1:** 25 DSM-IV social reciprocity score, mean ± SD: **G1:** 3.30 ± 0.68 DSM-IV social reciprocity score > 3, n: **G1:** 29 DSM-IV social interactions total score, mean ± SD: **G1:** 12.61 ± 3.01 **Communication/ language:** DSM-IV delayed communication score, mean ± SD: **G1:** 3.39 ± 0.50 DSM-IV delayed communication score > 3, n: **G1:** 33 DSM-IV no communication score, mean ± SD: **G1:** 3.09 ± 0.72	**Overall ratings:** Improvement for ¾ groups of symptoms, n: **G1:** 20/30 **Social skills:** DSM-IV visual contact score, mean ± SD: **G1:** 1.36 ± 1.19 DSM-IV visual contact score > 3, n: **G1:** 6 DSM-IV connection with equals score, mean ± SD: **G1:** 1.51 ± 1.00 DSM-IV connection with equals score > 3, n: **G1:** 6 DSM-IV delight partition score, mean ± SD: **G1:** 1.54 ± 1.06 DSM-IV delight partition score > 3, n: **G1:** 6 DSM-IV social reciprocity score, mean ± SD: **G1:** 1.51 ± 1.06 DSM-IV social reciprocity score > 3, n: **G1:** 6 DSM-IV social interactions total score, mean ± SD: **G1:** 5.94 ± 4.10 **G1/BL:** *P* = 0.0000

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Mousain-Bosc et al., 2006 (continued)			DSM-IV no communication score > 3, n: **G1:** 26 DSM-IV stereotyped language score, mean ± SD: **G1:** 2.85 ± 0.71 DSM-IV stereotyped language score > 3, n: **G1:** 24 DSM-IV social mimicking score, mean ± SD: **G1:** 3.27 ± 0.75 DSM-IV social mimicking score > 3, n: **G1:** 29 DSM-IV loss of communication total score, mean ± SD: **G1:** 12.61 ± 2.16 **Repetitive behavior:** DSM-IV stereotyped interest score, mean ± SD: **G1:** 3.03 ± 1.16 DSM-IV stereotyped interest score > 3, n: **G1:** 24 DSM-IV customs score, mean ± SD: **G1:** 1.88 ± 1.36 DSM-IV customs score > 3, n: **G1:** 12 DSM-IV motor affection score, mean ± SD: **G1:** 2.36 ± 1.14 DSM-IV motor affection score > 3, n: **G1:** 17	DSM-IV social interactions total score, change > 5, n: **G1:** 23/33 **Communication/ language:** DSM-IV delayed communication score, mean ± SD: **G1:** 2.00 ± 1.00 DSM-IV delayed communication score > 3, n: **G1:** 9 DSM-IV no communication score, mean ± SD: **G1:** 1.54 ± 0.87 DSM-IV no communication score > 3, n: **G1:** 4 DSM-IV stereo-typed language score, mean ± SD: **G1:** 1.54 ± 1.09 DSM-IV stereo-typed language score > 3, n: **G1:** 6 DSM-IV social mimicking score, mean ± SD: **G1:** 1.39 ± 1.05 DSM-IV social mimicking score > 3, n: **G1:** 5 DSM-IV loss of communication total score, mean ± SD: **G1:** 6.48 ± 3.77 **G1/BL:** *P* = 0.0000
Mousain-Bosc et al., 2006 (continued)			DSM-IV things handling score, mean ± SD: **G1:** 1.88 ± 1.17 DSM-IV things handling score > 3, n: **G1:** 10	DSM-IV loss of communication total score, change > 5, n: **G1:** 24/33 **Repetitive behavior:** DSM-IV stereo-

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
			DSM-IV stereotyped restricted behavior total score, mean ± SD: **G1:** 12.61 ± 2.16 **Adaptive behavior:** DSM-IV social interactions score, mean ± SD: **G1:** 3.26 ± 0.89 DSM-IV social interactions score > 3, n: **G1:** 28 DSM-IV language score, mean ± SD: **G1:** 3.39 ± 0.62 DSM-IV language score > 3, n: **G1:** 29 DSM-IV symbolic games score, mean ± SD: **G1:** 3.13 ± 0.88 DSM-IV symbolic games score > 3, n: **G1:** 27 DSM-IV abnormal or delayed functioning total score, mean ± SD: **G1:** 12.61 ± 2.16 **Medical:** Erc-Mg (mmol/L), mean ±SD: **G1:** 2.17 ± 0.4 i-Ca (mmol/L), mean ± SD: **G1:** 1.21 ±0.08	typed interest score, mean ± SD: **G1:** 1.27 ± 0.91 DSM-IV stereotyped interest score > 3, n: **G1:** 3 DSM-IV customs score, mean ± SD: **G1:** 0.64 ± 0.82 DSM-IV customs score > 3, n: **G1:** 1 DSM-IV motor affection score, mean ± SD: **G1:** 1.00 ± 0.90 DSM-IV motor affection score > 3, n: **G1:** 3 DSM-IV things handling score, mean ± SD: **G1:** 1.03 ± 1.04 DSM-IV things handling score > 3, n: **G1:** 3 DSM-IV stereotyped restricted behavior total score, mean ±SD: **G1:** 6.48 ±3.77 **G1/BL:** *P* = 0.0000
Mousain-Bosc et al., 2006 (continued)			s-Mg (mmol/L), mean ± SD: **G1:** 0.89 ± 0.06	DSM-IV stereotyped restricted behavior total score, change > 5, n: **G1:** 18/33 **Adaptive behavior:** DSM-IV social interactions score, mean ± SD: **G1:** 1.80 ± 1.22 DSM-IV social interactions score > 3, n: **G1:** 10

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				DSM-IV language score, mean ± SD: **G1:** 1.90 ± 1.22 DSM-IV language score > 3, n: **G1:** 10 DSM-IV symbolic games score, mean ± SD: **G1:** 1.66 ± 1.15 DSM-IV symbolic games score > 3, n: **G1:** 9 DSM-IV abnormal or delayed functioning total score, mean ± SD: **G1:** 6.48 ± 3.77 **G1/BL:** *P* = 0.0000 DSM-IV abnormal or delayed functioning total score, change > 5, n: **G1:** 17/33 **Medical:** Erc-Mg (mmol/L), mean ± SD:** **G1:** 2.42 ± 0.41 **G1/BL:** *P* = 0.0198
Mousain-Bosc et al., 2006 (continued)				Erc-Mg increased, post-treatment, n (%): **G1:** 11/17 (65) i-Ca (mmol/L), mean ± SD: **G1:** 1.20 ± 0.05 **G1/BL:** *P* = NS s-Mg (mmol/L), mean ± SD: **G1:** NR **G1/BL:** *P* = NS **Harms:** NR **Modifiers:** NR

Comments: *data only illustrated graphically
** Authors report when Mg supply was stopped, Erc-Mg values returned to low levels in about 2 months

Author: Nagaraj et al., 2006 **Country:** India	**Intervention:** Liquid suspension risperidone or placebo, 0.5 mg/day orally for two	**Inclusion criteria:** • Age ≤ 12 years • Diagnosed with autism according to DSM IV criteria	**Overall Ratings:** CARS score, median (range): **G1:** 39.5 (32.5-46) **G2:** 38.5 (31.5-43)	**Overall Ratings:** CARS score, median (range): **G1:** 32.0 (24.5-40.5)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Practice setting: Academic **Intervention setting:** Pediatric neuro-development clinic **Enrollment period:** January 2002 to December 2003 **Funding:** Postgraduate Institute of Medical Education and Research, Chandigarh **Author industry relationship disclosures:** NR **Design:** RCT, block randomization, double blind study	weeks then 1 mg/day for the remaining 6 months **Assessments:** CARS, CGAS conducted by investigator at intake and every 8 weeks for 6 months Parent questionnaire designed for study **Groups:** **G1:** risperidone **G2:** placebo **Co-interventions held stable during treatment:** Yes (psychoactive medications stopped 1 month in advance of entering trial; no other drugs administered concurrently except antiepileptics); non-medical interventions not reported **Frequency of contact during study:** Every 8 weeks **Concomitant therapies:** NR **N at enrollment:** **G1:** 19 **G2:** 21 **N at follow-up:** **G1:** 19 **G2:** 20	**Exclusion criteria:** • Severe mental retardation • Significant co-existing disease/illness • Severe malnutrition (weight for age < 60% of NCHS median) **Age, months ± SD:** **G1:** 57.95 ± 20.84 **G2:** 63.0 ± 20.12 Mental age: NR **Gender, n (%):** Male: **G1:** 16 (84.2) **G2:** 18 (90) Female: **G1:** 3 (15.8) **G2:** 2 (10) **Race/ethnicity:** NR **SES:** Maternal education: NR Socioeconomic class, n (%): Very high: **G1:** 3 (15.8) **G2:** 6 (30) Upper middle: **G1:** 10 (52.6) **G2:** 5 (25) Middle: **G1:** 5 (26.3) **G2:** 8 (40) Lower middle: **G1:** 1 (5.3) **G2:** 1 (5) **Diagnostic approach:** NR **Diagnostic tool/method:** Clinical interview, DSM-IV	CGAS score, mean ± SD: **G1:** 29.79 ± 7.27 **G2:** 32.65 ± 7.95 **IQ, n (%):** Borderline IQ: **G1:** 9 (47.4) **G2:** 8 (40) Mild retardation: **G1:** 6 (31.6) **G2:** 5 (25) Moderate retardation: **G1:** 4 (21.1) **G2:** 7 (35) **VABS social maturity score, mean ± SD:** **G1:** 61.92 ± 16.16 **G2:** 60.64 ± 19.31 **Communication/ language, n (%):** Simple sentences: **G1:** 3 (16) **G2:** 2 (10) Few meaningful words: **G1:** 5 (26.3) **G2:** 5 (25) Imitate speech sounds only: **G1:** 7 (36.8) **G2:** 7 (35) Nonverbal communication: **G1:** 2 (10.5) **G2:** 5 (25) No communication: **G1:** 2 (10.5) **G2:** 1 (5) **Medical:** Weight, mean kg ± SD: **G1:** 16.17 ± 3.38 **G2:** 18.25 ± 5.6 Previous medication, n (%): None: **G1:** 15 (79) **G2:** 16 (80)	**G2:** 37.5 (30-42.5) **G1/G2:** $P < 0.001$ CARS score ≥ 20% improvement from baseline: **G1:** 12/19 **G2:** 0/20 CGAS score, mean ± SD: **G1:** 40.94 ± 7.83 **G2:** 35.2 ± 9.38 **G1/G2:** $P = 0.035$ CGAS score ≥ 20% improvement from baseline: **G1:** 17/19 **G2:** 2/20 Parent impress-sions, global, n: Considerably improved: **G1:** 9/19 **G2:** 0/20 Improved to some extent: **G1:** 9/19 **G2:** 6/20 No change: **G1:** 0/19 **G2:** 9/20 Worsened: **G1:** 1/19 **G2:** 4/20 **G1/G2:** P = NS **Social skills:** Parent impress-sions, social responsiveness, n: Significantly improved: **G1:** 7/19 **G2:** NR **G1/G2:** $P = 0.014$

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Nagaraj et al., 2006 (continued)		**Diagnostic category, n (%):** Autism: 39 (100) **Other characteristics, n (%):** Lack of eye contact, gestures, other non-verbal communication: **G1:** 16 (84.2) **G2:** 19 (95) Impaired peer relation-ships, reciprocity, sharing emotions: **G1:** 19 (100) **G2:** 19 (95) Total lack of spoken language: **G1:** 12 (63.2) **G2:** 16 (80) Impaired general linguistic ability, comprehension: **G1:** 19 (100) **G2:** 20 (100) Impaired imaginative play: **G1:** 12 (63.2) **G2:** 15 (75) Restricted pattern of interests: **G1:** 14 (73.7) **G2:** 12 (60) Inflexible adherence to routine, stubbornness: **G1:** 10 (52.6) **G2:** 7 (35) Motor and verbal stereotypies: **G1:** 13 (68.4) **G2:** 11 (55) Hyperactivity: **G1:** 12 (63.2) **G2:** 14 (70) Aggressive behavior, tantrums: **G1:** 9 (47.4) **G2:** 11 (55) Irritability: **G1:** 17 (89.5) **G2:** 19 (95) Withdrawal, inattention: **G1:** 10 (52.6) **G2:** 10 (50) Self-injurious behavior: **G1:** 7 (36.8) **G2:** 5 (25)	Antipsychotic: **G1:** 3 (16) **G2:** 1 (5) Stimulant: **G1:** 1 (5) **G2:** 3 (15)	**Problem behavior:** Parent impress-sions, decreased hyperactivity, n: Significantly improved: **G1:** 7/19 **G2:** NR **G1/G2:** *P* = 0.002 Parent impress-sions, aggression and irritability, n: Significantly improved: **G1:** 5/19 **G2:** NR **G1/G2:** *P* = 0.016 **Communication/ language:** Parent impress-sions, nonverbal communication, n: Significantly improved: **G1:** 8/19 **G2:** NR **G1/G2:** *P* = 0.008 **Adaptive behavior:** Increased appetite/improved eating habits, n: **G1:** 17/19 **G2:** NR **Medical:** Weight, mean change kg ± SD: **G1:** 2.81 ± 2.04 **G2:** 1.71 ± 1.3 **Harms:** Mild Sedation: **G1:** 4/19 **G2:** NR Dyskinesias**:** **G1:** 3/19 **G2:** NR Drooling: **G1:** 1/19 **G2:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Nagaraj et al., 2006 (continued)		Seizures: **G1:** 5 (26.3) **G2:** 3 (15) Family structure, n (%): Nuclear: **G1:** 13 (68.4) **G2:** 15 (75) Joint: **G1:** 6 (31.6) **G2:** 5 (25)		

Comments: *(orolingual=2, left lower limb=1)

Author: Sams et al., 2006 **Country:** US **Practice setting:** Special treatment center, community college, hospital **Intervention setting:** School **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Occupational therapy with and without animals focused on facilitating sensory integration, language use, sensory skills and motor skills Frequency: two sessions per week, one lasting 26.3 ± 6.0 minutes, and one lasting 28.5 ± 5.3 minutes incorporating animals Children ranged between 2-12 sessions of each type over 15 weeks **Assessments:** Observers recorded instances of social interaction and language use on a behavioral rating form at each session **Groups:** **G1:** occupational therapy **Ga:** standard sessions **Gb:** animal sessions **Provider:** • Occupational therapists • Trained research assistants (senior undergraduate occupational therapy field study students) **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 22 **N at follow-up:** **G1:** 22	**Inclusion criteria:** • School age • Participating in school-based program (occupational therapy services through public schools) • Primary diagnosis of autism **Exclusion criteria:** • See inclusion criteria **Age, years ± SD (range):** 9.6 ± 1.7 (7-13) **Mental age:** NR **Gender:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** NR **Diagnostic category, n (%):** Autism: 22 (100) Cerebral palsy: 2 (9) **Other characteristics:** NR	NR	**Social skills:** Social interactions per minute, mean ± SD: **G1a:** 0.17 ± 0.09 **G1b:** 0.27 ± 0.10 **G1a/G1b:** *P* < 0.01 (ES = 1.0) **Communication/ language:** Uses of language per minute, mean ± SD: **G1a:** 0.98 ± 0.72 **G1b:** 1.27 ± 1.10 **G1a/G1b:** *P* < 0.05 (ES = 0.31) **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Wetherby et al., 2006 **Country:** US **Practice setting:** Academic **Intervention setting:** Home, classroom **Enrollment period:** NR **Funding:** U.S. Department of Education, Office of Special Education and Rehabilitation Services **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Early Social Interaction project (ESI): routines-based intervention in natural environments; individualized curriculum; parent-implemented curriculum; recommended 2 home visits/week G1 also participated in parent-child playgroup guided by two interventionists thru the FIRST WORDS project: attended for 9 weeks during the ESI intervention year **Assessments:** Pre- and post-intervention measures of social communication; MSEL, VABS **Groups:** **G1:** intervention (entered study at age 2 and received ESI for 1 year) **G2:** control (age 3) **Provider:** Speech language pathologists, early childhood education specialist **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 17 **G2:** 18 **N at follow-up:** **G1:** 17 **G2:** 18	**Inclusion criteria:** **G1** • CSBS behavior sample from children between ages 12-24 months and again between 25-36 months after 12 months ESI • Provisional diagnosis of autism or systemic observation of red flags of ASD during first behavior sample • Age ≤ 24 months • Family agreed to participate in ESI for 12 months • Family agreed to diagnostic evaluation of child at 36 months **G2:** • CSBS DP behavior sample from 25-36 months • No previous intervention services before behavior sample was videotaped • Suspicion of ASD • Family agreed to diagnostic evaluation at 36 months **Exclusion criteria:** • See inclusion criteria **Age, months ± SD:** Pre-ESI: **G1:** 18.19 ± 3.85 Post-ESI: **G1:** 30.72 ± 3.66 Upon recruitment: **G2:** 31.61 ± 3.45 **Mental age:** NR **Gender, %:** Male: **G1:** 88 **G2:** 78 Female: **G1:** 12 **G2:** 22 **Race/ethnicity, %:** Caucasian: **G1:** 65 **G2:** 61	**Communication/ language:** Social signals, mean ± SD: Gaze shifts: **G1:** 4.18 ± 1.67 **G2:** NA Shared positive affect: **G1:** 1.88 ± 1.83 **G2:** NA Gaze/point follow: **G1:** 0.35 ± 0.61 **G2:** NA Rate of communicating, mean ± SD: **G1:** 8.71 ± 5.36 **G2:** NA Communicative functions, mean ± SD: Behavior regulation: **G1:** 3.59 ± 2.12 **G2:** NA Social interaction: **G1:** 0.65 ± 0.93 **G2:** NA Joint attention: **G1:** 0.65 ± 0.93 **G2:** NA Communicative means inventory, mean ± SD: Gestures: **G1:**1.76 ± 1.15 **G2:** NA Consonants: **G1:** 1.0 ± 1.37 **G2:** NA Words: **G1:** 0.18 ± 0.53 **G2:** NA Symbolic capacity, mean ± SD: Understanding: **G1:** 0.82 ± 1.38 **G2:** NA	**Communication/ language:** Social signals, mean ± SD: Gaze shifts: **G1:** 5.18 ± 1.51 **G2:** 3.28 ± 1.71 **G1/BL:** $P = 0.091$ **G1/G2:** $P = 0.001$ Shared positive affect: **G1:** 3.41 ± 2.00 **G2:** 1.31 ± 1.38 **G1/BL:** $P = 0.053$ **G1/G2:** $P = 0.005$ Gaze/point follow: **G1:** 1.29 ± 0.85 **G2:** 0.61 ± 0.70 **G1/BL:** $P = 0.004$ **G1/G2:** $P = 0.014$ Rate of communicating, mean ± SD: **G1:** 16.18 ± 2.56 **G2:** 11.94 ± 5.51 **G1/BL:** $P < 0.001$ **G1/G2:** $P = 0.007$ Communicative functions, mean ± SD: Behavior regulation: **G1:** 5.53 ± 0.63 **G2:** 4.11 ± 1.81 **G1/BL:** $P = 0.002$ **G1/G2:** $P = 0.005$ Social interaction: **G1:** 2.29 ± 1.86 **G2:** 0.89 ± 1.28 **G1/BL:** $P = 0.002$ **G1/G2:** $P = 0.015$ Joint attention: **G1:** 2.94 ± 2.16 **G2:** 1.39 ± 1.54 **G1/BL:** $P = 0.001$ **G1/G2:** $P = 0.021$
Wetherby et al., 2006 (continued)		African-American: **G1:** 12 **G2:** 17 Hispanic:	Inventory of actions: **G1:** 3.88 ± 2.0 **G2:** NA Actions to others:	Communicative means inventory, mean ± SD: Gestures:

Evidence Table. Therapies for children with ASD

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		G1: 24 **G2:** 6 Asian: **G1:** 0 **G2:** 17 **SES:** Parent Education, years ± SD: Mother: **G1:** 15.7 ± 1.93 **G2:** 15.53± 1.63 Father: **G1:** 16.35 ± 2.5 **G2:** 15.41 ± 2.4 Hollinghead's index of SES, mean ± SD: **G1:** 53.0 ± 10.42 **G2:** 52.94 ± 10.33 **Diagnostic approach:** In Study/Referral **Diagnostic tool/method:** MSEL, VABS interview edition, survey form; ADOS, DSM-IV-TR **Diagnostic category:** See inclusion criteria **Other characteristics, age 3, mean ± SD:** MSEL, mean ± SD: Non-verbal DQ: **G1:** 81.98 ± 23.93 **G2:** 64.23 ± 17.74 Verbal DQ: **G1:** 73.55 ± 26.16 **G2:** 56.07 ± 24.96 VABS score, mean ± SD: Communication: **G1:** 77.06 ± 19.76 **G2:** 62.76 ± 16.91 Daily living: **G1:** 75.88 ± 10.51 **G2:** 65.88 ± 19.53 Social: **G1:** 77.06 ± 16.35 **G2:** 64.41 ± 18.99	**G1:** 0.53 ± 0.8 **G2:** NA Language stage, n (%): Pre-verbal: **G1:** 16 (94) **G2:** NA Verbal Early one-word: **G1:** 1 (6) **G2:** NA Late one-word: **G1:** 0 **G2:** NA Multiword: **G1:** 0 **G2:** NA Total: **G1:** 1 (6) **G2:** NA	**G1:** 3.76 ± 1.68 **G2:** 2.72 ± 1.53 **G1/BL:** $P = 0.001$ **G1/G2:** $P = 0.064$ Consonants: **G1:** 4.71 ± 2.69 **G2:** 3.72 ± 3.08 **G1/BL:** $P < 0.001$ **G1/G2:** $P = 0.321$ Words: **G1:** 6.00 ± 5.18 **G2:** 3.94 ± 4.40 **G1/BL:** $P < 0.001$ **G1/G2:** $P = 0.216$ Symbolic capacity, mean ± SD: Understanding: **G1:** 4.24 ± 3.29 **G2:** 2.00 ± 2.40 **G1/BL:** $P < 0.001$ **G1/G2:** $P = 0.030$ Inventory of actions: **G1:** 6.18 ± 2.90 **G2:** 5.00 ± 2.28 **G1/BL:** $P = 0.011$ **G1/G2:** $P = 0.193$ Actions to others: **G1:** 2.82 ± 1.70 **G2:** 2.56 ± 1.72 **G1/BL:** $P < 0.001$ **G1/G2:** $P = 0.065$ Language stage, n (%): Pre-verbal: **G1:** 4 (24) **G2:** 8 (44) Verbal early one-word: **G1:** 4 (24) **G2:** 5 (28) Late one-word: **G1:** 6 (35) **G2:** 2 (11) Multiword: **G1:** 3 (18) **G2:** 3 (17)
Wetherby et al., 2006 (continued)		Motor: **G1:** 83.76 ± 14.32 **G2:** 71.88 ± 21.45 Adaptive behavior Composite: **G1:** 73.82 ± 14.73 **G2:** 64.71 ± 7.20		Total: **G1:** 13 (77) **G2:** 10 (56) **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Yoder, 2006 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NIH and other communication disorders grant **Author industry relationship disclosures:** NR **Design:** Case series, prospective **Note:** Shares participants with Yoder et al. 2006a ({#516}), 2006b ({#487}) & 2009 ({#5719})	**Intervention:** Identify putative child (attention following, intentional communication, motor imitation, diversity of object play) and environmental factors associated with growth of lexical density Hours of treatment/month, mean ± SD (range): 16 ± 9 (11-145) Hours of communication treatment/month, mean ± SD (range): 10 ± 5 (11-29) **Assessment:** MSEL, Motor Imitation Scale, Developmental Play Assessment tests at baseline Lexical density measured at baseline, 6 months and 12 months using adapted version of ESCS-abridged and unstructured free play with examiner for 15 minutes Non-project treatment questionnaire administered monthly for first 6 months and at 12 months **Groups:** **G1:** intervention **Provider:** NR **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 35 **N at follow-up:** **G1:** 35	**Inclusion criteria:** • Diagnosis of autistic disorder or PDD-NOS • Age 18-60 months • Use of fewer than 10 words during two communication samples **Exclusion criteria:** • Severe sensory or motor deficits • English not primary language spoken at home **Age, months (range):** 33.6 (21-54) **Mental age, months ± SD (range):** MSEL nonverbal: 18.6 ± 3.7 (11.5-26.5) MSEL verbal: 11.9 ± 2.8 (7-19) **Gender, n (%):** Male: 31 (89) Female: 4 (11) **Race/ethnicity, n (%):** White: 24 (69) African American: 8 (23) Other: 3 (8) **SES:** Primary parent education, mean (range): 3-4 years college (10th grade to > 2 years graduate school) Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** ADOS **Diagnostic category, n (%):** Autism: 32 (91) PDD-NOS: 3 (9) Aspergers: NR **Other characteristics:** NR	**Communication/ language:** MSEL cognitive standard score, mean ± SD (range): 51 ± 5.3 (48-67) MCDI number of words child understands, mean ± SD (range): 86 ± 74 (1-277) ESCS and unstructured free play lexical density, mean ± SD (range): 0.5 ± 1.0 (0-5) ESCS attention following, mean ± SD (range): 1.6 ± 2.2 (0-8) ESCS and unstructured free play intentional communication, mean ± SD (range): 25 ± 17 (4-83) Motor Imitation Scale total raw score, mean ± SD (range): 7.8 ± 6.4 (0-32) Developmental Play Assessment diversity of object play, mean ± SD (range): 39 ± 22.5 (7-123) MSEL expressive language impairment, mean ± SD (range): 21 ± 3 (19-30)	**Communication/ language:** ESCS and unstructured free play lexical density, mean ± SD (range): 6 months: 3 ± 5 (0-17) 12 months: 7 ± 11 (0-50) **Harms:** NR **Modifiers:** Expressive language impairment is a significant predictor of growth in lexical density ($P = 0.004$) After controlling for expressive language impairment, the significant predictors of growth in lexical density are intentional communication ($P = 0.009$) and diversity of object play ($P = 0.002$), but these are significantly correlated ($r = 0.36$; $P < 0.05$) The amount of communication/ speech treatment was not related to growth rate of lexical density after controlling for expressive language impairment.
Yoder, 2006 (continued)				Neither the total amount of therapy nor the amount of communication/ speech/language therapy interacted with baseline attention following

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				to predict growth in lexical density

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Beglinger et al., 2005 **Country:** US **Practice setting:** Academic **Intervention setting:** Home **Enrollment period:** NR **Funding:** Washington State University **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Intensive behavioral treatment based on the UCLA model for 0-44 months for children enrolled in Multisite Young Autism Project (MYAP) 40 hrs /wk of one-to-one Intervention, initially extremely individualized discrete trial training to the child, later becoming complex, group-setting focused and adapted to the child's environment. **Assessments:** Participants administered core assessment tests at time of intake and annually thereafter (excluding WSQ, except in a small sub-sample); if children showed improvements in functioning, the Bayley was replaced with the WPPSI-R **Groups** (4 subtypes of autism based on social style)**:** **G1a:** Aloof **G1b:** Passive **G1c:** Active-but-odd **G1d:** Typically developing **Provider:** A team of project director, supervisor, lead therapist, student therapists and parents **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR	**Inclusion criteria:** • Diagnosis of autism by a licensed psychologist or psychiatrist, using the Autism Diagnostic Interview and DSM-IV Criteria • chronological age of not more than 42 months at referral and not more than 8 years at the time of enrollment into this study • acceptance into the MYAP and active participation in intensive treatment (approximately 30–40 h per week) of one to-one instruction • no major medical limitations that would impede treatment (such as cerebral palsy or motor deficits) • ratio IQ of 30 or higher on the Bayley Scales of Infant Development: Mental Development Index **Exclusion criteria:** See Inclusion criteria **Age, mean/yrs ± SD (range):** 5.42 ± 1.08 (3-6) **Mental age:** NR **Gender:** M, n (%): 32 (86.5) F, n (%): 5 (13.5) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral	**Educational/ cognitive/ academic attainment:** IQ, mean ± SD (range): 54.13 ± 12.63 (32-82) IQ scores by Scale, mean ± SD: **G1a:** 50.6 ± 13.4 **G1b:** 62.4 ± 11.9 **G1c:** 42.4 ± 12.7 **G1d:** 55.8 ± 12.1	**Educational/ cognitive/ academic attainment:** IQ, mean ± SD: **G1a:** 54.5 ± 13.5 **G1b:** 76.8 ± 13.4 **G1c:** 80.8 ± 15.2 **G1d:** 93.8 ± 10.1 Change in IQ in G1a was significantly smaller than in G1c (P< 0.05) and G1d (P < 0.0001) G1a subtype has the lowest functioning children followed by G1b, G1c and G1d at the highest end. **WSQ summary score by Scale, mean ± SD:** **G1a:** 29.1 ± 14.5 **G1b:** 33.5 ± 10.8 **G1c:** 28.2 ±10.3 **G1d:** 33.7 ± 15.5 None of WSQ scores were correlated with either age or months in treatment. Pearson values ranged from 0.19 to -0.14. Pre Tx IQ significantly correlated with WSQ summary score for G1a & G1d (P < 0.05) and is correlated with Current IQ (P = 0.001) **Harms:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Beglinger et al., 2005 (continued)	**N at enrollment:** 38 **N at follow-up:** 37 **G1a:** 14 **G1b:** 5 **G1c:** 7 **G1d:** 9	**Diagnostic tool/method**: ADI & DSM-IV **Diagnostic category, n (%):** Autism : 37 (100) **Other characteristics:** NR		**Modifiers:** G1a type was negatively correlated with all IQ measures (*P* = 0.001) G1d type was positively highly correlated with IQ change (*P* = 0.001)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Farrell et al., 2005 **Country:** UK **Practice setting:** Academic **Intervention setting:** School and home **Enrollment period:** NR **Funding:** LEA **Author industry relationship disclosures:** NR **Design:** Retrospective cohort **Note:** Full account of methodology and results from interviews can be found in Trigonaki & Farrell, 2002	**Intervention:** LUFAP vs. ABA/Lovaas LUFAP: children attended mainstream school full time, SSAs employed combination of delivery styles (in particular ABA techniques and TEACCH approach), weekly meetings with parents, SSA, project teacher, and class teacher ABA/Lovaas: children received a minimum of 30 hours one-to-one support per week, mainly at home, from up to 5 therapists **Assessments:** Semi-structured interviews conducted by staff from Manchester University near beginning and end of study with parents, class teachers, senior LEA officers, SSAs, ABA therapists, and ABA supervisors; VABS and BSID baseline and post test For all but one participant the gap between assessments was ≥ 18 months (that one participant gap between baseline and post assessment was 7 months); the mean time between assessments for G1 was 20 months and for G2 was 26 months **Groups:** **G1:** LUFAP **G2:** ABA/Lovaas **Provider:** • The LUFAP group was managed by project team (the Head of Pupil Services Division, the Head of SEN Assessment, a representative from educational psychology service, an SEN advisor, and a project teacher	**Inclusion criteria:** • Pre-school age children • G1 selected by EPs part of a team carrying out statutory assessment • G2 parents lobbied for Lovaas/ABA intervention **Exclusion criteria:** • See inclusion criteria **Age, 28 months into study, months:** **G1:** 69.4 **G2:** 75.6 **Mental age:** BSID delevopmental age, months: **G1:** 21.8 (n=8) **G2:** 15.6 (n=5) **Gender, n:** Male: **G1:** 7 **G2:** 6 Female: **G1:** 2 **G2:** 2 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral by educational psychologist in Lancashire **Diagnostic tool/method:** NR **Diagnostic category:** Autism: 17 (100) **Other characteristics:** NR	**Social skills:** VABS socialization, developmental age, months: **G1:** 15.7 **G2:** 11 (n = 6) **Communication/ language:** VABS communication, developmental age, months: **G1:** 17.9 **G2:** 11.6 (n = 6) **Adaptive behavior:** VABS daily living, developmental age, months: **G1:** 19.7 **G2:** 18.1 (n = 6) **Educational/cognitive/academic attainment:** BSID developmental age, months: **G1:** 21.8 (n=8) **G2:** 15.6 (n=5)	**Social skills:** VABS socialization, developmental age, months: **G1:** 27.4 (n=7) **G2:** 21 (n=7) VABS socialization, progress made per month, mean: **G1:** 1.02 (n=7) **G2:** 0.34 (n=6) **Communication/ language:** VABS communication, developmental age, months: **G1:** 50.6 (n=7) **G2:** 25.3 (n=7) VABS communication, progress made per month, mean: **G1:** 1.57 (n=7) **G2:** 0.43 (n=6) **Adaptive behavior:** VABS daily living, developmental age, months: **G1:** 35.0 (n=7) **G2:** 34.4 (n=7) VABS daily living, progress made per month, mean: **G1:** 0.65 (n=7) **G2:** 0.5 (n=6) **Educational/ cognitive/ academic attainment:** BSID developmental age, months: **G1:** 29.8 (n=5) **G2:** 27.2 (n=4)
Farrell et al., 2005 (continued)	• For the LUFAP group day-to-day implementation: project teachers (1.5 full time staff),			BSID, progress made per month, mean: **G1:** 0.9 (n=4)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	SSAs (one full time for each child), and half time speech and language therapist, supported by educational psychologists • The ABA/Lovass team consisted of children's parents, lead therapist, a team of therapists, trained ABA supervisors from the UK and ABA consultants from the USA **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 9 **G2:** 8 **N at follow-up:** **G1:** 7 **G2:** 7			**G2:** 0.56 (n=4) **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Grey et al., 2005 **Country:** Ireland **Practice setting:** Academic **Intervention setting:** University Classroom **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** case series	**Intervention:** Teacher Training in Applied Behavior Analysis using Person Focused Training (see Provider below) . Teachers identified target behavior and intervention goal for one child with autism in their classrooms. **Duration:** 10.2 Months **Frequency:** sessions with children Varied – See Baseline Measures **Assessments:** All of the following were Participant Completed: • Comprehensive Function Assessment – included child's ecological background, schedule of daily activities, social interactions, functions, cognitive ability, health issues, and life story • Inventory of favorite things • Communication Assessment - including receptive and expressive language ability **Groups:** **G1a:** goal of reduction in target Behavior **G1b:** goal of increase in target Behavior **Provider:** 11 Female Special Needs Teachers with general education degrees or diplomas. All teachers underwent 90 hours of classroom instruction/supervision (45 hours – basic principles of ABA, 45 hour – application of said principles in practical settings.) Duration of training lasted 13 days over a 7 month period	**Inclusion criteria:** • Autistic Disorder **Exclusion criteria:** See Inclusion Criteria **Age, mean/yrs (range):** 8 years 2 months (2 years 10 months – 15 years) **Mental age:** NR **Gender:** M, n (%): 8 (73) F, n (%): 3 (27) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** NR **Diagnostic category, n (%):** Autism: 11 (100) **Other characteristics:**	Baseline Sessions for each child, mean ± SD (range): 11.5 ± 7.4 (3-23) **Problem Behavior:** Frequency of Occurrence of target behavior, mean ± SD (range): **G1a:** 23.5 ± 19.8 (2.9-54) **G1b:** 5.8 ± 4.8 (1.4-11)	Intervention Sessions mean ± SD (range): 12 ± 9.3 (3-27) **Problem behavior:** Frequency of Target Behavior, mean ± SD (range): **G1a:** 7.2 ± 9.2 (0.6-26.7) **G1a:** Reduction in rate of target behavior (Z = -2.521, *P* < 0.05) **G1b:** 13.6 ± 11.3 (1.7-24.3) [not able to perform statistical tests] **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Grey et al., 2005 (continued)	**Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1a:** 8 **G1b:** 3 **N at follow-up:** **G1a:** 8 **G1b:** 3			

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Hollander et al., 2005 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** FDA NIH **Author industry relationship disclosures:** NR **Design:** Randomized double-blind, cross-over study	**Intervention:** Liquid fluoxetine or placebo 2.5 mg/day for week 1, titrated as indicated by subject's symptoms and side effects based on weight for the next 2 weeks up to 0.8 mg/kg/day (0.3 mg/kg for week 2, 0.5 mg/kg/day for week 3, and 0.8 mg/kg/day for weeks 4–8) Mean maximum dose for fluoxetine: 10.6 ±3.65 mg (range 4.8-20), or 0.38 ± 0.97 mg/kg Mean final dose for fluoxetine: 9.9 mg ± 4.35 (range 2.4-20 mg), or 0.36 ± 0.116 mg/kg. 3 treatment phases: 8 week randomized control trial 4 week wash out period 8 week cross over study **Assessments:** Clinical Global Improvement Scale Adapted to Autism, Children's Yale-Brown Obsessive –Compulsion Scale, Global Autism Composite Improvement , Overt Aggression Scale Subjects monitored and assessed weekly by the treating physician, who was blind to treatment condition, during the first 4 weeks of each fluoxetine/placebo phase of the study. For the remainder of the trial, and during the washout period, patients were monitored every other week.	**Inclusion criteria:** • Between 5-17 years old • Met criteria for ASD on DSM-IV, ADI-R, & ADOS-G – includes autism, Aspergers syndrome, and PDD • Patients free of psychiatric medications 6 weeks prior to study **Exclusion criteria:** • Diagnosis of DSM-IV psychotic disorders • History of seizures • Any clinically significant medical illness • Concurrent psychotropic medications or cognitive behavioral therapy • Individuals who were responding well to previous interventions or had only mild global severity • Subjects unable to tolerate a minimum dose of 2.4 mg/day of liquid fluoxetine **Age, mean/yrs ±SD (range):** 8.18 ± 3.04 (5-16) **Mental age, mean/yrs (range):** NR **Gender:** M, n (%): 30 (76.9) F, n (%): 9 (23.1) **Race/ethnicity, n (%):** Caucasian 22 (56.4) Asian 2 (5.1) Black 9 (23.1) Hispanic 6 (15.4) **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** **In Study**	**Overall ratings:** Global Improvement Scale Adapted to Global Autism (CGIAD) , mean ± SD: **G1:** 4.5 ± 0.84 **G2:** 4.7 ± 0.9 **Educational/ cognitive/ academic attainment:** IQ, mean ±SD: **G1:** 68.1 ± 26.7 **G2:** 59.2 ± 29.1 **Repetitive behavior:** Children's Yale-Brown Obsessive-Compulsion Scale, compulsions subscale (CY-BOCS), mean ± SD: **G1:** 13.5 ± 2.9 **G2:** 12.8 ± 2.6 **Adaptive behavior:** Vineland adaptive behavior composite, mean ± SD: **G1:** 47.9 ± 19.4 **G2:** 45.1 ± 24.6	**Overall ratings:** CGI-AD, mean ± SD: **G1:** RCT Week 8: 3.58 ± 0.8 Crossover Week 20: 3.06 ± 1.1 **G2:** RCT Week 8: 3.42 ± 1.2 Crossover Week 20: 3.19 ± 1.0 CGI-AD not significantly different between intervention and placebo (*P* = 0.519) Global Composite Improvement (reported at weeks 8 and 20), mean ± SD: **G1:** RCT Week 8: 3.21 ± 2.6 Crossover Week 20: 1.73 ± 3.6 **G2:** RCT Week 8: 2.21 ± 3.0 Crossover Week 20: 3.50 ± 3.0 Global Comp improvement trending toward significance (*P* = 0.056) **Repetitive behavior:** CY-BOCS, mean ± SD: **G1:** RCT Week 0: 13.45 ± 2.9 Week 4: 12.7 ± 3.2 Week 8: 12.95 ± 3.2 Crossover Week 12: 12.93 ± 3.5 Week 16: 11.94 ± 3.4 Week 20: 11.77 ± 3.2
Hollander et al., 2005 (continued)	Adverse effects monitored via the clinician	**Diagnostic tool/method**: DSM-IV TR diagnosis by		**G2:** RCT Week 0: 12.84 ± 2.6

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	administered FSEC at every visit. CY-BOCS and CGI-AD outcome assessments completed by blinded independent evaluator at baseline and every 4 weeks, until week 20 or termination. Fluoxetine Side Effects Checklist completed by parent with psychiatrist, if able to do so, at each visit. **Groups:** **G1:** placebo (RCT)/liquid fluoxetine (crossover) **G2:** liquid fluoxetine (RCT)/placebo (crossover) **Co-interventions held stable during treatment:** Yes **Frequency of contact during study:** Weekly during first 4 weeks of each fluoxetine/placebo phase of the study; every other week during the remainder of the trial and the washout period **Concomitant therapies, n (%):** No concurrent psychotropic medications or cognitive behavioral therapies were allowed during the study **N at enrollment:** 45 (G1 and G2 n's NR) **N continuing after randomization:** **G1:** 20 **G2:** 19 **N at follow-up:** **G1:** 18 **G2:** 16	psychiatric interview, ADI-R, ADOS-G, VABS, WPPSI-R, WISC-III, WAIS-III, LIPS-R **Diagnostic category, n (%):** **G1:** Autism: 17 (85) Aspergers: 3 (15) **G2:** Autism: 17 (89.5) Aspergers: 2 (10.5) **Other characteristics, n (%):** Mentally retarded: 23 (59)		Week 4: 11.05 ± 3.4 Week 8: 11.63 ± 3.8 Crossover Week 12: 12.24 ±3.5 Week 16: 12.13 ± 2.6 Week 20: 12.38 ± 2.4 Fluoxetine superior to placebo on CY-BOCS (*P* = 0.038) **Problem behavior:** OAS-M: no trend or significant effect of drug vs placebo on the suicide subscale Fluoxetine: 0 Placebo: 1 **Harms, n/N (%):** Insomnia: Fluoxetine: 14/39 (35.9) Placebo: 17/36 (47.2) Anxiety/nervousness: Fluoxetine: 6/39 (15.9) Placebo: 12/36 (33.3) Urinary incontinence: Fluoxetine: 4/39 (10.3) Placebo: 7/36 (19.4) Drowsiness/fatigue/sedation: Fluoxetine: 7/39 (17.9) Placebo: 4/36 (11.1) Agitation: Fluoxetine: 18/39 (46.2) Placebo: 16/36 (44.4)
Hollander et al., 2005 (continued)				Diarrhea: Fluoxetine: 2/39 (5.1) Placebo: 7/36 (19.4)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				Weight gain: Fluoxetine: 0/39 (0) Placebo: 1/36 (2.8) Anorexia: Fluoxetine: 6/39 (15.4) Placebo: 4/36 (11.1) Proportion of subjects having dosage reduction on the two treatment due to AEs was not statistically significant (*P* = 0.289) **Modifiers:** NR
Author: Howard et al., 2005 **Country:** US **Practice setting:** Academic **Intervention setting:** G1: Home, School, and Community G2: School G3: School **Enrollment period:** 1996-2003 **Funding:** Valley Mountain Regional Center Region 6 Autism Connection and California State University, Stanislaus **Author industry relationship disclosures:** NR **Design:** Prospective cohort	**Intervention:** Intensive behavior analytic treatment with individualized goals and objectives 25-30 hours/week 1:1 intervention for children <3 years of age and 35-40 hours/week of 1:1 intervention for children >3 years of age 50-100 learning opportunities/hour via discrete trial, incidental teaching, and other behavior analytic procedures Parents received training in basic behavior analytic strategies and implemented programs with children outside regular intervention hours, with agency staff meeting 1-2 times/month. **Assessments** Conducted by experienced psychologists and speech and language pathologists who were independent contractors	**Inclusion criteria:** • Diagnosed with autistic disorder or PDD-NOS according to DSM-IV criteria by qualified independent examiner prior to 48 months of age • Entry in an intervention program prior to 48 months of age • English as primary spoken language in child's home • No significant medical condition other than autistic disorder or PDD-NOS • No prior treatment >100 hours. • Referred from non-profit agencies ("regional centers') under contract with CA dept of Developmental services for developmental disability case management **Exclusion criteria:** See inclusion criteria **Age, mean/months ± SD:** At diagnosis: **G1:** 30.48 ± 5.96 **G2:** 39.31 ± 5.52 **G3:** 34.94 ± 5.18 At intake:	Intake conducted within 2 months of treatment entry **Overall ratings:** Composite Standard Scores, mean ± SD: **G1:** 70.46 ± 11.85 **G2:** 69.81 ± 10.48 **G3:** 71.62 ± 10.47 **Social skills:** Standard Scores, mean ± SD: **G1:** 72.79 ± 11.26 **G2:** 75.50 ± 14.25 **G3:** 75.07 ± 12.09 Age equivalents (months), mean ± SD: **G1:** 16.39 ± 4.89 **G2:** 22.06 ± 10.62 **G3:** 19.60 ± 5.68 Learning rates prior to intake, mean age equivalents per year ± SD: **G1:** 0.54 ± 0.18 **G2:** 0.58 ± 0.23 **G3:** 0.58 ± 0.19 **Communication/ language:** Standard Scores, mean ± SD: **G1:** 66.18 ±10.02	Follow-up testing conducted at an average 14 months after treatment entry **Overall ratings:** Composite Standard Scores, mean ± SD: **G1:** 81.32 ± 11.14 (*P* < 0.01 compared to G2/G3 mean) **G2:** 69.25 ± 12.91 **G3:** 68.25 ± 9.86 **Social skills:** Standard Scores, mean ± SD: **G1:** 82.08 ± 11.73 (*P* < 0.01 compared to G2/G3 mean) **G2:** 75.00 ± 18.01 **G3:** 70.56 ± 11.77 Age equivalents (months), mean ± SD: **G1:** 32.04 ± 10.23 (*P* < 0.05 compared to G2/G3 mean) **G2:** 30.06 ± 16.10 **G3:** 24.81 ± 7.23 Learning rates

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	with the local regional center and who were not involved in delivering treatment to any of the children in the study • BSID-2nd Edition • WISC-R • Developmental Profile-II • SB-FE • MPS • RDLS • VABS- Interview Edition	**G1:** 30.86 ± 5.16 **G2:** 37.44 ± 5.68 **G3:** 34.56 ± 6.53 At follow-up: **G1:** 45.66 ± 6.24 **G2:** 50.69 ± 5.64 **G3:** 49.25 ± 6.81 **Mental age:** See baseline measures	**G2:** 63.69 ± 9.68 **G3:** 66.20 ± 8.70 Age equivalents (months), mean ± SD: **G1:** 14.90 ± 4.32 **G2:** 16.19 + 6.44 **G3:** 16.53 ± 5.25 Learning rates prior to intake, mean age equivalents per year ± SD: **G1:** 0.49 ± 0.15 **G2:** 0.43 ± 0.15 **G3:** 0.49 ± 0.15	between intake and follow-up, mean age equivalents per year ± SD: **G1:** 1.04 ± 0.74 ($P < 0.05$ compared to G2/G3 mean) **G2:** 0.60 ± 0.94 **G3:** 0.40 ± 0.67
Howard et al., 2005 (continued)	Other (received by few children): • DAS • Development Assessment of Young Children • PEP-R • LIPS • PPVT-III • Expressive Vocabulary Test • Sequenced Inventory of Communication Development-Revised • PLS-3 • Rossetti Infant-Toddler Language Scale • Receptive-Expressive Emergent Language Scales-Revised • EOWPVT • ROWPVT • Denver Developmental Screening Test II • Rockford Infant Development Evaluation Scales **Groups:** **G1:** intensive behavior analytic intervention **G2:** intensive eclectic treatment **G3:** non-intensive public early intervention	**Gender:** **G1:** M, n (%): 25 (86) F, n (%): 4 (14) **G2:** M, n (%): 13 (81) F, n (%):3 (19) **G3:** M, n (%): 16 (100) F, n (%): 0 (0) **Race/ethnicity, n (%):** **G1:** Both parents Caucasian: 21 (72) One or both parents Hispanic: 4 (14) Other: 4 (14) **G2:** (percents only account for known) Both parents Caucasian: 6 (50) One or both parents Hispanic: 3 (25) Other: 3 (25) Unknown: 4 (33) **G3:** (percents only account for known) Both parents Caucasian: 8 (57%) One or both parents Hispanic: 4 (29) Other: 2 (14) Unknown: 2 (17) **SES:** Maternal education, mean ± SD: **G1:** 14.10 ± 2.34 **G2:** 13.00 ± 1.83	Receptive: Standard Scores, mean ± SD: **G1:** 52.16 ± 18.44 **G2:** 45.38 ± 14.97 **G3:** 49.00 ± 13.61 Age equivalents (months), mean ± SD: **G1:**14.57 ± 5.82 **G2:**16.81 ± 5.36 **G3:**16.60 ± 5.34 Learning rates prior to intake, mean age equivalents per year ± SD: **G1:** 0.48 ± 0.21 **G2:** 0.45 ± 0.15 **G3:** 0.48 ± 0.12 Expressive: Standard Scores, mean ± SD: **G1:** 51.88 ±12.91 **G2:** 43.88 ± 6.69 **G3:** 48.77 ± 11.61 Age equivalents (months), mean ± SD: **G1:** 14.76 ± 4.72 **G2:** 16.38 ± 2.99 **G3:** 17.87 ± 5.45 Learning rates prior to intake, mean age equivalents per year ± SD: **G1:** 0.49 ± 0.16 **G2:** 0.44 ± 0.06 **G3:** 0.53 ± 0.17 **Motor skills:** Standard Scores,	**Communication/ language:** Standard Scores, mean ± SD: **G1:** 85.44 ± 14.73 ($P < 0.01$ compared to G2/G3 mean) **G2:** 64.13 ± 14.18 **G3:** 68.69 ± 14.18 Age equivalents (months), mean ± SD: **G1:** 36.60 ± 12.23 ($P < 0.01$ compared to G2/G3 mean) **G2:** 23.88 ± 11.82 **G3:** 26.13 ± 8.74 Learning rates between intake and follow-up, mean age equivalents per year ± SD: **G1:** 1.43 ± 0.72 ($P < 0.01$ compared to G2/G3 mean) **G2:** 0.56 ± 0.76 **G3:** 0.69 ± 0.70 Receptive: Standard Scores, mean ± SD: **G1:** 71.31 ± 22.72 ($P < 0.05$ compared to G2/G3 mean) **G2:** 49.93 ± 19.62 **G3:** 49.21 ± 16.08 Age equivalents

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
		G3: 13 ± 1.41 Paternal education, mean ± SD: **G1:** 14.62 ± 2.77 **G2:** 13.13 ± 2.56 **G3:** 13.00 ± 1.81 Parents' education, mean ± SD **G1:** 14.36 ±2.22 **G2:** 13.06 ± 1.82 **G3:** 12.97 ± 1.36 **Diagnostic approach:** Referral	mean ± SD: **G1:** 95.11 ± 11.70 **G2:** 93.19 ± 10.10 **G3:** 92.08 ± 13.84 Age equivalents (months), mean ± SD: **G1:** 28.86 ± 5.86 **G2:** 33.56 ± 7.20 **G3:** 32.00 ± 6.25	(months), mean ± SD: **G1:** 2.23 ± 10.04 (*P* < 0.05 compared to G2/G3 mean) **G2:** 26.27 ± 11.56 **G3:** 25.38 ± 10.00
Howard et al., 2005 (continued)	**Provider:** • G1: 4-5 instructional assistants attending college trained and supervised by staff w/ masters degrees in psychology or special ed and experience in ABA with children with autism. Some supervisors assisted by staff with bachelor's degrees and graduate coursework in behavior analysis. Supervisors worked under direction of a Board Certified Behavior Analysis who was also a licensed psychologist and a licensed speech and language pathologist. • G2: classroom teachers received consultation from staff with 1-2 years graduate coursework in behavior analysis • G3: special education teachers or certified speech and language pathologists who supervised 1-2 paraprofessional aides **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** No for G1 G2: individual or small	**Diagnostic tool/method:** DSM-IV **Diagnostic category, n (%):** **G1:** Autism: 24 (83) PDD-NOS: 5 (17) **G2:** Autism: 12 (75) PDD-NOS: 4 (25) **G3:** Autism: 9 (56) PDD-NOS: 7 (44) **Other characteristics:** Severity of autism (number of DSM-IV criteria), mean ± SD **G1:** 7.55±1.39 **G2:** 7.27±1.56 **G3:** 7.33±2.02 **Marital status, n (%):** **G1:** Married: 23 (79) Not married, divorced or Separated: 6 (21) **G2:** (percent only for known) Married: 12 (80) Not married, divorced or Separated: 3 (20) Unknown: 1 (7) **G3:** Married: 9 (56) Not married, divorced or Separated: 7 (44)	Learning rates prior to intake, mean age equivalents per year ± SD: **G1:** 0.95 ± 0.18 **G2:** 0.90 ± 0.13 **G3:** 0.93 ± 0.18 **Educational/ cognitive/ academic attainment:** Standard Scores, mean ± SD: **G1:** 58.84 ± 18.15 **G2:** 53.69 ± 13.50 **G3:** 59.88 ± 14.85 Age equivalents (months), mean ± SD: **G1:**17.04 ± 6.07 **G2:**17.27 ± 4.71 **G3:**17.10 ± 3.93 Non-verbal: Standard Scores, mean ± SD: **G1:** 80.14 ± 11.86 **G2:** 67.44 ± 16.69 **G3:** 77.69 ± 12.33 Age equivalents (months), mean ± SD: **G1:** 24.43 ± 4.37 **G2:** 24.75 ± 6.01 **G3:** 26.83 ± 6.95 Learning rates prior to intake, mean age equivalents per year ± SD **G1:** 0.79 ± 0.14 **G2:** 0.67 ± 0.17 **G3:** 0.78 ± 0.12	Learning rates between intake and follow-up, mean age equivalents per year ± SD: **G1:** 1.23 ± 0.56 (*P* < 0.01 compared to G2/G3 mean) **G2:** 0.65 ± 0.47 **G3:** 0.48 ± 0.43 Expressive: Standard Scores, mean ± SD: **G1:** 70.46 ± 22.88 (*P* < 0.05 compared to G2/G3 mean) **G2:** 47.67 ± 23.39 **G3:** 46.79 ± 12.81 Age equivalents (months), mean ± SD: **G1:** 31.96 ± 12.00 (*P* < 0.05 compared to G2/G3 mean) **G2:** 24.00 ± 12.02 **G3:** 23.31 ± 7.36 Learning rates between intake and follow-up, mean age equivalents per year ± SD: **G1:** 1.22 ± 0.73 (*P* < 0.01 compared to G2/G3 mean) **G2:** 0.49 ± 0.78 **G3:** 0.33 ± 0.45

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	group speech therapy sessions G3: individual or small group speech therapy sessions **Concomitant therapies, n (%):** Speech/language therapy: **G2:** 7 (44) **G3:**13 (81)		**Adaptive behavior:** Self-Help: Standard Scores, mean ± SD: **G1:** 70.71 ± 10.14 **G2:** 68.06 ± 11.61 **G3:** 73.43 ± 10.39	**Motor skills:** Standard Scores, mean ± SD: **G1:** 98.16 ± 12.01 (*P* < 0.05 compared to G2/G3 mean) **G2:** 88.06 ± 13.43 **G3:** 89.50 ± 10.06
Howard et al., 2005 (continued)	**N at enrollment:** **G1:** 37 **G2+G3:** 41 **N at follow-up:** **G1:** 29 **G2:** 16 **G3:** 16 Number of children varies per follow-up measure		Age equivalents (months), mean ± SD: **G1:** 18.24 ±3.83 **G2:** 21.44 ± 7.78 **G3:** 21.20 ± 6.67 Learning rates prior to intake, mean age equivalents per year ± SD: **G1:** 0.61 ± 0.17 **G2:** 0.57 ± 0.16 **G3:** 0.62 ± 0.18	Age equivalents (months), mean ± SD: **G1:** 44.16 ± 8.22 (*P* < 0.05 compared to G2/G3 mean) **G2:** 43.00 ± 7.28 **G3:** 42.25 ± 6.58 Learning rates between intake and follow-up, mean age equivalents per year ± SD: **G1:** 0.99 ± 0.45 **G2:** 0.69 ± 0.49 **G3:** 0.83 ± 0.59 **Educational/ cognitive/ academic attainment:** Standard Scores, mean ± SD: **G1:** 89.88 ± 20.87 (*P* < 0.01 compared to G2/G3 mean) **G2:** 62.13 ± 19.63 **G3:** 68.81 ± 15.32 Non-verbal: Standard Scores, mean ± SD: **G1:** 101.67 ±1 9.14 (*P* < 0.01 compared to G2/G3 mean) **G2:** 73.56 ± 24.94 **G3:** 82.53 ± 16.76 Age equivalents (months), mean ± SD: **G1:** 44.54 ± 8.76 (*P* < 0.05

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				compared to G2/G3 mean) **G2:** 37.38 ± 13.14 **G3:** 40.80 ± 9.97
Howard et al., 2005 (continued)				Learning rates between intake and follow-up, mean age equivalents per year ± SD: **G1:** 1.44 ± 0.52 (*P* < 0.01 compared to G2/G3 mean) **G2:** 0.87 ± 0.74 **G3:** 0.90 ± 0.39 **Adaptive behavior:** Self-Help: Standard Scores, mean ±SD: **G1:** 76.56 ± 11.59 (*P* < 0.01 compared to G2/G3 mean) **G2:** 70.00 ± 11.92 **G3:** 65.19 ± 8.84 Age equivalents (months), mean ± SD: **G1:** 31.88 ± 8.74 (*P* < 0.05 compared to G2/G3 mean) **G2:** 31.75 ± 9.75 **G3:** 27.81 ± 5.75 Learning rates between intake and follow-up, mean age equivalents per year ± SD: **G1:** 0.91 ± 0.58 (*P* < 0.05 compared to G2/G3 mean) **G2:** 0.74 ± 0.80 **G3:** 0.48 ± 0.49 Difference in Change scores: Values are G1 minus G2/G3 mean change scores:

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Howard et al., 2005 (continued)				Standard scores, mean: Cognitive: 21.03 *P* < 0.01 Non-verbal: 16.16 *P* < 0.01 Receptive: 19.97 *P* < 0.01 Expressive: 19.78 *P* < 0.05 Communication: 15.88 *P* < 0.01 Self-help: 8.35 *P* < 0.05 Social: 10.43 *P* < 0.05 Motor: 4.75 *P* = NS Composite: 12.07 *P* < 0.01 Age equivalents, mean/months: Non-verbal: 7.95 *P* < 0.01 Receptive: 9.04 *P* < 0.01 Expressive: 10.66 *P* < 0.01 Communication: 12.42 *P* < 0.01 Self-help: 4.76 *P* < 0.05 Social: 8.78 *P* < 0.01 Motor: 3.97 *P* = NS Learning rates (age equivalents per year), mean: Non-verbal: 0.49 *P* < 0.05 Receptive: 0.64 *P* < 0.01 Expressive: 0.79 *P* < 0.01 Communication: 0.76 *P* < 0.01 Self-help: 0.28 *P* < 0.05 Social: 0.56 *P* < 0.05

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Howard et al., 2005 (continued)				Motor: 0.17 *P* = NS **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Mahoney et al., 2005 **Country:** US **Practice setting:** Academic **Intervention setting:** Home or Center-based **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Relationship-Focused (RF) intervention using Responsive Teaching (RT) curriculum Weekly 1 hr parent-child sessions for 1 year **Assessments:** Child & family data collected at the beginning & end of intervention. Trans-disciplinary Play-Based assessment, ITSEA to assess socio-emotional behavior and TABS for problem behavior. Both parents responded to instruments. CBRS to rate child's Pivotal behavior and MBRS to assess parents' style of interaction. **Groups:** **G1:** pervasive development disorder – not otherwise specified **Provider:** Early intervention specialists Children received RT on an average of 32.6 ± 12.9 sessions Hours/week of intervention activities at home: 15.1± 2.4 **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 20	**Inclusion criteria:** • Children with either PDD /other developmental disabilities (DD) with age ranging from 12-54 months • Meeting the DSM-IV criteria for PDD **Exclusion criteria:** See inclusion criteria **Age, mean/months ± SD:** **G1:** 32.4 ± 7.3 **Mental age:** NR **Gender:** M, %: **G1:** 65 F, %: **G1:** 35 **Race/ethnicity, %:** White: **G1:** 95.2 **SES:** Education, mean/yrs ± SD : Maternal: **G1:** 15.5 ± 2.6 Paternal: **G1:** 15.9 ± 2.6 Married, n (%): **G1:** 20 (100) Employment, %: Employed: **G1:** 52.1 Part time: **G1:** 28.6 Full time: **G1:** 23.8 Household income: NR **Diagnostic approach:** **In Study:** Diagnosed by physicians **Diagnostic tool/method:** DSM-IV	**Social skills:** Socio-emotional Functioning: ITSEA, mean ± SD: Internalizing: **G1:** 49.5 ± 8.1 Externalizing: **G1:** 47.9 ± 8.6 Self-regulation: **G1:** 41.3 ± 8.6 Social competence: **G1:** 30.2 ± 15.8 **Communication/ language:** Trans-disciplinary Play-Based Assessment, mean ± SD: Object relations: **G1:** 16.5 ± 6.0 Symbolic behavior: **G1:** 15.2 ± 5.3 Expressive language: **G1:** 13.8 ± 6.7 Receptive language: **G1:** 12.1 ± 7.2 **Problem behavior:** Temperament Atypical Behavior Scale (TABS) mean ± SD: Detached: **G1:** 21 ± 21.1 Hypersensitivity/hyperactivity: **G1:** 39.7 ± 15.0 Under reactivity: **G1:** 34.7 ± 16.3 Self-regulation: **G1:** 33.8 ± 16.3 Overall: **G1:** 55.1 ± 37.3	**Social skills:** Socio-emotional Functioning: ITSEA, mean ± SD: Internalizing: **G1:** 52.9 ± 8.8 $P < 0.05$ Externalizing: **G1:**49 ± 9 Self-regulation: **G1:** 47.2 ± 7.8 Social competence: **G1:** 36.6 ± 11.4 **Communication/ language:** Trans-disciplinary Play-Based Assessment, mean ± SD: Expected: Object relations: **G1:** 22.1 ± 7.4 Symbolic behavior: **G1:** 20.3 ± 6.6 Expressive language: **G1:** 18.4 ± 8.6 Receptive language**:** **G1:**16.1 ± 9.1 Observed: Object relations: **G1:** 27.5 ± 8.2 PCI: G1: 2.2 Symbolic behavior: **G1:** 24.9 ± 10.0 PCI: G1: 2.03 Expressive language: **G1:** 24.1 ± 10.2 PCI: G1: 3.36

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Mahoney et al., 2005 (continued)	**N at follow-up:** **G1:** 20	**Diagnostic category, n (%):** PDD-NOS : **G1:** 20 (40) **Other characteristics, n:** **G1:** Autism: 10 Autism + mental retardation: 3 PDD: 7	**Adaptive behavior:** Child Behavior Rating Scale (CBRS), mean ± SD: Attention: **G1:** 2.9 ± 1.2 Persistence: **G1:** 2.9 ± 1.3 Interest: **G1:** 2.2 ± 1.1 Cooperation: **G1:** 2.1 ± 0.9 Initiation: **G1:** 2.7 ± 1.5 Joint attention: **G1:** 1.9 ± 1.0 Affect: **G1:** 3.3 ± 0.8 Maternal Behavioral Rating Scale (MBRS), mean ± SD: Responsiveness: **G1:** 2.7 ± 0.7 Affect: **G1:** 2.8 ± 0.6 Achievement orientation: **G1:** 3 ± 0.6 Directiveness: **G1:** 3.2 ± 0.5	Receptive language: **G1:** 22.9 ± 8.4 PCI: G1:3.59 Children made greater improvements in object relations and receptive language and in all 4 developmental measures **Problem behavior:** Temperament Atypical Behavior Scale (TABS), mean ± SD: Detached: **G1:** 35.2 ± 22.0 Hypersensitivity/ hyperactivity: **G1:** 43.6 ± 13.7 Under reactivity: **G1:** 47.1 ± 13.6 Self-regulation: **G1:** 43.6 ± 11.5 Overall: **G1:** 75.4 ± 38.5
Mahoney et al., 2005 (continued)				Children with PDDs made improvements in 3 subscales (self-regulation, detached, underactivity) as well as on the overall TABS scores which increased by an average of 1.5 SD **Adaptive behavior:**

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				Child Behavior Rating Scale (CBRS), mean ± SD: Attention: **G1:** 4.1 ± 0.7 Persistence: **G1:** 4.5 ± 0.8 Interest: **G1:** 3.8 ± 0.8 Cooperation: **G1:** 3.5 ± 0.9 Initiation: **G1:** 4.2 ± 0.7 Joint attention: **G1:** 3.6 ± 1.0 Affect: **G1:** 4.1 ± 0.7 Maternal Behavioral Rating Scale (MBRS), mean ± SD: $P < 0.001$ Responsiveness**:** **G1:** 3.8 ± 0.5 Affect: **G1:** 3.5 ± 0.5 Achievement orientation: **G1:** 2.9 ± 0.4 Directiveness: **G1:** 3.1 ± 0.3
Mahoney et al., 2005 (continued)				Mothers of children with PDD made increases in responsiveness and affect Each of the behaviors measured by CBRS increased during intervention and showed improvement on all items

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				The pivotal behavior both at the start and during the intervention did not significantly contribute to the socio-emotional measures **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: McConachie et al., 2005 **Country:** UK **Practice setting:** Academic **Intervention setting:** Home **Enrollment period:** NR **Funding:** Community Fund (National Lottery Charities Board), The NHS Executive R&D Northern and Yorkshire Region (for training course leaders) **Author industry relationship disclosures:** NR **Design:** Non randomized controlled trial	**Intervention:** More Than Words course to improve parents' skills in social interaction with child and improve communication with child The More Than Words course lasted 3 months with weekly group instruction sessions (totaling 20 hours) and 3 home visits for individual discussion/feedback Interval between assess-ments, months ± SD: **G1:** 8.65 ± 1.50 **G2:** 5.16 ± 1.31 **Assessments:** Pre-treatment and at 7 months: VABS, MCDI, ADI-R, ADOS, BSQ assessments conducted in home by study psychologist; Joy and Fun assessment (unpublished checklist created for study to document positive parent strategies), QRS-F, PFQ by parents **Groups:** **G1:** More Than Words **G2:** waitlist control **Ga:** autism diagnosis **Gb:** NCA diagnosis **Provider:** Developmental psycho-logist (second author) **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** Yes **Concomitant therapies, n (%):** **G1:** 17 (65.4) **G2:** 16 (61.5)	**Inclusion criteria:** • Child Identified by the local community pediatrician or speech and language therapist as having language delay and some aspect of concern about social behavior that raised the suspicion of ASD • Age 24-48 months • Parents agreed to attend More than Words course **Exclusion criteria:** • Serious organic medical disorder • About to start an intensive home program **Age, months ± SD:** **G1:** 38.12 ± 6.54 **G2:** 34.96 ± 6.68 **Mental age:** NR **Gender, n (%):** Male: **G1:** 21 (81) **G2:** 21 (84) Female: **G1:** 25 (19) **G2:** 4 (16) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral, confirmed in Study **Diagnostic tool/method:** ADOS **Diagnostic category, n (%):** Autism: **G1:** 17 (65) **G2:** 12 (48) NCA: **G1:** 9 (35) **G2:** 13 (52)	**Communication/ language:** MCDI total speech production score, mean ± SD: **G1a:** 34.65 ± 62.74 **G1b:** 188.22 ± 159.18 **G2a:** 30.75 ± 54.35 **G2b:** 77.54 ± 79.22 **Social Skills:** ADOS reciprocal social interaction and communication score, mean ± SD: **G1a:** 17.35 ± 2.45 **G1b:** 4.33 ± 2.78 **G2a:** 17.17 ± 3.76 **G2b:** 7.15 ± 5.24 **Problem behavior:** BSQ score, mean ± SD: **G1a:** 11.59 ± 4.70 **G1b:** 9.33 ± 4.21 **G2a:** 12.42 ± 3.94 **G2b:** 9.31 ± 3.71 Joy and Fun assessment score, mean ± SD **G1a:** 11.18 ± 4.30 **G1b:** 10.89 ± 2.98 **G2a:** 10.83 ± 3.86 **G2b:** 12.85 ± 3.91 Adapted QRS-F score, mean ± SD: **G1a:** 19.53 ± 9.50 **G1b:** 18.44 ± 9.88 **G2a:** 19.60 ± 5.32 **G2b:** 15.08 ± 8.63 Parent Feelings Questionnaire score, mean ± SD: **G1a:** 145.00 ± 20.40 **G1b:** 150.33 ± 26.06 **G2a:** 146.36 ± 18.35 **G2b:** 159.31 ± 22.36	**Communication/ language:** MCDI total speech production score, mean ± SD: **G1a:** 72.6 ± 100.07 **G1b:** 271.38 ± 148.43 **G2a:** 38.92 ± 54.89 **G2b:** 131.54 ± 114.7 **G1a/BL:** $P < 0.05$ **G1b/BL:** $P < 0.05$ **G2a/BL:** $P < 0.05$ **G2b/BL:** $P < 0.05$ **G2a/G1a:** $P = 0.019$ **G2b/G2a:** $P < 0.001$ **Social skills:** ADOS reciprocal social interaction and communica-tion score, mean ± SD: **G1a:** 14.82 ± 6.47 **G1b:** 6.00 ± 3.87 **G2a:** 14.00 ± 6.45 **G2b:** 7.69 ± 5.84 **G1a/BL:** *P* = NS **G1b/BL:** *P* = NS **G2a/BL:** *P* = NS **G2b/BL:** *P* = NS **G2a/G1a:** *P* = NS **G2b/G2a:** *P* = NS **Problem behavior:** BSQ score, mean ± SD: **G1a:** 12.50 ± 5.05 **G1b:** 8.44 ± 3.40 **G2a:** 12.92 ± 4.10 **G2b:** 9.23 ± 3.98 **G1a/BL:** *P* = NS **G1b/BL:** *P* = NS **G2a/BL:** *P* = NS **G2b/BL:** *P* = NS **G2a/G1a:** *P* = NS **G2b/G2a:** *P* = NS
McConachie et al., 2005 (continued)	**N at enrollment:** **G1:** 26 **G1a:** 17 **G1b:** 9 **G2:** 21	**Other characteristics:** VABS composite score, mean ± SD: **G1:** 66.42 ± 11.44 **G2:** 67.76 ± 9.81		Joy and Fun assessment score, mean ± SD: **G1a:** 13.94 ± 4.68

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	G2a: 12 **G2b:** 13 **N at follow-up:** **G1:** 26 **G1a:** 17 **G1b:** 9 **G2:** 21 **G2a:** 12 **G2b:** 13			**G1b:** 11.11 ± 3.44 **G2a:** 11.58 ± 4.54 **G2b:** 13.77 ± 3.49 **G1a/BL:** *P* < 0.05 **G1b/BL:** *P* = NS **G2a/BL:** *P* < 0.05 **G2b/BL:** *P* = NS **G2a/G1a:** *P* = 0.05 **G2b/G2a:** *P* = NS **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: RUPP, 2005 **Country:** US **Practice setting:** Academic centers **Intervention setting:** Clinic **Enrollment period:** June 1999 to April 2001 **Funding:** NIH; Kor-czak Foundation; Janssen (provided study medication) **Author industry relationship disclosures:** NR **Design:** Open label extension phase followed by RCT discontinuation phase	**Intervention:** Part 1: 4 month open-label Rx with Risperidone, starting at the optimal dose Part 2: 8 week randomized double-blind gradual placebo-substitution for risperidone **Open label extension phase intervention (16 weeks):** Responders from the RCT or the extension trial were invited to continue into the open label extension Clinicians were allowed to adjust the total daily dose according to response and side effects, up to a maximum of 3.5 mg/day for children weighing 15-45 kg and up to 4.5 mg/ day for children > 45 kg Last values were carried forward for individuals not completing this phase Mean risperidone dose at week 0= 1.96 mg/day. Mean risperidone dose at week 16=2.08 mg/day (6% increase over 4 month period) **Randomized discontinuation phase (8 weeks):** Participants randomized to risperidone or placebo. Placebo group had risperidone replaced by placebo by 25% each week for the first four weeks; enrollment halted after 32 participants were randomized (interim safety review indicated significantly increased relapse rate among placebo vs. risperidone	**Inclusion criteria:** • Children meeting DSM-IV criteria for autistic disorder, with tantrums, aggression, self-injurious behavior, or a combina-tion of these problems • Aged 5 to 17 years • Weight ≥ 15 kg • Mental age ≥ 18 months • Clinically significant behavioral problems with clinician-determined rating of ≥ moderate on CGI-S and score ≥ 18 on ABC Irritability subscale rated by parent and confirmed by caregiver (children reassessed at baseline, 7-14 days after initial assessment to confirm first values) **Exclusion criteria:** • Serious medical disorders • Other psychiatric disorders requiring medication • Children receiving a psychotropic drug that was deemed effective for the treatment of aggression, tantrums, or self-injurious behavior **Age, years** (mean ± sd)**:** 8.6 ± 2.8 (5-17), n=63 **Mental age:** Mental development, n (%): IQ: Average or above average: 3 (4.8) Borderline: 7 (11.1) Mild retardation: 17 (27) Moderate: 12 (19) Severe: 11 (17.5) Profound: 7 (11.1) Unable to assess: 6 (9.5) **Gender: n (%):** Male: 49 (77.8)	**Overall ratings:** Extension phase: (end of initial 8 weeks of medication exposure) : (n=63) **ABC-C, mean ± SD:** Irritability: **G1:** 9.5 ± 6.8 Social withdrawal: **G1:** 7.3 ± 5.4 Stereotypy: **G1:** 4.9 ± 4.3 Hyperactivity: **G1:** 15.1 ± 10 Inappropriate speech: **G1:** 3.4 ± 3.6 **CGI Improvement score, n (%):** **G1:** Very much improved: 19 (30.2) Much improved: 42 (66.7) Minimally improved: 0 (0.0) No change: 2 (3.2) Worse: 0 (0.0) Much worse: 0 (0.0) **Discontinuation phase participants, mean ± SD:** (n=38) ABC-hyperactivity: 34.4 ± 8.7 ABC-Irritability: 27.6 ± 6.1	4- month open label extension phase: **ABC-C, mean ± SD:** Irritability: **G1:** 11.7 ± 8 ; F = 5.35, *P* = 0.028 Lethargy / social withdrawal: **G1:** 6.8 ± 5.9; F = 2.61, *P* = NS Stereotypy: **G1:** 5.8 ± 4.7; F = 5.47, *P* = 0.02 Hyperactivity: **G1:** 15.8 ± 10.2; F = 0.43, *P* = NS Inappropriate speech: **G1:** 3.4 ± 3.2 ; F = 0.39, *P* = NS **CGI Improvement score, n (%)** **G1:** Very much improved: 19 (30.2) Much improved: 33 (52.4) Minimally improved: 6 (9.5) No change: 0 (0.0) Worse: 3 (4.8) Much worse: 2 (3.2) **RCT participants:** Relapse during discontinuation phase, n (%): **G1:** 2/16 (12.5) **G2:** 10/16 (62.5) **G1/G2:** *P* = 0.01 Time to relapse, discontinuation phase, median days: **G1:** 57 **G2:** 34 **Harms (n=63), %:** Nasal congestion: 11.1 Appetite increase: 7.9 Coughing: 6.3

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	treated patients			
RUPP, 2005 (continued)	**Assessments:** Intelligence testing, Lab tests, ECGS, at entry into the extension phase and prior to the discontinuation phase VABS maladaptive behavior at entry to the open label extension phase Vital signs, height, weight at each visit Neurological side effects done by Simpson – Angus Rating scale and AIMS. medical history, physical examination Clinician rated CGI and monthly scores on the parent rated subscales of ABC-C weekly assessment in the discontinuation phase **Groups:** Open label extension phase: **G1:** risperidone Discontinuation phase: **G1:** risperidone **G2:** placebo **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at start of extension phase:** **G1:** 63* **N at end of extension phase:** **G1:** 51 **N at enrollment of discontinuation phase:** Total: 38 **N at end of discontinuation phase:** **G1:** 16 **G2:** 16	**Race/ethnicity, RCT population, n (%):** White: 44 (69.8) Black: 6 (9.5) Hispanic: 3 (4.8) Asian or Pacific islander: 4 (6.3) Other: 6 (9.5) **SES:** Education of parent or primary caregiver, n (%): Less than high school: 1 (1.6) High school: 13 (20.6) Trade or Technical school: 4 (6.3) At least some college: 35 (55.6) Advanced degree: 10 (15.9) Annual household income, n (%): < $20,000: 6 (9.5) $20,001-$40,000: 17 (27) $40,001-$60,000: 15 (23.8) > $60,000: 23 (36.5) **Diagnostic approach:** In Study **Diagnostic tool/method:** Diagnosis corroborated by ADI-R, administered by a clinician with special training and systematic review to ensure reliability **Diagnostic category:** See inclusion criteria **Other characteristics, n (%):** Educational placement of child: (n=63) Regular class: 4 (6.3) Special education program: 47 (74.6) Special school: 11 (17.5) Residential school: 0 Other: 1 (1.6) Current anticonvulsant treatment: n (%): 1/63 (1.6)		Anxiety, Difficulty falling asleep, Fever, Skin irritation, Vomiting: 4.8 Accidental injury , Constipation, Drowsiness/sedation, Enuresis, Headache, Hypersalivation, Sore throat: 3.2 Depression, Diarrhea, Difficulty urinating, Dyskinesia,Earache , Restlessness/agitation , Sinus condition, Stomach/abdominal discomfort, Tiredness/fatigue, Tremor, Weight gain, Muscle rigidity, Other: 1.6 **Modifiers**: No predictors of relapse were identified
RUPP, 2005 (continued)		Previous medication (n=63): Medication naïve: 11		

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
		(17.7) Antipsychotic agent: 4 (6.5) SSRI: 9 (14.5) Stimulant: 16 (25.8) Alpha-2 agonist: 11 (17.7) Child living at home with at least 1 parent: 56 (88.9%)		

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Sallows et al., 2005 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** 1996 to 1997 **Funding:** NIH **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Intensive clinic-directed vs. less intensive parent-directed groups using treatment based on UCLA model (without aversives and the addition of procedures from subsequent approaches) Clinic-directed treatment parents had 6-10 hours/ week of 2-3 hour in-home consultation sessions with a senior therapist, team meetings for 1 hour per week, and an hour-long progress review per week for 1-2 years and every other month thereafter; parent-directed treatment had one 3 hour consultation session with a senior therapist every 2 weeks, team meetings for 1 hour every 1-2 weeks, and an hour-long progress review every other month Duration: 4 years Frequency, 1:1 direct treatment, hours/week ± SD: Year 1: **G1:** 38.60 ± 2.91 **G2:** 31.67 ± 5.81 Year 2: **G1:** 36.55 ± 3.83 **G2:** 30.88 ± 4.04 **Assessments:** BSID, Merrill-Palmer scales, RDLS, VABS communication, daily living and socials skills, WASI, WISC-III, Leiter R, Clinical Evaluation of Language Fundamentals administered by investtigator or independent psychologist at pre-treatment and annually for 4 years	**Inclusion criteria:** • Recruited through local birth-3 special education programs • Age 24-42 months at intake • Ratio estimate of mental age/chronological age by Mental Development Index ≥ 35 • Neurologically within "normal" limits as determined by a pediatric neurologist • Diagnosis of autism by independent child psychiatrists familiar with autism and known for their experience • Met DSM-IV criteria for autism as determined by trained examiner **Exclusion criteria:** • See inclusion criteria **Age, months ± SD:** Pre-test: **G1:** 33.23 ± 3.89 **G2:** 34.20 ± 5.06 During treatment: **G1:** 35.00 ± 4.86 **G2:** 37.10 ± 5.36 Post-test: **G1:** 83.23 ± 8.92 **G2:** 82.50 ± 6.61 **Mental age:** See baseline measures **Gender, n (%):** Male: **G1:** 11 (84.6) **G2:** 8 (80) Female: **G1:** 2 (15.4) **G2:** 2 (20) **Race/ethnicity:** NR **SES:** Maternal education to BA level, n (%): **G1:** 9/12 (75) **G2:** 9/10 (90)	**Educational/ cognitive/ academic attainment:** FSIQ, mean ± SD **G1:** 50.85 ± 10.57 **G2:** 52.10 ± 8.98 **Ga:** 55.27 ± 8.96 **Gb:** 47.83 ± 9.37 Nonverbal IQ, mean ± SD: **G1:** 70.58 ± 16.54 **G2:** 82.67 ± 14.94 **Ga:** 83.56 ± 14.84 **Gb:** 69.83 ± 15.93 **Communication/ language:** VABS communication score, mean ± SD **G1:** 57.46 ± 4.97 **G2:** 63.20 ± 5.58 **Ga:** 60.82 ± 4.02 **Gb:** 59.17 ± 7.22 RDLS score, mean ± SD: Receptive language: **G1:** 38.85 ± 6.09 **G2:** 38.78 ± 6.44 **Ga:** 39.30 ± 6.91 **Gb:** 38.42 ± 5.59 Expressive language: **G1:** 47.92 ± 6.17 **G2:** 48.44 ± 6.96 **Ga:** 49.90 ± 7.75 **Gb:** 47.50 ± 6.54 **Adaptive behavior:** VABS score, mean ± SD: Daily living skills: **G1:** 63.92 ± 5.53 **G2:** 64.20 ± 3.68 **Ga:** 66.45 ± 4.25 **Gb:** 61.83 ± 4.20 Composite: **G1:** 59.54 ± 5.31 **G2:** 60.90 ± 5.94 **Ga:** 61.73 ± 4.59 **Gb:** 58.67 ± 6.09	**Educational/ cognitive/ academic attainment:** FSIQ, mean ± SD **G1:** 73.08 ± 33.08 **G2:** 79.60 ± 21.80 **Ga:** 103.73 ± 13.35 **Gb:** 50.42 ± 6.98 **Ga/BL:** $P < 0.01$ **Gb/BL:** P = NS ANOVA: time ($P < 0.01$)* Verbal IQ, mean ± SD: **G1:** 78.00 ± 33.48 **G2:** 76.30 ± 26.66 **Ga:** 101.45 ± 18.72 **Gb:** 47.44 ± 2.06 **Ga/BL:** $P < 0.01$ **Gb/BL:** P = NS ANOVA: time ($P < 0.01$)* PIQ, mean ± SD: **G1:** 84.90 ± 25.86 **G2:** 90.70 ± 20.72 **Ga:** 107.55 ± 9.44 **Gb:** 63.67 ± 8.43 **Ga/BL:** $P < 0.01$ **Gb/BL:** $P < 0.01$ ANOVA: time ($P < 0.01$)* Nonverbal IQ, mean ± SD **G1:** 77.58 ± 25.24 **G2:** 89.44 ± 18.35 **Ga:**108.78 ± 10.96 **Gb:** 67.70 ± 12.35 **Ga/BL:** P = NS **Gb/BL:** P = NS ANOVA: time (P = NS)*
Sallows et al., 2005 (continued)	ADI-R administered by investigator/psychologist and Personality Inventory for Children completed by parent after 3 years treatment Child Behavior Checklist	Paternal education to BA level, n (%): **G1:** 10/12 (83.3) **G2:** 6/9 (66.7) Household income, median (range): **G1:** \$62,000 (\$35,000-	**Social skills:** VABS socialization score, mean ± SD: **G1:** 58.38 ± 6.17 **G2:** 60.30 ± 5.76 **Ga:** 61.55 ± 6.58 **Gb:** 57.08 ± 4.63	Personality Inventory for Children, parent rated, cognitive development score, mean ± SD:

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Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	and VABS completed by parents and teachers after 4 years treatment; teachers administered Woodcock Johnson III tests of Achievement for subjects at age 7 in regular education classes UCLA Early Learning Measure administered in first 6 months of treatment by investigator **Groups:** **G1:** clinic-directed **G2:** parent-directed **Ga:** rapid learners by Early Learning Measure **Gb:** moderate learners by Early Learning Measure **Provider:** 18 or older with minimum of 1 year college and 30 hours of training **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 13 **G2:** 11 **N at follow-up:** **G1:** 13 **G1a:** 5 **G1b:** 8 **G2:** 10 **G2a:** 6 **G2b:** 4	\$100,000+) **G2:** \$59,000 (\$30,000-\$100,000+) **Diagnostic approach:** See inclusion criteria **Diagnostic tool/method:** **DSM-IV** **Diagnostic category, n (%):** Autism: 23 (100) PDD-NOS: 0 Aspergers: 0 **Other characteristics:** One-parent families, n (%): **G1:** 0/13 (0) **G2:** 1/10 (10) Number of siblings, mean: **G1:** 2 **G2:** 2 Non-verbal, n (%): **G1:** 8/13 (62) G2: 2/10 (20)	ADI-R score, mean ± SD: Social skills: **G1:** 17.54 ± 3.73 **G2:** 18.90 ± 1.14 **Ga:** 16.45 ± 3.26 **Gb:** 19.67 ± 1.55 Communication: **G1:** 12.85 ± 2.44 **G2:** 12.90 ± 1.22 **Ga:** 11.00 ± 3.54 **Gb:** 13.75 ± 0.60 **Repetitive behavior:** ADI-R ritualistic score, mean ± SD: **G1:** 5.38 ± 1.69 **G2:** 6.40 ± 1.11 **Ga:** 5.91 ± 1.62 **Gb:** 5.92 ± 1.44	**Ga:** 64.18 ± 13.65 **Gb:** 97.55 ± 18.77 **Ga/Gb:** $P < 0.01$ Child Behavior Checklist, parent rated, thought problems score, mean ± SD: **Ga:** 65.64 ± 9.87 **Gb:** 70.42 ± 7.92 **Ga/Gb:** P = NS **Communication/ language:** VABS communi-cation score, mean ± SD: **G1:** 73.69 ± 32.32 **G2:** 81.40 ± 24.33 **Ga:** 105.09 ± 12.83 **Gb:** 51.33 ± 10.94 **Ga/BL:** $P < 0.01$ **Gb/BL:** $P < 0.05$ ANOVA: time ($P < 0.05$)* VABS communi-cation, teacher rated, mean ± SD: **Ga:** 94.44 ± 13.97 **Gb:** 58.58 ± 7.90 **Ga/Gb:** $P < 0.01$ RDLS score, mean ± SD: Receptive language: **G1:** 55.85 ± 36.23 **G2:** 65.78 ± 25.81 **Ga:** 93.60 ± 12.64 **Gb:** 31.83 ± 9.87 **Ga/BL:** $P < 0.01$ **Gb/BL:** P = NS ANOVA: time ($P < 0.01$)*
Sallows et al., 2005 (continued)				Expressive language: **G1:** 53.38 ± 31.91 **G2:** 59.22 ± 25.13 **Ga:** 85.70 ± 15.07 **Gb:** 30.83 ± 5.89 **Ga/BL:** $P < 0.01$ **Gb/BL:** $P < 0.01$ ANOVA: time (P = NS)* ADI-R communi-cation score, mean ± SD: **G1:** 8.08 ± 6.91

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G2: 8.80 ± 7.43 **Ga:** 2.00 ± 2.73 **Gb:** 14.81 ± 3.59 **Ga/BL:** *P* < 0.01 **Gb/BL:** *P* = NS ANOVA: time (*P* < 0.01)* **Adaptive behavior:** VABS score, mean ± SD: Daily living skills: **G1:** 66.23 ± 25.95 **G2:** 64.20 ± 12.42 **Ga:** 82.27 ± 16.34 **Gb:** 49.83 ± 10.61 **Ga/BL:** *P* < 0.01 **Gb/BL:** *P* < 0.01 ANOVA: time (*P* = NS)* Composite: **G1:** 69.00 ± 28.04 **G2:** 66.70 ± 14.68 **Ga:** 88.64 ± 15.68 **Gb:** 49.08 ± 7.76 **Ga/BL:** *P* < 0.01 **Gb/BL:** *P* < 0.05 ANOVA: time (*P* < 0.05)*
Sallows et al., 2005 (continued)				**Social skills:** VABS socialization score, mean ± SD: **G1:** 73.92 ± 23.49 **G2:** 68.90 ± 10.11 **Ga:** 87.73 ± 14.94 **Gb:** 57.08 ± 6.40 **Ga/BL:** *P* < 0.01 **Gb/BL:** *P* = NS ANOVA: time (*P* < 0.01)* VABS socialization score, teacher rated, mean ± SD: **Ga:** 89.89 ± 18.36 **Gb:** 61.58 ± 6.02 **Ga/Gb:** *P* < 0.01 ADI-R social skills score, mean ± SD: **G1:** 12.33 ± 10.58 **G2:** 13.10 ± 9.42 **Ga:** 4.18 ± 4.37 **Gb:** 21.18 ± 6.28 **Ga/BL:** *P* < 0.01 **Gb/BL:** *P* = NS

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				ANOVA: time (P < 0.01)* Personality Inventory for Children, parent rated, social incompetence score, mean ± SD: **Ga:** 62.36 ± 8.34 **Gb:** 79.25 ± 9.42 **Ga/Gb:** P < 0.01 Child Behavior Checklist score, mean ± SD: Withdrawn: Parent rated: **Ga:** 59.09 ± 6.26 **Gb:** 58.83 ± 6.27 **Ga/Gb:** P = NS Teacher rated: **Ga:** 57.00 ± 7.34 **Gb:** 64.33 ± 6.03 **Ga/Gb:** P < P<.01
Sallows et al., 2005 (continued)				Social problems: Parent rated: **Ga:** 57.82 ± 7.49 **Gb:** 61.92 ± 7.35 **Ga/Gb:** P = NS Teacher rated: **Ga:** 56.73 ± 6.30 **Gb:** 58.00 ± 5.57 **Ga/Gb:** P = NS **Repetitive behavior:** ADI-R ritualistic score, mean ± SD: **G1:** 5.08 ± 3.75 **G2:** 5.60 ± 3.50 **Ga:** 2.73 ± 2.67 **Gb:** 7.91 ± 2.47 **Ga/BL:** P < 0.01 **Gb/BL:** P < 0.05 ANOVA: time (P = NS)* **Problem behavior:** Personality Inventory for Children, parent rated, undisci-plined/poor self control score, mean ± SD **Ga:** 53.45 ± 9.38 **Gb:** 66.83 ± 12.93

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				Ga/Gb: $P < 0.01$ **Commonly occurring co-morbidities:** Child Behavior Checklist score, mean ± SD: Anxious/ depressed: Parent rated: **Ga:** 55.40 ± 6.14 **Gb:** 51.75 ± 3.06 **Ga/Gb:** $P < 0.05$ Teacher rated: **Ga:** 55.90 ± 6.93 **Gb:** 55.17 ± 6.56 **Ga/Gb:** P = NS
Sallows et al., 2005 (continued)				Attention problems: Parent rated: **Ga:** 62.64 ± 9.12 **Gb:** 67.67 ± 8.17 **Ga/Gb:** $P < 0.05$ Teacher rated: **Ga:** 59.36 ± 12.33 **Gb:** 63.25 ± 7.94 **Ga/Gb:** P = NS Aggression: Parent rated: **Ga:** 52.91 ± 4.98 **Gb:** 53.33 ± 4.62 **Ga/Gb:** P = NS Teacher rated: **Ga:** 57.60 ± 6.11 **Gb:** 61.25 ± 7.45 **Ga/Gb:** $P < 0.01$ Thought problems: Parent rated: **Ga:** 65.64 ± 9.87 **Gb:** 70.42 ± 7.92 **Ga/Gb:** P = NS Teacher rated: **Ga:** 65.55 ± 11.37 **Gb:** 72.58 ± 7.06 **Ga/Gb:** $P < 0.05$ **Sensory:** Personality Inventory for Children, parent rated, Internalizing/somatic symptoms score, mean ± SD: **Ga:** 55.27 ± 13.90 **Gb:** 49.73 ± 8.77 **Ga/Gb:** P = NS

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				Harms: NR **Modifiers:** NR

Comments: *For all outcome measures, both treatment (G1 vs. G2) and time X treatment were not significant in the ANOVA.

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Sofronoff et al., 2005 **Country:** Australia **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding Agency:** NR **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Cognitive behavioral therapy: 6 week study (6 two-hour sessions); children were allocated in groups of 3 with 2 therapists in each group, within each treatment group by age and sex (girls grouped together) Sessions: • Exploring positive emotions • Exploration of anxiety and recognition of speech, thinking, physiological and behavior changes • Exploration of social tools • Measures of the degrees of emotion • Exploring social stories • Working together to design a program to improve the management of anxiety In the child-only treatment, parents received no training but got instructions for the weekly home-based projects; in the child and parents treatment, parents were trained to work as co-therapists and to complete home-based projects **Assessments:** Measures administered pre- and post-intervention and at 6 week follow-up: James and the Maths Test, SCAS-P, SWQ-P **Groups:** **G1:** child only **G2:** child and parents **G3:** wait-list group **Provider:** Therapists **Measure of treatment fidelity reported:** Yes	**Inclusion criteria:** • Primary diagnosis of Asperger syndrome from a pediatrician • Phone interview with a parent to establish DSM-IV criteria • CAST score > 15 **Exclusion criteria:** • See inclusion criteria **Age, mean/yrs ±SD:** **G1:** 10.56 ± 0.99 **G2:** 10.54 ± 1.26 **G3:** 10.75 ± 1.04 **Mental age:** IQ, mean ± SD (range): **G1:** 107.5 ± 27.3 (90-137) **G2:** 105.6 ± 21.2 (90-135) **G3:** 101 ± 27.2 (95-125) **Gender, n (%):** Male: **G1:** 20 (87) **G2:** 22 (88) **G3:** 20 (87) Female: **G1:** 3 (13) **G2:** 3 (12) **G3:** 3 (13) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** DSM-IV checklist/CAST **Diagnostic category, n (%):** Autism: 0 PDD-NOS: 0 Aspergers: 71 (100) **Other characteristics:** Children's depression inventory, mean ± SD: **G1:** 11.5 (8.27) **G2:** 10.25 (7.82) **G3:** 8.62 (5.80)	**Commonly occurring co-morbidities:** SCAS-P score, mean ± SD: Total: **G1:** 40.23 ± 20.42 **G2:** 35.25 ± 16.44 **G3:** 36.64 ± 16.67 Separation anxiety: **G1:** 7.01 ± 4.46 **G2:** 6.79 ± 4.71 **G3:** 8.18 ± 4.45 OCD: **G1:** 5.11 ± 4.65 **G2:** 5.21 ± 3.67 **G3:** 4.96 ± 4.08 Social phobia: **G1:** 9.03 ± 4.45 **G2:** 7.93 ± 5.03 **G3:** 7.21 ± 4.75 Panic: **G1:** 4.88 ± 4.67 **G2:** 3.89 ± 2.84 **G3:** 4.18 ± 4.28 Personal injury: **G1:** 5.69 ± 3.37 **G2:** 5.07 ± 2.97 **G3:** 5.54 ± 3.28 GAD: **G1:** 8.42 ± 3.41 **G2:** 6.36 ± 3.30 **G3:** 6.57 ± 3.65 SWQ-P score, mean: **G1:** NR* **G2:** NR* **G3:** NR* James and the Maths test score, mean: **G1:** NR* **G2:** NR* **G3:** NR*	**Commonly occurring co-morbidities:** SCAS-P score, 6 week follow-up, mean ± SD: Total: **G1:** 29.42 ± 15.3 **G2:** 21.11 ± 10.1 **G3:** 36.32 ± 13.3 **G1/BL:** *P* < 0.01 **G2/BL:** *P* < 0.01 **G3/BL:** *P* = NS **G1/G2:** *P* < 0.025 ANOVA: time (*P* < 0.0001), time X treatment (*P* < 0.0001) Separation anxiety: **G1:** 5.38 ± 3.7 **G2:** 3.03 ± 2.2 **G3:** 8.89 ± 4.5 **G1/BL:** *P* < 0.01 **G2/BL:** *P* < 0.0001 **G3/BL:** *P* = NS **G1/G2:** *P* < 0.02 **G1/G3:** *P* < 0.02 **G2/G3:** *P* < 0.001 ANOVA: treatment (*P* < 0.01), time (*P* < 0.0001), time X treatment (*P* < 0.0001) OCD: **G1:** 2.88 ± 2.9 **G2:** 2.21 ± 1.9 **G3:** 5.71 ± 4.4 **G1/BL:** *P* < 0.0001 **G2/BL:** *P* < 0.0001 **G3/BL:** *P* = NS ANOVA: time (*P* < 0.05), time X treatment (*P* < 0.05) Social phobia: **G1:** 7.38 ± 4.43 **G2:** 5.96 ± 4.32 **G3:** 6.61 ± 4.49 **G1/BL:** *P* < 0.05 **G2/BL:** *P* < 0.01 **G3/BL:** *P* = NS ANOVA: time (*P* < 0.05), time X treatment (*P* < 0.05)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Sofronoff et al., 2005 (continued)	**Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 23 **G2:** 25 **G3:** 23 **N at follow-up:** **G1:** 22 **G2:** 24 **G3:** 20	Spence Child Anxiety Scale total score, mean ± SD: **G1:** 29.29 (17.45) **G2:** 32.23 (17.71) **G3:** 27.46 (12.19) Spence Child Anxiety Scale score, parent-rated, mean: Total score: 37.30 Panic/Agorophobia: 4.30 OCD: 5.10 Social phobia: 8.03 Physical injury: 5.43 Separation anxiety: 7.35 GAD: 7.09		Panic: **G1:** 3.31 ± 3.5 **G2:** 2.68 ± 2.4 **G3:** 3.35 ± 2.7 **G1/BL:** *P* < 0.01 **G2/BL:** *P* < 0.05 **G3/BL:** *P* = NS Personal injury: **G1:** 5.00 ± 3.9 **G2:** 3.32 ± 2.2 **G3:** 5.17 ± 3.8 **G1/BL:** *P* = NS **G2/BL:** *P* < 0.0001 **G3/BL:** *P* = NS GAD: **G1:** 5.46 ± 2.67 **G2:** 3.89 ± 2.36 **G3:** 6.57 ± 3.56 **G1/BL:** *P* < 0.0001 **G2/BL:** *P* < 0.0001 **G3/BL:** *P* = NS ANOVA: time (*P* < 0.05), time X treatment (*P* < 0.05) SWQ-P score, 6 week follow-up, mean: **G1:** NR* **G2:** NR* **G3:** NR* **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.0001 **G3/BL:** *P* = NS **G1/G2:** *P* = 0.06 **G1/G3:** *P* < 0.01 **G2/G3:** *P* < 0.0001 ANOVA: time (*P* < 0.0001), time X treatment (*P* < 0.0001)
Sofronoff et al., 2005 (continued)				James and the Maths test score, 6 week follow-up, mean: **G1:** NR* **G2:** NR* **G3:** NR* **G1/BL:** *P* < 0.0001 **G2/BL:** *P* < 0.0001 **G3/BL:** *P* = NS **G1/G2:** *P* < 0.001 **G1/G3:** *P* < 0.001 **G2/G3:** *P* < 0.001 ANOVA: treatment (*P* < 0.0001), time (*P* < 0.0001), time

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				X treatment (*P* < 0.0001) **Harms**: NR **Modifiers**: Parent involvement in comparison of interventions associated with less SCAS-P symptoms.

Comments: *data only illustrated graphically

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Akhondzadeh et al., 2004 **Country:** Iran **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** January 2002 to January 2003 **Funding:** NR **Author industry relationship disclosures:** NR **Design:** RCT, double-blind placebo controlled	**Intervention:** Cyproheptadine titrated up to 0.05 mg/kg/day plus haloperidol titrated up to 0.2 mg/kg/day All patients received biperiden at 0.04 mg/kg/day as a prophylaxis against extrapyramidal symptoms Duration: 8 weeks **Assessments:** ABC-C, CARS, extra-pyramidal symptoms all assessed by third year psychiatry resident at baseline, 2, 4, 6 and 8 weeks after the start of medication **Groups:** **G1:** cyproheptadine plus haloperidol **G2:** placebo plus haloperidol **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** Baseline and every two weeks **Concomitant therapies:** NR **N at enrollment:** **G1:** 20 **G2:** 20 **N at follow-up:** **G1:** 20 **G2:** 20	**Inclusion criteria:** • Ages 3-11 years • DSM-IV clinical diagnosis of autism, confirmed by two child psychiatrists • Outpatients from a specialty clinic for children at Roozbeh Psychiatric Teaching Hospital • Chief complaint of severely disruptive symptoms related to autistic disorder **Exclusion criteria:** • Previously received neuroleptics • Receiving any psychotropic drug treatment 6 months prior to recruitment • Significant active medical problem **Age, years (SE) (range):** **G1:** 6.40 (0.48) (3-11) **G2:** 6.90 (0.42) (3-11) **Mental age:** NR **Gender, n (%):** Male: **G1:** 13 (65) **G2:** 11 (55) Female: **G1:** 7 (35) **G2:** 9 (45) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In-study **Diagnostic tool/method:** DSM-IV **Diagnostic category, n (%):** Autism: 40 (100)	**Overall ratings:** CARS score, mean: **G1:** NR* **G2:** NR* **G1/G2:** $P = 0.76$ **Problem behavior:** ABC-C score, mean: **G1:** NR* **G2:** NR* **G1/G2:** $P = 0.42$	**Overall ratings:** CARS score, week 8, mean change ± SD: **G1:** -1.85 ± 2.08 **G2:** -0.37 ± 0.48 **G1+G2/BL:** $P = 0.003$ **G1/G2:** $P = 0.004$ ANOVA: time ($P < 0.0001$), treatment ($P = 0.045$), time x treatment ($P = 0.004$) **Problem behavior:** ABC-C score, week 8, mean change ± SD: **G1:** 10.90 ± 7.19 **G2:** 3.70 ± 7.16 **G1+G2/BL:** $P = 0.003$ **G1/G2:** $P = 0.006$ ANOVA: time ($P < 0.0001$), treatment ($P = 0.048$), time x treatment ($P = 0.002$) **Harms:** Extrapyramidal symptoms: **G1:** 2 **G2:** 6 **G1/G2:** $P = 0.23$ Side effects, n:** Trouble swallowing: **G1:** 2 **G2:** 4 Stiffness: **G1:** 1 **G2:** 3 Constipation: **G1:** 4 **G2:** 2 Diarrhea: **G1:** 2 **G2:** 3 Daytime drowsiness: **G1:** 1 **G2:** 2

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Akhondzadeh et al., 2004 (continued)		**Other characteristics:** Weight, kg (SE): **G1:** 24.35 (1.29) **G2:** 25.00 (1.49)		Slow movement: **G1:** 1 **G2:** 3 Restlessness: **G1:** 1 **G2:** 4 Morning drowsiness: **G1:** 3 **G2:** 2 Increased appetite: **G1:** 9 **G2:** 4 Fatigue: **G1:** 3 **G2:** 2 **Modifiers:** NR

Comments: *Data only illustrated graphically.
**The between group difference was not significant for any side effects.

Author: Aldred et al., 2004 **Country:** UK **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Shirley foundation **Author industry relationship disclosures:** NR **Design:** RCT **Note:** See Aldred, Pollard, Phillips, and Adams, 2001 (not included in this report) for description of intervention	**Intervention:** Social communication intervention aiming to increase the quality of parental adaptation and communication with children with autism; monthly treatment sessions for 6 months followed by 6 months of less frequent maintenance sessions **Assessments:** ADI at baseline; ADOS modules 1 and 2 at baseline and post treatment; VABS, MCDI and PSI (parent completed), coding of 30-minute child/parent free play session with standardized toys to record frequency of communication acts (child and parent), semantic contingency, shared attention; conducted at baseline and end of 12 month follow-up **Groups:** **G1:** intervention and routine care **G2:** control (routine care only) **Ga:** aged 24-27 months,	**Inclusion criteria:** • Ages 2-5:11 years • Clinical diagnosis of autism by assessing professional • Fulfilling full diagnostic for classical autism on the ADI **Exclusion criteria:** • Severe global developmental delay • Severe environmental deprivation in infancy • First language other than English • Diagnosed hearing impairment • Diagnosed visual impairment • Known chronic psychiatric or physical illness in parents • No evidence of any desire to interact with an adult **Age, median months (range):** **G1:** 48 (29-60) **G1a:** 37.5 (29-45) **G1b:** 44 (38-44) **G1c:** 61 (51-70) **G1d:** 60 (53-60 **G2:** 51 (24-71) **G2a:** 42 (32-47)	**Overall ratings:** ADI score, median (range): **G1:** 44 (24-56) **G1a:** 45 (24-56) **G1b:** 40 (30-48) **G1c:** 53 (50-56) **G1d:** 38 (34-38) **G2:** 38 (22-66) **G2a:** 34 (22-62) **G2b:** 36 (28-39) **G2c:** 38 (22-66) **G2d:** 52 (28-54) ADOS total score, median (range): **G1:** 16.5 (11-21) **G1a:**12.5 (11-16) **G1b:** 20 (18-20) **G1c:** 16 (11-17) **G1d:** 21 (19-21) **G2:** 16.5 (11-22) **G2a:** 13 (11-15) **G2b:** 19 (19-21) **G2c:** 16 (11-16) **G2d:** 20 (18-22) ADOS total score, mean ± SD: **G1:** 16.1 ± 4.5 **G1a:** 12 ± 3.3 **G1b:** 19 ± 1.3 **G1c:** 14 ± 3.3 **G1d:** 20 ± 1 **G2:** 15.6 ± 4.9 **G2a:** 11 ± 2.3 **G2b:** 19 ± 1	**Overall ratings:** ADOS total score: mean ± SD: **G1:** 11.8 ± 6.4 **G1a:** 6 ± 3.6 **G1b:** 13 ± 5.6 **G1c:** 11 ± 4.5 **G1d:** 17 ± 2.6 **G2:** 16.1 ± 4.4 **G2a:** 13 ± 4 **G2b:** 16 ± 4.3 **G2c:** 16 ± 1.3 **G2d:** 20 ± 0.6 **Communication/ language:** MCDI raw score, mean ± SD: Language comprehension: **G1:** 222.7 ± 40,431* **G2:** 146.8 ± 11,426* **G1/G2:** *P* = 0.1 Expressive language: **G1:** 199.4 ± 25,606* **G2:** 33.1 ± 683* **G1/G2:** *P* < 0.001 **Adaptive behavior:** VABS communication score, mean ±

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	total ADOS score 11-17 (young high functioning) **Gb:** aged 24-47 months; total ADOS score 18-24 (young low functioning) **Gc:** aged 48-71 months; total ADOS score 11-17 (older high functioning) **Gd:** aged 48-71 months; total ADOS score 18-24 (older low functioning) **Provider:** Parent training by therapist **Measure of treatment fidelity reported:** No	**G2b:** 33 (24-40) **G2c:** 64 (54-71) **G2d:** 67 (54-71) **Mental age:** NR **Gender, n (%):** Male: **G1:** 13 (93) **G1a:** 4 (100) **G1b:** 3 (100) **G1c:** 4 (100) **G1d:** 3 (75) **G2:** 12 (86) **G2a:** 4 (100) **G2b:** 2 (66) **G2c:** 3 (100) **G2d:** 3 (75)	**G2c:** 14 ± 3.3 **G2d:** 20 ± 1.3 **Communication/ language:** MCDI, raw score, mean ± SD: Language comprehension: **G1:** 71.7 ± 2383* **G2:** 95.4 ± 426* Expressive language: **G1:** 28 ± 467* **G2:** 25.6 ± 683* **Adaptive behavior:** VABS communication, mean ± SD: **G1:** 22.6 ± 13.3 **G2:** 20.0 ± 10.8	SD: **G1:** 36.9 ± 21.2 **G2:** 28.7 ± 16.6 **G1/G2:** *P* = NS Parent-child interaction codes, mean frequency ± SD: Parent synchrony: **G1:** 65.1 ± 14.3 **G2:** 49.5 ± 18.9 **G1/G2:** *P* = 0.016 Parent asynchrony: **G1:** 32.6 ± 14.3 **G2:** 50.5 ± 18.8 **G1/G2:** *P* = 0.009
Aldred et al., 2004 (continued)	**Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 14 **G1a:** 4 **G1b:** 3 **G1c:** 4 **G1d:** 3 **G2:** 14 **G2a:** 4 **G2b:** 3 **G2c:** 4 **G2d:** 3 **N at follow-up:** **G1:** 14 **G1a:** 4 **G1b:** 3 **G1c:** 4 **G1d:** 3 **G2:** 14 **G2a:** 4 **G2b:** 3 **G2c:** 4 **G2d:** 3	Female: **G1:** 1 (7) **G1a:** 0 **G1b:** 0 **G1c:** 0 **G1d:** 1 (25) **G2:** 2 (14) **G2a:** 0 **G2b:** 1 (33) **G2c:** 0 **G2d:** 1 (25) **Race/ethnicity, mothers, n:** African-Caribbean: 2 Caucasian: 26 **SES:** Maternal education, median years (range): 16.5 (16-21) Paternal education, median years (range): 17.6 (16-21) Household income: NR **Diagnostic approach:** Clinician/self referral and in study **Diagnostic tool/method:** ADI **Diagnostic category, n (%):** Autism: 28 (100) **Other characteristics:** NR	Parent-child interaction codes, mean frequency ± SD: Parent synchrony: **G1:** 57.8 ± 15 **G2:** 57.1 ± 49.5 Parent asynchrony: **G1:** 39.7 ± 16.1 **G2:** 42.9 ± 16.1 Child communication acts: **G1:** 30.8 ± 10.2 **G2:** 30.1 ± 11.1 Parent communication acts: **G1:** 66.3 ± 11.8 **G2:** 70.7 ± 11 Child shared attention: **G1:** 72 ± 23.6 **G2:** 62.8 ± 24.5 Parent shared attention **G1:** 93.5 ± 5.3 **G2:** 81.3 ± 22.3	Child communication acts: **G1:** 37.6 ± 10.1 **G2:** 27.6 ± 16.5 **G1/G2:** *P* = 0.041 Parent communication acts: **G1:** 64.4 ± 13 **G2:** 72.4 ± 16.5 **G1/G2:** *P* = 0.293 Child shared attention: **G1:** 77.6 ± 17.8 **G2:** 62.6 ± 32.7 **G1/G2:** *P* = 0.204 Parent shared attention: **G1:** 88.6 ± 8.7 **G2:** 80.3 ± 30.1 **G1/G2:** *P* = 0.176 **Harms:** NR **Modifiers:** NR

Comments: *Standard deviations (as reported in paper) appear to be in error.

Author: Chez et al.,	**Intervention:** 12 week open-label study with	**Inclusion criteria:** Based on diagnosis of	**Overall ratings:** CARS, mean ± SD:	**Changes from baseline to 12**

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
2004 **Country:** US **Practice setting:** Specialty treatment center **Intervention setting:** Clinic **Enrollment period:** Month : NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective case series	Rivastigmine tartarate At BL, 0.2 ml (0.4 mg) of rivastigmine tartarate given twice daily in a liquid suspension (2mg.ml). If any adverse event, dosage was halved or discontinued. If no improvement after 2 wks of starting on the medicaton, dosage was doubled to 0.4 ml (0.8mg) twice daily Maximum daily dose was 0.4 ml (0.8mg) twice daily **Assessments:** Expressive One Word Vocabulary Test, Childhood Autism Rating Scale administered by study coordinator at baseline, 6wks and 12 wks. Conners' Parent Rating Scale completed by parents at baseline, 6wks, 12 wks. **Groups:** **G1:** Rivastigmine tartarate **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** Testing at Baseline, 6 weeks, 12 weeks. Nurses contacted parents weekly to check for any concerns. **Concomitant therapies, n:** Anticonvulsants: 21 CNS stimulants: 8 Adrenergic blockers: 4 Antipsychotics: 2 Antidepressants: 1 Corticosteroids: 1 **N at enrollment:** **G1:** 32	ASD or PDD-NOS per DSM-IV **Exclusion criteria:** See inclusion criteria **Age, mean/yrs (range):** 6.91 (2.85-12) **Mental age:** NR **Gender:** M, n (%): 24 (75) F, n (%): 8 (25) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study/Referral **Diagnostic tool/method:** DSM-IV **Diagnostic category, n (%):** Autism: 11 (34.4) PDD-NOS : 21 (65.6) **Other characteristics, n (%):** Previous diagnosis of nocturnal epileptiform EEG abnormalities: 13 (40.6)	34 ± 6.36 **Communication/ language:** Expressive one-word Picture vocabulary test, mean ± SD: 34.91 ± 33.61 Receptive One-word Picture Vocabulary test, mean ± SD: 37.78 ± 29.70 **Problem behavior:** Conner's parent rating scale, mean ± SD: 34.5 ± 12.30	**weeks:** **Overall ratings:** CARS, mean ± SD**:** 30.84 ± 8.71 *P* = 0.001 **Communication/ language:** Expressive one-word Picture vocabulary test , mean ± SD: 41.44 ± 36.74 *P* = 0.001 Receptive One-word Picture Vocabulary test, mean ± SD: 39.53 ± 32.47 *P* = NS **Problem behavior**: Conner's parent rating scale, mean ± SD: 28.28 ± 13.53 *P* = 0.005 **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Chez et al., 2004 (continued)	**N at follow-up:** **G1:** 32			
Author: Dillenburger et al., 2004 **Country:** Ireland **Practice setting:** Academic **Intervention setting:** Home and academic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Retrospective case series	**Intervention:** Applied Behavior Analysis (parents educated in general ABA principles for use at home with their children) Frequency: parent training every 2 weeks for 18 weeks; parents supposed to apply skills from course at home "as frequently as possible" throughout the day; weekly family visit from ABA professional to supervise and adjust **Assessments:** ABA evaluation questionnaires were completed by families (post-intervention only) Possible responses for difference: • Great difference • Some difference • Little difference • Don't Know • Not applicable Possible responses for effectiveness: • Very effective • Effective • Not effective • Don't know • Not applicable **Groups:** **G1:** long term group (≥ 18 months of ABA) **G2:** short term group (≤ 12 months of ABA) **Provider:** ABA professionals **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR	**Inclusion criteria:** • Actively engaged in home-based ABA program at time of study • Children with ASD (diagnostic process/ criteria not described) **Exclusion criteria:** • See inclusion criteria **Age, months (range):** Study entry: **G1:** 125 **G2:** 52 Start of ABA **G1:** 91 **G2:** 46 Age, study entry, range (years): Total: 3-13 **Mental age:** NR **Gender, n (%):** Male: **G1:**10 (83.3) **G2:** 9 (90) Female: **G1:** 2 (16.7) **G2:** 1 (10) **Race/ethnicity:** NR **SES:*** Maternal education: NR Parents employed, n: **G1:** 8 **G2:** 5 **Diagnostic approach:** NR **Diagnostic tool/method:** NR **Diagnostic category:** NR **Other characteristics:** Number of other children, mean (range): **G1:** 3 (1-4) **G2:** 2.5 (1-3)	NR	**Overall ratings:** Parent perceived difference from ABA on child behavior, n: Independence: Great difference: **G1:** 3/11 **G2:** 5/10 Some difference: **G1:** 8/11 **G2:** 4/10 No difference: **G1:** 0 **G2:** 1/10 Quality of life: Great difference: **G1:** 7/11 **G2:** 8/10 Some difference: **G1:** 2/11 **G2:** 2/10 Little difference: **G1:** 1/11 **G2:** 0 Don't know: **G1:** 1/11 **G2:** 0 Skills develop-ment: Great difference: **G1:** 8/11 **G2:** 8/10 Some difference: **G1:** 3/11 **G2:** 2/10 Skills mainte-nance: Great difference: **G1:** 6/11 **G2:** 6/10 Some difference: **G1:** 5/11 **G2:** 4/10 Interaction: Great difference: **G1:** 6/11 **G2:** 7/10 Some difference: **G1:** 5/11 **G2:** 3/10

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Dillenburger et al., 2004 (continued)	**N at enrollment:** **G1:** 25 **G2:** 25 **N at follow-up:** **G1:** 12 **G2:** 10	Length of involvement with ABA, months (range): **G1:** 35.5 (18-72) **G2:** 6.1 (2-12)		Parent perceived effectiveness of ABA on child behavior, n: Self-help skills: Very effective: **G1:** 6/12 **G2:** 4/10 Effective: **G1:** 3/12 **G2:** 4/10 Not effective: **G1:** 2/12 **G2:** 0 Don't know: **G1:** 1/12 **G2:** 2/10 Social skills: Very effective: **G1:** 9/12 **G2:** 4/10 Effective: **G1:** NR **G2:** 5/10 Not Effective: **G1:** 1/12 **G2:** 1/10 Problem behavior: Very effective: **G1:** 9/12 **G2:** 5/10 Effective: **G1:** 3/12 **G2:** 5/10 Obsessive behavior: Very effective: **G1:** 8/12 **G2:** 4/10 Effective: **G1:** 4/12 **G2:** 3/10 Not applicable: **G1:** 0 **G2:** 3/10 Gross motor skills: Very effective: **G1:** 9/12 **G2:** 6/10 Effective: **G1:** 3/12 **G2:** 3/10
Dillenburger et al., 2004 (continued)				Not applicable: **G1:** 0 **G2:** 1/10 Fine motor skills:

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				Very effective: **G1:** 9/12 **G2:** 6/10 Effective: **G1:** 3/12 **G2:** 4/10 Communication: Very effective: **G1:** 9/12 **G2:** 7/10 Effective **G1:** 3/12 **G2:** 3/10 Concentration: Very effective: **G1:** 10/12 **G2:** 9/10 Effective: **G1:** 2/12 **G2:** 1/10 **Harms:** NR **Modifiers:** NR

Comments: *G1 and G2 described as "equivalent" with regards to socioeconomic status; details NR.

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Mukaddes et al., 2004 **Country:** Turkey **Practice setting:** Academic **Intervention setting:** clinic, home **Enrollment period:** 2000 to 2005 **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Psychoeducational program developing reciprocal interaction, enhancing communication, modifying stereotypic behavior, and increasing self-care; focused on parent training using principles from TEACCH; 11-14 weekly 45-min sessions. First stage (sessions 1+2) parent education. 2nd stage (10-12 sessions) child-directed play. **Groups:** **G1:** Autism **Assessments:** Ankara Development Screening Inventory at baseline and end of intervention **Provider:** Experienced child educators **Measure of treatment**	**Inclusion criteria:** NR **Exclusion criteria:** NR **Age, mean/months ± SD (range):** **G1:** 43.2 ± 15.17 (24-66) **Mental age:** NR **Gender:** **G1:** M, n (%): 10 (100) F, n (%): 0 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In study **Diagnostic tool/method:** Based on DSM-IV **Diagnostic category:** NR	**Overall ratings:** Ankara Development Screening Inventory (ADSI), median total development score: **G1:** 16.5 Language-cognitive subscale: **G1:** 15.5 Social/self-care abilities subscale: **G1:** 16.5 Fine motor subscale: **G1:** 18.5 Gross motor subscale: **G1:** 49.0	**Overall ratings:** ADSI, median total development score (p-values within group differences from baseline): **G1:** 22.5 *P* = 0.005 Language-cognitive subscale: **G1:** 20.0 *P* = 0.005 Social/self-care abilities subscale: **G1:** 26.75 *P* = 0.002 Fine motor subscale: **G1:** 26.75 *P* = 0.002 Gross motor subscale: **G1:** 51 *P* = 0.008

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	fidelity reported: No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 10 **N at follow-up:** **G1:** 10	**Other characteristics:** NR		**Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Posey et al. 2004 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** October 1997 to April 2001 **Funding:** National Alliance for Research in Schizophrenia and Depression, Daniel X. Freedman Psychiatric Fellowship, NIMH, and Department of Housing and Urban development **Author industry relationship disclosures:** NR **Design:** Retrospective case series	**Intervention:** Guanfacine (.25-9 mg daily in divided doses Mean daily dose: 2.6 ± 1.7 mg Mean duration of treatment: 334 ± 374 days, range 7-1776 days N=70 (age range, 3-11 years, mean daily dose = 2 mg) N=10 (age range, 13-18 years, mean daily dose= 3.4 mg) Dosing frequency: N=2 (once daily) N=48 (twice daily) N=29 (three times daily) N=1 (four times daily) **Assessments:** Conducted by 2 board-certified child and adolescent psychiatrists; CGI **Groups:** **G1:** Guanfacine **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** NR **Concomitant therapies, n (%):** Overall: 44(55) Atypical antipsychotics: 16 (20%) SSRIs: 13 (16%) Stimulants: 9 (11%) Non-SSRI antidepressants: 8 (10%) Mood stabilizers: 8 (10%) Conventional antipsychotics: 3 (4%) **N at enrollment:** **G1:** 80	**Inclusion criteria:** • Treated at the Autism/PDD Clinic at the James Whitcomb Riley Hospital for Children • Diagnosis of PDD by DSM-IV • History of guanfacine treatment within the clinic **Exclusion criteria:** See inclusion criteria **Age, mean/yrs ± SD (range):** **G1:** 7.7 ±3.5 (3-18) **Mental age:** NR **Gender:** **G1:** M, n (%): 70 (87) F, n (%): 10 (13) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In-study **Diagnostic tool/method:** DSM-IV criteria clinical **Diagnostic category, n (%):** **G1:** Autistic disorder: 46 (56) Asperger's disorder: 6 (8) PDD-NOS: 28 (35)	**Overall ratings:** CGI severity, mean ± SD: Inattention: 4.58 ± 0.68 Hyperactivity: 4.75 ± 0.9 Impulsivity: 4.61 ± 0.73 Aggression/self-injury: 4.54 ± 0.95 Anxiety/worry: 4 ± 0.59 Irritability: 4.65 ± 0.66 Insomnia: 4.04 ± 0.82 Repetitive behaviors: 3.67 ± 0.78 Tics: 3.83 ± 0.75 Social impairment: 4.05 ± 0.87 Language: 4.23 ± 1.04 Overall: 4.83 ±0.71 Medical: mean ± SD: SBP:109.6 ± 13.8 DBP: 65.7 ± 10.9 Heart rate: 95.7 ± 15.8	**Overall ratings:** CGI, n (%): 19 (23.8) subjects considered responders based on "much improved" or "very much improved" CGI global improvement item CGI Global Improvement score, mean ± SD: Responders: 1.9 ± 0.2 Non-responders: 3.6 ± 0.6 Improvement in CGI Severity score, mean ± SD: 4.25 ± 0.91 T = 6.5 (*P* < 0.0001) CGI severity, mean ± SD (%) improvement, n/N subjects showing improvement: Inattention: 3.91 ± 0.87 (21.10), 16/76 Hyperactivity: 3.92 ± 1.05 (26.7), 20/75 Impulsivity: 4.07 ± 0.9 (17.4), 12/69 Aggression/self-injury: 4.13 ± 1.03 (14.5), 10/69 Anxiety/worry: 3.64 ± 0.72 (11.1), 4/36 Irritability: 4.06 ± 0.92 (16.9), 13/77 Insomnia: 3.22 ± 0.99 (27.5), 14/51 Repetitive behaviors: 3.59 ± 0.74 (0), 0/54 Tics: 2.33 ± 0.82 (50), 3/6

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Posey et al. 2004 (continued)	**N at follow-up:** G1: 80	**Other characteristics, n (%):** Comorbid mental retardation: 56 (70) • Mild: 25 (31.25) • Moderate: 25 (31.25) • Severe: 6 (7.5) Seizure disorders: 11 (14)		Social impairment: 3.97 ± 0.82 (0), 0/78 Language: 4.05 ± 1.01 Communication impairment, % improvement, n/N: 3.1, 2/65 Medical, mean ± SD: SBP: 107.6 ± 16.1 DBP: 64.3 ± 10.6 Heart rate: 94.6 ± 16.6 No difference in BPs or heart rate following treatment with guanfacine **Harms, n (%):** Transient sedation: 25 (31) Irritability: 5 (6) Constipation: 3 (4) Headache: 2 (3) Nocturnal Enuresis: 2 (3) **Modifiers:** PDD-NOS (39.3% responders) and Asperger's (33.3% responders) had greater rate of global response than those with autistic disorder (13.0% responders) (*P* = 0.009) Responders had history of significantly fewer psychotropic drug trials than non-responders (1.3 ± 1.6 vs. 3.0 ± 3.4, *P* = 0.046).
Posey et al. 2004 (continued)				Responders were less aggressive at baseline by CGI severity item (*P* = 0.04).

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Sofronoff et al., 2004 **Country:** Australia **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** RCT **Note:** See related paper with overlapping participants, Sofronoff et al., 2004 ({#1039})	**Intervention:** Parent Management Training (PMT), in the form of a 1-day workshop or six weekly individual sessions. Both groups followed a manual with six components (1 hour each), including: psycho-education, comic strip conversations (Gray, 1994a), social stories (Gray, 1994b), management of behavior problems, management of rigid behaviors, routines, and special interests, and anxiety management. **Groups:** **G1:** workshop **G2:** individual **G3:** wait-list **Provider:** Clinical master's or PhD students completing an internship at the Behavior Research and Therapy Center (University of Queensland) **Assessment:** ECBI, Child's Social Skills questionnaire at baseline, 4 weeks and 3 month follow-up **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 18 **G2:** 18 **G3:** 15 **N at follow-up:** **G1:** 18 **G2:** 18 **G3:** 15	**Inclusion criteria:** NR **Exclusion criteria:** NR **Age, years (range):** **G1:** 9.33 (6-12) **Gender:** NR **Race/ethnicity:** NR **SES:** NR **Diagnostic approach:** In Study **Diagnostic tool/method:** By pediatrician at clinic site **Diagnostic category, n (%):** Asperger: 51 (100) **Other characteristics:** NR	**Problem behavior:** ECBI, number of problem behaviors, mean ± SD: **G1:** 17.44 ± 5.77 **G2:** 16.89 ± 5.84 **G3:** 18.13 ± 5.19 ECBI, intensity of problem behaviors, mean ± SD: **G1:** 149.72 ± 29.78 **G2:** 140.44 ± 22.59 **G3:** 144.73 ± 26.39 **Social Skills:** Social skills questionnaire score, mean ± SD: **G1:** 23.66 ± 8.92 **G2:** 25.22 ± 10.01 **G3:** 25.07 ± 6.64	**Problem behavior:** ECBI, number of problem behaviors, 3 months, mean ± SD: **G1:** 12.50 ± 6.96 **G2:** 8.67 ± 4.93 **G3:** 18.20 ± 6.21 **G1/BL:** $P < 0.005$ **G2/BL:** $P < 0.0001$ **G3/BL:** P = NS **G1/G2:** P = NS **G1/G3:** $P < 0.01$ **G2/G3:** $P < 0.0001$ MANOVA: time ($P < 0.0001$), treatment ($P < 0.005$), time X treatment ($P < 0.001$) ECBI, intensity of problem behaviors, 3 months, mean ± SD: **G1:** 129 ± 18.13 **G2:** 106.44 ± 22.99 **G3:** 144.40 ± 31.85 **G1/BL:** $P < 0.0001$ **G2/BL:** $P < 0.0001$ **G3/BL:** P = NS **G1/G2:** $P < 0.01$ **G1/G3:** P = NS **G2/G3:** $P < 0.0001$ MANOVA: time ($P < 0.0001$), treatment ($P < 0.01$), time X treatment ($P < 0.001$)
Sofronoff et al., 2004 (continued)				**Social Skills:** Social skills questionnaire score, 3 months, mean ± SD: **G1:** 31 ± 9.01

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G2: 36.61 ± 8.24 **G3:** 24.27 ± 8.57 **G1/BL:** *P* < 0.0001 **G2/BL:** *P* < 0.0001 **G3/BL:** *P* = NS **G1/G2:** *P* = 0.057 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.0001 MANOVA: time (*P* < 0.0001), treatment (*P* < 0.05), time X treatment (*P* < 0.001) **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Solomon et al., 2004 **Country:** US **Practice setting:** Academic, medical center **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** UC Davis MIND Institute, UC Davis Health System, UC Davis **Author industry relationship disclosures:** NR **Design:** RCT, age and IQ matched intervention and waiting list control	**Intervention:** • Social adjustment enhancement curriculum targeting social skills in a group setting with standardized agenda including welcome song, review of previous lessons, conversational and motor activity skills interventions • Curriculum focused on teaching skills in emotion/facial expression recognition in self and others, theory of mind, executive functions with emphasis on problem solving, and conversational skills • Parent training component with focus on enhancing parental understanding of child's social problems • Weekly problem behavior logs completed by parents to facilitate child social behavior management **Assessments:** DANVA, Theory of Mind, Faux Pas Stories, Test of Problem Solving, conducted in clinic by examiner; Children's Depression Inventory, Beck Depression Inventory competed by child with mother present in clinic; parent-completed weekly social behavior problem logs **Duration:** 20 weeks **Frequency:** weekly, 1.5 hours/week	**Inclusion criteria:** • Ages 8-12 years • Prior diagnosis of High Functioning Autism (HFA), Asperger Syndrome (AS) or Pervasive Developmental Disorder NOS (PDDNOS) confirmed by ADOS-G and ADI-R and DSM-IV criteria for HFA, PDDNOS or AS based on clinical interview • Full Scale IQ score from within past 2 years ≥75 as measured by WISC-III or WASI • Demonstrated ability to pass Smarties false belief task **Exclusion criteria:** • Serious conduct problems **Age, months (range):** **G1a:** 103 (93-117) **G1b:** 130 (111-146) **G2a:** 100 (88-117) **G2b:** 122 (108-140) **Mental age:** VIQ, mean (range): **G1a:** 126 (117-136) **G1b:** 86 (75-94) **G2a:** 121 (92-142) **G2b:** 82 (59-91) PIQ, mean (range): **G1a:** 103 (89-112) **G1b:** 88 (63-115) **G2a:** 114 (85-136) **G2b:** 108 (90-122) FSIQ, mean (range): **G1a:** 115 (99-124) **G1b:** 86 (75-100) **G2a:** 119 (88-143) **G2b:** 95 (83-104) **Gender, n (%):** Male: 18 (100) Female: 0 (0) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR	**Communication/ language:** DANVA score, mean ± SD (range): Adult faces: **G1a:** 12.2 ± 1.1 (11-14) **G1b:** 10.5 ± 1.3 (9-12) **G2a:** 11.8 ± 2.2 (10-15) **G2b:** 12.4 ± 1.3 (11-14) Child faces: **G1a:** 11.6 ± 1.5 (10-14) **G1b:** 12.0 ± 2.4 (10-15) **G2a:** 13.0 ± 1.2 (12-15) **G2b:** 12.8 ± 0.9 (12-14) Total faces: **G1a:** 23.8 ± 1.3 (23-26) **G1b:** 22.5 ± 2.9 (19-26) **G2a:** 24.8 ± 3.1 (22-30) **G2b:** 25.2 ± 2.2 (23-28) Theory of Mind score, mean ± SD (range): Strange stories: **G1a:** 10 ± 1 (9-11) **G1b:** 6.5 ± 1.7 (7-11) **G2a:** 9.2 ± 1.6 (4-8) **G2b:** 7.4 ± 1.3 (6-9) Faux pas: **G1a:** 2.6 ± 2.1 (0-5) **G1b:** 0.75 ± 0.5 (1-4) **G2a:** 2.8 ± 1.3 (0-1) **G2b:** 1.2 ± 0.5 (1-2)	**Communication/ language:** DANVA score, mean ± SD (range): Adult faces: **G1a:** 13.4 ± 1.1 (12-15) **G1b:** 12.8 ± 2.9 (9-15) **G2a:** 11.2 ± 1.3 (10-13) **G2b:** 11.8 ± 2.4 (10-15) **G1/BL:** $P < 0.05$ **G1/G2:** $P < 0.05$ **Ga/Gb:** P = NS Child faces: **G1a:** 13.2 ± 1.8 (11-16) **G1b:** 12.0 ± 1.8 (10-14) **G2a:** 12.8 ± 1.5 (11-15) **G2b:** 11.8 ± 2.1 (9-14) **G1/BL:** $P < 0.05$ **G1/G2:** $P < 0.05$ **Ga/Gb:** $P = 0.05$ Total faces: **G1a:** 26.6 ± 1.5 (25-29) **G1b:** 24.8 ± 3.4 (20-28) **G2a:** 24.0 ± 2.3 (22-28) **G2b:** 23.6 ± 3.3 (19-27) Theory of Mind score, mean ± SD (range): Strange stories: **G1a:** 10.4 ± 0.9 (9-11) **G1b:** 7.3 ± 0.5 (7-11) **G2a:** 9.4 ± 1.8 (7-8) **G2b:** 7.5 ± 1.3 (6-9) **G1-2/BL:** P = NS **G1/G2:** P = NS
Solomon et al., 2004 (continued)	**Provider:** Social skills group leaders consisting of psychologists, a psychiatrist, a speech and language	**Diagnostic approach:** In study **Diagnostic tool/method:** ADOS-G and ADI-R and	TOPS elementary-revised, percentile rank score, mean ± SD (range): **G1a:** 32.2 ± 13.9	Faux pas: **G1a:** 5.4 ± 0.9 (4-6) **G1b:** 3.0 ± 2.2 (1-6)

Evidence Table. Therapies for children with ASD

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	pathologist; providers working with parents were a developmental and behavioral pediatrician and a social worker **Groups:** **G1:** received curriculum **G2:** randomized to wait list for later participation in curriculum (controls) **Ga:** younger participants with higher mean FSIQ **Gb:** older participants with lower mean FSIQ **Treatment manual followed:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 9 **G1a:** 5 **G1b:** 4 **G2:** 9 **G2a:** 5 **G2b:** 4 **N at follow-up:** **G1:** 9 **G1a:** 5 **G1b:** 4 **G2:** 9 **G2a:** 5 **G2b:** 4	DSM-IV criteria for HFA, PDDNOS or AS based on clinical interview **Diagnostic category, N:** **G1a:** Asperger's Syndrome:3 High-Functioning Autism:1 PDD-NOS:1 **G1b:** Asperger's Syndrome:2 High-Functioning Autism:2 **G2a:** Asperger's Syndrome:5 **G2b:** Asperger's Syndrome:2 High-Functioning Autism:2 **Other characteristics:** ADOS mean (range): **G1a:** 9 (97-14) **G1b:** 15 (12-18) **G2a:** 9 (7-13) G2b: 14 (11-17)	(13-44) **G1b:** 2.25 ± 1.5 (1-4) **G2a:** 41.6 ± 30 (2-73) **G2b:** 2.75 ± 0.5 (2-3) Children's Depression Inventory score, mean ± SD (range): **G1a:** 6.0 ± 1.6 (4-8) **G1b:** 6.25 ± 4.3 (2-12) Beck Depression Inventory score, mothers, mean ± SD (range): **G1:** 5.9 ± 7.2 (0-20) Problem Behavior Logs, first 8 weeks, mean: Problem behavior reports per time: 9.6 Parent satisfaction with their handling of children's problem behavior: 6.2/10	**G2a:** 3.6 ± 2.5 (0-5) **G2b:** 3.0 ± 1.2 (2-4) **G1-2/BL:** *P* < 0.001 **G1/G2:** *P* = NS TOPS elementary-revised, percentile rank score, mean ± SD (range): **G1a:** 43.2 ± 22 (10-65) **G1b:** 1.5 ± 1 (1-3) **G2a:** 23.8 ± 13 (6-42) **G2b:** 2.0 ± 1.2 (1-3) **G1/BL:** *P* < 0.05 **G1/G2:** *P* < 0.05 Children's Depression Inventory score, mean ± SD (range): **G1a:** 8.4 ± 5.0 (4-17) **G1b:** 3.8 ± 3.2 (1-7) **G1a/G1b:** *P* < 0.05 Beck Depression Inventory score, mothers, mean ± SD (range): **G1:** 3.89 ± 3.3 (0-9) **G1/BL:** *P* = NS
Solomon et al., 2004 (continued)				Problem Behavior Logs, first 8 weeks, mean: Problem behavior reports per time: 5.9 (*P* < 0.05) Parent satisfaction with their handling of children's problem behavior: 6.9/10 (*P* = 0.11) **Harms:** NR **Modifiers:** Theory of Mind: significant

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				correlation with VIQ (*P* < 0.001) & FSIQ (*P* < 0.05) TOPS: significant correlation with VIQ (*P* < 0.001) & FSIQ (*P* < 0.05) Average problem behavior log satisfaction with handling problem behaviors was correlated (*P* < 0.10) with mother's depression score but not statistically significant

Comments: *"all four children who engaged in combinations with their augmentative system also used single spoken language for the communication; as a result, these four children are reported in both categories"(p.79)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Stahmer & Ingersoll, 2009 **Country:** US **Practice setting:** Academic **Intervention setting:** Classroom **Enrollment period:** NR **Funding:** Children's Hospital Research grant NIH California Early Start **Author industry relationship disclosures:** NR **Design:** Case series, prospective	**Intervention:** Children's Toddler School (CTS), • inclusive classroom serving 8 children with ASD and 8 typically developing children (4 in the morning, 4 in the afternoon), inclusion sessions 3 hours a day, 5 days a week, • special skills training: 30 min/4 days a week of one-to-one teaching • arranged like typical toddler classroom (i.e. toys for appropriate levels of paly) • Family participation component: weekly 2 hour home visit, home teacher and psychologist accompany family through transition **Assessments:** Administered at entry and approx. 1 week before child completed treatment: BSID-II (by program psychologist), VABS (by program director to parent), GARS (parent questionnaire), and checklist of functional skills developed by authors (by program psychologist). Mean age at exit: 35 mo. **Groups:** **G1:** Children's Toddler School (CTS) **Provider:** • Special and early education classroom teachers, at least bachelor's degree • Speech therapist/occupational therapist	**Inclusion criteria:** • participated in CTS program for a minimum of 6 months • received from a clinician not associated with the project an independent diagnosis of ASD • minimum nonverbal mental age of 12 mo. (on BSID-II) • less than 2 years 6 mo. of age **Exclusion criteria:** See above **Age, mean/months (range):** 27.6 (22-31) **Mental age, BSID-II mean ± SD:** **G1**: 67.2 ± 14.7 (n=19) **Gender: n (%):** M, 16 (80%) F, 4 (20%) **Race/ethnicity, n (%):** White: 12(60) Asian: 2 (10) Hispanic: 4(20) Filipino: 2(10) **SES:** Maternal education: NR Household income: NR Four Factor Index of Social Status, n (%): Major business/ professional: 5(25) Med. business/minor professional: 10(50) Skilled workers: 2(10) Semiskilled workers: 3(15) Unskilled laborers: 0(0) **Diagnostic approach:** Referral **Diagnostic tool/method:** DSM-IV	**Overall ratings:** VABS, n, mean age equivalent: **G1:** 16, 14 GARS, n, mean ± SD: **G1:** 19, 87.2 ± 11.2 **Social skills:** VABS Socialization, n, mean ± SD: **G1:** 16, 70.4 ± 8.9 VABS socialization range of functioning, n (%): Typical range 1 (6) Reported functional social interaction skills, n (%): Avoidant: 8 (40) Facilitated: 8 (40) Parallel play: 4 (20) Responsive to peers: 0 (0) Reciprocal play: 0 (0) **Communication/ language:** VABS Communication, n, mean ± SD: **G1:** 16, 71.1 ± 13.9 VABS communication range of functioning, n (%): Severely delayed range: 1 (6) Mildly delayed range: 7 (44) Borderline range: 7 (44) Average range: 1 (6) Reported functional communication skills, %: No functional communication system: 50	**Overall ratings:** VABS, n, mean age equivalent: **G1:** 16, 21 GARS, n, mean ± SD: **G1:** 19, 76.5 ± 23.0 *P* < 0.05 **Social skills:** VABS Socialization, n, mean ± SD: **G1:** 16, 75.0 ± 10.9 *P* < 0.05 VABS socialization range of functioning, n (%): Typical range: 5 (31) Reported functional social interaction skills, n (%): Avoidant: 0 (0) Facilitated: 3 (15) Parallel play: 5 (25) Responsive to peers: 5 (25) Reciprocal play: 7 (35) *P* < 0.01 **Communication/ language:** VABS Communication, n, mean ± SD: **G1:** 16, 79.3 ± 17.1 *P* < 0.01 44% of children showed increases VABS communication range of functioning, n (%):

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Stahmer & Ingersoll, 2009 (continued)	**Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies, n (%):** Gluten/casein-free diets: 4 (20) Individual occupational therapy: 2 (10) Individual speech therapy: 1 (5) 10 hours a week of discrete trial training: 1 (5) 3 hours a week of naturalistic intervention: 1 (5) **N at enrollment:** **G1:** 20 **N at follow-up:** **G1:** 20	Diagnosis confirmed in study using standardized assessments including: CARS GARS **Diagnostic category, %:** Autism: 55 PDD-NOS: 45 **Other characteristics:** NR	Single signs or PECS: 0 Combinations with augmentative system: 0 Single spoken words: 35 Phrases: 15 Commenting/sharing: 0 **Adaptive behavior:** VABS Daily Living Skills, mean ± SD: **G1:** 16, 71.2 ± 8.9 Reported functional play skills, n (%): No functional play: 7 (35) Cause/effect play: 3 (15) Relational play: 7 (35) Simple pretend play: 3 (15) Complex pretend play: 0 (0) **Motor skills:** VABS Motor Skills, n, mean ± SD: **G1:** 16, 88.9 ± 12.5 Educational/ cognitive/ academic attainment: BSID-II, n, mean ± SD: **G1:** 19, 67.2 ± 14.7 IQ score (BSID-II), n (%): **G1:** below 70 (significantly delayed range): 11 (58) 70-84 (mildly delayed range): 6 (32) 85-115 (normally developing range): 2 (11)	Severely delayed range: 0 (0) Mildly delayed range: 6 (38) Borderline range: 5 (31) Average range: 5 (31) 4 of 15 (27) moved to normal range Reported functional communication skills, n (%): No functional communication system: 2 (10) Single signs or PECS: 2 (10) Combinations with augmentative system: 4 (20)* Single spoken words: 4 (20)* Phrases: 3 (15) Commenting/sharing: 9 (45) *P* < 0.01 **Adaptive behavior:** VABS Daily Living Skills, n, mean ± SD: **G1:** 16, 72.8 ± 9.4 *P* = NS Reported functional play skills, n (%): No functional play: 0 (0) Cause/effect play: 0 (0) Relational play: 7 (35) Simple pretend play: 5 (25) Complex pretend play: 8 (40) P<.01
Stahmer & Ingersoll, 2009 (continued)			BSID-II nonverbal mental age, mean, rate of development	**Motor skills:** VABS Motor Skills, n, mean ±

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			(as compared to typical children): **G1:** 18, 64 BSID-II verbal mental age, rate of development (as compared to typical children): **G1:** 53	SD: **G1:** 16, 87.4 ± 16.1 *P* = NS Educational/ cognitive/ academic attainment: BSID-II, n, mean ± SD: **G1**: 19, 74.6 ± 17.9 *P* < 0.01 developmental quotient increased in 47% of children IQ score (BSID-II), n (%): **G1:** Below 70 (significantly delayed range): 8 (42) 70 – 84 (mildly delayed range): 4 (21) 85 – 115 (normally developing range): 7 (37) 67% of children in mildly delayed range increased to normal range 5% (1 child) increased from significantly delayed range to normal range BSID-II nonverbal mental age, mean, rate of development (as compared to typical children): **G1:** 26, 74
Stahmer & Ingersoll, 2009 (continued)				BSID-II nonverbal mental age developmental trajectory: **G1:** (graph) 10% increase in

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				developmental progress BSID-II verbal mental age, rate of development (as compared to typical children): **G1:** 67 BSID-II verbal mental age developmental trajectory: **G1:** (graph) 14% increase in developmental progress **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Stigler et al., 2004 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** October 1997 to January 2002 **Funding:** National Alliance for Research in Schizophrenia and Depression. NIH. Department of Housing and Urban development **Author industry relationship disclosures:** NR **Design:** Retrospective case series	**Intervention:** Stimulants Recent trials: 2.5 mg orally (morning and noon) increased by 2.5 mg/week if needed Mean dosage ± SD (range) in mg/day & duration ± SD (range) in days: Methylphenidate (144 total trials): Dosage: 12.9 ± 11.4 (2.5-80) Duration: 545.1 ± 731.2 (1-3650) Amphetamine/dextroamphetamine (68 total trials): Dosage: 10.4 ± 7.1 (2.5-45) Duration: 237.3 ±324.8 (1-1095) Dextroamphetamine (39 total trials): Dosage: 5.8 ± 2.8 (2.5-10) Duration: 196.5 ± 340.6 (7-1424) Pemoline (23 total trials) : Dosage: 33.3 ± 18.2 (18.5-75) Duration: 557.2 ± 889.1 (14-2492) **Assessments:** CGI-I administered pre- and post-trial (clinician and parent report) to determine improvement **Groups:** **G1:** Stimulants **Co-interventions held stable during treatment:** Yes **Frequency of contact during study:** NR	**Inclusion criteria:** • Outpatients hospital-based autism treatment center • Met DSM-IV criteria for PDD by one of two board-certified child and adult psychiatrist • Recent or past stimulant trial • Evaluated in clinic within Enrollment Period **Exclusion criteria:** See inclusion criteria **Age, mean/yrs ± SD (range) :** **G1:** 7.26 ± 3.45 (2-19) **Mental age:** NR **Gender:** **G1:** M, n (%): 174 (89) F, n (%): 21 (11) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In-study **Diagnostic tool/method:** DSM-IV criteria clinical **Diagnostic category, n (%):** **G1:** Autistic disorder: 104 (53) Asperger's disorder: 34 (17) PDD-NOS: 57 (29) **Other characteristics, n (%):** Mental retardation: 93 (48)	NR	**Responders (CGI-I rating of 1 or 2), %:** Patients with history of one stimulant trial: 24.6 Patients with history of two stimulant trials: 23.2 Patients with history of three stimulant trials responded to first trial: 11.1 **Responders, n/N (%):** (Did not respond to 1st trial) 2nd trial: 6/43 (14.05) 3rd trial: 2/14 (14.3) **Harms:** Adverse Effects, n (%): Aggression: 15 (8) Agitation: 50 (26) Anxiety: 2 (1) Dyspepsia: 15 (8) Dysphoria: 23 (12) Insomnia: 10 (5) Irritability: 16 (8) Sedation: 2 (1) Tics: 9 (5) Weight loss: 14 (7) Total: 154/268 trials (57.5) **Modifiers:** PDD subtype ($P <$ 0.013) Use of concomitant medication ($P <$ 0.007)
Stigler et al., 2004 (continued)	**Concomitant therapies, n:** Atypical antipsychotics:			

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	14 Conventional antipsychotics: 4 Selective serotonin reuptake inhibitors: Other antidepressants: Imipramine: 2 Clomipramine: Nortriptyline: 1 Mirtazapine: 2 Venlafaxine: 1 Bupropion: 1 Mood stabilizers: 14 Alpha-2 adrenergic agonists: 17 Beta-adrenergic Antagonists: 2 **N at enrollment:** **G1:** 195 **N at follow-up:** **G1:** 195			

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Author: Whitaker, 2004 **Country:** UK **Practice setting:** Community **Intervention setting:** School **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Case series, prospective	**Intervention:** Peer tutoring, 20 to 30 minutes on a weekly basis for 20 weeks, each pair involved in 20 to 24 play sessions **Assessments:** The fourth or fifth play session and a further completed session was videotaped after a minimum of 20 weeks; videotaped sessions were coded for joint attention, communication, and shared play. A semi-structured face-to-face interview was conducted by the author with each peer tutor in the final 3 weeks for the project. **Groups:** **G1:** peer tutoring **Provider:** Peer tutors, supervised by an experienced learning support assistant or nursery nurse **Measure of treatment fidelity reported:** NR **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 10 **N at follow-up:** **G1:** 9 (for coded variables)	**Inclusion criteria:** • Attended village primary school with a unit for children with high levels of autism and moderate learning difficulties **Exclusion criteria:** • See inclusion criteria **Age, range (years):** 6-7 **Mental age:** NR **Gender, n:** Male: 9 Female: 1 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** ICD-10 **Diagnostic category, %:** Autism: 100 **Other characteristics, n:** CARS, severely autistic: 4/4 Complex utterances: 1 No language: 1 2 to 4 word sentences: 3 Mainly single words with infrequent simple word combinations: 5 Receptively at or above level of 3 information-carrying words: 2 Receptively at or below single-word stage: 2 Moderate to severe or severe levels of learning difficulty: 10	**Social skills:** Joint attention, percent of coded intervals: **G1:** < 5 **Communication/ language:** Requesting, percent of coded intervals: **G1:** < 3.5 **Adaptive behavior:** Shared play, mean percent: **G1:** 42	**Social skills:** Joint attention, percent of coded intervals: **G1:** < 5 **G1/BL:** P = NS **Communication/ language:** Requesting, percent of coded intervals: **G1:** 10 **G1/BL:** $P < 0.025$ **Adaptive behavior:** Shared play, mean percent: **G1:** 66 **G1/BL:** P = NS **Harms:** None **Modifiers:** NR

Evidence Table. Therapies for children with ASD

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Author: Arick et al., 2003 **Country:** US **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** 1998 **Funding:** U.S. Department of Education **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Study of Oregon regional programs for children with ASD designed to track educational progress of students receiving home or school based services over time. **Assessments:** Outcome data were collected at baseline and quarterly, biannually, and annually; measures included standardized tests, non-standardized forms, surveys, and interviews ASIEP-2, EOWPVT (if reached ceiling on vocal behavior subtest of ASIEP-2, quarterly), EBASAS (if reached ceiling on educational assessment of ASIEP-2, quarterly), Battelle Developmental Inventory (annually), VABS (annually), SLP, Program Implementation Checklist (at baseline & biannually), parent survey (annually), classroom observation form (annually) **Groups:** **G1:** children with ASD **Provider:** • School based interventions tracked via a program implementation checklist • Assessment specialists trained by special education professionals **Measure of treatment fidelity reported:** No Co-interventions held stable during treatment: No	**Inclusion criteria:** • Preschool students 2-6 years of age • Primary diagnosis for services was ASD (confirmed by initial assessment results) • Nominated from Oregon regional programs for students with ASD • Child already involved in some type of school and/or home behavioral program **Exclusion criteria:** • See inclusion criteria **Age, years, n:** **G1:** 2: 9 3: 23 4: 22 5: 10 6: 3 **Mental age:** NR **Gender:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** ASIEP **Diagnostic category, n (%):** ASD: 67 (100) **Other characteristics:** NR	**Overall ratings:** ASIEP-2 autism behavior checklist score, mean ± SD: Body/object use: **G1:** 12.03 ± 7.08 Language: **G1:** 14.07 ± 6.10 Total score: **G1:** 70.47 ± 19.82 ASIEP-2 educational assessment score, mean ± SD: Receptive language: **G1:** 4.98 ± 3.08 Expressive language: **G1:** 2.83 ± 2.78 Body concept: **G1:** 4.38 ± 3.80 Speech imitation: **G1:** 5.22 ± 3.40 Total score: **G1:** 28.82 ± 12.63 ASIEP-2 social interaction assessment score, mean ± SD: Appropriate social interactions: **G1:** 5.63 ± 5.27 Self-stimulation/ nonresponsive to adult: **G1:** 22.86 ± 11.88 Total score: **G1:** 65.21 ± 15.35 ASIEP-2 vocal behavior score, mean ± SD: Noncommunicative utterances: **G1:** 35.97 ± 14.03 Unintelligible utterances: **G1:** 37.41 ± 14.08 Words used during sample: **G1:** 25.39 ± 36.0 Expressive language age: **G1:** 23.21 ± 8.50	**Overall ratings:** ASIEP-2 autism behavior checklist score, 12-16 months, mean ± SD: Body/object use: **G1:** 9.90 ± 7.87 **G1/BL:** $P \le 0.05$ Language: **G1:** 12.23 ± 5.97 **G1/BL:** $P \le 0.05$ Total score: **G1:** 61.60 ± 25.86 **G1/BL:** $P \le 0.05$ ASIEP-2 educational assessment score, 12-16 months, mean ± SD: Receptive language: **G1:** 6.87 ± 3.50 **G1/BL:** $P \le 0.01$ Expressive language: **G1:** 4.63 ± 4.30 **G1/BL:** $P \le 0.01$ Body concept: **G1:** 7.27 ± 4.37 **G1/BL:** $P \le 0.01$ Speech imitation: **G1:** 7.37 ± 4.10 **G1/BL:** $P \le 0.01$ Total score: **G1:** 37.90 ± 15.44 **G1/BL:** $P \le 0.01$ ASIEP-2 social interaction assessment score, 12-16 months, mean ± SD: Appropriate social interactions: **G1:** 9.18 ± 8.15 **G1/BL:** $P \le 0.01$ Self-stimulation/ nonresponsive to adult: **G1:** 17.37 ± 12.60 **G1/BL:** $P \le 0.01$ Total score: **G1:** 56.19 ± 18.60 **G1/BL:** $P \le 0.01$
Arick et al., 2003 (continued)	**Concomitant therapies, n:**			ASIEP-2 vocal behavior score,

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	Gluten-free and casein-free diet: 8 Secretin: 7 Vitamins: 6 Dimethylglycine: 5 ABA programs: 4 Magnesium: 3 B-6 vitamins: 3 Swimming: 3 Dairy-free diet: 3 Speech therapy: 3 Private preschool: 3 Gluten-free diet: 3 Yeast-free diet: 2 Audio sensory training: 2 Respite care: 2 In-home aide to assist with functional skills: 2 Occupational therapy: 2 19 others: 1 **N at enrollment:** **G1:** 67 **N at follow-up:** **G1:** 56			mean ± SD: Noncommunica-tive utterances: **G1:** 23.17 ± 18.20 **G1/BL:** $P \leq 0.01$ Unintelligible utterances: **G1:** 24.68 ± 20.43 **G1/BL:** $P \leq 0.01$ Words used during sample: **G1:** 52.37 ± 52.32 **G1/BL:** $P \leq 0.01$ Expressive language age: **G1:** 33.51 ± 16.70 **G1/BL:** $P \leq 0.01$ **Harms:** NR **Modifiers:** Gain in expressive language age at follow-up was significantly correlated with follow-up IQ score (r = 0.469, P = 0.05), and Battelle Develop-mental Inventory cognitive domain age-equivalent scores at baseline (r = 0.498, P = 0.05) and follow-up (r = 0.511, P = 0.05).

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Chez et al., 2003 **Country:** US **Practice setting:** Specialty center **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Donepezil hydrochloride (DH), 6 weeks, QD, 2.5 mgs (dose was decreased to 1.25 mgs if parents noted persistent GI distress or changes in behavior and discontinued if GI intolerability or behavior changes lasted > 1 day – considered an adverse event) Placebo: first 6 weeks of placebo then 6 weeks open label treatment for all subjects **Assessments:** Each completed at baseline and 6 weeks: ROWPVT 11 (clinician); EOWPVT-R (clinician); CARS (clinician and parent also completed at 12-week appointment) **Groups:** **G1:** DH capsule **G2:** placebo/DH capsule **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** Testing administered at baseline, 6 weeks and 12 weeks; weekly phone logs **Concomitant therapies, n (%):** Anticonvulsants (divalproex sodium, valproic acid or lamotrigine): **G1:** 20 **G2:** 12 Corticosteroids (pulse dose prednisone or prednisolone): **G1:** 4 **G2:** 2	**Inclusion criteria:** • Ages 2-10 years • Prior diagnosis of AD, PDD-NOS, or Landau-Kleffner Syndrome **Exclusion criteria:** • Concomitant neurological syndrome or disease with neurological compromise (e.g., neurofibromatosis) **Age, years (range):** **G1:** 6.8 (2.1-9.9) **G2:** 6.9 (4.1-10.3) **Mental age:** NR **Gender, n (%):** Male: **G1:** 19 (83) **G2:** 16 (80) Female: **G1:** 4 (17) **G2:** 4 (20) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** DSM-IV **Diagnostic category, n:** Autistic disorder: **G1:** 8 **G2:** 5 PDD-NOS: **G1:** 14 **G2:** 13 Landau-Kleffner syndrome: **G1:** 1 **G2:** 2 **Other characteristics, n (%):** Nocturnal epileptiform EEG abnormalities: 28 (72) Normal 24 EEG patterns: 11 (28)	**Overall ratings:** CARS score, mean ± SD: **G1:** 34.7 ± 7.7 **G2:** 35.1 ± 7.9 **G1/G2:** P = NS **Communication/ language:** EOWPVT-R score, mean ± SD: **G1:** 35.7 ± 27.8 **G2:** 31.9 ± 31.1 **G1/G2:** P = NS ROWPVT 11 score, mean ± SD: **G1:** 38.8 ± 23.5 **G2:** 33.5 ± 27.9 **G1/G2:** P = NS	**Overall ratings:** CARS score, 6 weeks, mean ± SD: **G1:** 33.3 ± 8.0 **G2:** 32.9 ± 7.7 **G1/BL:** P = NS **G2/BL:** $P < 0.05$ **G1/G2:** P = NS CARS, 12 weeks, mean ± SD: **G1:** 30.8 ± 7.9 **G2:** 30.9 ± 9.1 **G1/BL:** $P < 0.05$ **G2/BL:** $P < 0.05$ **G1/G2:** P = NS **Communication/ language:** EOWPVT-R score, 6 weeks, mean ± SD: **G1:** 43.3 ± 27.2 **G2:** 33.8 ± 32.9 **G1/BL:** $P < 0.05$ **G2/BL:** P = NS **G1/G2:** P = NS EOWPVT-R score, 12 weeks, mean ± SD: **G1:** 42.5 ± 28.5 **G2:** 40.9 ± 38.8 **G1/BL:** $P < 0.05$ **G2/BL:** $P < 0.05$** **G1/G2:** P = NS ROWPVT 11 score, 6 weeks, mean ± SD: **G1:** 50.3 ± 27.0 **G2:** 39.83 ± 27 **G1/BL:** $P < 0.05$ **G2/BL:** P = NS **G1/G2:** P = NS ROWPVT 11 score, 12 weeks, mean ± SD: **G1:** 49.7 ± 34.2 **G2:** 87.37 ± 14.2 **G1/BL:** $P < 0.05$** **G2/BL:** $P <$ 0.05*** **G1/G2:** P = NS
Chez et al., 2003 (continued)	CNS stimulants (dextroamphetamine/ amphetimine or methylphenidate): **G1:** 5 **G2:** 3			**Harms:** First 6 weeks: Increased irritability, mood swings, crying, lability:

Evidence Table. Therapies for children with ASD

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	Antidepressants (fluoxetime hydrochloride or paroxitene): **G1:** 2 **G2:** 5 Antipsychotics (risperidone):* **G1:** 4 **G2:** 4 Alpha adrenergic blocking agents (clonidine): **G1:** 1 **G2:** 8 **N at enrollment:** **G1:** 23 **G2:** 20 **N at follow-up:** **G1:** 17 **G2:** 17			**G1:** 5 **G2:** 0 Lethargy: **G1:** 1 **G2:** 0 Frequent urination: **G1:** 1 **G2:** 0 Troubled sleep: **G1:** 1 **G2:** 0 Second 6 weeks: Diarrhea, stomach cramping: **G1:** 2 **G2:** 0 Increased irritability, mood swings, crying, lability: **G1:** 4 **G2:** 2 More stimming: **G1:** 1 **G2:** 0 Withdrawal due to adverse events, n: **G1:** 6 **G2:** 0 Withdrawal due to no show, 6 week appointment, n: **G1:** 0 **G2:** 3 **Modifiers:** NR

Comments: *The paper also reports the total number of children in G1 and G2 on antipsychotics is 4, so these numbers may be in error.
**Change is statistically significant when compared to BL or 6 month value.
***Change is statistically significant when compared to 6 month value.

Author: Evangeliou et al., 2003 **Country:** Greece **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** May 1999	**Intervention:** Ketogenic diet (John Radcliffe diet) Applied for 6 months, with continuous administration for 4 weeks, interrupted by 2 week diet-free intervals **Assessments:** CARS at baseline and following intervention **Groups:** **G1:** Ketogenic diet	**Inclusion criteria:** • 4-10 years of age with autistic behavior as diagnosed by a child psychiatrist according to CARS • Mild-moderate cases=CARS 30-36 • Severe cases= CARS ≥ 37 **Exclusion criteria:** See inclusion criteria **Age, median/yrs (range):** 7 (4-10) **Mental age:**	**Overall ratings:** **CARS, n, mean ± SD:** Mild / Moderate autistic cases: 2 (CARS=34, 36) Severe cases: 28 (CARS: 37-54) Pre-CARS: 2, 35 ± 1.41 Pre-CARS: 8, 41.88 ± 3.14	**Overall ratings:** **CARS, mean ± SD:** Improvement: 4.77 ± 0.89 *P* < 0.001 Significant improvement observed in those with lower initial CARS scores Diet tolerated, n (%): 23 (76.6)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
to May 2000 **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Co-interventions held stable during treatment:** NR **Frequency of contact during study:** End of each 4 week diet phase and at the end of each 2 week diet-free phase Monthly Psychiatric examination at the end of the diet and every month after discontinuation of diet for 6 months **Concomitant therapies, n (%):** Haloperidol: 30 (100) **N at enrollment:** **G1:** 30 **N at follow-up:** **G1:** 30	NR **Gender:** M, n (%): 16 (53.3) F, n (%): 14 (46.7) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** CARS **Diagnostic category, n (%):** Autism : 30 (100) **Other characteristics:** NR	Pre-CARS: 8, 45.25 ± 2.76 Elevated 3-ohisovaleric acid: 3 Pathologic levels of beta - hydroxybutyrate abnormal (1.05 - 1.45 mmol/L): 6	Improvement in Social behavior, interactions, speech, stereotypy & learning, n (%): 18 (60) Elevated beta-OHb following diet, n (%): 4 (13.3) Interrupted diet, n (%): 5 (16.7) Elevated beta-OHb following diet, n (%): 2 (6.7) Improvement significantly (CARS > 12 units): 2 (CARS=16, 13 units) Average (CARS > 8-12 units): 8 (CARS mean=7.1 units) Minor (CARS 2-8 units): 8 (CARS mean =7.1 units)
Evangeliou et al., 2003 (continued)				Among 6 with the pathologic levels of beta - hydroxybutyrate, improvement , n: Significant: 1 Average: 2 Minor: 1 (2 discontinued the diet) **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Levy et al., 2003 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NIH, MRDDRC **Author industry relationship disclosures:** NR **Design:** RCT (double-blind cross-over)	**Intervention:** Single IV dose of human synthetic secretin (2CU/kg) to a maximum dose of 75 CU injected slowly over 1 minute Infusions separated by a 6-week washout period **Assessments:** GBRS completed by families and teachers or therapists; daily log of gastrointestinal symptoms completed by parents; CSBS completed by study examiners at BL and two weeks after each infusion; Ritvo Real-life Rating Scale completed by study examiners at BL and two weeks after each infusion; occurrence of adverse effects monitored throughout the study **Groups:** **G1:** infusion of secretin followed by placebo six weeks later **G2:** infusion of placebo followed by secretin six weeks later **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** Families & teachers or therapists completed GBRS weekly **Concomitant therapies, n:** Prozac: **G1:** 3* **G2:** 1 Adderall: **G1:** 0 **G2:** 2 Risperidone **G1:** 1 **G2:** 0 Guanfacine: **G1:** 1* **G2:** 2	**Inclusion criteria:** • Children in the age range of 3-8 years with ASD as diagnosed by ADI-R **Exclusion criteria:** • Significant hearing or vision loss • Other neurological disorders (e.g., cerebral palsy, phenylketonuria, tuberous sclerosis, neurofibromatosis, seizure disorder) • Genetic disorder • Prematurity (< 32 weeks gestation) • Diagnosis of coeliac disease or other gastrointestinal disease, associated with malabsorption • Previous treatment with secretin • Anaemia and plumbism **Age, months ± SD:** **G1:** 70.65 ± 18.2 **G2:** 76.53 ± 14.33 **Age, range:** 43-103 **Mental age:** NR **Gender, %:** Male: **G1:** 87 **G2:** 74 Female: **G1:** 13 **G2:** 26 **Race/ethnicity, %:** Caucasian: **G1:** 87 **G2:** 94 **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** ADI-R	**Overall ratings:** CARS total score, mean ± SD: **G1:** 34.1 ± 3.13 **G2:** 37.32 ± 6.23 **G1/G2:** *P* = 0.02 CARS score < 37 (mild-moderate), %: **G1:** 84 **G2:** 55 **G1/G2:** *P* = 0.003 **Adaptive behavior:** VABS communication standard score, mean ± SD: **G1:** 54.50 ± 14.03 **G2:** 54.44 ± 13.81 **G1/G2:** *P* = NS CSBS standard score, mean ± SD: **G1:** 72.75 ± 7.86 **G2:** 75.03 ± 10.65 **G1/G2:** *P* = NS Ritvo subscale score, mean ± SD: Sensory motor: **G1:** 0.46 ± 0.06 **G2:** 0.41 ± 0.06 **G1/G2:** *P* = NS Social relatedness: **G1:** 1.03 ± 0.06 **G2:**1.16 ± 0.06 **G1/G2:** *P* = NS Affect: **G1:** 0.64 ± 0.10 **G2:** 0.74 ± 0.10 **G1/G2:** *P* = NS Sensory: **G1:** 0.61 ± 0.05 **G2:** 0.68 ± 0.05 **G1/G2:** *P* = NS Language: **G1:** 0.80 ± 0.04 **G2:** 0.88 ± 0.05 **G1/G2:** *P* = NS	**Adaptive behavior:** CSBS standard score, period 1, mean change ± SD: **G1:** 0.14 ± 8.28 **G2:** -0.27 ± 7.36 CSBS standard score, period 2, mean change from BL ± SD: **G1:** 2.19 ± 7.73 **G2:** -0.70 ± 7.90 Ritvo global score, period 1, mean change ± SD: **G1:** 0.01 ± 1.35 **G2:** -0.18 ± 0.79 Ritvo global score, period 2, mean change from BL ± SD: **G1:** 0.12 ± 0.66 **G2:** -0.27 ± 0.96 GBRS score, teacher-rated, period 1, mean change ± SD: **G1:** 0.34 ± 0.72 **G2:** 0.14 ± 0.71 GBRS score, teacher-rated, period 1, mean change ± SD: **G1:** 0.33 ± 1.01 **G2:** 0.29 ± 1.06 GBRS score, parent-rated, period 1, mean change ± SD: CARS < 37: **G1:** 0.20 ± 0.76 (n=25) **G2:** 0.30 ± 0.71 (n=14) CARS ≥ 37: **G1:** 0.73 ± 0.60 (n=5) **G2:** 0.14 ± 0.58 (n=16)
Levy et al., 2003 (continued)	Methylphenidate: **G1:** 0 **G2:** 2 **N at enrollment:**	**Diagnostic category, n (%):** Autism: 61 (100) PDD-NOS: NR		GBRS score, parent-rated, period 2, mean change from BL ±

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	G1: 31 **G1a:** 26 **G1b:** 5 **G2:** 31 **G2a:** 16 **G2b:** 15 **N at follow-up:** **G1:** 30 **G1a:** NR **G1b:** NR **G2:** 31 **G2a:** 16 **G2b:** 15	Aspergers: NR **Other characteristics, %:** GI symptoms: **G1:** 63 G2: 50		SD: CARS < 37: **G1:** 0.74 ± 0.86 (n=24) **G2:** 0.19 ± 1.08 (n=13) CARS ≥ 37: **G1:** 0.00 ± 0.42 (n=5) **G2:** 0.30 ± 0.70 (n=16) **Harms:** Adverse events, n: Elevated LFT: 3 Hyperactivity: 2 Emotional lability: 1 Fractures: 2 Stomach ache: 1 **Modifiers:** CARS by treatment interaction for parent-rated GBRS (*P* = 0.0001)

Comments: *One child in G1 received both prozac and guanfacine.

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Magiati et al., 2003 **Country:** UK **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** NR **Funding:** Agency: Three Guineas Trust, UK **Author industry relationship disclosures:** NR	**Intervention:** Picture Exchange Communication system (PECS). Assessment carried out in the 2 month period prior to training with rates of change measured during 2 month periods over 6 months following training (time1 / BL, time2, time3, time 4) **Assessments:** Teachers completed initial measures of children's communicative ability 2 mos before onset of PECS training; same assessments completed immediately after PECS workshop and at 2 monthly intervals	**Inclusion criteria:** • Diagnosis of Autism • Special schools with a full dedicated provision for children with ASD • No or minimal prior experience of PECS **Exclusion criteria:** • Very well developed verbal skills • Any increase of Behavioral difficulties • See inclusion criteria **Age, mean/yrs ± SD (range):** Both groups: 7.66 ± 2 (5-12) **Mental age:** NR **Gender:** M, n (%): 29 (85.3) F, n (%): 5 (14.7)	**Vineland scores**: Age equivalent, mean/yrs:mos ± SD, (range): Communication: 1:6 ± 7, (0:8-2:8) Daily living skills: 2:7 ± 7, (1:4-3:9) Socialization: 1:6 ± 7, (0:7-2:10) **PECS, mean ± SD:** Level: 0.91 ± 1.26 Vocabulary: 0.85 ± 1.18 Frequency: 1.65 ± 1.89 Number of signs: 1.18 ± 1.31 Number of words: 2.53 ± 2.19 Number of phrases:	**Vineland scores:** NR **PECS, mean ± SD:** Level: 4.58 ± 1.26 (*P* = 0.001) Vocabulary: 4.31 ±1.12 (*P* = 0.001) Frequency: 4.71 ±1.59 (*P* = 0.001) Number of signs: 1.62 ± 1.56 (*P* = 0.01) Number of words: 3.21 ± 2.01 (*P* = 0.001) Number of phrases: 1.53 ± 1.98 (*P* = 0.02)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Design: Prospective case series	thereafter ASQ, VABS, ATEC Parental information on child's general level of functioning and severity of autistic symptoms prior to onset of PECS training **Groups:** **G1a:** Initially using little/no speech **G1b:** Vocabulary of > 10 words when training began **Provider:** Teachers **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** None **N at enrollment:** **G1a:** 18 **G1b:** 16	**Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study/Referral: Referral **Diagnostic tool/method:** ADI-R **Diagnostic category, n (%):** Autism : 34 (100) **G1a:** 18 **G1b:** 16	1 ± 1.58 Overall level of spontaneous communication: 5.91 ± 2.02 **Rimland Autism Treatment Evaluation Checklist, mean ± SD:** Total score: 74.9 ± 20.98 Communication: 19.50 ± 5.43 Socialization: 16.02 ± 8.05 Sensory/cognitive: 22.58 ± 6.37 Physical/mood: 16.76 ± 7.38	Overall level of spontaneous communication: 7.38 ±1.47 (*P* = 0.001) Rimland Autism Treatment Evaluation Checklist, mean ± SD: Total score: 65.11 ± 20.89 Communication: 17.29 ± 5.45 Socialization: 13.97 ± 7.13 Sensory/cognitive: 19.00 ± 7.97 (*P* < 0.01) Physical/mood: 14.85 ± 7.1 **Harms:** NR **Modifiers:** Changes according to initial language level: Baseline vs. Follow up, mean ± SD:
Magiati et al., 2003 (continued)	**N at follow-up:** **G1a:** 18 **G1b:** 16	**Other characteristics, n (%):** Hyperactivity: 1 (2.9) Non-verbal: 10 (29.4) Single words: 10 (29.4) Phrase speech: 14 (41.2)		**G1a:** PECS Level: 1.3 ± 1.13 vs. 4.0 ± 1.14 Vocabulary: 1.05 ± 0.87 vs. 4.06 ± 0.94 Frequency: 2.4 ± 1.76 vs. 4.4 ± 1.61 [all 3 *P* < 0.01] Overall level of spontaneous communication: 4.94 ± 1.55 vs. 6.39 ± 1.14 *P* < 0.001 Number of signs: *P* < 0.03 Number of words: *P* = 0.001 **G1b:** PECS Level: <1 vs. 5.3

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				P < 0.001 Pictures used: <1 to 21-50 *P* < 0.001 Frequency of PECS use <1 to 11-20 symbols *P* < 0.001 Number of words *P* = NS Number of phrases *P* = NS Number of signs: *P* = NS Overall level of spontaneous Communication: 6.9 ± 2.01 vs. 8.47 ± 0.91 *P* < 0.001
Magiati et al., 2003 (continued)				Prior exposure to PECS: experienced group vs. naïve group: Experienced: PECS Freqs : baseline vs. follow-up *P* = NS PECS vocabulary: *P* = 0.02 Naïve group: PECS level, freq, vocabulary all rose significantly between times 1 & 4 (*P* < 0.001) School differences: pupils in schools with little or no prior experience of PECS actually reached higher PECS levels at follow-up than pupils in schools where PECS was already established

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Sofronoff et al., 2003 **Country:** Australia **Practice setting:** NR **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** School of Psychology, University of Queensland **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** A cognitive behavior therapy program "Exploring Feelings," taught in 6 weekly two-hour sessions; treatment goal: teach strategies to manage feelings and broaden emotional and behavioral repertoire Two therapists per group of three children; while children in the group with parents involved received the intervention, their parents worked through the "Expoloring Feelings" program with therapists **Assessments:** James and the Maths Test (child measure developed for the study), parent measure of self efficacy in management of 15 behaviors related to Asperger; given pre-intervention, post-intervention, and at 6 week follow-up. Parent evaluation of intervention assessed at 6 week follow-up **Groups:** **G1:** behavior therapy, parents not involved **G2:** behavior therapy, parents taught separately **G3:** waitlist controls **Provider:** Clinical psychologists **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 24 **G2:** 27 **G3:** 14	**Inclusion criteria:** • Age 10-12 years • Diagnosis of Asperger syndrome • Presence of anxiety based on parental report **Exclusion criteria:** • See inclusion criteria **Age:** NR **Mental age:** NR **Gender:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** NR **Diagnostic category, n (%):** Aspergers: 65 (100) **Other characteristics:** NR	**Problem behavior:** James and the Maths Test score, mean: **G1:** NR* **G2:** NR* **G3:** NR* **G1/G2/G3:** P = NS Parental self efficacy rating, mean: **G1:** NR** **G2:** NR** **G3:** NR** **G1/G2/G3:** P = NS	**Problem behavior:** James and the Maths Test score, mean: Post-treatment: **G1:** NR* **G2:** NR* **G3:** NR* **G1/G2:** $P < 0.01$ **G1/G3:** $P < 0.0001$ **G2/G3:** $P < 0.0001$ 6 week follow-up: **G1:** NR* **G2:** NR* **G3:** NR* **G1/G2:** $P < 0.0001$ **G1/G3:** $P < 0.0001$ **G2/G3:** $P < 0.0001$ Parental self efficacy rating, mean: **G1:** NR** **G2:** NR** **G3:** NR** Post-treatment: **G1:** NR* **G2:** NR* **G3:** NR* **G1/G2:** P = NS **G1/G3:** $P < 0.05$ **G2/G3:** $P < 0.05$ 6 week follow-up: **G1:** NR* **G2:** NR* **G3:** NR* **G1/G2:** P = NS **G1/G3:** $P < 0.05$ **G2/G3:** $P < 0.05$ **Harms:** NR **Modifiers:** NR
Sofronoff et al., 2003 (continued)	**N at follow-up:** NR			

Comments: *data only illustrated graphically in Figure 1

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
**data only illustrated graphically in Figure 2, which appears to erroneously be a reproduction of Figure 1				

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Masi et al., 2003 **Country:** Italy **Practice setting:** Third level research Hospital **Intervention setting:** Clinic **Enrollment period:** March 1999 to April 2002 **Funding:** NR **Author industry relationship disclosures:** First author-Eli Lilly, Pfizer, GlaxoSmithKline & Janssen **Design:** Prospective case series	**Intervention:** Risperidone monotherapy. Duration of treatment ranged from 3-32 months. Started on a dose of 0.25 mg at bedtime. Subsequent titration was by 0.25mg increments at no more than weekly intervals depending on clinical response and occurrence of side effects. Max daily dose was 1mg. **Assessments:** CPRS, CGI-I, CGAS, and side effects checklist administered by independent examiners at baseline, after 8 wks, and at irregular intervals during follow up (mean follow up 7.9±6.8 mos, range 1-32 mos). CARS, Griffiths Developmental Scales, Leiter International Performance Scale administered at baseline. **Groups:** **G1a:** Autistic disorder **G1b:** PDD-NOS **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** Behavioral symptoms at baseline, after 8 weeks and again at irregular intervals during follow-up**.** **Concomitant therapies:** None **N at enrollment:** 53	**Inclusion criteria:** • Diagnosis of autistic disorder or PDD-NOS according to DSM-IV criteria and CARS score above 30 • Absence of comorbid medical or neurologic conditions • Severe behavioral symptoms • Written parental informed consent to treatment **Exclusion criteria:** See inclusion criteria **Age, mean/yrs ± SD:** 4.6 ± 0.7 (3.6-6.6) **G1a:** 4.4 ± 0.6 **G1b:** 5 ± 0.8, *P* = 0.01 **Mental age:** NR **Gender:** M, n (%): 45 (84.9) F, n (%): 8 (15.1) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** Clinical interview, DSM-IV, CARS score above 30 **Diagnostic category, n (%):** Autism : 37 (69.8) PDD-NOS : 16 (30.2) **Other characteristics, n (%):**	**Overall ratings:** CPRS, mean ± SD: Total: 51.07 ± 5.2 **G1a:** 51 ± 5.9 **G1b:** 41.8 ± 4.6 *P* < 0.0001 22 with a CGI-I score of 1/2 showed at least a 25% reduction in CPRS total score and were considered responders Among responders (n=22): CARS : 40.1 ± 7 CPRS: 50.5 ± 6.0 Among non-responders (n=25): CARS: 42.7 ± 5.2 CPRS: 50.7 ± 5.4 Prolactin level, ng/ml. mean ± SD: 13.3 ± 7.8 CARS: **G1a:** 43.9 ± 5.3 **G1b:** 35.9 ± 4.0 *P* < 0.0001 CGAS, mean ± SD: Overall: 20.87± 4.6 **G1a:** 19.6 ± 4.0 **G1b:** 23.9 ± 4.6 *P* = 0.002 Responders/non-responders: **G1a:** 12/21 **G1b:** 10/4 *P* = 0.06 Weight in kg, mean ± SD:	**Overall ratings:** CGAS, mean ± SD: **G1a:** 27.1 ± 5.9 **G1b:** 33.4 ± 4.7 *P* < 0.0001 CPRS, mean ± SD: **G1a:** 42.5 ± 5.4 **G1b:** 34.6 ± 3.2 *P* < 0.0001 Serum Prolactin level, mean ± SD: Responders: 24.3 ± 16.3 Non-responders: 27.5 ± 23.2 (*P* = 0.64) Prolactin level at last observation: 28.38 ± 22.45 (t = -3.8, df = 72, *P* < 0.0001) **G1a:** 29 ± 21.3 **G1b:** 26.1 ± 26.0 *P* = 0.70 Weight in kg, mean ± SD: Overall: 23.3 ± 6.3 **G1a:** 21.5 ± 5.9 **G1b:** 26.1 ± 5.3 *P* = 0.02 Responders / non-responders: mean ± SD: Maximum dosage-mg/d: 0.70 ± 0.18 / 0.57 ± 0.16 (*P* = 0.012) Optimal dosage, mg/d: 0.61 ± 0.22 / 0.49 ± 0.16 (*P* =

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	N at follow-up: 47 (treated with risperidone for at least 2 mos)	Mental retardation: 43 (81) Mild: 10 Moderate: 21 Severe: 12	Overall: 20.6 ± 5.5 **G1a:** 19.1 ± 5.0 **G1b:** 22.9 ± 4.3 *P* = 0.02	0.036) Duration of treatment (mo): 11.3 ± 8.1 / 6.5 ± 4.3 (*P* = 0.013)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Masi et al., 2003 (continued)				Weight gain, kg: 3.61 ± 3.40 / 1.76 ± 1.98 (*P* = 0.026) CPRS(total score): 40.44 ± 5.9, 21% improvement from baseline, *P* < 0.0001 >30% improvement, %: Hyperactivity: 34 Fidgetiness: 33 Angry effect: 31 Liability of affect: 31 > 20% improvement, %: Negative uncooperative behavior: 27.1 Withdrawal: 26 Non-spontaneous relation with examiner: 20 Rhythmic motions: 21 CGI-I score, n: Very much/much improved: 22 Minimally improved: 22 Unchanged: 3 CGAS, mean ± SD (%) improvement: 29.2 ± 6.2 (28), (t = -15.423, *P* < 0.0001)
Masi et al., 2003 (continued)				**Harms:** 12 (22.6 %) discontinued treatment due to side effects (6 due

Evidence Table. Therapies for children with ASD

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				to increased prolactin levels Other causes: loss of consciousness with suspected epileptic seizure, dystonic episode, tachycardia and fushes, subjective vision disorders) Side effects that did not cause discontinuation of treatment, n : Increased appetite: 8 Agitation:4 Enuresis: 4 Decreased appetite : 2 Sedation & hypoactivity: 3 Tremors: 2 Elevated liver enzymes: 1 Increase of platelets > 500,000/mm: 1 Mean weight gain in the total sample: 2.4 ± 2.8 kg **Modifiers**: See above for the effect by Diagnosis type (G1a/ G1b) Drug response not affected by severity of mental retardation

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Bibby et al., 2002 **Country:** UK **Practice setting:** Academic **Intervention setting:** Home **Enrollment period:** September 1998 to May 2000 **Funding:** Autism and Developmental Disorders Education Research Ltd. **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Parent-managed behavioral intervention patterned after UCLA workshop model **Groups:** **G1:** intervention **G1a:** children with an early (before or within 3 months of intervention start) IQ score **G1b:** children with an early (before or within 3 months of intervention start) VABS **G1c:** children at a minimum age of 72 months after at least 24 months behavioral intervention **Assessments:** Conducted by seven psychology graduates with ≥ 12 months post-graduate experience working with children with autism with same age range as groups IQ scores (assessed by primary assessors, research assistants, third author and psychologist), Bayley Scales of Infant Development (2nd ed.), WPPSI-R, WISC-III, Reynell Developmental Language Scales (3rd EK ed.), VABS (survey form from Interview Edition (assessed by trained rater), ADI-R (assessed by research assistants) **Provider:** Parent-managed approach with care provided by consultants, family members, and volunteers (19-20% UCLA Level II, 29-35% PhD or registered clinical psychologist level without meeting UCLA criteria, 47-51% MA or BA level paraprofessionals)	**Inclusion criteria:** • Children with autism whose parents who sought legal advice from the first author concerning public funding for behavioral interventions **Exclusion criteria:** • Unable to arrange for assessment • Additional diagnosis of cerebral palsy • Rett's disorder **Age, mean months ± SD:** Study entry: **G1a:** 43.4 ± 12.6 Follow-up: **G1c:** 85.5 ± 11.7 **Mental age, months:** **G1a:** 21.3 (n=17) **Gender, n:** Male: 55 Female: 11 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** NR **Diagnostic category, n (%):** Autism: 58 PDD-NOS: 2 Aspergers: 0 **Other characteristics:** Age at beginning of treatment, months ± SD: 45.0 ± 11.2 Duration of behavioral treatment at time of study entry, n (%): < 12 months: 11 (18) 12-24 months: 31 (52) > 24 months: 18 (30)	**Overall ratings:** Sum pathology score, early, mean points: **G1:** 4.9 **Social skills:** VABS socialization score, mean: **G1:** 62.8 VABS socialization, developmental age, months: **G1:** 26.3 **Communication/ language:** VABS communication score, mean: **G1:** 66.9 VABS communication, developmental age, months: **G1:** 35.2 Reynell developmental language scale, months: Comprehension: **G1:** 31.9 Expressive: **G1:** 31.2 **Adaptive behavior:** VABS composite score, early, mean: **G1b:** 54.5 VABS composite score, mean: **G1:** 58.8 VABS composite, developmental age, months: **G1:** 31.8 VABS daily living score, mean: **G1:** 59.0 VABS daily living, developmental age, months: **G1:**33.7	**Overall ratings:** Sum pathology score, 12 months, mean points: **G1:** 2.2 **G1/BL:** $P < 0.01$ **Social skills:** VABS socialization score, 12 months, mean: **G1:** 65.9 **G1/BL:** P = NS VABS socialization, 12 months, developmental age, months: **G1:** 36.2 **G1/BL:** $P < 0.01$ **Communication/ language:** VABS communication score, 12 months, mean: **G1:** 70.3 **G1c:** 66.3 **G1/BL:** $P < 0.05$ VABS communication, 12 months, developmental age, months: **G1:** 47.5 **G1c:** 63.0 **G1/BL:** $P < 0.01$ Reynell developmental language scale, 12 months, months: Comprehension: **G1:** 37.5 **G1/BL:** $P < 0.01$ Expressive: **G1:** 35.7 **G1/BL:** $P < 0.01$ **Adaptive behavior:** VABS composite scores, 12 months, mean: **G1:** 61.0 **G1b:** 63.4 **G1c:** 55.2 **G1/BL:** P = NS
Bibby et al., 2002 (continued)	**Measure of treatment fidelity reported:** No	Secondary diagnoses of additional neurological disorders or epilepsy, n: 0	VABS maladaptive behavior score, mean:	VABS composite, 12 months, developmental

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	Co-interventions held stable during treatment: No **Concomitant therapies, %:** At least one other intervention chosen by parents (e.g., diets, vitamins, minerals, secretin, homeopathic preparations, sensory treatments): 81 **N at enrollment:** **G1:** 75 **G1a:** 22* **G1b:** 21* **N at follow-up:** **G1:** 60 **G1c:** 42*	Hours of one-to-one treatment received at follow-up, mean ± SD: **G1c:** 4743 ± 1508 Weekly hours of one-to-one treatment received at follow-up, mean ± SD: **G1c:** 23.7 ± 10.4 Duration of treatment at follow-up, months ± SD: **G1c:** 36.8 ± 10.3 Weekly hours of school attendance at follow-up, mean ± SD: **G1c:** 15.9 ± 11.0 School placement at follow-up, n:** Attending special education setting with one-on-one assistance: 9 Attending special education setting with no one-on-one assistance: 4 Mainstream for at least part of school week with full-time individual adult support: **G1c:** 23 Mainstream for at least part of school week with part-time individual adult support: **G1c:** 2 Mainstream for at least part of school week with no individual adult support (educationally normal functioning): G1c: 0	**G1:** 16.3 **Educational/ cognitive/ academic attainment:** IQ, early, mean: **G1a:** 50.8 IQ, mean: **G1:** 57.6 Mental age, months: **G1:** 34.0 Merrill-Palmer mental age, mean months: **G1:** 48.8	age, months: **G1:** 41.4 **G1/BL:** *P* < 0.01 VABS daily living score, 12 months, mean: **G1:** 56.9 **G1c:** 50.4 **G1/BL:** *P* = NS VABS daily living, 12 months, developmental age, months: **G1:** 41.3 **G1/BL:** *P* < 0.01 VABS maladaptive behavior score, 12 months, mean: **G1:** 15.2 **G1/BL:** *P* = NS **Educational/ cognitive/ academic attainment:** IQ, 12 months, mean: **G1:** 58.5 (n=58) **G1a:** 55.0 **G1/BL:** *P* = NS IQ > 85, 12 months, n: **G1:** 10/66 IQ, 12 months, mean ± SD (95% CI) **G1c:** 53.1 ± 20.0 (46.8-59.4) Merrill-Palmer mental age, 12 months, mean months: **G1:** 55.6 **G1c:** 58.3 **G1/BL:** *P* < 0.01 Mental age, 12 months, months: **G1:** 39.4 (n=51) **G1/BL:** *P* < 0.01
Bibby et al., 2002 (continued)				**Harms:** NR **Modifiers:** There was a significant correlation between early IQ and IQ at study

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				entry and 12 months (both r = 0.78) and between IQ at study entry and IQ at 12 months (r = 0.93). VABS composite scores at study entry and 12 months were significantly correlated (r = 0.91), but not with early VABS composite score. Change in IQ from early measure to study entry was predicted only by age at start of behavioral treatment (r = -0.39, *P* = 0.04). There was no effect of group level of consultants on changes in IQ and VABS scales from study entry to 12 months.

**Comments: ***There were 12 children in both G1a and G1c and 9 children in both G1a and G1b. Means and variances were not significantly different between G1a and G1b, so the authors considered these values as representative for the overall group of participants at baseline.

**Among 6 who had ceased to receiving EIBI before follow-up, 5 were receiving special needs school education and 1 had no school placement.

Evidence Table. Therapies for children with ASD

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Author: Chez et al., 2002 **Country:** US **Practice setting:** Specialty treatment center **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** double Blind RCT	**Intervention:** 800 mg of L-Carnosine daily for 8 weeks **Assessments:** Baseline & 8-weeks: expressive language (EOWPVT), receptive language (ROWPVT), autism severity ratings (CARS & GARS), and CGI of Change; all completed by parents in a pediatric neurology clinic in a room dedicated to assessment Every two weeks, parents faxed a CGI of Change; they were not allowed to refer back to faxes from the prior 2-week period **Groups:** **G1:** L-Carnosine **G2:** Placebo **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** every 2 weeks **Concomitant therapies, n (%):** Valproic acid**:** NR **N at enrollment:** **G1:** 14 **G2:** 17 **N at follow-up:** **G1:** 14 **G2:** 17	**Inclusion criteria:** • Age 3-12 years • Prior diagnosis of ASD, PDD by DSM-IV-Revised **Exclusion criteria:** • Family HX of seizure disorder or fragile X syndrome, or other genetic disorder or • etiology of their spectrum disorder **Age, mean/months ± SD:** G1: 85.69 ± 24.57 G2: 92.47 ± 28.95 **Mental age:** NR **Gender:** M, n (%): 21 (67.7) F, n (%): 10 (32.3) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In study **Diagnostic tool/method:** DSM-IV **Diagnostic category, n (%):** Autism /PDD-NOS: 31 (100) **Other characteristics:** NR	**Overall ratings:** Clinical Global Impression, mean ± SD: **G1:** 14.50 ± 3.65 **G2:** 12.94 ± 4.18 *P* = NS Childhood Autism Rating Scale, mean ± SD: **G1:** 31.71 ± 6.55 **G2:** 34.85 ± 6.69 *P* = NS Gilliam Autism Rating Scale, mean ± SD: **G1:** 55.50 ± 16.35 **G2:** 50.88 ± 16.96 *P* = NS **Communication/ language:** Expressive One-Word Picture Vocabulary test (raw) , mean ± SD: **G1:** 35.36 ± 20.87 **G2:** 30.65 ± 26.28 *P* = NS Expressive One-Word Picture Vocabulary test (age adjusted), mean ± SD: **G1:** 40.71 ± 23.44 **G2:** 35.41 ± 29.94 *P* = NS Receptive One-Word Picture Vocabulary test (raw), mean ± SD: **G1:** 38.00 ± 23.67 **G2:** 34.29 ± 28.56 *P* = NS Receptive One-Word Picture Vocabulary test (age adjusted), mean ± SD: **G1:** 40.57 ± 24.55 **G2:** 39.65 ± 27.91 *P* = NS	**Overall ratings:** Changes in children after 8 wks on Active Carnosine: Clinical Global Impression, mean ± SD(baseline vs. 8 wk): **G1:** 16.39 ± 4.36 *P* = 0.06 Clinical Global Impression, mean ± SD(2 wk vs. 6 wk): **G1:** 4.92 ± 5.69 *P* = 0.04 Changes in children after 8 wks on Active Carnosine: Childhood Autism Rating Scale, mean ± SD: **G1:** 29.75 ± 7.53 *P* = 0.07 Gilliam Autism Rating Scale, mean ± SD: **G1:** 44.35 ± 14.93 *P* = 0.01 Changes in children after 8 wks on Active Carnosine: Expressive One-Word Picture Vocabulary test (raw), mean ± SD: **G1:** 37.28 ± 25.66 *P* = NS Expressive One-Word Picture Vocabulary test (age adjusted), mean ± SD: **G1:** 43.78 ± 28.22 *P* = NS

Evidence Table. Therapies for children with ASD

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Chez et al., 2002 (continued)			GARS Communication Scale, mean ± SD: **G1:** 21.64 ± 7.99 **G2:** 15.23 ± 6.68 *P* = 0.02 **Adaptive behavior:** GARS Behavior Scale, mean ± SD: **G1:** 15.71 ± 6.65 **G2:** 17.17 ± 8.71 *P* = NS **Social skills:** GARS Socialization Scale, mean ± SD: **G1:** 18.14 ± 6.30 **G2:** 18.47 ± 6.40 *P* = NS	Receptive One-Word Picture Vocabulary test (raw), mean ± SD: **G1:** 44.64 ± 26.56 *P* = 0.01 Receptive One-Word Picture Vocabulary test (age adjusted), mean ± SD: **G1:** 47.86 ± 28.37 *P* = 0.01 GARS Communication Scale, mean ± SD: **G1:** 18.14 ± 6.27 *P* = 0.03 **Adaptive behavior:** GARS Behavior Scale, mean ± SD: **G1:** 12.86 ± 5.95 *P* = 0.04 **Social skills:** GARS Socialization Scale, mean ± SD: **G1:** 13.36 ± 6.58 *P* = 0.01 Changes in children after 8 wks on Placebo:
Chez et al., 2002 (continued)				Clinical Global Impression, mean ± SD (baseline vs. 8 wk): **G2:** 14.25 ± 4.51 *P* = NS Clinical Global Impression, mean ± SD(2 wk vs. 6 wk) : **G2:** 4.71 ± 5.02 *P* = NS Childhood Autism

Evidence Table. Therapies for children with ASD

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				Rating Scale, mean ± SD: **G2:** 33.76 ± 6.54 *P* = NS Gilliam Autism Rating Scale, mean ± SD: **G2:** 49.88 ± 16.80 *P* = NS **Communication/ language:** Expressive One-Word Picture Vocabulary test (raw), mean ± SD: **G2:** 31.65 ± 29.19 *P* = NS Expressive One-Word Picture Vocabulary test (age adjusted), mean ± SD: **G2:** 37.12 ± 33.38 *P* = NS Receptive One-Word Picture Vocabulary test (raw), mean ± SD: **G2:** 37.11 ± 30.89 *P* = NS
Chez et al., 2002 (continued)				Receptive One-Word Picture Vocabulary test (age adjusted), mean ± SD: **G2:** 41.65 ± 30.46 *P* = NS GARS Communication Scale, mean ± SD: **G2:** 16.88 ± 6.48 *P* = NS **Adaptive behavior:** GARS Behavior Scale, mean ± SD: **G2:** 15.82 ± 7.74 *P* = NS

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				Social skills: GARS Socialization Scale, mean ± SD: **G2:** 17.18 ± 7.76 *P* = NS **Harms:** Parent report of sporadic hyperactivity **Modifiers:** NR

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Author: Delong et al., 2002 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Agency:NR **Author industry relationship disclosures:** NR **Design:** Retrospective case series	**Intervention:** Fluoxetine (0.15 to 0.5 mg/kg) for 5-76 months with discontinuation trials Optimal dose was 4 to 8 mg/day or 15-40 mg/day **Assessments:** Family histories obtained using family history method in repeated interviews; diagnosis validated by CARS performed by TEACCH or research team & ADOS **Groups:** **G1a:** Good / excellent responders **G1b:** Poor / fair responders **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** trials discontinued after 1 year for a period ranging from 4 days to several months among those with excellent/good response **Concomitant therapies:** NR **N at enrollment:** 155 **N at follow-up:** 129	**Inclusion criteria:** • Children 2-8 years old • CARS scores > 30 **Exclusion criteria:** • Neurological / chromosomal disorders • Severe global impairment **Age, mean/yrs (range):** 4.6 (2.83-7.5) **Mental age:** NR **Gender:** M: NR F: NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In study **Diagnostic tool/method:** Autism Diagnostic Observation Schedule (ADOS) & validated by CARS **Diagnostic category, n (%):** Autism: 129 (100) **Other characteristics:** History of regression, n/N (%): **G1a:** 64/83 (77) **G1b:** 22/36 (61) *P* = 0.12 Family hx of MAD + family hx of BPD, n/N (%): **G1a:** 32/83 (38.6)	NR	**Responders:** Fluoxetine response, n (%): Excellent: 22 (17) Good: 67 (52) Fair/poor: 40 (31) Fluoxetine response by family history of major affective disorder, n/N (%): Excellent/good : 67/70 (85) Poor/fair: 19/38 (50) *P* < 0.001 Fluoxetine response by family history of unusual achievement, n/N (%): With FH: 76/147 (52) Excellent/good response: 52/76 (68) Poor/fair response: 16/76 (21) Without FH: 71/147 (48) Excellent/good response: 21/71 (30) Poor/fair response: 34/71 (48) *P* < 0.001 Family history of unusual achievement with or without major affective disorder, n/N (%): Families with unusual achievement & major affective disorder: 69/76 (91) Families without unusual achievement & major affective disorder: 37/71 (52) *P* < 0.001
Delong et al., 2002 (continued)		Regression of language & social skills at the onset of recognition of autism, n/N		Family history of unusual achievement with or

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		(%): **G1a:** 56/67 (83.6) Verbal ability, n: **G1a:** 86 **G1b:** 38 Some verbal ability, n/N (%): **G1a:** 66 (77) **G1b:** 20/38 (52.6) No verbal ability, n: **G1a:** 20 Hyperlexia, n (%): **G1a:** 24 (27) **G1b:** 1		without family history of bipolar disorder, n/N (%): Families with unusual achievement & bipolar disorder: 42/ 76 (55) Families without unusual achievement: 4/71 (6) *P* < 0.001 Status of children treated for >36 months, n/N: Clinical regression: 18/30 **Educational placement, n/N:** Regular: 14/30 With other autism children: 5/30 Home school: 3/30 Special classes: 3/30 With Bipolar disorder: 5 males/30 (3 in regular class, 1 in learning disability class, 1 clearly autistic) >3 years treatment with Fluoxetine: 5 **Other treatment agents:** Lithium : 4 Valproate: 1 (3 discontinued Fluoxetine) **Harms :** Incidence of diarrhea / rash: 1 Mania: 1
Delong et al., 2002 (continued)				**Modifiers:** Treatment response did not correlate with age at starting treatment (data NR)

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Author: Drew et al., 2002 **Country:** UK **Practice setting:** Academic **Intervention setting:** Hospital clinic **Enrollment period:** NR **Funding:** Agency: Medical research council Project grant & from the Special Trustees of Guy's Hospital **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Parent-training components included behavior management strategies, development of social and communicative competence, play skills, holistic learning, and integration into the routine. Local services group included speech and language therapy, portage home worker input and other paramedical therapy services (OT), ABA: Lovaas Follow up conducted 12 months later (mean age=35 months) **Assessments:** Research team administered at baseline and follow-up: MCDI, Griffiths Scale of Infant Development, & ADI-R **Groups:** **G1:** Parent training **G2:** Local services **Frequency of contact:** Hrs/week, mean ± SD: **G1:** 6.3 ± 10.7 **G2:** 3.5 ± 3.6 **Provider:** Research team **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies, n (%):** **G2:** 3 in intensive home-based behavioral program Hrs/week of Other interventions: **G1:** 0.3 ± 0.1 **G2:** 8.4 ± 14.9 F(1,23) = 3.6, $P = 0.07$	**Inclusion criteria:** Failure of all 6 items of Shortened version of the CHAT ICD-10 criteria for childhood autism **Exclusion criteria:** General developmental delay **Age, mean/months ± SD:** **G1:** 21.4 ± 2.7 **G2:** 23.6 ± 3.8 **Mental age:** NR **Gender, n (%):** **G1:** M: 11(91.7) F: 1 (8.3) **G2:** M: 8 (66.7) F: 4 (33.3) Race/ethnicity: **NR** **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In study **Diagnostic tool/method:** CHAT –for screening ADI-R & structures child-adult interaction assessment ICD-10 Structured clinical interview **Diagnostic category, n (%):** Autism/PDD-NOS: 24 (100) **Other characteristics:** Hrs/wk spent in playgroup / nursery, mean ± SD: **G1:** 6.3 ± 10.7 **G2:** 3.5 ± 3.6 P = NS	**Educational/ cognitive/ academic attainment:** Non-Verbal IQ, mean ± SD: **G1:** 88.1 ± 11.2 **G2: 66.0** ± 16.5 NVIQ significantly different between G1 & G2 ($P < 0.001$) **Communication/ language:** Words understood, mean ± SD: **G1:** 52 ± 60.5 **G2:** 53.0 ± 63.7 Words said, mean ± SD: **G1:** 6.8 ± 20.9 **G2:** 6.6 ± 13.7 Total gestures produced, mean ± SD: **G1:** 20.9 ± 7.0 **G2:** 20.9 ± 14.4 ADI-Non-Verbal Communication, mean ± SD: **G1:** 12.8 ± 1.6 **G2:** 12 ± 2.4 ADI overall language rating, n: **G1:** Nonverbal (< 5 words): 11 Single words: 1 Phrase speech: 0 **G2:** Nonverbal (<5 words): 11 Single words: 1 Phrase speech: 0 **Social skills:** ADI-Reciprocal Social Interaction, mean ± SD: **G1:** 19.6 ± 3.0 **G2:** 20.3 ± 4.5	**Educational/ cognitive/ academic attainment:** Non-Verbal IQ, mean ± SD: **G1:** 77.9 ± 14.8 **G2:** 66.1 ± 17.1 P = NS **Communication/ language:** Words understood, mean ± SD: **G1:** 176.1 ± 121.9 **G2:** 100.3 ± 80.2 $P = 0.09$ Words said, mean ± SD: **G1:** 96.6 ± 118.8 **G2:** 44.0 ± 50.2 P = NS Total gestures produced, mean ± SD: **G1:** 38.6 ± 12.5 **G2:** 29.1 ± 18.4 P = NS Words understood & gestures produced both significantly different between the 2 groups ($P < 0.05$) ADI- Non-Verbal Communication, mean ± SD: **G1:** 11.0 ± 2.8 **G2:** 11.9 ± 1.8

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Drew et al., 2002 (continued)	Speech & language therapy services, mean/hrs ± SD: **G1:** 0.3 ± 0.3 **G2:** 0.6 ± 1.1 1 to 1 structured activities with child, mean/hrs ± SD: **G1:** 1 ± 0.7 **G2:** 1.6 ± 1.1 **N at enrollment:** **G1:** 12 **G2:** 12 **N at follow-up:** **G1:** 12 **G2:** 12		**Repetitive behavior:** ADI-Repetitive & Stereotyped Behavior, mean ± SD: **G1:** 3.2 ± 1.1 **G2:** 3.7 ± 1.6 **Other:** Parenting Stress Inventory, mean ± SD: **G1:** 113.8 ± 21.7 **G2:** 110 ± 28.6	ADI overall language rating, n: **G1:** Nonverbal (<5 words): 4 Single words: 5 Phrase speech: 3 **G2:** Nonverbal (<5 words): 9 Single words: 3 Phrase speech: 0 **Social skills:** ADI- Reciprocal Social Interaction, mean ± SD: **G1:** 18.3 ± 4.9 **G2:** 20.1 ± 4.3 **Repetitive behavior:** ADI- Repetitive & Stereotyped Behavior, mean ± SD: **G1:** 3.9 ± 1.8 **G2:** 4.2 ± 2.0 **Other:** Parenting Stress Inventory, mean ± SD: **G1:** 104.3 ± 20.0 **G2:** 112.1 ± 20.1 PSI significantly different at $P < 0.01$ **Harms:** NR
Drew et al., 2002 (continued)				**Modifiers:** Play group, speech and language therapy, other intervention or parent time spent on 1-to-1 activities were not significantly associated with NVIQ, language measures, symptom severity or parental stress at follow-up

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Author: Escalona et al., 2002 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NIH, Johnson & Johnson **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Imitation vs. contingently responsive Four phases, each 3 minutes long: • Phase 1: still face • Phase 2: unfamiliar adult imitative or contingently responsive to behaviors of child • Phase 3: still face • Phase 4: spontaneous play interaction **Assessments:** PEP-R, 3-minute videotaped sessions **Groups:** **G1:** imitation **G2:** contingently responsive **Provider:** NR **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 10 **G2:** 10 **N at follow-up**: **G1:** 10 **G2:** 10	**Inclusion criteria:** • Diagnosed with autism • Nonverbal behavior (unspecified) **Exclusion criteria:** • See inclusion criteria **Age, years (range):** Total: NR (3-7) Female: 4.8 (NR) Male: 5.5 (NR) **Mental age:** PEP-R cognitive performance, mean developmental level: **G1:** 19 **G2:** 17 **G1/G2:** P = NS **Gender, n :** Male: 12 Female: 8 **Race/ethnicity, %:** White: 41 Hispanic: 27 Black: 23 Other ethnic group: 9 **SES:** Maternal education: NR Household income: NR Hollingshead Index: 2.7 **Diagnostic approach:** Referral **Diagnostic tool/method:** DSM-IV ("children diagnosed with autism by the age of 3 by the school's experienced clinical psychologist") **Diagnostic category, n (%):** Autism: 20 (100) **Other characteristics:** NR	**Overall ratings:** CARS score, mean: **G1:** 38 **G2:** 37 **G1/G2:** P = NS **Social skills:** Time spent looking at adult, %: **G1:** 7.9 **G2:** 2.6 Time spent more than 5 feet from adult, %: **G1:** 91.8 **G2:** 94.6 Time touching adult with a smooth, light touch ("socially positive way"), %: **G1:** 0.1 **G2:** 0 **Communication/ language:** Time spent in silence, %: **G1:** 85.3 **G2:** 84.7 **Repetitive behavior:** Time spend showing motor sterotypies, %: **G1:** 0.9 **G2:** 0.6 **Motor skills:** Time spent in motor activity (running/ walking/jumping), %: **G1:** 6.2 **G2:** 4.4 PEP-R cognitive verbal score, mean developmental level: **G1:** 17 **G2:** 14 **G1/G2:** P = NS	**Social skills:** Time spent looking at adult, phase 3, %: **G1:** 6.0 **G2:** 5.1 **G1/BL:** P = NS **G2/BL:** $P < 0.05$ **G1/G2:** P = NS Time spent more than 5 feet from adult, phase 3, %: **G1:** 69.6 **G2:** 68.6 **G1/BL:** $P < 0.01$ **G2/BL:** $P < 0.01$ **G1/G2:** P = NS Time touching adult with a smooth, light touch ("socially positive way"), phase 3, %: **G1:** 0.9 **G2:** 0.2 **G1/BL:** $P < 0.05$ **G2/BL:** P = NS **G1/G2:** P = NS **Communication/ language:** Time spent in silence, phase 3, %: **G1:** 81.2 **G2:** 77.9 **G1/BL:** P = NS **G2/BL:** $P < 0.05$ **G1/G2:** P = NS **Repetitive behavior:** Time spend showing motor sterotypies, phase 3, %: **G1:** 0.9 **G2:** 1.1 **G1/BL:** P = NS **G2/BL:** $P < 0.05$ **G1/G2:** P = NS
Escalona et al., 2002 (continued)				**Motor skills:** Time spent in motor activity (running/walking/ jumping), phase 3, %: **G1:** 2.1 **G2:** 4.3

Evidence Table. Therapies for children with ASD

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				G1/BL: *P* = NS **G2/BL:** *P* = NS **G1/G2:** *P* < 0.01 **Harms:** NR **Modifiers:** NR

Comments: *****Entries in baseline column are for phase 1.

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Jarusiewicz, 2002 **Country:** US **Practice setting:** Specialty treat-ment center **Intervention setting:** Clinic **Enrollment period:** NR **Funding** Agency: NR **Author industry relationship disclosures:** 1 of 1 EEG Spectrum International (1) **Design:** RCT	**Intervention:** Neurofeedback: 30 minute sessions between 1-3 times per week; all completed 20 or more sessions (mean 36, range: 20-69) **Assessments:** ATEC and 15-minute free-play videos similar to FEAS were conducted prior to and upon completion of the study; parent interview (not described) Other assessments conducted to determine arousal levels (details NR) **Groups:** **G1:** neurofeedback **G2:** control **Provider:** NR **Measure of treatment fidelity reported:** NR **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 20 G2: 20 **N at follow-up:** **G1:** 12 **G2:** 12	**Inclusion criteria:** • Prior diagnosis of autism **Exclusion criteria:** • See inclusion criteria **Age, years (range):** **G1:** 7 (4-13) **G2:** 7 (4-11) **Mental age:** NR **Gender, n:** Male: **G1:** 11 **G2 :** 11 Female: **G1:** 1 **G2:** 1 **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method:** Independent diagnosis by physician (as reported by parents) **Diagnostic category, n (%):** Autism: 40 (100) **Other characteristics:** NR	**Overall ratings:** ATEC score, mean (range): ATEC Health: **G1:** 19 (8-42) **G2:** 21 (8-36) ATEC Total: **G1:** 65 (26-109) **G2:** 63 (29-90) **Communication/ language:** ATEC Speech: **G1:** 14 (6-25) **G2:** 12 (4-24) **Social skills:** ATEC Socialization: **G1:** 15 (2-25) **G2:** 15 (2-24) **Sensory:** ATEC Sensory: **G1:** 18 (10-25) **G2:** 15 (4-26)	**Overall ratings:** ATEC score, mean: ATEC Health: **G1:** 14 **G2:** 20 **G1/BL:** $P < 0.015$ **G2/BL:** P = NS ATEC Total: **G1:** 48 **G2:** 61 **G1/BL:** $P < 0.001$ **G2/BL:** P = NS **Communication/ language:** ATEC Speech: **G1:** 10 **G2:** 12 **G1/BL:** $P < 0.001$ **G2/BL:** P = NS **Social skills:** ATEC Socialization: **G1:** 10 **G2:** 14 **G1/BL:** $P < 0.01$ **G2/BL:** P = NS **Sensory:** ATEC Sensory: **G1:** 15 **G2:** 15 **G1/BL:** $P < 0.001$ **G2/BL:** P = NS **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Molloy et al., 2002 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NIH **Author industry relationship disclosures:** NR **Design:** RCT (double-blind cross-over trial)	**Intervention:** IV Synthetic Human Secretin (2IU/kg at the first visit, followed by equal volume of saline placebo at week 6); other group in the reverse order **Assessments:** Participants evaluated on 5 occasions: baseline prior to first infusion, week 3, week 6 prior to cross-over infusion, & weeks 9 and 12; each evaluation took place in same room & included CARS, GARS, & DTVP or selected tests of MPS all administered by a clinical psychologist Parents completed ABC and the Autism Behavior Checklist, which were interpreted by the clinical psychologist; parents were asked about stool patterns at each visit, as well as inter-current illnesses, medical problems and medications, and adverse events Receptive language skills evaluated by team of two speech & language pathologists using PPVT-III & Receptive Language Scale of MSEL Expressive language abilities assessed at each visit using 15-minute videotaped sample of spontaneous language during play with caregiver Clinical lab evaluation obtained before each infusion and at week 12 **Groups:** **G1:** secretin first, followed by placebo **G2:** placebo first, followed by secretin	**Inclusion criteria:** • 2-15 years of age • Autism criteria met as per DSM-IV following a multidisciplinary evaluation • Diagnosis by developmental pediatrician if from outside this center **Exclusion criteria:** • Chromosomal/genetic disorders • Structural abnormality on neuroimaging • Acute or chronic pancreatic disease • Any medical condition that makes participation unsafe **Age, months ± SD:** **G1:** 83.5 ± 32.4 **G2:** 80.7 ± 30.7 **Mental age:** NR **Gender, n (%):** Male: **G1:** 17 (89.5) **G2:** 20 (87) Female: **G1:** 2 (10) **G2:** 3 (13) **Race/ethnicity, n (%):** Caucasian: **G1:** 15 (79) **G2:** 17 (74) **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In study **Diagnostic tool/method:** DSM-IV **Diagnostic category, n (%):** Autism: 42 (100%) PDD-NOS: NR Aspergers : NR **Other characteristics:** NR	**Overall ratings:** CARS score, mean ± SD: **G1:** 40.2 ± 5 **G2:** 39.2 ± 5.6 **G1/G2:** *P* = NS GARS autism quotient, mean ± SD: **G1:** 102 ± 7.9 **G2:** 98.6 ± 9.2 **G1/G2:** *P* = NS **Communication/ language:** Merrill-Palmer scale, mean ± SD: **G1:** 22.1 ± 28.5 **G2:** 30.1 ± 34.6 **G1/G2:** *P* = NS Mullen receptive language score, mean ± SD: **G1:** 18.3 ± 10.5 **G2:** 18.5 ± 11.5 **G1/G2:** *P* = NS PPVT score, mean ± SD: **G1:** 10 ± 22.4 **G2:** 13.3 ± 25.1 **G1/G2:** *P* = NS Utterance, mean length ± SD: **G1:** 1.10 ± 1.09 **G2:** 1.06 ± 1.04 **G1/G2:** *P* = NS Type token ratio, mean ± SD: **G1:** 0.42 ± 0.41 **G2:** 0.45 ± 0.41 **G1/G2:** *P* = NS	**Overall ratings:** CARS score, week 12, mean ± SD: **G1:** 40.2 ± 4.9 **G2:** 38.6 ± 5 **G1/BL:** *P* = NS **G1/BL:** *P* = NS **G1/G2:** *P* = NS GARS autism quotient week 12, mean ± SD: **G1:** 98.1 ± 8.4 **G2:** 94.9 ± 8.3 **G1/BL:** *P* = NS **G1/BL:** *P* = NS **G1/G2:** *P* = NS **Communication/ language:** Merrill-Palmer scale, week 12, mean ± SD: **G1:** 29.5 ± 39.6 **G2:** 40.1 ± 34.8 **G1/BL:** *P* = NS **G1/BL:** *P* = NS **G1/G2:** *P* = NS Mullen receptive language score, week 12, mean ± SD: **G1:** 19.5 ± 10.4 **G2:** 21.1 ± 11 **G1/BL:** *P* = NS **G1/BL:** *P* = NS **G1/G2:** *P* = NS PPVT score, week 12, mean ± SD: **G1:** 14.2 ± 24.1 **G2:** 16.9 ± 27.3 **G1/BL:** *P* = NS **G1/BL:** *P* = NS **G1/G2:** *P* = NS Utterance, week 12, mean length ± SD: **G1:** 0.82 ± 1.11 **G2:** 0.94 ± 1.07 **G1/BL:** *P* = NS **G1/BL:** *P* = NS **G1/G2:** *P* = NS
Molloy et al., 2002 (continued)	**Co-interventions held stable during treatment:** NR **Frequency of contact during study:**			Type token ratio, week 12, mean ± SD: **G1:** 0.22 ± 0.31 **G2:** 0.31 ± 0.3

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	Evaluated at weeks 1, 3, 6, 9, 12 **Concomitant therapies:** NR **N at enrollment:** **G1:** 23 **G2:** 19 **N at follow-up:** G1: 23 (one participant did not return for the final visit) **G2:** 19			**G1/BL:** P = NS **G1/BL:** P = NS **G1/G2:** P = NS **Harms, n:** Worsening of constipation: 1 Elevated AST levels at the first visit: 6 Transient AST elevation: 5 Elevated amylase/ lipase: 3 **Modifiers:** Age and secretin response (data NR)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Salt et al., 2002 **Country:** Scotland UK **Practice setting:** Specialty treatment center **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NHS **Author industry relationship disclosures:** NR **Design:** Non-RCT	**Intervention:** Individualized treatment focusing on social, communicative, play, and adaptive behaviors; 8 hours every two weeks for 11 months Parent training component focusing on behavior management and teaching new skills **Assessments:** All occurred pre- and post-treatment Parent reports: Standardized stress measure and satisfaction questionnaire Clinician conducted: Bayley Scales of Infant Development – 2nd ed; British Picture Vocabulary Scale; VABS; PVCS; MCDI; Symbolic Play Test – 2nd ed; ESCS; PSI – 3rd ed. **Groups:** **G1:** (SCA) intervention **G2:** Control/other intervention Duration (mean ± SD): Non-SCA intervention (hrs/fortnight): Nursery: **G1:** 27.58 ± 13.32 **G2:** 38.7 ± 19.45 Other 1:1 therapy: **G1:** 2.79 ± 9.06 **G2:** 2.2 ± 2.28 **Provider:** • Therapists including nursery nurses, teachers, OT, PT, SLT • Parents **Treatment manual followed:** NR **Defined protocol followed:** NR	**Inclusion criteria:** • Preschool age range • Accessible geographical location • Diagnosis of Autism • Children not excluded on the basis of developmental delay **Exclusion criteria:** • See inclusion criteria **Age, months ± SD:** **G1:** 42.36 ± 7.16 **G2:** 37.67 ± 3.08 **Mental age, months ± SD:** **G1:** 17 ± 5.51 **G2:** 20.83 ± 2.32 **Gender, n (%):** Male: **G1:** 11 (92) **G2:** 3 (60) Female: **G1:** 1 (8) **G2:** 2 (40) **Race/ethnicity, n (%):** White: 16 (94) Middle eastern: 1 (6) **SES:** NR **Diagnostic approach:** Referral **Diagnostic tool/method:** ICD-10 (WHO, 1993) diagnosis of childhood autism **Diagnostic category, n (%):** Autism: 17 (100) **Other characteristics, IQ (MA/CA) x 100, mean ± SD:** **G1:** 39.43 ± 13.47 **G2:** 55.67 ± 6.59	**Social skills:** VABS score, mean ± SD: Socialization: **G1:** 51.83 ± 1.9 **G2:** 55.0 ± 3.39 Symbolic play test score, mean ± SD: **G1:** 2.27 ± 3.5 **G2:** 12.8 ± 4.82 **Communication/ language:** VABS Communication: **G1:** 51.17 ± 2.79 **G2:** 54.8 ± 3.11 MCDI, mean ± SD: Words understood: **G1:** 62.55 ± 44.68 **G2:** 55.6 ± 42.75 Words produced: **G1:** 4.73 ± 7.46 **G2:** 11.6 ± 15.08 PVCS imitation score, mean ± SD: **G1:** 1.92 ± 2.15 **G2:** 1.6 ± 0.55 ESCS score, mean ± SD: Joint attention: **G1:** 5.44 ± 3.17 **G2:** 6.0 ± 3.39 Requesting behavior: **G1:** 3.67 ± 2.12 **G2:** 6.6 ± 5.59 Social interaction: **G1:** 3.33 ± 2.0 **G2:** 4.2 ± 2.86 **Adaptive behavior:** VABS Composite score: **G1:** 49.5 ± 3.75 **G2:** 54.6 ± 4.83 VABS Daily living skills: **G1:** 53.08 ± 6.26 **G2:** 59.0 ± 3.46 **Motor skills:** VABS Motor skills: **G1:** 55.92 ± 11.37 **G2:** 69.8 ± 10.89	**Social skills:** VABS socialization score, mean ± SD: **G1:** 54.08 ± 2.91 **G2:** 52.8 ± 2.95 *P* < 0.05 ESCS symbolic play test score, mean ± SD: **G1:** 6.91 ± 5.94 **G2:** 19.6 ± 3.78 *P* = NS ESCS joint attention score, mean ± SD: **G1:** 9.11 ± 5.58 **G2:** 4.6 ± 2.97 *P* < 0.05 ESCS request behavior score, mean ± SD: **G1:** 10.33 ± 6.96 **G2:** 6.2 ± 2.77 *P* = NS (*P* < 0.06) ESCS social interaction score, mean ± SD: **G1:** 5.22 ± 2.73 **G2:** 3.2 ± 0.84 *P* < 0.05 **Communication/ language:** VABS communication score, mean ± SD: **G1:** 46.17 ± 15.07 **G2:** 50.6 ± 1.82 *P* = NS MCDI, words understood, mean ± SD: **G1:** 91.18 ± 68.51 **G2:** 79.8 ± 50.16 *P* = NS MCDI, words produced, mean ± SD: **G1:** 17.82 ± 40.94 **G2:** 31.20 ± 22.61 *P* = NS
Salt et al., 2002 (continued)	**Measure of treatment fidelity reported:** Yes **Measure of reliability reported:**			PVCS imitation score, mean ± SD: **G1:** 7.67 ± 5.35 **G2:** 3.8 ± 0.84

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	Yes **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 14 **G2:** 6 **N at follow-up:** **G1:** 12 **G2:** 5			$P < 0.05$ **Adaptive behavior:** VABS composite score, mean ± SD: **G1:** 49.33 ± 7.09 **G2:** 48.6 ± 2.3 $P < 0.05$ VABS daily living skills score, mean ± SD: **G1:** 53.67 ± 9.93 **G2:** 50.8 ± 2.95 $P < 0.05$ **Motor skills:** VABS motor skill score, mean ± SD: **G1:** 55.92 ± 15.06 **G2:** 55.66 ± 5.32 $P < 0.05$ **Harms:** NR **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Sofronoff et al., 2002 **Country:** Australia **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Prospective cohort study Note: see related paper with overlapping participants, Sofronoff 2004 {#814}	**Intervention:** Parent Management Training (PMT) Workshop: attended a 1-day workshop Individual: Six weekly sessions Both groups followed manual with six components (1 hour each) including psychoeducation, comic strip conversations (Gray, 1994a), social stories (Gray, 1994b), management of behavior problems, management of rigid behaviors, routines, and special interests, and anxiety management **Groups:** G1: Workshop G2: Individual G3: Wait-list **Assessment:** ECBI (Eyeberg Child behavior Inventory) Parental self-efficacy Questionnaire Used at 3 time points, pre-intervention (T1), 4 weeks Post (T2) and 3 months follow-up (T3) **Provider:** • Clinical psychologist **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** **NR**	**Inclusion criteria:** • NR **Exclusion criteria:** • NR **Age, mean/years (range):** **G1:** 8.25 (6-12) **Gender:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** **In Study (method):** DSM-IV criteria; diagnosis of Asperger syndrome by pediatrician and psychologist at clinic site **Diagnostic category:** NR **Other characteristics:** NR	**Child problem behaviors:** Number of reported problem behaviors by graphical illustration only **Parental self-efficacy, mean ± SD:** **G1:** Combined: 2.89 ± 0.84 G1a: 3.03 ± 0.79 G1b: 2.75 ± 0.88 **G2:** Combined: 2.79 ± 0.9 G2a: 2.61 ± 0.95 G2b: 2.97 ± 0.83 **G3:** Combined: 3.23 ± 0.89 G3a: 3.21 ± 1.13 G3b: 3.25 ± 0.62	**Child problem behaviors:** Number of reported problem behaviors by graphical illustration only Main effect for Time (F=16.98, *P* < 0.0001) Significant reduction in problem behaviors between T1 & T2 (*P* < 0.001) for both G1 & G2 & T1 & T3 (*P* < 0.002) No significant difference between G1 & G2 Significant time X group interaction (F=8.28, *P* < 0.001) **Parental self-efficacy, mean ± SD:** Time 3: **G1:** Combined: 3.26 ± 0.77 G1a: 3.78 ± 0.42 G1b: 2.94 ± 0.79 G1a & G1b significantly different from T1 (*P* < 0.05) **G2:** Combined: 3.47 ± 0.67 G2a: 3.65 ± 0.76 G2b: 3.29 ± 0.58 G1a & G1b significantly different from T1 (*P* < 0.05) **G3**: Combined: NR G3a: NR G3b: NR
Sofronoff et al., 2002 (continued)	**N at enrollment:** G1a: 17 mothers			**Harms:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	G1b: 16 fathers G2a: 18 mothers G2b: 18 fathers G3a: 10 mothers G3b: 10 fathers **N at follow-up:** G1a: 17 mothers G1b: 16 fathers G2a: 18 mothers G2b: 18 fathers G3a: 10 mothers G3b: 10 fathers			**Modifiers:** List reported

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Unis et al., 2002 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NIH **Author industry relationship disclosures:** NR **Design:** RCT (double-blind)	**Intervention:** Single Infusion of either extracted porcine secretin (2 CU/kg), synthetic porcine secretin (0.4 µg/kg) or an appropriate volume of placebo over 2 minutes **Assessments:** During 1 week prior to infusion (telephone interview) and 4 weeks after infusion; Secretin Outcome Survey (SOS) and ABC-C at 2 weeks postinfusion and 4 weeks ADOS-G, EOWPVT-R, ABC-C **Groups:** **G1:** biologic secretin **G2:** synthetic secretin **G3:** placebo **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** Telephone interview 1 week after infusion; follow-up assessments 4 weeks after infusion **Concomitant therapies:** NR **N at enrollment:** 90 **N at follow-up:** Total: 85 **G1:** 26 **G2:** 26 **G3:** 33	**Inclusion criteria:** • Aged 3-12 years • DSM-IV diagnosis of autism or PDD-NOS by a physician or clinical psychologist **Exclusion criteria:** • Previously received secretin • Any medical condition for which autism was considered symptomatic • Had comorbid epilepsy • Receiving psychotropic drug Rx 6 months prior to recruitment • Known allergies to pork products • NVIQ < 35 **Age, months ± SD:** **G1:** 76.5 ± 25.7 **G2:** 80.7 ± 29.8 **G3:** 78.3 ± 24.9 **Mental age, non-verbal IQ, months ± SD:** Total: 55 ± 13 **Gender:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In study **Diagnostic tool/method:** ADOS-G **Diagnostic category, n (%):** Autism/PDD-NOS: 85 (100) Aspergers: NR **Other characteristics:** NR	**Communication/ language:** ADOS communication: score, mean ± SD: **G1:** 5.6 ± 1.7 **G2:** 6 ± 1.8 **G3:** 5.7 ± 2 **G1/G2/G3:** *P* = 0.75 MacArthur vocabulary score, mean ± SD: **G1:** 226.2 ± 242.2 **G2:** 225.3 ± 229.4 **G3:** 245.9 ± 228.3 **G1/G2/G3:** *P* = 0.93 EOW vocabulary score, mean ± SD: **G1:** 15.2 ± 19.5 **G2:** 14.9 ± 17.6 **G3:** 14.6 ± 15.1 **G1/G2/G3:** *P* = 0.99 **Social Skills:** ADOS social score, mean ± SD: **G1:** 10 ± 2.0 **G2:** 9.8 ± 2.3 **G3:** 9.6 ± 2.1 **G1/G2/G3:** *P* = 0.78 **Problem behavior:** ABC total score, parent-rated, mean ± SD: **G1:** 61.4 ± 22.1 **G2:** 54.2 ± 24 **G3:** 58.9 ± 32 **G1/G2/G3:** *P* = 0.63 ABC total score, teacher-rated, mean ± SD: **G1:** 54.8 ± 22.3 **G2:** 56.4 ± 24.0 **G3:** 57.5 ± 20.4 **G1/G2/G3:** *P* = 0.90 **Medical:** SOS score, teacher-rated, mean ± SD: **G1:** 4.7 ± 1.3 **G2:** 4.7 ± 1.6 **G3:** 4.7 ± 1.2 **G1/G2/G3:** *P* = 0.99	**Communication/ language:** ADOS communication score, mean change (95% CI): **G1:** -0.2 (-0.8, 0.4) **G2:** -0.2 (-0.8, 0.5) **G3:** 0.2 (-0.5, 0.8) ANOVA: time & treatment (*P* = NS) MacArthur vocabulary score, mean change (95% CI): **G1:** 16.5 (-11.7, 44.8) **G2:** 12.3 (-5.6, 30.2) **G3:** 23.4 (9.7, 37.1) ANOVA: time (*P* < 0.01) treatment (*P* = NS) EOW vocabulary score, mean change (95% CI): **G1:** 1.2 (-0.4, 2.9) **G2:** -0.7 (-2.2, 0.7) **G3:** 2.1 (0.2, 4.1) ANOVA: time & treatment (*P* = NS) **Social Skills:** ADOS social score, mean change (95% CI): **G1:** 0.0 (-0.9, 0.9) **G2:** 0.0 (-0.9, 0.9) **G3:** -0.5 (-1.3, 0.3) ANOVA: time & treatment (*P* = NS)
Unis et al., 2002 (continued)			SOS total score, parent-rated, mean ± SD: **G1:** 4.3 ± 1.5 **G2:** 4.4 ± 1.5 **G3:** 4.0 ± 1.9	**Problem Behavior:** ABC total score, parent-rated, mean change (95% CI):

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			G1/G2/G3: *P* = 0.64	**G1:** -10.6 (-18.9, -2.3) **G2:** -5.2 (-10.0, -0.3) **G3:** -5.8 (-12.4, 0.9) ANOVA: time (*P* < 0.001) treatment (*P* = NS) ABC total score, teacher-rated, mean change (95% CI): **G1:** 0.4 (-8.3, 9.1) **G2:** -7.9 (-16.1, 0.3) **G3:** -12.0 (-18.2, -5.7) ANOVA: time (*P* < 0.01) treatment (*P* < 0.05) **Medical:** SOS total score, parent-rated, mean change (95% CI): **G1:** -0.5 (-0.9, -0.1) **G2:** -0.7 (-1.0, -0.4) **G3:** -0.5 (-0.9, -0.1) ANOVA: time (*P* < 0.001) treatment (*P* = NS)
Unis et al., 2002 (continued)				SOS total score, teacher-rated, mean change (95% CI): **G1:** -0.2 (-1.0, 0.7) **G2:** -0.5 (-1.1, 0.0) **G3:** -0.6 (-1.3, 0.1) ANOVA: time (*P* < 0.05) treatment (*P* = NS) **Harms:** 1 child developed fever and illness after the infusion; protocol was completed, but data not included in the analyses

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				Modifiers: Analyses using subgroups (Vineland communication scores < 60, children age < 72 months, those with & without GI problems) were similar to the original sample analyses No evidence of secretin efficacy. No significant treatment effect was noticed for subgroups as defined below. SG1: Vineland communication < 60 SG2: Age < 72 months SG3: Current GI problems SG4: No current GI problems

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Carmody et al., 2001 **Country:** Hong Kong **Practice setting:** Academic **Intervention setting:** Child development center **Enrollment period:** July 1994 to December 1995 **Funding:** Portion sponsored by NYU **Author industry relationship disclosures:** NR **Design:** Case series	**Intervention:** 2 sets of eyeglasses with prism lenses (5 diopters), 1 with lenses oriented prism base-up and the other oriented prism base-down All children assessed without glasses (habitual viewing) and with each of the two study eyeglasses (base-up viewing and base-down viewing) Base-up, base-down ambient lenses trials for 60-90 seconds/trial with a random order of lenses Facilitating lenses: the prism eyeglasses that worked best for an individual patient **Assessment**: Each participant assessed independently by one experimenter in a single session lasting 20–30 minutes. Behavior assessment done by raters, performance videotaped **Groups:** **G1:** all participants **Provider:** Optometrist or pediatrician **Treatment manual followed:** No **Defined protocol followed:** Yes **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NA	**Inclusion criteria:** • Children consecutively referred to a child development center and diagnosed with autistic disorder by DSM-IV or WHO criteria **Exclusion criteria:** • See inclusion criteria **Age, median years (range):** 8 (3-18) **Mental age:** NR **Gender, n (%):** M: 22 (91.7) F: 2 (8.3) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Referral **Diagnostic tool/method**: DSM-IV, WHO criteria **Diagnostic category, n (%):** Autistic disorder: 24 (100) **Other characteristics, n:** Normal visual acuity: 18 Far-sighted: 3 Near-sighted: 3	**Motor skills:** Ball catch score, mean % ± SD: Habitual viewing: 31.30 ± 22.53 Ball misses, %: Habitual viewing: 49 Ball passive catches (ball caught after rebounding off child's body), %: Habitual viewing: 31 Ball active catches (ball caught on swing without hitting child first), %: Habitual viewing: 20	**Motor skills:** Ball catch score, mean % ± SD: Facilitating lenses: 70.91 ± 24.94 Habitual vs. Facilitating lenses, t(22) = 7.656, $P < 0.0001$ Ball misses, %: Facilitating lenses: 24 Ball passive catches (ball caught after rebounding off child's body), %: Facilitating lenses: 12 Ball active catches (ball caught on swing without hitting child first), %: Facilitating lenses: 64 Children's ability to catch a ball was significantly better with use of facilitating lenses as compared with habitual viewing ($P < 0.0001$) **Harms** NR **Modifiers** NR
Carmody et al., 2001 (continued)	**Concomitant therapies:** NR			

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	N at enrollment: **G1:** 24 **N at follow-up:** **G1:** 24			

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Coniglio et al., 2001 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Children's Healthcare of Atlanta Foundation **Author industry relationship disclosures:** NR **Design:** RCT (method of randomization not described)	**Intervention:** Porcine secretin administered IV (test dose of 0.1 ml; if no acute anaphylactic reaction in 1 minute, 2.0 CU/kg (maximum of 75 CU) administered over 1 minute) **Assessments:** 1 pre-injection and 2 post-injection developmental/ behavioral assessments: Presence or absence of normal development in early infancy and any associated gastro-intestinal disturbances Performed by 4 evaluators (2 clinical psychologists, 1 advanced psychology graduate student, 1 developmental pediatrician) **Groups:** **G1:** secretin **G2:** placebo (saline) **Co-interventions held stable during treatment:** No; approximately 7% of parents indicated that they had started a new treatment regimen since beginning the study **Frequency of contact during study:** At screening and injection, and at 3 and 6 weeks post-injection **Concomitant therapies:** NR **N at enrollment:** **G1:** 30 **G2:** 30 **N at follow-up:** **G1:** 28 **G2:** 29	**Inclusion criteria:** • Met DSM-IV criteria for diagnosis of autism • CARS score ≥ 30 • Total PLS-3 ≤ 60 months **Exclusion criteria:** • See inclusion criteria **Age, months ± SD:** **G1:** 84.6 ± 25.2 **G2:** 83.5 ± 28.9 **Mental age:** NR **Gender, %:** Male: **G1:** 73 **G2:** 77 Female: **G1:** 23 **G2:** 27 **Race/ethnicity, %:** White: **G1:** 80 **G2:** 77 African American: **G1:** 17 **G2:** 13 Other: **G1:** 3 **G2:** 10 **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** DSM-IV criteria were assessed for each child to provide documentation of the diagnosis of autism before study entry **Diagnostic category, %:** Autism: **G1:** 50 **G2:** 52 PDD: **G1:** 24 **G2:** 14	**Overall ratings:** CARS total score, mean ± SD: **G1:** 42.4 ± 5.4 **G2:** 41.3 ± 6.3 GARS autism quotient, mean ± SD: **G1:** 104.1 ± 15.4 **G2:** 108.1 ± 11.9 PLS total age, months ± SD: **G1:** 15.4 ± 9.5 **G2:** 22.0 ± 12.8	**Overall ratings:** CARS total score, 3 weeks, mean ± SD: **G1:** 39.2 ± NR **G2:** 41.9 ± NR **G1/BL:** *P* = 0.051 CARS total score, 6 weeks, mean ± SD: **G1:** 41.8 ± NR **G2:** 41.7 ± NR ANOVA: time & treatment (P = NS) Improvement in CARS total scores BL to 6 weeks, %: **G1:** 36 **G2:** 28 **G1/G2:** *P* = NS GARS autism quotient, 3 weeks, mean ± SD: **G1:** 92 ± NR **G2:** 99 ± NR GARS autism quotient, 6 weeks, mean ± SD: **G1:** 92 ± NR **G2:** 99 ± NR ANOVA: time (P = 0.000) treatment (P = NS) PLS total age, 3 weeks, months ± SD: **G1:** 16 ± NR **G2:** 21 ± NR PLS total age, 6 weeks, months ± SD: **G1:** 17 ± NR **G2:** 21 ± NR ANOVA: time & treatment (P = NS)
Coniglio et al., 2001 (continued)		Autism and PDD: **G1:** 24 **G2:** 36 Aspergers: **G1:** 0 **G2:** 0 **Other characteristics:** DSM-IV diagnostic characteristics, %:		**Social skills:** Parent reported changes in social behavior or language, %: **G1:** 67 **G2:** 42 **Medical:** Parent-reported

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		Impairment in nonverbal behaviors: **G1:** 97 **G2:** 100 Failure to develop peer relationships: **G1:** 97 **G2:** 100 Lack of spontaneous relationships with others: **G1:** 52 **G2:** 75 Lack of social or emotional reciprocity: **G1:** 48 **G2:** 71 Delay in or total lack of spoken language: **G1:** 97 **G2:** 82 In those without severe language impairment, inability to initiate or sustain conversation with others: **G1:** 55 **G2:** 50 Stereotyped or repetitive use of language: **G1:** 43 **G2:** 57 Lack of spontaneous make-believe or social play: **G1:** 72 **G2:** 75 Preoccupation with one or more stereotypes: **G1:** 83 **G2:** 89 Inflexible adherence to routines or rituals: **G1:** 48 G2: **57**		changes in GI symptoms, %: 26 Formed stools at enrollment, %: Subjects who displayed sus-tained change: 89 Subjects who did not display sus-tained change: 42 (*P* = 0.02) No differences in average stools/ day or presence of blood in stools were noted **Harms:** Parents observed side effects since injection (transient irritability; hyper-activity; nausea/ vomiting), %: 13 **Modifiers:** Correlation of PLS and CARS score: Baseline: -0.57 (*P* < 0.000) 3 weeks: -0.44 (*P* < 0.001) 6 weeks: -0.3 (*P* < 0.004) No significant correlation between PLS and GARS
Coniglio et al., 2001 (continued)		Stereotyped and repetitive motor mannerisms: **G1:** 83 **G2:** 79 Persistent preoccupation with parts of objects: **G1:** 55 **G2:** 54 Delay in social interaction: **G1:** 90 **G2:** 93 Delay in language: **G1:** 100		

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
		G2: 93 Delay in symbolic or imaginative play: **G1:** 90 **G2:** 82 Height, inches ± SD: **G1:** 45.8 ±7.2 **G2:** 46.5 ±7.5 Weight, kg ± SD: **G1:** 27.8 ±12.3 **G2:** 26.6 ±11.2 Age at symptom onset, months ± SD: **G1:** 18.2 ± 8.5 **G2:** 20.1 ± 8.5 Age at first diagnosis, months ± SD: **G1:** 33.1 ± 10.2 **G2:** 33.7 ± 10.1 Initial normal development, %: **G1:** 62 **G2:** 90 **G1/G2:** $P = 0.014$ Average stools/day, %: 0-1: **G1:** 40 **G2:** 33 1-2: **G1:** 30 **G2:** 37 2-4: **G1:** 20 **G2:** 20 > 4: **G1:** 10 **G2:** 10		
Coniglio et al., 2001 (continued)		Stool consistency, %: Watery: **G1:** 0 **G2:** 10 Applesauce: **G1:** 40 **G2:** 30 Formed: **G1:** 60 **G2:** 60 Blood in stools, %: Never: **G1:** 97 **G2:** 93 Once/month: **G1:** 3 **G2:** 7		

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Escalona et al., 2001 **Country:** US **Practice setting:** Academic **Intervention setting:** home **Enrollment period:** NR **Funding:** NIH, Johnson & Johnson **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** massage therapy provided by parents for 15 minutes just prior to bedtime every night for 1 month. Parents were trained by massage therapists. Parents of the attention control group read Dr. Seuss stories on the same time schedule to their children **Groups:** **G1:** massage therapy administered by parents **G2:** reading attention control group **Assessments:** Revised Conners Scales Classroom and playground behavior observations Sleep diaries **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** Assessments on 1st and last days of study; intervention/control activities occurred daily with parents **Concomitant therapies:** NR **N at enrollment:** **G1+G2:** 20 **N at follow-up:** **G1+G2:** 20	**Inclusion criteria:** • Children with autism recruited from a school for children with autism • Ages 3-6 years **Exclusion criteria:** • See inclusion criteria **Age, mean/yrs ± SD:** 5.2 ± 1.8 **Mental age:** NR **Gender:** M, n (%): 12 (60) F, n (%): 8 (40) **Race/ethnicity, %:** White: 72 Hispanic: 20 African American: 8 **SES:** Middle socioeconomic status: Hollingshead Index, mean: **G1 & G2:** 1.8 **Diagnostic approach:** Children had been diagnosed by 2 independent clinicians ~1-3 years earlier using DSM III-R criteria. **Diagnostic tool/method:** DSM-III-R **Diagnostic category, n (%):** Autism: 20(100) **Other characteristics:** NR	**Revised Conners Scales, mean:** ADHD Index, parent rating: **G1:** 66 **G2:** 65 Restless-impulsive behaviors, parent rating: **G1:** 66 **G2:** 66 Emotional index, teacher rating: **G1:** 62 **G2:** 62 Emotional index, parent rating: **G1:** 58 **G2:** 55 Global index DSM-IV scale for inattentiveness, teacher rating: **G1:** 56 **G2:** 60 DSM-IV scale for inattentiveness, parent rating: **G1:** 62 **G2:** 56 **Classroom/ playground, frequency of behaviors, %:** On-task behavior, classroom: **G1:** 81 **G2:** 81 Stereotypical behavior, classroom: **G1:** 8 **G2:** 5 Stereotypical behavior, playground: **G1:**13 **G2:**12 Social relatedness to teacher, playground: **G1:**14 **G2:**14	**Revised Conners Scales, mean:** ADHD Index, parent rating: **G1:** 60 **G2:** 64 t = 1.91, (*P* < 0.05) Restless-impulsive behaviors, parent rating: **G1:** 60 **G2:** 63 t = 2.05, (*P* < 0.05) Emotional index, teacher rating: **G1:** 55 **G2:** 60 t = 1.83, (*P* < 0.05) Emotional index, parent rating: **G1:** 54 **G2:** 55 t = 2.11, (P < 0.05) Global index DSM-IV scale for inattentiveness, teacher rating: **G1:** 50 **G2:** 62 t = 1.75, (*P* < 0.05) DSM-IV scale for inattentiveness, parent rating: **G1:** 63 **G2:** 61 t = 1.97, (*P* < 0.05) **Classroom/ playground, frequency of behaviors, %:** On-task behavior, classroom: **G1:** 94 **G2:** 91 t = 2.13, (*P* < 0.05)
Escalona et al., 2001 (continued)				Stereotypical behavior, classroom:

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				G1: <1 **G2:** 2 t = 2.01, (*P* < 0.05) Stereotypical behavior, playground: **G1:** 2 **G2:** 8 t = 3.29, (*P* < 0.01) Social relatedness to teacher, playground: **G1:** 20 **G2:** 11 t = 2.04, (*P* < 0.05) **Sleep diaries** Measures not provided, described as indicating greater declines for massage group on fussing/restlessness, crying, self-stimulating behavior, and getting out of bed. Teachers Conners Scales: Significant Group x Days interaction effect (F(5,14)=3.08, *P* < 0.05) Observation behaviors: Significant group x days interaction effect (F(6,13)=2.98, *P* < 0.05) **Harms:** NR **Modifiers:** NR

Comments: *Results in baseline section are behaviors during spontaneous play in the first session (not a true baseline as the probe occurred after the first intervention had begun).

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Hartshorn et al., 2001 **Country:** US **Practice setting:** Academic **Intervention setting:** School for children with autism **Enrollment period:** NR **Funding:** NIH, Johnson and Johnson **Author industry relationship disclosures:** NR **Design:** Non randomized controlled trial	**Intervention:** 30 minute movement sessions held twice a week for two months Controls matched on age and developmental level **Assessments:** Behavior coded in 10-second time sample units for 6 one-minute periods during the first 18 minutes of first and last sessions; controls observed during two sessions two months apart **Groups:** **G1:** intervention **G2:** controls **Provider:** • Sessions given by trained movement therapists. • Behaviors observed and coded by psychology graduate students with prior training to 80% reliability **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 38 **G2:** 38 **N at follow-up:** **G1:** 38 **G2:** 38	**Inclusion criteria:** • From a school for children with autism • Control group matched on age and development level with movement therapy group (from same school) **Exclusion criteria:** • See inclusion criteria **Age, years (range):** **G1:** 5 (3-7) **G2:** NR **Mental age:** NR **Gender:** NR **Race/ethnicity, %:*** White: **G1:** 80 Hispanic: **G1:** 10 Black: **G1:** 10 **SES:** Maternal education: NR Household income:* **G1:** "Middle SES" **Diagnostic approach:** In Study/Referral **Diagnostic tool/method:** NR **Diagnostic category:** See inclusion criteria **Other characteristics:** NR	Percentage of time behavior observed in session, mean ± SD: **Adaptive behavior:** Stereotypical behaviors: **G1:** 2.0 ± 0.5 **G2:** 3.0 ± 0.4 Wandering: **G1:** 14.0 ± 2.4 **G2:** 16.0 ± 2.8 **Social skills:** Responding to touch negatively: **G1:** 5.0 ± 8 **G2:** 4.0 ± 0.9 On-task passive: **G1:** 16.0 ± 4.3 **G2:** 15.0 ± 5.9 On-task active: **G1:** 77.0 ± 15.6 **G2:** 9.0 ± 13.2 Eye contact: **G1:** 9.0 ± 2.5 **G2:** 11.0 ± 3.1 Social relatedness toward teacher: **G1:** 28.0 ± 9.3 **G2:** 25.0 ± 11.2 Resisting teacher: **G1:** 9.0 ± 1.7 **G2:** 12.0 ± 1.5	Percentage of time behavior observed in session, mean ± SD: **Adaptive behavior:** Stereotypical behaviors: **G1:** 2.0 ± 0.7 **G2:** 4.0 ± 1.2 **G1/G2:** P = NS Wandering: **G1:** 10.0 ± 3.1 **G2:** 15.0 ± 2.9 **G1/G2:** $P < 0.05$ **Social skills:** Responding to touch negatively: **G1:** 1.0 ± 2 **G2:** 3.0 ± 0.5 **G1/G2:** $P < 0.01$** On-task passive: **G1:** 37.0 ± 116 **G2:** 19.0 ± 7.3 **G1/G2:** $P < 0.001$** On-task active: **G1:** 76.0 ± 19.1 **G2:** 67.0 ± 16.3 **G1/G2:** P = NS Eye contact: **G1:** 7.0 ± 1.9 **G2:** 9.0 ± 2.4 **G1/G2:** P = NS Social relatedness toward teacher: **G1:** 25.0 ± 7.9 **G2:** 21.0 ± 8.3 **G1/G2:** P = NS Resisting teacher: **G1:** 4.0 ± 1.5 **G2:** 10.0 ± 1.3 **G1/G2:** $P < 0.05$** **Harms:** NR **Modifiers:** NR

Comments: *This measure for G2 is described as "similar" to G1 but otherwise not reported.
**The p-values for three behaviors were different in the table (reported above) and the text: responding to touch negatively (text $P < 0.005$; table $P < 0.01$), on-task passive (text $P < 0.05$; table $P < 0.001$), and resisting teacher (text: $P < 0.01$; table: $P < 0.05$).

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Kern et al., 2001 **Country:** US **Practice setting:** Community **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** FoodScience Corporation **Author industry relationship disclosures:** NR **Design:** Double-blind, randomized controlled trial	**Intervention:** Oral dimethylglycine, 125 mg/day (placebo group received mannitol tablets of the same size and frequency) Titration by weight: < 40 lbs: 1 tablet 41-70 lbs: 2 tablets 71-100 lbs: 3 tablets 101-130 lbs: 4 tablets > 131 lbs: 5 tablets **Assessments:** Neurological and behavioral assessments performed in childcare room at University of Dallas with toys and activity centers; a variety of items were available to use during the behavioral observations, such as wooden blocks, crayons, pencils, paper, and balls; parents were present Behavioral: VABS maladaptive behavior domain, ABC subscales I-V; obtained at baseline and 4 weeks post treatment; videotaped Neurologic: examination of coordination, posturing, toe walking **Groups:** **G1:** dimethylglycine **G2:** placebo **Co-interventions held stable during treatment, n:** Yes **Frequency of contact during study:** Participants met with investigators at baseline and 4 weeks after treatment began	**Inclusion criteria:** • Met the DSM-IV diagnostic criteria for autism or PDD **Exclusion criteria:** • See inclusion criteria **Age, years (range):** NR (3-11) **Mental age:** NR **Gender:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** DSM-IV **Diagnostic category, n (%):** Autistic or PDD-NOS: 37 (100) **Other characteristics, n (%):** Gross/fine motor skill delay: 26 (70) Problems with gross/fine ocular pursuit: 4 (11) Poor muscle tone: 5 (14) Non-verbal: 10 (27) Echolalic: 12 (32) Difficulty sleeping: 16 (43) Eating disorders: 16 (43) Hyperlexia: 4 (11)	**Problem behavior:** VABS maladaptive behavior score, mean: **G1:** NR **G2:** NR **G1/G2:** $P < 0.35$ ABC irritability and self-abusive behavior score, mean: **G1:** NR **G2:** NR **G1/G2:** $P < 0.46$ **Social skills:** ABC lethargy, social withdrawal, and withdrawal score, mean: **G1:** NR **G2:** NR **G1/G2:** $P < 0.0003$ **Repetitive behavior:** ABC stereotypic behavior score, mean: **G1:** NR **G2:** NR **G1/G2:** $P < 0.58$ ABC hyperactivity score, mean: **G1:** NR **G2:** NR **G1/G2:** $P < 0.35$ **Communication/ language:** ABC inappropriate speech score, mean: **G1:** NR **G2:** NR **G1/G2:** $P < 0.84$ **Neurologic assessments:** Standard neurological exam, n: **G1:** 17 **G2:** 16	**Overall ratings:** Main behavioral effect change, mean (range across all assessment methods): **G1:** 0.71 (0.06, 1.94) **G2:** 0.87 (0.32**,** 1.68) **G1/G2:** P = NS Parent report of treatment effect, n (%): Positive response: **G1:** 11 (58) **G2:** 10 (53) Negative response: **G1:** 3 (16) **G2:** 6 (32) No response: **G1:** 5 (26) **G2:** 3(16) **Social skills:** ABC lethargy, social withdrawal, and withdrawal score, mean change (% improvement): **G1:** 1.94 (15.3) **G2:** 0.95 (13.6) **G1/G2:** $P < 0.12$ **Communication/ language:** ABC inappropriate speech score, mean change: **G1:** NR **G2:** NR **G1/G2:** P = NS **Repetitive behavior:** ABC stereotypic behavior score, mean change: **G1:** NR **G2:** NR **G1/G2:** P = NS
Kern et al., 2001 (continued)	**Concomitant therapies:** Psychoactive medication (clonidine, thioridazine, paroxetine, imipramine, methylphenidate, & fluoxetine): 7 **N at enrollment:**			ABC hyperactivity score, mean change: **G1:** NR **G2:** NR **G1/G2:** P = NS **Problem**

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	G1: 20 **G2:** 19 **N at follow-up:** **G1:** 18 **G2:** 19			**behavior:** VABS maladaptive behavior score, mean change: **G1:** NR **G2:** NR **G1/G2:** P = NS ABC irritability and self-abusive behavior score, mean change: **G1:** NR **G2:** NR **G1/G2:** P = NS **Motor skills:** Improved gross motor function, neurologic assessment, n: **G1:** 3/17 **G2:** 0/16 **G1/G2:** P = 0.57 **Harms, n (%):** Hyperactivity: **G1:** 2 (11) **G2:** 4 (21) Increased aggression: **G1:** 1 (5) **G2:** 2 (11) Difficulty sleeping: **G1:** 1 (5) **G2:** 2 (11) Any negative effects, %: **G1:** 16 **G2:** 32 Withdrawn due to adverse behavioral changes, n: Total: 1 **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: King et al., 2001 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** Cerebrus PLC **Author industry relationship disclosures:** NR **Design:** Multi-center, Double-blind, randomized, placebo controlled trial	**Intervention:** Week 1 (run-in): 2.5mg/kg/day placebo given to both groups Week 2: amantadine chloride or placebo given 2.5mg/day at breakfast Week 3-5: amantadine chloride or placebo given 2.5mg/kg 2 times per day at breakfast and afternoon **Assessments:** Visit 0: screen (subject screening and recruitment) Visit 1: baseline, end of 1-week placebo run-in (at end of week 1, subject's compliance and ABC-C was assessed) Visits 2,3,4,&5: treatment ABC-C (parent or care provider completed instrument at visits 0, 1, & 2-5 inclusive; ADOS-G (videotaped and at visits 0 & 5); CGI (visit 1 and visits 2-5 inclusive) **Groups:** **G1:** amantadine chloride **G2:** placebo control **Co-interventions held stable during treatment, n (%):** Patients on SSRI's stable for >1month remained on medication **G1:** 4 (20) **G2:** 6 (30) **Frequency of contact during study:** Every week **Concomitant therapies:** SSRI: **G1:** 4/19 **G2:** 6/20 N at enrollment: **G1:** 19 **G2:** 20	**Inclusion criteria:** • Diagnosis of autism by DSM-IV and ICD-10 criteria using ADI-R and ADOS-G • ABC-CV subscales for irritability (subscale I) and hyperactivity (subscale IV) were > age adjusted 75 percentile • VABS age equivalent > 18 mos **Exclusion criteria:** • IQ score <35 on Mullen Scales or Differential Ability scale • Presence of Fragile X and tuberous sclerosis complex • Receiving neuroleptic, anticonvulsant, or stimulant medication • Evidence of clinically evident medical illness **Age, mean/yrs (range):** **G1:** 7 (5-11) **G2:** 7 (5-15) **Mental age:** NR **Gender, n (%):** M: **G1:** 15 (80) **G2:** 19 (95) F: **G1:** 4 (20) **G2:** 1 (5) **Race/ethnicity, n (%):** White: **G1:** 15(79) **G2:** 15 (75) Other: **G1:** 4 (21) **G2:** 5 (25) **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study	**Problem behavior:** ABC-irritability, mean (range): **G1:** 19.1 (3-38) **G2:** 18.7 (3-33) **Commonly occurring comorbidities:** ABC-hyperactivity, mean (range): **G1:** 29.4 (16-42) **G2:** 32.7 (17-46)	**Overall ratings:** CGI-rate illness severity, (success rate %): **G1:** 53 **G2:** 25 *P* = 0.076 **Communication/ language:** ABC-inappropriate speech, mean change (95% CI): Provider: -2.24 (-3.85 to -0.63) **Repetitive behavior:** ABC-stereotyped behavior, mean change (95% CI): Provider: -2.20 (-4.74 to 0.33) **Problem behavior** ABC-irritability (parent-rated), mean change (95% CI): Parent : **G1:** NR **G2:** NR *P* = 0.178 **Commonly occurring co-morbidities:** ABC-hyperactivity (parent-rated), mean change (95% CI): Parent : **G1:** -4.9 **G2:** -1.6 Total: -4.81 (-11.63 to 2.00) Care provider: -5.75 (-11.39 to -0.1)
King et al., 2001 (continued)	**N at follow-up:** **G1:** 19	**Diagnostic tool/method:** DSM-IV, ICD-9, ABC-CV,		**Harms, n (%):** Insomnia:

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	G2: 20	ADOS-G, ADI-R **Diagnostic category, n (%):** Autism 39 (100) **Other characteristics:** CGI-rate illness severity, n (% NR): Mild: **G1:** 0 **G2:** 1 Moderate: **G1:** 11 **G2:** 11 Severe: **G1:** 8 **G2:** 7		**G1:** 4 (21) **G2:** 2 (10) Somnolence: **G1:** 2 (11) Antisocial behaviors: **G1:** 2 (11) **G2:** 4 (20) **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Owley et al., 2001 **Country:** US **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** UC Davis MIND Institute, NIH, Jean Young and Walden Shaw Foundation, Irving Harris Foundation **Author industry relationship disclosures:** NR **Design:** Multisite double-blind, parallel group RCT crossover design	**Intervention:** Porcine secretin or saline placebo 2 CU/kg infused at baseline or end of week 4, injected over 1 minute **Assessment:** DAS; MSEL for children under 5 and those for which a basal could not be established on subtests of the DAS; DTVP-II, ADOS, PPVT-III (> 5 years and able to establish basal) VABS Interview Edition and CGI scales at baseline and end of weeks 4 and 8, GARS and ABC-C at baseline and end of weeks 2, 4, 6, and 8 **Groups:** **G1:** secretin first, followed by placebo **G2:** placebo first, followed by secretin **Co-interventions held stable during treatment:** Yes **Frequency of contact during study:** Baseline and assess-ments at week 4 (primary outcome) and week 8 (crossover assessment) **Concomitant therapies, n:** SSRI: 3 Atypical neuroleptics: 3 Alpha adrenergic agonist: 1 Psychostimulants: 8 **N at enrollment:** **G1:** 28 **G2:** 28 **N at follow-up:** **G1:** 28 **G2:** 28	**Inclusion criteria:** • Diagnosis of autism confirmed in study • For subjects younger than 5, non verbal ratio IQ > 20 according to Mullen Scales of Early Learning • For subjects with non verbal IQ 20-34, VABS age equivalent of ≥ 24 months **Exclusion criteria:** • History of allergy to porcine products • Significant history of illness including nonfebrile seizures and excluding autism **Age, months ± SD:** **G1:** 79.6 ± 21.8 **G2:** 81.4 ± 24.4 **Mental age:** Non-verbal IQ, mean ± SD: **G1:** 55.9 ± 24.5 **G2:** 56.9 ± 19.4 **Gender, n (%):** Male: **G1:** 24 (85.7) **G2:** 24 (85.7) Female: **G1:** 4 (14.3) **G2:** 4 (14.3) **Race/ethnicity, n (%):** African American: **G1:** 1 (3.6) **G2:** 3 (10.7) Hispanic: **G1:** 2 (7.1) **G2:** 4 (14.3) Asian: **G1:** 1 (3.6) **G2:** 0 White: **G1:** 24 (85.7) **G2:** 21 (75) **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study	**Overall ratings:** CGI-S score, mean ± SD: **G1:** 3.0 ± 0.8 **G2:** 2.8 ± 0.8 GARS autism quotient, mean ± SD: **G1:** 93.6 ± 12.0 (n=26) **G2:** 86.5 ± 11.7 (n=27) **G1/G2:** *P* = 0.03 **Social skills:** ADOS social interaction score, mean ± SD: **G1:** 11.9 ± 1.5 **G2:** 10.8 ± 1.9 **G1/G2:** *P* < 0.018 GARS social interaction score, mean ± SD: **G1:** 8.4 ± 2.4 (n=26) **G2:** 6.9 ± 2.2 (n=27) **G1/G2:** *P* = 0.02 ADOS play score, mean ± SD: **G1:** 2.6 ± 1.6 **G2:** 2.2 ± 1.5 Vineland socializa-tion score, mean ± SD: **G1:** 35.5 ± 18.0 **G2:** 39.5 ± 19.2 **Communication/ language:** ADOS communica-tion score, mean ± SD: **G1:** 6.8 ± 1.8 **G2:** 6.5 ± 2.1 ADOS communi-cation + social interaction scores, mean ± SD: **G1:** 18.7 ± 3.7 **G2:** 17.3 ± 3.5	**Overall measures:** CGI-S score, week 4, mean ± SD: **G1:** 2.9 ± 0.8 **G2:** 2.7 ± 0.9 GARS autism quotient, week 4, mean ± SD: **G1:** 86.9 ± 13.2 (n=26) **G2:** 82.5 ± 15.2 **Social skills:** ADOS social interaction score, week 4, mean ± SD: **G1:** 11.5 ± 1.5 **G2:** 10.1 ± 1.8 GARS social interaction score, week 4, mean ± SD: **G1:** 7.3 ± 2.7 **G2:** 6.2 ± 2.5 ADOS play score, week 4, mean ± SD: **G1:** 2.7 ± 1.3 **G2:** 2.0 ± 1.4 Vineland sociali-zation score, week 4, mean ± SD: **G1:** 34.6 ± 17.9 **G2:** 39.3 ± 18.4 **Communication/ language:** ADOS Communi-cation score, wweek 4, mean ± SD: **G1:** 6.5 ± 1.7 **G2:** 6.3 ± 2.2 ADOS communi-cation + social interaction scores, week 4, mean ± SD: **G1:** 18.1 ± 2.5 **G2:** 16.4 ± 3.5 GARS commu-nication score, week 4, mean ± SD: **G1:** 9.2 ± 3.0 (n=22) **G2:** 8.0 ± 3.3
Owley et al., 2001 (continued)		**Diagnostic tool/method:** ADI-R, ADOS confirmed with DSM-IV diagnosis **Diagnostic category, n (%):** Autistic disorder:	GARS communica-tion score, mean ± SD: **G1:** 9.5 ± 2.7 (n=22) **G2:** 8.5 ± 2.4 (n=27) Mullen/DAS/PPVT/	Mullen/DAS/PPVT/DTVP-2 receptive language score, week 4, months ± SD: **G1:** 29.1 ± 21.8 **G2:** 40.1 ± 31.6

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
		G1: 28 (100) **G2:** 28 (100) **Other characteristics**: ADI score, mean ± SD: Social interaction: **G1:** 23.4 ± 3.6 **G2:** 23.0 ± 4.5 Communication verbal: **G1:** 13.5 ± 3.8 (n=21) **G2:** 13.3 ± 3.4 (n=23) Communication-nonverbal: **G1:** 18.7 ± 2.1 (n=7) **G2:** 15.6 ± 3.5 (n=5) Repetitive behavior: **G1:** 6.0±2.5 **G2:** 5.4±1.9 Abnormality of development: **G1:** 4.3 ± 0.7 G2: **4.1 ± 0.9**	DTVP-2 receptive language score, months ± SD: **G1:** 29.0 ± 23.8 **G2:** 37.4 ± 28.9 Mullen/DAS/PPVT/ DTVP-2 fine motor score, months ± SD: **G1:** 45.9 ± 25.4 **G2:** 47.5 ± 23.4 Vineland communication score, mean ± SD: **G1:** 35.9 ± 22.2 **G2:** 41.7 ± 26.7 **Problem behavior:** ADOS stereotyped behavior, mean ± SD: **G1:** 3.6 ± 1.6 **G2:** 2.5 ± 1.3 **G1/G2:** P < 0.007 GARS stereotyped behaviors, mean ± SD: **G1:** 9.4 ± 2.4 (n=26) **G2:** 8.0 ± 2.7 (n=27) **G1/G2:** P = 0.049 ABC-C subscale score, mean ± SD: Irritability: **G1:** 11.6 ± 7.5 (n=27) **G2:** 10.1 ± 7.1 (n=27) Lethargy: **G1:** 13.7 ± 7.1 (n=27) **G2:** 8.3 ± 6.7 (n=27) **G1/G2:** P = 0.006 Stereotypy: **G1:** 7.3 ± 4.0 (n=27) **G2:** 5.1 ± 3.5 (n=27), **G1/G2:** P = 0.035	Mullen/DAS/PPVT/DTVP-2 fine motor score, week 4, months ± SD: **G1:** 44.6 ± 25.1 (n=27) **G2:** 45.6 ± 20.8 (n=27) Vineland communication score, week 4, mean ± SD: **G1:** 38.3 ± 24.7 **G2:** 41.7 ± 24.9 **Problem Behavior:** ADOS stereotyped behavior score, week 4, mean ± SD: **G1:** 3.8 ± 1.5 **G2:** 3.2 ± 1.8 GARS stereo-typed behaviors score, week 4, mean ± SD: **G1:** 7.6 ± 3.0 (n=26) **G2:** 7.1 ± 2.9 ABC-C subscale score, week 4, mean ± SD: Irritability: **G1:** 10.1 ± 10.2 (n=26) **G2:** 10.9 ± 8.1 Lethargy: **G1:** 10.2 ± 5.9 (n=26) **G2:** 7.8 ± 7.1 Stereotypy: **G1:** 6.3 ± 4.2 (n=26) **G2:** 5.2 ± 4.9 (n=27) Hyperactivity: **G1:** 18.5 ± 10.6 (n=26) **G2:** 18.6 ± 11.4 (n=27) Inappropriate speech: **G1:** 2.6 ± 2.8 (n=26) **G2:** 3.5 ± 3.6 (n=27) **Adaptive behavior:** Vineland daily living score, week 4, mean ± SD: **G1:** 43.6 ± 18.4 **G2:** 41.7 ± 17.0 (n=26)
Owley et al., 2001 (continued)			Hyperactivity: **G1:** 21.3 ± 10.3 (n=27) **G2:** 18.6 ± 9.6 (n=27) Inappropriate speech: **G1:** 2.6 ± 2.8 (n=27) **G2:** 2.9 ± 2.3 (n=27) **Adaptive behavior:** Vineland daily living **G1:** 43.3 ± 19.5	Vineland adaptive behavior composite score, week 4, mean ± SD: **G1:** 39.1 ± 17.9 **G2:** 40.6 ± 18.1 **Motor skills:** DTVP-2 visual motor integration score, week 4, mean ± SD: **G1:** 79.6 ± 16.85 (n=6) **G2:** 74.4 ± 19.5 (n=8)

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
			G2: 40.8 ± 16.9 (n=27) Vineland adaptive behavior composite **G1:** 38.2 ± 17.8 **G2:** 40.3 ± 18.4 **Motor skills:** DTVP-2 visual motor integration **G1:** 78.8 ± 20.9 (n=7) **G2:** 76.8 ± 23.5 (n=8)	**Harms, n:** Abdominal rash: 1 Non-febrile seizures: 1 Vomiting: 1 Flu-like symptoms: 1 Hyperactivity/ problem behavior: 2 No harms clearly attributed to intervention **Modifiers:** NR

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Roberts et al., 2001 **Country:** Canada **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Randomized placebo controlled trial	**Intervention:** Porcine secretin or placebo, 2 occasions six weeks apart, 0.1 ml of secretin or saline placebo test dose. After vital signs were taken, 2 ml/kg (0.2 ml/kg) of secretin or saline was injected. Monitored for 4 hours **Assessments:** ADOS-G (baseline & both follow-ups), LIPS-R (baseline & final follow-up), PLS-II (baseline & both follow-ups), GSQ (baseline), Treatment Behavior/Side-Effect Rating Scale & Autism Behavior Checklist (end of each week) **Groups:** **G1:** porcine secretin **G2:** saline placebo **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** 1 every 6 weeks **Concomitant therapies, n (%):** (If begun > 6 weeks before the baseline assessment) Selective serotonin reuptake inhibitors: **G1:** 1 (3) **G2:** 1 (3) Anticonvulsant: **G1:** 1 (3) **G2:** 1 (3) Stimulants: **G1:** 1* (3) **G2:** 1** (3) Melatonin: **G1:** 0 (0) **G2:** 1 (3) Ranitidine: **G1:** 0 (0) **G2:** 1 (3)	**Inclusion criteria:** • Met criteria for Autism by ADI-R, ADOS-G, DSM-IV **Exclusion criteria:** • See inclusion criteria **Age, months ± SD:** **G1:** 62.31 ± 14.86 **G2:** 63.16 ± 15.87 **Mental age:** Leiter IQ, mean ± SD: **G1:** 83.05 ± 22.48 **G2:** 77.85 ± 24.11 **Gender, n (%):** Male: **G1:** 26 (81) **G2:** 29 (91) Female: **G1:** 6 (19) **G2:** 3 (9) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In Study **Diagnostic tool/method:** ADI-R, ADOS-G, DSM-IV **Diagnostic category, n (%):** Autism: 64 (100) **Other characteristics, n (%):** GI symptoms: **G1:** 7 (22) **G2:** 8 (25)	**Communication/ language:** PLS-3 score, mean ± SD: Expressive: **G1:** 17.03 ± 8.3 **G2:** 15.86 ± 10.28 Receptive: **G1:** 20.34 ± 10.01 **G2:** 19.48 ± 12.64 Total: **G1:** 53.9 ± 7.32 **G2:** 54.38 ± 10.88 **Adaptive behavior:** Autism Behavior Checklist subscale score, mean ± SD: Sensory: **G1:** 16.67 ± 6.69 **G2:** 15.14 ± 6.01 Relating: **G1:** 25.33 ± 9.31 **G2:** 23.64 ± 6.93 Body/object use: **G1:** 21.41 ± 10.78 **G2:** 18.21 ± 8.13 Language: **G1:** 18.15 ± 7.28 **G2:** 15.46 ± 7.48 Social/self-help: **G1:** 19.41 ± 4.39 **G2:** 17.75 ± 2.84	**Communication/ language:** PLS-3 score, mean ± SD: Expressive: **G1:** NR **G2:** NR ANOVA: time (performance increased; P < 0.05) treatment (*P* = NS) Receptive: **G1:** NR **G2:** NR ANOVA: time (performance increased; P < 0.05) treatment (*P* = NS) Total: **G1:** NR **G2:** NR ANOVA: time & treatment (*P* = NS) **Adaptive behavior:** Autism Behavior Checklist relating subscale, mean: **G1:** 27.91 ± NR **G2:** 21.08 ± NR **G1/G2:** *P* < 0.005 **Harms, n (%):** Rash: **G1:** 1 (3) **G2:** 0 Fever/tachycardia/vomiting: **G1:** 1 (3) **G2:** 0 Photosensitivity: **G1:** 1 (3) **G2:** 0 Irritability: **G1:** 3 (9) **G2:** 0 Generalized flushing of neck, face, chest: **G1:** 7 (22) **G2:** 0 Hyperactivity **G1:** 3 (9) **G2:** 3 (9)
Roberts et al., 2001 (continued)	**N at enrollment:** **G1:** 34 **G2:** 34 **N at follow-up:** **G1:** 32 **G2:** 32			Aggression **G1:** 2 (6) **G2:** 1 (3) **Modifiers:** No significant treatment differences noticed

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
				when analysis was done by subgroups (GI symptoms, IQ, or history of regression)

Comments: *dextroamphetamine
**methylphenidate

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
Author: Stahmer et al., 2001 **Country:** US **Practice setting:** Tertiary care hospital, academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** United Way **Author industry relationship disclosures:** NR **Design:** Prospective cohort	**Intervention:** Parent information support group, 1 hr/week for 12 weeks (G1 only) Parent education course on pivotal response training (PRT), also 1 hr/week for 12 weeks (both groups) **Assessments:** BSID, MDI, MCDI, 5-minute videotapes of parents interacting with children before and after treatment to assess parent use of program techniques and child's words **Groups**:** **G1:** Parent support group and education course **G2:** Parent education course only **Ga:** Parents met criteria for mastery of PRT post-treatment (correct use of PVT techniques in > 75% of intervals scored) **Gb:** Parents did not meet criteria for mastery of PRT **Provider:** • For parent education content: first author served as parent educator (clinical director of a hospital-based autism intervention center and research scientist) • For information support group: second author served as group facilitator (director of a children's hospital department of developmental services, not formally trained in PRT) **Measure of treatment fidelity reported:** NR	**Inclusion criteria:** • Age < 5 years • Recent ASD diagnosis • Initial diagnosis within the 6-month period preceding participation in the education program **Exclusion criteria:** • See inclusion criteria **Age, months (range):** **G1:** 35 (19-48) **G2:** 35.6 (29-50) **Mental age:** BSID II developmental age, months (range): **G1:** 51 (<50-90) **G2:** 51 (<50-85) **Gender:** NR **Race/ethnicity:** NR **SES:** Maternal education: NR Household income, n: > $50,000: **G1:** 9 **G2:** 6 $40,000-$50,000: **G1:** 0 **G2:** 4 $30,000-$40,000: **G1:** 0 **G2:** 0 $20,000-$30,000: **G1:** 1 **G2:** 0 $10,000-$20,000: **G1:** 1 **G2:** 1 **Diagnostic approach:** Referral **Diagnostic tool/method:** NR **Diagnostic category, n (%):** ASD: 22 (100)	**Communication/ language:** MCDI, words understood, mean: **Ga:** 119 **Gb:** 160 **Ga/Gb:** *P* = NS MCDI, words produced, mean: **Ga:** 29 **Gb:** 57 **Ga/Gb:** *P* = NS MCDI, communicative gestures, mean: **Ga:** NR **Gb:** NR Words used during videotaped play, mean: **Ga:** NR **Gb:** NR	**Communication/ language:** Correct use of PRT techniques, % of intervals scored, mean (range): **G1:** 75 (68-86) **G2:** 60 (29-78) **G1/G2:** $P < 0.05$ Parents met criteria for mastery (correct use of PRT techniques in > 75% of intervals scored), n: **G1:** 8 **G2:** 4 MCDI, words understood, mean change: **Ga:** 135 **Gb:** 28 **Ga/Gb:** $P < 0.01$ MCDI, words produced, mean change: **Ga:** 69 **Gb:** 32 **Ga/Gb:** $P < 0.01$ MCDI, communicative gestures, mean change: **Ga:** NR* **Gb:** NR* **Ga/Gb:** *P* = NS Words used during videotaped play, mean change: **Ga:** NR **Gb:** NR **Ga/BL:** $P < 0.05$ **Gb/BL:** $P < 0.05$ **Ga/Gb:** *P* = NS **Harms:** NR **Modifiers:** NR
Stahmer et al., 2001 (continued)	**Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:**	**Other characteristics:** Marital status, n: Married: **G1:** 10 **G2:** 10 Widow:		

Evidence Table. Therapies for children with ASD

Study Description	Intervention	Inclusion/Exclusion Criteria/Population	Baseline Measures	Outcomes
	G1: 11 **G2:** 11 **N at follow-up:** **G1:** 11 **G1a:** 8 **G1b:** 3 **G2:** 11 **G2a:** 4 **G2b:** 7	**G1:** 1 **G2:** 0 Single: **G1:** 0 **G2:** 1		

Comments: *Data only illustrated graphically.
**Enrollment in G1 vs. G2 was non-randomized and depended on availability on enrollment in patient education program; if group was available, it was a requirement for participation.

Author: Tjus et al., 2001 **Country:** Sweden **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** NR **Funding:** Swedish Council of Social Research, Queen Silvia's Jubilee Fund for Research on Children and Handicaps **Author industry relationship disclosures:** NR **Design:** Prospective case series	**Intervention:** Swedish version of the Alpha program (a multi-media program for increasing literacy skills and language learning through voice, animation, video, and sign language feedback); 25.6 ± 7.5 sessions lasting 32.0 ± 12.6 minutes over 16.9 ± 5.7 weeks **Assessments:** Videotaped sessions of children and their teachers evaluated at start and end of training to assess 15 variables of verbal and non-verbal behavior; observations coded by one of the authors. All interviews and observations conducted by a psychologist who was not blind to group assignment. **Groups:** **G1:** autism **Provider:** Four teachers **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 11 **N at follow-up:** G1: 11	**Inclusion criteria:** • Confirmed diagnosis of autism according to DSM-III-R **Exclusion criteria:** • See inclusion criteria **Age, months ± SD:** **G1:** 112 ± 28 **Mental age (CPM), months ± SD:** **G1:** 81 ± 25 **Gender, n:** Male: 9 Female: 2 **Race/ethnicity:** NR **SES:** NR **Diagnostic approach:** Referral **Diagnostic tool/method:** DSM-III-R **Diagnostic category, n (%):** Autism: 11 (100) Other characteristics: RDLS language age, months ± SD: 57 ± 22 CARS score, median (range): 42 (21.5-57)	**Social skills:** Enjoyment, median frequency (range): **G1:** 4 (0-15) **Communication/ language:** Verbal expressions, median frequency (range): **G1:** 29 (4-44) **Problem behavior:** Ignores, median frequency (range): **G1:** 1 (0-10) Off task, median frequency (range): **G1:** 2 (0-26) Protests, median frequency (range): **G1:** 0 (0-10) **Adaptive behavior:** Complies, median frequency (range): **G1:** 9 (4-21) Seeks help, median frequency (range): **G1:** 0 (0-4)	**Social skills:** Enjoyment, median frequency (range): **G1:** 10 (0-20), **G1/BL:** $P < 0.05$ **Communication / language:** Verbal expressions, median frequency (range): **G1:** 37 (4-49) **G1/BL:** $P < 0.02$ **Problem behavior:** Ignores, median frequency (range): **G1:** 1 (0-7) **G1/BL:** P = NS Off task, median frequency (range): **G1:** 6 (2-18) **G1/BL:** P = NS Protests, median frequency (range): **G1:** 0 (0-2) **G1/BL:** P = NS **Adaptive behavior:** Complies, median frequency (range): **G1:** 7 (3-20) **G1/BL:** P = NS Seeks help, median frequency (range): **G1:** 2 (0-9) **G1/BL:** $P < 0.05$ **Harms:** NR **Modifiers:** Teacher recasts correlated with pre- and post-treatment verbal expressions ($P < 0.05$)
Author: Chez et al. 2000	**Intervention:** Study 1: Secretin, 2 IU/kg per kg of body	**Inclusion criteria:** • Met DSM-IV criteria for PDDNOS or Autistic	**Overall ratings:** CARS score, mean ± SD:	**Overall ratings:** CARS score, mean ± SD:

Country: US **Practice setting:** Clinic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** Study 1: Prospec-tive case series Study 2: Not included (N < 30)	weight over 1-2 mins **Assessments:** CARS at baseline and post injection office visits Physicians or nurses assessed GI function, eye contact, expressive speech, and receptive language; parents noted changes in eye contact, interpersonal relations, self-stimulatory behavior, bowel movement consistency, toy play, expressive language/ verbalizations, receptive language, and overall behavior with observational diaries; observed for 1 hour post-injection **Groups:** **G1:** secretin **Co-interventions held stable during treatment:** NR **Frequency of contact during study:** Study 1: 2 times, follow-up (3.7 ± 1.4 weeks; range 3-6 weeks) **Concomitant therapies, n (%):** Other drug treatments: 45 (80.4) Antidepressants: 9 (16.1) CNS stimulants: 9 (16.1) **N at enrollment:** **G1:** 56 **N at follow-up:** **G1:** 56	disorder **Exclusion criteria:** • See inclusion criteria **Age, years ± SD:** 6.4 ± 2.7 **Mental age:** NR **Gender, n (%):** Male: 49 (88) Female: 7(13) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** Self-Referral **Diagnostic tool/method:** DSM-IV **Diagnostic category, n (%):** Autism: 22 (40) PDD-NOS: 34 (60) **Other characteristics, n (%):** GI distress: 33 (59) Abnormal EEG: 31 (63)	**G1:** 36.5 ± 6.4	**G1:** 33.2 ± 5.4 **G1/BL:** *P* < 0.01 CARS score, decrease from baseline, n: ≥ 6 (clinically meaningful): 13 1 to 5.5: 32 0 (no change): 2 -0.5 to -11 (worsening): 9 **Social skills, n (%):** Improved eye contact: 19 (34) **Communication / language, n (%):** Improved expres-sive language: 30 (34) Receptive speech improvements: 15 (27) Improvements in expressive speech: 30 (54) Improvements in receptive speech: 15 (27) Worsening of expressive speech: 1 (1.8) **Medical, n (%):** Improved GI: 19 (34) Worsening of GI function & eye contact: 1 (1.8) **Harms:** Reports of in-creased agitation, decreased focu-sing & decreased responsiveness to others **Modifiers:** NR
Author: Dunn-Geier et al., 2000 **Country:** Canada **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment**	**Intervention:** Single dose of secretin (test dose 0.1 CU injected through saline lock; if no immediate hyper-sensitivity occurred after 1 minute, injection of 2 CU/kg (0.2 ml/kg) to a maximum of 1 vial (75 CU)) **Assessments:** Autism Behavior Check-	**Inclusion criteria:** • Diagnosis of autism based on behavioral observation of the child and semistructured interview with the parent (CARS score ≥ 30) • Score of ≥ 6 on DSM-IV criteria for autism • Clinical judgment by a development	**Overall ratings:** CARS score, mean ± SD: **G1:** 38.5 ± 4.5 **G2:** 37.9 ± 4.4 Autism Behavior Checklist, total score, mean ± SD: **G1:** 79.0 ± 31.6 **G2:** 79.9 ± 26.9 Autism Behavior Checklist body and	**Overall ratings:** CARS score, mean change (SE): **G1:** -1.2 (0.3) **G2:** -1.5 (0.4) **G1/G2:** P = 0.62 Autism Behavior Checklist, total score, mean change (SE): **G1:** -13.1 (2.6) **G2:** -14.0 (2.7) **G1/G2:** P = 0.81

period: NR **Funding:** Children's Hospital Eastern Ontario Research Institute; PA Woodward's Foundation; Children at Risk Ottawa **Author industry relationship disclosures:** NR **Design:** RCT, double blind, placebo controlled; stratified by site and age	list, GI symptoms and side effect questionnaire designed for study completed by parents; CARS administered by observer in clinic **Groups:** **G1:** secretin **G2:** placebo (saline) **Co-interventions held stable during treatment:** Yes **Frequency of contact during study:** At baseline; injection (up to 1.5 hours post-injection); and 3 week follow-up **Concomitant therapies, n (%):** ABA: **G1:** 15 (33) **G2:** 24 (51) Speech: **G1:** 37 (79) **G2:** 34 (72) Floor time: **G1:** 5 (12) **G2:** 4 (10) Magnesium B6: **G1:** 1 (2) **G2:** 4 (9) DMG3: **G1:** 2 (5) **G2:** 3 (6) School/preschool placement: **G1:** 41 (91) **G2:** 42 (91)	pediatrician and a registered psy-chologist experienced in the field of PDD **Exclusion criteria:** • Patients with recogni-zable neurological or genetic disorder • Pancreatic or liver disorder • Allergy to lidocaine or prilocaine • Previous use of secretin • Any treatment initiated or changed within the 2 months immediately before enrollment • Any treatment planned to begin within the 3 weeks after injection **Age, years ± SD:** **G1:** 5.1 ± 1.2 **G2:** 5.1 ± 1.4 **Mental age:** NR **Gender, n (%):** Male: **G1:** 42 (89) **G2:** 46 (96) Female: **G1:** 5 (11) **G2:** 2 (4) **Race/ethnicity, n (%):** White: **G1:** 34 (72) **G2:** 41 (85) **SES:** NR **Diagnostic approach:** In study	object use score, mean ± SD: **G1:** 17.5 ± 9.4 **G2:** 17.0 ± 8.7 **Social skills:** Autism Behavior Checklist socialization score, mean ± SD: **G1:** 14.7 ± 5.9 **G2:** 15.3 ± 5.4 Autism Behavior Checklist social related-ness score, mean ± SD: **G1:** 19.1 ± 8.3 **G2:** 19.1 ± 8.6 **Communication/ language:** PLS total score, mean ± SD **G1:** 25.2 ± 11.8 **G2:** 31.0 ± 15.6 PLS auditory comprehension score, mean ± SD: **G1:** 12.2 ± 7.5 **G2:** 16.2 ± 19.2 PLS expressive communication score, mean ± SD: **G1:** 12.9 ± 4.8 **G2:** 14.6 ± 7.0 ABC language score, mean ± SD: **G1:** 13.3 ± 7.6 **G2:** 13.5 ± 6.7	Autism Behvaior Checklist body and object use score, mean change (SE): **G1:** -2.6 (0.9) **G2:** -2.7 (0.9) **G1/G2:** P = 0.89 **Social skills:** Autism Behavior Checklist socialization score, mean change (SE): **G1:** -2.5 (0.6) **G2:** -2.1 (0.8) **G1/G2:** P = 0.64 Autism Behavior Checklist social relatedness score, mean change (SE): **G1:** -3.9 (1.0) **G2:** -4.0 (1.0) **G1/G2:** P = 0.90 **Communication/ language:** PLS total score, mean change (SE): **G1:** 2.4 (0.8) **G2:** 1.1 (0.6) **G1/G2:** P = 0.25 PLS auditory comprehension score, mean change (SE): **G1:** 1.5 (0.6) **G2:** 0.6 (0.4) **G1/G2:** P = 0.2
Dunn-Geier et al., 2000 (continued)	Medication: **G1:** 9 (19) **G2:** 5 (11) **N at enrollment:** **G1:** 47 **G2:** 48 **N at follow-up:** **G1:** 47 **G2:** 48	**Diagnostic tool/method:** CARS, DSM-IV **Diagnostic category, n (%):** Autism: 95 (100) PDD-NOS: 0 Aspergers: 0 **Other characteristics:** Height, cm ± SD: **G1:** 108.6 ± 8.4 **G2:** 111.2 ± 9.9 Weight, kg ± SD: **G1:** 19.8 ± 3.5 **G2:** 21.3 ± 6.1 Seizure, n (%): **G1:** 3 (6) **G2:** 2 (4) Abnormal CT, n (%): **G1:** 1 (2)	**Medical:** Number of GI problems, mean ± SD: **G1:** 1.0 ± 1.1 **G2:** 1.2 ± 1.2 **Sensory:** Autism Behavior Checklist sensory score, mean ± SD: **G1:** 13.3 ± 7.4 **G2:** 13.9 ± 6.5	PLS expressive communication score, mean change (SE): **G1:** 0.6 (0.4) **G2:** 0.6 (0.4) **G1/G2:** P = 0.93 Improvement on PLS-3 scale ≥ 4 (small), n (%): **G1:** 16 (34) **G2:** 10 (21) **G1/G2:** P = 0.17 Improvement on PLS-3 scale ≥ 6 (moderate/large), n (%) **G1:** 8 (17) **G2:** 4 (8) **G1/G2:** P = 0.23 Autism Behavior

		G2: 1 (2) Cognitive measure, mean ± SD: **G1:** 38.1 ± 19.4 **G2:** 39.8 ± 16.2		Checklist language score, mean change (SE): **G1:** -0.9 (0.6) **G2:** -1.8 (1.0) **G1/G2:** P = 0.46 **Medical:** Number of GI problems, mean change (SE): **G1:** -0.4 (0.2) **G2:** -0.2 (0.1) **G1/G2:** P = 0.35 **Sensory:** Autism Behavior Checklist sensory score, mean change (SE): **G1:** -2.4 (0.8) **G2:** -2.7 (0.9) **G1/G2:** P = 0.77 **Harms:** Tachycardia: 0 Edema/swelling: 0 Headache: 0 Dizziness/light-headedness: 0 Nausea/vomiting: 0 Skin rash/pruritis: 0 Abdominal pain: 0 Flushing **G1:** 3 **G2:** 4
Dunn-Geier et al., 2000 (continued)				**Modifiers:** Mean difference between groups for PLS-3 total score is still not significant when analysis is limited to patients with at least one GI problem.
Author: Harris et al., 2000 **Country:** US **Practice setting:** Academic **Intervention setting:** Classroom **Enrollment period:** 1990 to 1992 **Funding:** NR **Author industry relationship**	**Intervention:** Intensive applied behavioral analysis treatment program, 35-45 hours weekly, 5 days a week for 12-months. Each family was expected to provide an additional 10 to 15 hours a week of home-based instruction. Questionnaire sent to parents about current educational placement. **Assessments:** IQ & CARS included in follow-up questionnaire 7 years after entry into preschool classroom of	**Inclusion criteria:** • Met DSM-III-R criteria for autism by outside source and confirmed by clinical psychologist at intake • Entered Douglass Developmental Disabilities Center between 1990-1992 • Every child with data on pre, post IQ data, CARS at baseline and age at admission **Exclusion criteria:** • See Inclusion criteria **Age at admission, mean/mos (range):**	**Overall measures:** CARS, mean (range): **G1:** 34.17 (range 30-40) **Educational/ cognitive/ academic attainment:** Stanford Binet (IQ), mean (range): **G1:** 59 (range 35-109)	**Educational/ cognitive/ academic attainment:** IQ, mean: 77.59 **Harms:** NR **Modifiers:** Significant association between age at admission and academic placement *r*(25) = 0.658, *P* < 0.005 (younger students more likely to be in

disclosures: NR **Design:** Prospective Case Series	the DDDC **Groups:** **G1:** intensive applied behavior analysis **Provider:** Therapists at Douglass Developmental Disabilities Center (DDDC) **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 27 **N at follow-up:** **G1:** 27	49 (31-65) **Age at follow-up, mean/mos (range):** 142 (122-170) **Mental age:** NR **Gender, n (%):** M: 23 (85) F: 4 (15) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In study **Diagnostic tool/method:** DSM III-R clinical interview **Diagnostic category, n (%):** Autism 27(100) **Other characteristics:** NR	regular education settings at follow-up) Treatment before 48mo: 10/13 in regular education settings Treatment after 50months: 1/14 in a regular class (Fisher exact test *P* <0 .005) Significant association between higher IQ at admission and the greater likelihood of a regular education, mean: 77.59 *r*(25) = 0.655, *P* < 0.005 IQ ≤52 at intake in regular setting: 1/14 IQ ≤52 at intake in special education: 13/14
Harris et al., 2000 (continued)			IQ ≥59 at intake in regular education: 10/13 IQ ≥59 at intake in special education: 3/13 Discharge IQ ≥80 in regular classes: 11/13 Discharge IQ ≥80 in special education: 3/13 IQ ≤76 at discharge in special education: 13/13 (*P* < 0.005) Significant association between age at intake and IQ when child left program (*P* < 0.025); younger children at intake

				had higher IQs at discharge No significant correlations between age and IQ at intake, or between CARS score at intake and education setting at follow-up.

Evidence Table: Therapies for Children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
Author: Luiselli et al., 2000 **Country:** US **Practice setting:** Specialty treatment center **Intervention setting:** Home **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** retrospective case series; children randomly selected (unspecified methodology) from those of specific age groups for analysis	**Intervention:** home-based treatment based on Lovaas and described by Anderson (1987) **Groups:** **G1a:** initiated treatment at under 3 years of age **G1b:** initiated treatment at over 3 years of age Duration, mean months ± SD: **G1a:** 11.6 ± 7.00 **G1b:** 7.12 ± 2.41 Frequency, mean hours/week ± SD: **G1a:** 11.8±3.72 **G1b:** 15.6±1.76 Total hours (mean±SD): **G1a:** 583.50 ± 435.27 **G1b:** 455.00 ± 204.17 **Assessments:** Pretreatment: standardized instruments (service delivery & ELAP or LAP), direct observations, parent interviews, and videotape segments; completed by May Center for Early Childhood Education staff **Provider:** Therapists with BA or MA degrees with specializations in psychology, early childhood education, or special education, training	**Inclusion criteria:** • In receipt of home-based services from May Center for Early Childhood Education • Diagnosed as having autism or pervasive developmental disorder by evaluators not associated with the center (method not provided) **Exclusion criteria:** • See inclusion criteria **Age, mean/yrs (range):** **G1a:** 2.63 years **G1b:** 3.98 years **Mental age:** NR **Gender:** NR Race/ethnicity: NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** See inclusion criteria **Diagnostic tool/method:** NR **Diagnostic category, n (%):** **G1a:** Global developmental delay: 1 (12.5) PDD: 2 (25) PDD-NOS: 3 (37.5)	Early Learning Accomplishments Profile (ELAP) or Learning Accomplishments Profile (LAP); baseline values not provided. Only change data presented.	**Communication/ language:** ELAP/LAP Communication, mean change ± SD: **G1a:** 21.00 ± 18.42 (*P* = 0.015) **G1b:** 8.25 ± 10.11 (*P* = 0.054) **Educational/ cognitive/ academic attainment:** Cognitive, mean change ± SD: **G1a:** 21.00 ± 15.38 (*P* = 0.006) **G1b:** 11.25 ± 6.75 (*P* = 0.002) **Motor skills:** Fine motor, mean change ± SD: **G1a:** 20.75 ± 21.88 (*P* = 0.031) **G1b:** 13.50 ± 12.31 (*P* = 0.017) Gross motor, mean change ± SD: **G1a:** 16.85 ± 16.15 (*P* = 0.036) **G1b:** 10.50 ± 11.89 (*P* = 0.041) **Adaptive behavior:** Self-Care, mean change ± SD: **G1a:** 15.00±

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	in procedures, and weekly supervision and case consultation from director of home-based services **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR	Autistic disorder: 1 (12.5) PDD/autistic disorder: 1 (12.5) **G1b:** Developmental delay: 1 (12.5) PDD: 6 (75) Autistic disorder: 1 (12.5) **Other characteristics:** NR		12.82 (*P* = 0.013) **G1b:** 12.75 ± 11.31 (*P* = 0.015) **Social skills:** Social-Emotional, mean change ± SD: **G1a:** 24.00 ± 21.98 (*P* = 0.018) **G1b:** 17.25 ± 12.18 (*P* = 0.005)
Luiselli et al., 2000 (continued)	**Concomitant therapies:** NR **N at enrollment:** **G1a:** 8 **G1b:** 8 **N at follow-up:** **G1a:** 8 **G1b:** 8			**Harms:** NR **Modifiers:** Duration of treatment predicted change scores and was significant for communication (*P* < 0.002), cognition (*P* < 0.001) and social-emotional (*P* < 0.001) domains.
Author: Moore et al., 2000 **Country:** US **Practice setting:** Academic **Intervention setting:** School **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR **Design:** RCT	**Intervention:** Children taught 6 nouns (3/day for two days) by teacher or computer instruction with follow-up testing at 1 week post-intervention **Assessment:** Learning , attention & motivation measures **Groups:** **G1:** Teacher (Behavioral) **G2:** Computer software program (Educational) **Provider:** • Teacher • Computer **Measure of treatment fidelity reported:** No **Co-interventions held stable during treatment:** NR **Concomitant therapies:**	**Inclusion criteria:** • Children with autism enrolled at one school **Exclusion criteria:** • See inclusion criteria **Age, range: 3-6 years** **Mental age:** NR **Gender, n (%):** M: 12 (85.7) F: 2 (14.3) **Race/ethnicity:** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** NR **Diagnostic tool/method:** NR **Diagnostic category, n (%):** Autism: 14 (100)	NR	**Social skills:** Amount of time spent paying attention to instruction, %: **G1:** 62 **G2:** 97 $F(1,13) = 13.28$, $P < 0.01$ **Communication/ language:** Nouns recalled, mean (%): **G1:** 2.43 (41) **G2:** 4.43 (74) $F(1,13) = 10.89$, $P < 0.01$ **Educational/ cognitive/ academic attainment:** Interest in continuing intervention at end of session vs. going to play, %: **G1:** 0 **G2:** 56

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	NR **N at enrollment:** **G1:** 7 **G2:** 7 **N at follow-up:** **G1:** 7 **G2:** 7	**Other characteristics:** 5 of 7 children in G2 had used a computer and knew how to use a mouse; the other two were given an initial practice session All children in G1 had previously experienced behavioral training		*P* < 0.05 **Harms:** NR **Modifiers:** The more children attended in either condition, the more they learned F(1,13) = 38.45 (*P* < 0.001)
Author: Mudford et al., 2000 **Country:** UK **Practice setting:** Academic **Intervention setting:** Clinic **Enrollment period:** NR **Funding:** National Health Service Research and Development Programme for People with Physical and Complex Disabilities **Author industry relationship disclosures:** NR **Design:** RCT, crossover design	**Intervention:** Auditory integration training using Audio Tone Enhancer/Trainer CD player and headphones 10 hours training across 10 consecutive working days, 2 30-minute sessions per day at least 3.5 hours apart Children were observed for average 3.83 hours across one school day monthly, except month 12 Study was 14 months total, with 3-5 months of pretreatment baseline and at least 4 months between treatments Groups: **G1:** auditory integration therapy--control **G2:** control –auditory integration therapy **Provider:** Persons trained by a Director of the Society of Auditory Intervention Techniques; trainer and assistants had at least 4 years experience working with children with autism and problem behaviors **Assessments:** Vineland Adaptive Behavior Composite Reynell Developmental Language Scales-III Leiter International Performance Scale	**Inclusion criteria:** • Diagnosis of autism confirmed by DSM-IV and ICD-10 by consultant psychologists **Exclusion criteria:** • See inclusion criteria **Age, mean/yrs ± SD (range):** 9.42 years ± 29 months (5.75-13.92 years) **Mental age:** NR **Gender, n (%):** M: 17 (81) F: 4 (19) **Race/ethnicity, n (%):** NR **SES:** Maternal education: NR Household income: NR **Diagnostic approach:** In study **Diagnostic tool/method:** Confirmed based on ICD-10 and SDM-IV classifications by previous assessments, direct observation and discussion with teachers **Diagnostic category, n (%):** Autism: 16 (100) **Other characteristics:** IQ for 15 for whom it was available, mean (range): 56 (8-125)	**Problem behavior:** ABC-P hyperactivity, mean ± SD 23.7 ± 9.4 NCBRF-P hyperactive, mean ± SD: 13.9 ± 5.5 **Educational/ cognitive/ academic attainment:** Leiter IQ (n=11), mean: 68 **Adaptive behavior:** VABS composite, mean: 31 **Communication/ language:** Derived language quotient (age equivalent/ chronological age x 100), mean: 26 Language comprehension quotient, mean: 28 Comprehension age/months equivalent, mean: 31 Reynell Language Development Scales-III expressive language age equivalents: 28 **Medical:** Ear occlusion, % mean ± S D: 8.2 ±	Change at Audio Integration Training **Problem behavior**: ABC-P hyperactivity, mean ± SD: 0.3 ± 3.6 (*P* < 0.05) NCBRF-P hyperactive, mean ± SD: -0.3 ± 2.0 (*P* < 0.10) Change at control **Problem behavior:** ABC-P hyperactivity, mean ± SD: -4.1 ± 3.9 NCBRF-P hyperactive, mean ± SD: -2.0 ± 2.2 **Educational/ cognitive/ academic attainment:** Leiter IQ (n=11), mean: 66 (*P* = NS) **Adaptive behavior:** VABS composite, mean: 29 t(15) = 3.36 *P* = 0.004

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
	Aberrant Behavior Checklist Nisonger Child Behavior Rating Form **Measure of treatment fidelity reported:** No		12.8	**Communication/ language:** Derived language quotient (age equivalent/chronological agex100), mean: 24 , t(15) = 2.01, (P = 0.06)
Mudford et al., 2000 (continued)	**Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** 21 **N at follow-up:** 16 **G1:** 7 **G2:** 9			Language comprehension quotient, mean: 26 (P = NS) Reynell Language Development Scales-III comprehension age equivalents described as unchanged across the study, mean/months: 31 Reynell Language Development Scales-III expressive language age equivalents: 29, t(15) = 1.83, P = 0.09 **Medical:** Ear occlusion, change at audio integration training, % mean ± SD: 3.7% ± 5.9 P < 0.10 Ear occlusion, Change at control, % mean ± SD: 1.2 ± 6.4 **Harms, n:** Diarrhea: 1 Excessive sleepiness: 1 More distraught: 1 **Modifiers:** NR
Author: Smith et al.	**Intervention:** Intensive training, 30	**Inclusion criteria:** • 18-42 months at time of	**Educational/ cognitive/**	**Educational/ cognitive/**

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
2000 **Country:** US **Practice setting:** Specialty treatment center **Intervention setting:** Clinic, Home **Enrollment period:** 1989 to 1992 **Funding:** Department of education & UCLA Regents **Author industry relationship disclosures:** NR **Design:** RCT	hrs/week for 2-3 years from therapist, parent with therapist 5 hrs/week for first 3 months Parent intervention, families taught techniques from Lovaas manual 2 sessions/week in homes for 3-9 months **Assessments:** Once intake assessments had been completed on 4-8 children, they were divided into 2 cohorts (autism & PDD); children were paired by statistician on IQ (Bayley), and then randomly assigned 1 member of each pair to treatment or parent-training group **Groups:** **G1:** intensive training **G2:** parental training **Provider:** Therapists in UCLA Young Autism Project **Measure of treatment fidelity reported:** Yes **Co-interventions held stable during treatment:** NR **Concomitant therapies:** NR **N at enrollment:** **G1:** 15 **G2:** 13 **N at follow-up:** **G1:** 15 **G2:** 13	referral • Residence within 1 hr of UCLA center • IQ between 35-75 • Diagnosis of ASD or PDD-NOS • Absence of major medical problems **Exclusion criteria:** • See inclusion criteria **Age, mean/months ± SD:** At Intake: **G1:** 36.07 ± 6.00 **G2:** 35.77 ± 5.37 Follow-up: **G1:** 94.07 ± 13.17 **G2:** 92.23 ± 17.24 **Mental age:** NR **Gender, n (%):** M: **G1:**12 (80) **G2:**11 (85) F: **G1:** 3 (20) **G2:** 2 (15) **Race/ethnicity, n (%):** White: **G1:** 7 (47) **G2:** 7 (54) Hispanic: **G1:** 4 (26) **G2:** 2 (15) Black: **G1:** 1 (7) **G2:** 3 (23) Asian: **G1:** 3 (20) **G2:** 1 (8) **SES:** Maternal education, median (range): **G1:** 12 (10-16+) **G2:** 15 (12-16+) Paternal education, median (range): **G1:** 13-14 (<6-16+) **G2:** 15 (12-16+)	**academic attainment**: Stanford Binet or Bayley Scales of Infant Development-Mental Development Index (scored as IQ), mean ± SD: **G1:** 50.53 ± 11.18 **G2:** 50.69 ± 13.88 Merrill-Palmer Scale of Mental Tests, mean ± SD: **G1:** 21.60 ± 4.49 **G2:** 21.92 ± 5.50 **Communication/ language:** Reynell Development Language Scale Total, mean ± SD: **G1:** 28.60 ± 4.07 **G2:** 30.00 ± 6.34 Comprehension, mean ± SD: **G1:** 13.47 ± 3.60 **G2:** 13.69 ± 3.73 Expressive, mean ± SD: **G1:** 15.13 ± 0.52 **G2:** 16:31 ± 2.69 Developmental Language Scale G1:69.93(8.37) G2:70.62(11.50) **Adaptive Functioning** Vineland Adaptive Behavior Scales Composite, mean ± SD: **G1:** 63.4 ± 9.35 **G2:** 65.2 ± 9.44 Communication, mean ± SD: **G1:** 58.20 ± 5.56 **G2:** 62.00 ± 6.11	**academic attainment**: Bayley Scales of Infant Development-Mental Development Index (scored as IQ), mean ± SD: **G1:** 66.49 ± 24.08 **G2:** 49.67 ± 19.74 *P* < 0.05 Merrill-Palmer Scale of Mental Tests, mean ± SD: **G1:** 64.33 ± 18.74 **G2:** 49.17 ± 21.43 *P* < 0.05 **Communication/ language:** Reynell Development Language Scale Total, mean ± SD: **G1:** 87.40 ± 46.21 **G2:** 61.33 ± 31.88 *P* < .05 Comprehension, mean ± SD: **G1:** 42.87 ± 22.29 **G2:** 33.00 ± 16.86 *P* = NS Expressive, mean ± SD: **G1:** 44.53 ± 23.48 **G2:** 36.23 ± 21.19 *P* = NS Developmental Language Scale, mean ± SD: **G1:** 62.33 ± 25.76 **G2:** 63.00 ± 16.97 *P* = NS
Smith et al. 2000 (continued)		Household income, median (range): **G1:** 40-50,000 (<10,000 to 75-100,000)	Socialization, mean ± SD: **G1:** 62.4 ± 7.82 **G2:** 69.15 ± 8.75	**Adaptive Functioning** Vineland Adaptive Behavior Scales

Evidence Table: Therapies for Children with ASD (continued)

Study Description	Intervention	Inclusion/ Exclusion Criteria/ Population	Baseline Measures	Outcomes
		G2: 40-50,000 (<10,000 to 75-100,000) **Diagnostic approach:** Referral-Independent diagnosis from psychologist at State regional developmental coordination center. 19 received second independent diagnosis **Diagnostic tool/method:** NR **Diagnostic category, n (%):** Autism: 14 (50) PDD-NOS: 14 (50) **Other characteristics:** Motor delays: **G1:** 2 **G2:** 1	Daily Living, mean ± SD: **G1:** 69.93 ± 8.37 **G2:** 70.62 ± 11.50	Composite, mean ± SD: **G1:** 61.19 ± 29.72 **G2:** 58.50 ± 16.58 *P* = NS Communication, mean ± SD: **G1:** 67.87 ± 30.08 **G2:** 60.77 ± 17.26 *P* = NS Socialization, mean ± SD: **G1:** 66.33 ± 24.78 **G2:** 68.92 ± 16.94 Daily Living, mean ± SD: **G1:** 62.33 ± 25.76 **G2:** 63.00 ± 16.97 **Academic Achievement** Wechsler Individualized Achievement Test, mean ± SD: **G1:** 75.51 ± 21.31 **G2:** 58.44 ± 18.43 **Harms** NR **Modifiers** NR

Appendix D. List of Excluded Studies

Reasons for Exclusion:
X-1: Does not include participants with ASD ages 2-12 or 0-2 at risk for ASD
X-2: Is not original research
X-3: Has <10 participants; <30 in medical interventions
X-4: Not applicable to any key questions
X-5: Not published in English
X-6: Does not have extractable data; only presents individual participant data; missing pages
X-10: Published before 2000

1. What is a reasonable cost of appropriate education? J Autism Dev Disord. 1980 Dec;10(4):459-72. X-2, X-4,X-10
2. Sex education and sexual awareness building for autistic children and youth: some viewpoints and considerations. J Autism Dev Disord. 1985 Jun;15(2):213-27. X-1, X-2, X-3, X-4, X-10
3. Community care: suffering acts of omission. Nurs Stand. 1992 Jun 17-23;6(39):50-1. X-4, X-10
4. Position of the American Dietetic Association: nutrition in comprehensive program planning for persons with developmental disabilities. J Am Diet Assoc. 1992 May;92(5):613-5. X-10
5. Auditory integration training. ASHA. 1994 Nov;36(11):55-8. X-10
6. Auditory integration training and facilitated communication for autism. American Academy of Pediatrics. Committee on Children with Disabilities. Pediatrics. 1998 Aug;102(2 Pt 1):431-3. X-1, X-2, X-3, X-4, X-10
7. MMR vaccine coverage shows signs of recovery. Commun Dis Rep CDR Wkly. 1999 Sep 24;9(39):345. X-1. X-2, X-3, X-4, X-10
8. Significant achievement award. A comprehensive program for treating profoundly autistic children--Center for Autistic Children, Philadelphia. Psychiatr Serv. 2000 Nov;51(11):1439-40. X-1, X-2, X-3, X-4
9. American Academy of Pediatrics: Counseling families who choose complementary and alternative medicine for their child with chronic illness or disability. Committee on Children With Disabilities. Pediatrics. 2001 Mar;107(3):598-601. X-1, X-2, X-3, X-4
10. Autism and Lovaas treatment: a systematic review of effectiveness evidence. Int J Technol Assess Health Care. 2001 Spring;17(2):252. X-1, X-2, X-3, X-4
11. JAMA patient page. Autistic disorder. JAMA. 2001 Apr 4;285(13):1798. X-1, X-2 ,X-3, X-4
12. Technical report: the pediatrician's role in the diagnosis and management of autistic spectrum disorder in children. Pediatrics. 2001 May;107(5):E85. X-1 ,X-2 ,X-3, X-4
13. Is there a link between MMR vaccine and autism?...and an expert's commentary. Child Health Alert. 2002 Dec;20:1-2. X-1, X-2, X-3, X-4

14. Science finds no link between MMR vaccine and autism. Mich Med. 2002 Sep-Oct;101(5):37. X-1, X-2, X-3, X-4

15. Autism: neural basis and treatment possibilities. Symposium proceedings. London, United Kingdom, 18-20 June 2002. Novartis Found Symp. 2003;251:1-310. X-1, X-2, X-3, X-4

16. MMR vaccine--how effective and how safe? Drug Ther Bull. 2003 Apr;41(4):25-9. X-1, X-2, X-3, X-4

17. Autism: a new treatment seems unsuccessful. Child Health Alert. 2004 Feb;22:1-2. X-1, X-2, X-3, X-4

18. Asperger's syndrome. Harv Ment Health Lett. 2005 Feb;21(8):4-5. X-1, X-2, X-3, X-4

19. Global Advisory Committee on Vaccine Safety, 2-3 December 2004. Wkly Epidemiol Rec. 2005 Jan 7;80(1):3-7. X-1, X-2, X-3, X-4

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Appendix F. Approach to Categorizing Study Designs

- Cohort, prospective: studies in which subjects receive more than one type of treatment or exposure (e.g. ABA therapy or DIR/floortime compared to another treatment or no treatment) in order to make comparisons of the outcomes of treatment, in which the investigator(s) does not assign the treatment or non-treatment states for the purposes of comparing them. For the purpose of this review, we termed studies with more than one “exposure” group prospective cohorts to distinguish them from case series. Analysis is focused on estimating the risk or odds of the outcome(s) based on the participants’ exposure (treatment group status). These would include comparative studies in which the treatment is set based on “happenstance” conditions such as availability of a therapist, or parental choice. These types of studies can also be described as employing a non-randomized pre-post group comparison design.
- Cohort, retrospective: studies in which subjects having more than one type of treatment (more than one “exposure”) are identified after having had intervention (e.g., chart review of children with ASD receiving either risperidone or olanzapine). Studies that have some component of follow-up should be classified as retrospective if the intent to follow-up the cohort was not designed and future data collection planned prior to the time of the treatment under investigation. Analysis estimates the risk or odds of the outcome(s) based on the participants’ exposure (treatment group status).
- Randomized clinical trials: special instances of prospective cohorts in which the “exposure” or treatment group is assigned by the investigator through use of an allocation method; treatment and non-treatment are assigned by study investigators using an a priori protocol.
- Controlled trials (nonrandomized): special instances of prospective cohorts in which the exposure or treatment group is assigned by the investigator but without using a randomization scheme.
- Case-control studies: studies that identify cases based on the outcome under study. A control, comparison population is identified that is intended to be a representative sample of similar children. In order to assure similar characteristics overall with respect to covariates not being studied, matching is often used, such as matching on age or race to assure a similar distribution of these potential confounders. Analysis is technically estimating the odds of having had a particular exposure or characteristic given known presence or absence of the outcome.
- Case series, prospective: studies in which subjects (ideally consecutive participants) having the same type of treatment for symptoms of ASD are identified prior to treatment and consented to participate (i.e., all participants receive the same treatment). The components of the study and outcome follow-up are designed before the participants are enrolled. Data analysis is descriptive including the full range of potential outcome measures such as reduction in problem behaviors, changes in IQ, etc. Analysis may include construction of predictive models that seek to examine influences on outcomes, such as IQ at intake, etc. Studies may also present data for groups of participants (e.g., males vs. females) though all participants received the same treatment. Case series might include experimental approaches or analyses such as multiple baseline, reversal, ABAB, alternating treatments, or changing

criterion studies in this literature. Group designed studies from which we could only collect data from one arm (e.g., studies that inappropriately compared the effects of an intervention in children with ASD to normally developing children) were considered case series.

- Case series, retrospective: studies in which investigators obtain permission to review existing clinical records in order to summarize the outcomes from a sequence (ideally consecutive patients) receiving the same treatment. Follow-up of the members of a case series identified from medical records or databases using methods such as surveys should still be counted as "retrospective" if the design of the study and future data collection were not established prior to the time of the treatment under study. Analysis is descriptive.

APPENDIX G. Discussion of Recent Systematic Reviews of Therapies for Children with ASDs

We conducted a scan of recent (2008-2010) systematic reviews addressing therapies for children with ASD in order to inform the present review. We considered systematic reviews as those literature reviews that employed reproducible, explicit methods to locate and summarize a body of literature; we required that systematic reviews included in our assessment:

- Include a focused question or topic area to be assessed in the review
- Include explicit inclusion/exclusion criteria for studies included in the review
- Include only studies of therapies for children (defined as participants ≤ 18 years of age for this examination of reviews) with ASD
- Articulate approaches used to locate studies including the resources searched; search strategies used; and time frame for searches
- Articulate approaches used to assess the relevance of studies included in the review
- Provide an accounting of included and excluded studies
- Summarize the characteristics of included studies
- Assess the quality of included studies
- Synthesize results of studies using statistical approaches where appropriate and possible

Methods. We searched the MEDLINE, ERIC, and PsycInfo databases using the autism search string employed to locate studies for the full review with the addition of terms to limit retrieval to reviews (systematic review, meta-analysis, review); we also limited searches to the years 2008 to 2010 and reviews published in English only given that the team lacked translators for potentially relevant non-English studies. We assessed the titles and abstracts of reviews for relevance to the inclusion/exclusion criteria and subsequently assessed the full text of included studies using a standard form developed by the Vanderbilt EPC (Appendix B). We abstracted descriptive data about the reviews including publication characteristics (author, year of publication, last update date/search date), study and methodological characteristics (number of studies included, study designs included, search parameters, quality measures employed) and primary results into a spreadsheet.

Content of the literature. Of 218 reviews retrieved in our searches, ten{, #4988;, #3640;, #3763;, #4990;, #3;, #4991;, #4994;, #4992;, #6084;, #6085} were eligible for inclusion. The bulk of excluded reviews either did not focus on ASD in children, were narrative or descriptive reviews, and/or included studies of both children and adults (defined as ≥ 18 years old). Five systematic reviews addressed early behavioral intervention approaches, {, #4990;, #4988;, #3640;, #3763;, #3}. The remaining reviews addressed augmentative and alternative communication interventions (AAC) including the Picture Exchange Communication System (PECS),{, #4991;, #6085} gluten free-casein free (GFCF) diets,{, #4994;, #6084} and drug and non-drug interventions in general.{, #4992} Six reviews were published by investigators in the US,{, #3763;, #3640;, #3;, #4991;, #6084;, #6085} two from the UK,{, #4992;, #4994} and one each from Norway{, #4988} and Australia.{, #4990}

Databases commonly noted as searched for the reviews included MEDLINE, PsycInfo, EMBASE, ERIC, the Cochrane database and trial registry, and CINAHL, and years searched for each review varied from the 1960s to 2006-2008,{, #4988;, #3;, #4994} to the 1980s or 1990s to 2006-2009.{, #4990;, #4992;, #6085} Four reviews explicitly noted the date of their last search update,{, #4992;, #4994;, #3;, #6085} while six provided a complete description of search terms used.{, #4990;, #3;, #4991;, #4994;, #6085;, #6084} Most of the reviews described other resources searched in addition to bibliographic databases; such resources included reviewing the reference lists of studies in the review and existing reviews, contacting experts in the area, and scanning relevant websites such as the Food and Drug Administration.{, #6085;, #6084;, #3640;, #3763;, #3;, #4991;, #4994;, #4992} All of the reviews appeared to employ an *a priori* design, though this was not always explicitly stated. Most investigators also noted dual review of included studies.{, #4988;, #3640;, #4990;, #3;, #4991;, #4994;, #6085;, #6084}

Six reviews included group design studies employing experimental or quasi-experimental designs with either control or comparison groups,{, #4988;, #4990;, #4994;, #4992;, #6084;, #6085} and four also included multiple baseline studies.{, #3763;, #4991;, #6085;, #6084} Reichow and colleagues' review of studies of interventions based on the UCLA/Lovaas model{, #3640} and the Blue Cross Blue Shield Association's review of EIBI interventions{, #3} included one group pre-post designs as well as comparative studies, while Millward and colleagues' review of GFCF diets included only RCTs.{, #4994} The number of studies included in the reviews ranged from two (in Millward's{, #4994} review of RCTs) to 22 in Rogers and colleagues' review of early intensive behavioral interventions.{, #3763} Several reviews included only papers with study populations in the preschool age range.{, #4988;, #3640;, #3763;, #4990;, #3} Reviews of GFCF diets{, #4994;, #6084}, a meta-analysis of PECS{Flippin, 2010 #6085}, and an overarching review of therapies for children with ASD{, #4992} included both younger children and adolescents. The number of participants in studies in the reviews ranged from 35 in the Cochrane review of GFCF diets{, #4994} to over 600 in Parr's comprehensive review of interventions.{, #4992} Four reviews also reported meta-analyses.{, #4988;, #3640;, #4990;, #6085} Table G1 provides additional data on parameters of each review.

Summary of recent systematic reviews of therapies for ASD. Millward et al.{, #4994} reviewed RCTs of GFCF diets for ASD, locating two studies comprising three papers published in 2002, 2003, and 2006 and including 35 participants with ASD. The age range of the 20 participants in one single blind study conducted over one year was 59 to 127 months;{Knivsberg, 2002 #1047;Knivsberg, 2003 #4445} the age range of the 15 participants in the second, double blind, 18 week crossover study was 2 to 16 years.{Harrison Elder, 2006 #2689} The studies assessed various outcomes: autistic traits and severity, linguistic age, motor skills, cognitive level, urinary peptide levels, and language and communication outcomes; different outcome measures were used in each study. A beneficial treatment effect was shown in reduction in autistic traits in the Knivsberg study; however, the Elder study showed no significant difference on the Childhood Autism Rating Scale (CARS) scores between the diet and control groups. The review reports that much of the data in both studies was skewed, which obviated review investigators' calculation of treatment effect sizes for all measures assessed. Though not reporting a washout period, the Elder trial was described as well-designed, with blinding and adequate concealment of allocation.

Mulloy and colleagues review of gluten free and/or casein free diets{, #6084} included 14 studies (including the Elder and Knivsberg trials) collectively including 188 participants ranging from 2 to 17 years of age. Most participants (93 percent) were diagnosed with autism or Asperger syndrome. Twelve studies examined GFCF diets while one assessed a gluten free and one a casein free regime. Diets were followed across studies for a mean of 10 months (range 4 days to 4 years), and four studies also included additional interventions such as vitamin supplementation, chelation, and behavior modification. Review investigators characterized the certainty of evidence of studies based on study design and methodological rigor, rating studies as suggestive, preponderant, or conclusive in line with classifications developed by Simeonsson and Bailey{, #6011} and Smith; 11 studies were rated as suggestive. Methodological concerns included use of measurements subject to bias, lack of blinding and control groups, use of only post-treatment measures, short intervention durations, and failure to control for the effects of maturation. Investigators considered 3 studies as providing a level of certainty of evidence for the lack of effectiveness of GFCF diets. Overall, the review authors conclude that the evidence supporting GFCF diets in ASD is limited and weak.

Schlosser and colleagues' review of AAC interventions on speech production{, #4991} included nine single subject design studies with 27 total participants and two group design studies with 98 total participants; all studies were published between 1988 and 2007. Single subject studies included between 1 and 6 participants (mean age 81 months, range 37-144). All but one participant lacked functional speech, and interventions evaluated were PECS, manual signing, speech generating devices, and enhanced milieu teaching. Speech measurement techniques varied across studies and ranged from mean length of utterance to word approximations to word elicitation. The mean age of participants in group design studies was 60 months and 33 months; participants appeared to possess some spoken speech at baseline. Interventions represented were PECS, manual signing and speech training, and RPMT, and both studies assessed child-initiated spoken words. Overall, no studies included in the review reported a decline in speech production, and most participants in most of the studies showed modest gains in speech. One study comparing PECS to RPMT{Yoder, 2006 #487}demonstrated more nonimitative spoken communication acts and different nonimitative words in children receiving PECS.

The review judged quality by evaluating design and implementation, interobserver agreement, and treatment integrity, appraising the evidence as conclusive, preponderant, suggestive, or inconclusive based on Simeonsson and Bailey's taxonomy.{, #6011} The review investigators rated one single subject study of PECS as conclusive, two (1 of PECS, 1 of speech generating devices) as preponderant, and four (2 of PECS and 2 of speech-generating devices) as suggestive; two studies were not rated. Group design studies were rated as conclusive (PECS/RPMT) and suggestive (speech and signing methods).

A meta-analysis from Flippin et al.{, #6085} included 10 studies (7 single subject and 3 group design studies) and a total of 178 participants. Five studies reported a measurement of treatment fidelity, and most assessed changes in the numbers of PECS exchanges and initiations of communication. Meta-analysis showed small to moderate effects of the efficacy of PECS on communication-related outcomes in the short term. Evidence for maintenance and generalization of effects was limited. Results related to speech outcomes were variable across group and single subject studies. The review assessed the quality of studies using scales adapted from guidelines from Horner{, #6087} and Wolf{, #6088} for single subject studies and Gersten{, #6086} for group designs. Four studies received a quality rating of strong, 4 of adequate, and 2 of inadequate. Studies were typically limited by their measurement and reporting of treatment fidelity, generalization, and social validity.

Parr's review of medical and behavioral treatments{, #4992} included studies with at least 20 participants with ASD and reports benefits, harms, and a brief assessment of a study's quality by intervention. Based on "very low quality evidence," EIBI was reported as potentially improving IQ and adaptive behavior; the More than Words training was reported as potentially yielding improved communication outcomes compared to participants with delayed access to the training; TEACCH was reported as potentially improving psycho-educational scores compared to usual care. PECS was reported as of unknown effectiveness compared to other or no treatment at increasing speech frequency or communication scores, but the review notes consensus surrounding its benefit in children with ASD based on very low quality evidence.

Based on "low quality evidence," GFCF diets were reported to potentially improve autistic trait scores compared to no dietary advice and MPH was seen as modestly reducing hyperactivity compared to placebo. Based on "moderate quality" evidence, Child's Talk was reported as potentially yielding gains in social interactions and language outcomes compared to existing care alone; risperidone was reported as more effective in reducing problem behaviors compared to placebo and secretin as apparently not more effective in treating autism symptoms compared to placebo.

Interventions for which no "clinically important results from RCTs, quasi-randomised trials, or cohort studies" were found included the Autism Preschool Program, CBT, the Earlybird Program, DIR/Floortime, portage, RDI, social skills training, social stories, the Son-Rise program, music therapy, facilitated communication, digestive enzymes, omega-3 fish oil, probiotics, vitamin A, vitamin B6 plus magnesium, vitamin C, melatonin, immunoglobulins, memantine, SSRIs, olanzapine, auditory or sensory integration, and chelation. Harms noted by the review included appetite and weight changes; sleep difficulties, including drowsiness and trouble sleeping; tremors; and prolactin elevation. The review also reports that chelation is under careful review given deaths of some children receiving edetate disodium. The review evaluated quality of studies using the GRADE system; overall, four studies were considered very low quality, two were considered low quality, and three were considered moderate quality.

Reviews assessing early behavioral interventions included between 9 and 22 studies and including participants ranging in age from 30 months to four to five years. Among included studies, the Cohen et al. non-randomized controlled trial{, #546} and the Smith et al. RCT{, #1264} were addressed in all the reviews; the Sallows et al. RCT{, #647} and Eikeseth and colleagues' 2002 RCT{, #1117} were included in 4 reviews. Studies addressed in three reviews included Magiati's 2007 study,{, #288} Sheinkopf's 1998 retrospective study,{, #1378}, Bibby and colleagues 2002 study,{, #1065} Eikeseth's 2007 study,{, #328} and Howard's 2005 study.{, #734} Nine studies were reported in two reviews, and 15 studies were reported in at least one review.

The review from Rogers and Vismara{, #3763}included early intervention studies published between 1998 and 2006 and employing either group design or single subject design with more than three subjects. The investigators assessed the quality of the 22 studies meeting their inclusion criteria using the Nathan and Gorman{, #6012}and Chambless et al.{, #6013} classifications and categorized 4 studies as Type 1, with a randomized design, clear reporting of methods, state-of –the-art diagnosis, and treatment fidelity measures. Six studies met criteria as Type 2, comparative studies without "critical design flaws," and eleven were considered Type 3, studies with significant methodological flaws including lacking a control groups or retrospective design. The investigators categorized one study designed as an RCT but which presented no outcome data as Type 6, defined as case reports. The investigators also described potential mediators and moderators of outcomes, noting that studies addressed pretreatment IQ, intake age, treatment intensity, family characteristics, social variables including social avoidance, and biological variables including physical anomalies and head circumference, among others. Overall the review notes that existing studies, though flawed, suggest that early intervention, particularly at younger ages, may yield gains in language and communication and increases in IQ.

The evidence report from the Blue Cross Blue Shield Association Technology Evaluation Center (TEC){, #3} drew similar conclusions about the weak quality and consistency of the 16 early intervention studies included. The review included group and single arm studies but excluded single subject designs and those reporting on interventions delivered for less than 20 hours/week. The review reports insufficient evidence to judge the effectiveness of EIBI approaches compared to other alternatives. The investigators also examined potential predictors of treatment success, finding that age and cognitive functioning had been examined as predictors in four studies; results were variable with three of four studies reporting that cognitive functioning at intake significantly predicted outcomes, and some studies finding that younger intake age predicted better outcomes. Investigations of the effects of treatment intensity were similarly mixed.

A review and meta-analysis from Spreckley et al.{, #4990} included 13 group design studies, of which only six were considered were considered higher quality according to the Physiotherapy Evidence Database (PEDro) Scale and only four contained data adequate for meta-analysis. The analysis pooled cognitive, expressive and receptive language, and adaptive results and noted no significant improvement for early intervention approaches compared to standard care across these outcomes. Meta-analyses from Reichow and Wolery{, #3640} and Eldevik et al.{, #4988}included 14 and 9 studies, respectively, and noted significant effects for early intervention on cognitive outcomes. Reichow{, #3640} also assessed methodological quality and group assignment as moderators of IQ effects but found no statistically significant relation. Among treatment and participant variables (e.g. intensity, provider characteristics, intake IQ, etc.) examined as moderators of effects, only provider/supervisor training showed a significant relationship to IQ change (p=0.01). The investigators also reported the possibility of publication bias, with funnel plots suggesting the absence of two studies which, if included, would reduce mean effect size. Eldevik{, #4988} aimed to replicate and extend the Reichow analysis and included only studies with comparison or control groups and full scale measures of intelligence, noting significant effects on IQ and adaptive behavior. No publication bias was found.

Most of the reviews generally concluded that the evidence base for EIBI is inadequate, noting variability in treatment and intervention, limited follow-up, lack of comparative studies, need for replication, and unclear inclusion and exclusion criteria.{, #4990;, #3;, #3763} Meta-analyses from Reichow{, #3640} and Eldevik,{, #4988} reported more positive results, noting strong evidence for EIBI's effects in some children.{, #4988;, #3640} Eldevik's meta analysis of 9 studies found an average large effect size for IQ change (1.103, 95 percent CI [CI=.871, 1.335]) and medium effect size for change on the VABS composite score (.660, 95 percent CI [CI=.41, .90]). The meta-analysis from Reichow and Wolery,{, #3640} including studies exclusively based on Lovaas' treatment manuals or replicating the UCLA/Lovaas model and computing mean effect size based on change in the EIBI group only, also reported a large effect size of .69 for IQ change and mean difference effect sizes suggesting greater gains for children receiving

EIBI compared to those receiving minimal behavioral intervention, usual treatment, or eclectic treatment. Each of these reviews, however, notes significant concerns about the included studies, such as limited accounting for the effects of maturity, lack of equivalent groups, uncertain treatment fidelity, and small sample sizes. Several authors also noted the need for studies comparing EIBI to other approaches that have been similarly empirically tested.

Across all the reviews, areas noted for improvement in the literature included the need for more RCTs, though investigators acknowledge the difficulty of conducting RCTs with interventions of such complexity and ethical issues of withholding treatment for comparison purposes. Other areas for improvement noted included a need for larger sample sizes; longer follow-up to allow for evaluation of the durability of effects; greater treatment fidelity; improved reporting of methodological and participant characteristics; and greater consistency in treatment approaches and outcomes measurement.

In terms of the quality of the reviews themselves, we considered the reviews described here to be of generally good quality, though some elements of reporting were spotty across reviews. For example, only two reviews{, #4994;, #4990} explicitly reported author conflicts of interest, though, for example, investigators in one meta-analysis were authors of papers included in the analysis. Use of an *a priori* design was not always clearly stated though generally implied, and we considered review designs *a priori* if a standardized approach appeared to be employed. Similarly, methods for reviewing abstracts and the full papers of studies were not always clearly described (e.g. use of dual reviewers), and six out of 10 reviews provided a complete (ample enough to likely permit replication) description of search terminology.{, #4990;, #4991;, #4994;, #6084;, #6085;, #3} The reviews typically fully described inclusion/exclusion criteria and characteristics of studies included. Reviews generally stated elements used to evaluate study quality and/or cited quality instruments and, overall, seem to make conclusions warranted by the evidence. Meta-analyses appear to be appropriately conducted; however, they are limited by the heterogeneity of interventions and outcomes assessed in the included studies.

Our discussion of recent reviews is limited by our exclusion of reviews including studies with participants over age 18; several comprehensive and rigorously conducted reviews, such as the National Autism Center's 2009 National Standards report,{Center, 2009 #5988} Ospina and colleagues review of behavioral and developmental interventions{, #4993} and Seida and colleagues umbrella review of psychosocial interventions{, #4987} are not addressed here.

Our findings in the current review are largely in line with the findings of reviews included here; some evidence points to the effectiveness of early intervention approaches and communication interventions such as PECS, but evidence is lacking for many approaches.

Table G1. Characteristics of recent systematic reviews

Author, year Country COI noted	Interventions assessed	N studies	N participants	Quality assessment	Publication bias assessed
Flippin (2010) US Not stated	PECS	10	178	Horner et al. (2005), Wolf (1978), Gersten et al. (2005)	Not stated
Mulloy (2010) US	Gluten Free Casein Free diets	14	188	Simeonsson and	Not stated

Yes—no disclosures to make	Bailey (1991)

Table G1. Characteristics of recent systematic reviews (continued)

Author, year Country COI noted	Interventions assessed	N studies	N participants	Quality assessment	Publication bias assessed
Eldevik (2009) Norway Not stated	EIBI intervention as described by Green et al. (2002)	9	153 in EIBI groups; 105 in control groups ; 39 in comparison groups	Nathan and Gorman (2002)	Yes
Parr (2009) UK Not stated	Early intensive multidisciplinary approaches, dietary interventions, drug treatments, allied health, CAM	14	612	GRADE	Not stated
Reichow (2009) US Not stated	Interventions replicating UCLA Young Autism Program	14	373	Assessed elements of research design, tx fidelity	Yes
Rogers (2008) US Yes—no disclosures to make	Behavioral/psycho -social interventions; Lovaas replications	22	431	Nathan and Gorman (2002); Chambless, criteria	Not stated
Spreckley (2008) Australia Yes—no disclosures to make	Applied behavioral intervention approaches to behavioral management	13	101 included in the 4 studies used in meta-analysis	Physiotherapy Evidence Database (PEDro) scale of quality assessment	Not stated
TEC report (2009) US Not stated	EIBI approaches	16	~518	US Preventive Service Task Force, Carey and Boden (2003)	Not stated

Table G1. Characteristics of recent systematic reviews (continued)

Author, year Country COI noted	Interventions assessed	N studies	N participants	Quality assessment	Publication bias assessed
Schlosser (2008) US Not stated	AAC interventions as defined by the American Speech Language Hearing Association, 2002 (e.g., PECS, RPMT, speech generating devices)	11	27 (single subject); 98 (group)	Simeonsson and Bailey (1991)	Not stated
Millward (2008) UK Yes—one author noted as parent of child with ASD	Gluten Free-Casein Free diets	2	35	Cochrane methods	Not stated

AAC- augmentative and alternative communication; ASD-autism spectrum disorders; EIBI-early intensive behavioral intervention; PECS-Picture Exchange Communication System; RPMT- Responsive Education and Prelinguistic Milieu Teaching; tx-treatment

APPENDIX H. Quality of the Literature

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Adams 2009{, #5813;, #5727}	+	-	+	N	-	-	-	-	+	-	+	+	-	+	-	-	-	+	+	+	+	+	N	N	+	+	+	+	+	-	P
Akhondzadeh 2004{, #857}	+	+	+	+	-	-	-	+	-	+	+	+	N	+	N	-	-	+	+	+	+	+	+	N	-	N	N	+	+	-	F
Akhondzadeh 2008{, #250}	+	+	+	+	-	-	-	+	-	-	+	+	N	+	N	-	+	+	+	+	+	+	+	+	N	N	N	-	-	-	F
Akhondzadeh 2010{, #5879}	+	+	+	+	-	-	-	+	-	-	+	N	N	+	N	-	-	+	+	+	+	+	+	N	-	N	N	+	-	-	F
Aldred 2004{, #803}	+	+	+	+	-	-	+	-	-	+	+	+	N	+	-	-	-	+	+	+	+	+	+	N	-	N	N	+	+	-	F
Allam 2008{, #170}	+	+	+	+	-	+	-	-	-	-	+	+	N	+	-	-	+	+	+	+	+	+	+	N	-	N	N	-	-	-	F

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Aman 2009{, #5657}	+	+	+	-	-	+	-	-	-	+	+	+	-	+	+	+	+	+	+	+	-	+	+	N	-	N	N	+	+	-	F
Anan 2008{, #2542}	-	-	-	N	-	-	-	+	-	+	+	+	-	+	-	-	-	+	+	+	-	-	N	N	-	-	N	+	+	-	P
Andersen 2008{, #192}	-	-	-	N	-	-	-	+	-	-	+	+	N	+	N	-	+	-	+	+	-	+	N	N	N	+	+	+	+	+	P
Arick 2003{, #2853}	-	-	-	N	-	-	-	-	+	+	+	-	N	-	+	-	-	+	+	+	-	+	N	N	-	-	N	+	+	-	P
Baker-Ericzen 2007{, #2629}	-	-	-	N	-	-	-	+	-	-	-	+	+	+	-	-	-	+	+	+	-	+	N	N	+	+	+	+	+	-	P
Bass 2009{, #5609}	+	+	+	-	-	-	-	+	-	+	-	+	-	+	-	-	-	+	+	+	-	-	-	N	-	N	N	+	+	-	P
Bauminger 2006{, #422}	-	N	-	N	-	+	-	-	-	+	+	+	+	+	-	-	-	+	+	+	+	+	N	N	-	N	N	-	+	-	F

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Bauminger 2006{, #423}	-	N	-	N	-	+	-	-	-	+	+	+	N	+	-	-	-	+	+	+	+	+	N	N	-	N	N	-	+	-	F
Beaumont 2008{, #125}	+	+	+	-	-	-	+	-	-	+	+	+	N	+	+	-	-	+	+	+	-	-	-	N	-	N	N	+	+	+	P
Beglinger 2005{, #670}	-	-	-	N	-	+	-	-	-	+	+	+	+	+	-	-	-	+	+	+	-	+	N	N	-	N	N	+	+	-	F
Ben-Itzchak 2007{, #538}	-	-	-	N	+	-	-	-	-	+	+	+	N	-	-	-	-	+	+	+	-	+	N	N	-	N	N	-	+	-	P
Bibby 2002{, #1065}	-	-	-	N	-	-	-	-	+	+	+	+	-	+	-	-	+	+	+	+	-	-	N	N	-	+	+	+	+	+	P
Boyd 2001{, #1121}	-	-	-	N	-	-	-	+	-	+	+	+	-	+	-	-	-	+	+	+	-	-	N	N	N	-	N	+	+	-	P
Carmody 2001{, #1226}	-	-	-	N	-	-	-	-	+	-	-	N	N	+	-	+	-	+	+	+	-	-	N	N	-	-	-	-	-	-	P

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Carr 2008, 2007{, #165;, #462}	+	+	+	-	-	-	-	-	+	+	+	+	N	+	-	-	-	+	+	+	-	+	+	N	N	N	N	-	+	-	P
Chalfant 2006{, #387}	+	+	+	-	-	-	-	-	+	+	+	+	+	+	-	-	-	+	+	+	-	-	-	N	-	N	N	+	+	-	P
Chan 2009{, #5606}	+	+	+	-	-	-	-	-	+	+	-	+	N	+	-	+	-	-	+	+	-	-	-	N	-	N	N	+	+	-	P
Chez 2000{, #1271}	-	-	-	N	-	-	-	+	-	+	-	+	N	+	N	+	+	+	+	+	-	-	N	N	+	-	N	+	+	-	P
Chez 2002{, #988}	+	+	+	+	-	-	-	+	-	+	+	+	N	+	N	-	-	+	+	+	+	+	+	N	+	N	N	+	+	-	F
Chez 2003{, #2844}	+	+	+	-	-	-	-	+	-	+	+	+	+	+	N	-	+	+	+	+	+	-	-	N	-	N	N	+	+	-	F
Chez 2004{, #850}	-	-	-	-	-	-	-	+	-	+	-	+	N	+	N	-	+	+	+	+	-	+	-	N	-	N	N	+	+	-	P

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Coben 2007{, #2636}	+	-	+	N	-	-	-	-	+	-	-	+	N	+	-	-	+	+	+	+	-	+	N	N	+	+	+	+	+	-	P
Cohen 2006{, #546}	+	-	+	N	-	-	+	-	-	+	+	+	+	+	-	-	-	+	+	+	-	+	N	N	-	N	N	-	+	+	F
Coniglio 2001{, #1201}	+	+	+	-	-	-	-	+	-	+	+	+	+	+	N	+	+	+	+	+	+	-	-	-	-	N	N	+	+	-	F
Corbett 2007{, #297}	+	+	+	-	-	+	-	-	-	+	+	-	N	+	-	-	-	+	+	+	+	-	N	-	N	N	N	-	-	-	F
Correia 2009{, #6120}	-	N	-	N	-	-	+	-	-	+	+	+	-	+	N	-	-	+	+	+	-	-	N	N	-	+	+	+	+	-	P
Cotugno 2009{, #5071}	+	-	-	N	-	-	-	+	-	+	+	+	N	+	-	-	-	+	+	+	-	-	N	N	-	+	+	+	+	-	F
Dawson 2010{, #5715}	+	+	+	+	+	-	-	-	-	+	+	+	-	+	+	+	+	+	+	+	-	-	-	N	-	N	N	+	+	-	G

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Delong 2002{, #1020}	-	-	-	N	-	-	+	-	-	-	+	+	N	+	N	-	-	-	-	+	-	-	N	N	-	-	N	-	-	-	P
Dillenburger 2004{, #2797}	-	-	-	N	-	-	-	-	+	-	-	+	-	-	-	-	-	-	+	+	-	-	N	N	N	-	N	+	+	-	P
Dosman 2007{, #347}	-	N	-	N	-	-	+	-	-	-	+	+	-	+	-	+	-	+	+	+	-	+	N	N	N	+	+	+	+	-	P
Drew 2002{, #997}	+	+	+	+	-	-	-	-	+	+	+	+	N	+	-	-	+	+	+	+	-	+	+	N	-	N	N	+	+	-	F
Dunn-Geier 2000{, #1232}	+	+	+	+	-	-	+	-	-	+	+	+	N	+	N	+	+	+	+	+	+	-	+	+	-	N	N	+	+	-	F
Eikeseth 2002, 2007{, #1117;, #328}	+	-	+	N	-	-	-	-	+	+	+	+	-	+	-	+	-	+	+	+	+	+	N	N	-	N	N	+	+	+	F

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Eikeseth 2009 & Hayward 2009{, #5680;, #3630}	+	-	-	N	-	-	-	-	+	+	+	+	+	+	+	+	-	+	+	+	+	+	N	N	-	+	+	+	+	-	F
Eldevik 2006{, #588}	+	-	+	N	-	-	-	-	+	+	+	+	-	+	-	-	-	+	+	+	-	-	N	N	-	-	N	+	+	+	P
Escalona 2001{, #1120}	+	+	+	-	-	-	-	-	+	+	-	+	N	+	N	-	-	+	+	+	-	+	+	N	-	N	N	+	+	-	P
Escalona 2002{, #4810}	+	+	+	-	-	-	-	+	-	+	-	+	N	+	+	-	-	+	+	+	-	+	+	N	-	N	N	-	-	-	P
Evangeliou 2003{, #970}	-	-	-	N	-	-	-	-	+	-	-	+	-	+	-	-	+	+	+	+	-	+	N	N	N	N	N	-	-	+	P
Farrell 2005{, #4808}	+	-	+	N	-	-	-	-	+	-	-	+	-	+	-	-	-	+	+	+	-	-	N	N	-	-	N	+	+	-	P

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Fazlioglu 2008{, #118}	+	+	+	+	-	-	-	+	-	-	+	+	N	+	-	-	-	+	+	+	-	+	+	N	N	N	N	-	-	-	P
Field 2001{, #1135}	+	+	+	-	-	-	-	+	-	+	-	+	N	+	-	-	-	+	+	+	-	+	+	N	-	N	N	-	-	-	P
Frankel 2010{, #5826}	+	+	+	+	-	-	+	-	-	+	+	+	-	+	+	-	-	+	+	+	-	-	-	N	-	N	N	+	+	-	F
Gabriels 2001{, #1122;, #3842}	-	-	-	N	-	+	-	-	-	+	+	+	-	-	-	-	+	+	+	+	-	+	N	+	-	+	+	+	+	+	P
Gevers 2006{, #569}	-	-	-	N	-	-	-	+	-	-	-	N	N	-	-	-	-	+	+	+	-	-	N	N	-	-	N	+	+	-	P
Golan 2010{, #5892}	+	+	+	-	-	-	-	-	+	+	+	+	-	+	+	+	-	+	+	+	-	-	-	N	+	N	N	+	+	-	P
Granpeesheh 2009{, #5717}	-	N	-	N	-	-	-	-	+	+	+	N	N	+	-	-	-	+	+	+	-	-	N	N	N	-	N	-	-	-	P

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Green 2010{, #6090}	+	+	+	+	-	-	+	-	-	+	+	+	+	+	+	+	+	+	+	+	+	-	+	N	-	N	N	+	+	-	F
Greenberg 2008{, #3784}	-	N	-	N	-	-	-	-	+	-	-	N	N	+	+	-	-	+	+	+	-	-	N	N	N	-	N	+	+	-	P
Grey 2005{, #664}	-	-	-	N	-	-	-	-	+	-	-	+	N	-	-	-	-	-	+	+	-	+	N	N	-	N	N	+	+	-	P
Gulsrud 2007{, #2578}	+	+	+	-	-	-	+	-	-	+	+	+	+	+	+	-	-	+	+	+	-	-	-	N	-	N	N	-	+	-	P
Gulsrud 2010{, #5893}	-	-	-	N	-	-	+	-	-	+	+	+	-	+	-	-	-	+	+	+	+	+	N	N	+	+	+	+	-	-	F
Gutstein 2007{, #246}	-	N	-	N	-	-	+	-	-	+	+	N	-	+	-	-	+	+	+	+	-	+	N	N	-	+	+	+	+	+	P
Handen 2009{, #4350}	+	+	+	+	-	+	-	-	-	-	+	+	-	+	N	+	+	+	+	+	+	+	+	+	-	N	N	+	+	-	G

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Harris 2000{, #1270}	-	-	-	N	-	-	-	-	+	+	+	+	N	+	-	-	-	+	-	+	-	+	N	N	N	+	+	+	+	+	P
Hartshorn 2001{, #3016}	+	-	+	N	-	-	-	-	+	-	-	+	N	+	-	-	-	+	+	+	-	+	N	N	-	N	N	-	+	-	P
Heimann 2006{, #2677}	+	+	+	-	-	-	-	-	+	+	-	+	N	+	-	-	-	+	+	+	-	+	+	N	-	N	N	-	-	-	P
Henry 2006{, #578}	-	-	-	N	-	-	-	+	-	-	+	N	N	+	N	-	-	+	+	+	-	+	N	N	N	N	N	-	-	-	P
Hollander 2005{, #777}	+	+	+	-	+	-	-	-	-	+	+	+	-	+	N	-	+	+	+	+	+	+	+	N	-	N	N	+	+	-	F
Howard 2005{, #734}	+	-	+	N	-	-	-	+	-	+	+	+	-	+	-	-	-	+	+	+	-	+	N	N	-	+	+	-	+	-	F
Howlin 2007{, #312}	+	+	+	+	-	-	-	+	-	-	+	+	-	+	-	-	-	+	+	+	-	+	+	+	-	N	N	-	+	-	P

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Itzchak 2008{, #252}	+	-	-	-	+	-	-	-	-	+	-	+	-	-	-	-	-	+	+	+	-	-	N	N	N	-	N	-	-	-	P
Itzchak 2009{, #3844}	-	N	-	N	+	-	-	-	-	+	-	+	N	+	-	-	-	+	+	+	-	+	N	N	-	+	+	+	+	-	P
Jarusiewicz 2002{, #2953}	+	+	+	N	-	-	-	-	+	-	-	+	-	+	N	-	-	+	+	+	-	+	-	N	-	N	N	+	+	-	P
Jung 2006{, #2698;, #4951}	+	-	-	N	-	-	-	+	-	+	-	+	N	+	-	-	-	+	+	+	-	-	N	N	-	-	N	-	-	-	P
Kasari 2006, 2008{, #540;, #184}	+	+	+	-	-	-	+	-	-	+	+	+	-	+	+	+	+	+	+	+	+	-	-	N	-	N	N	+	+	+	F
Keen 2007{, #383}	-	N	-	N	-	-	-	+	-	-	-	+	N	-	-	-	-	-	+	+	-	+	N	N	-	N	N	-	+	-	P

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Kern 2001{, #1208}	+	+	+	-	-	-	-	+	-	+	+	+	-	+	N	-	+	+	+	+	+	-	-	-	-	N	N	+	+	-	F
Kim 2008, 2009{, #106;, #4314}	+	+	+	-	-	-	+	-	-	-	-	+	-	+	-	-	-	+	+	+	+	-	-	N	-	N	N	+	+	-	P
King 2001{, #1192}	+	+	+	-	+	-	-	-	-	+	+	+	N	+	N	-	+	+	+	+	+	+	+	N	-	N	N	+	+	-	F
King 2009{, #4321}	+	+	+	+	+	-	-	-	-	+	+	+	-	+	N	+	+	+	+	+	+	+	+	+	-	N	N	+	-	-	G
Kroeger 2007{, #3901}	+	-	+	-	-	-	-	-	+	+	+	+	-	+	-	-	-	+	+	+	+	-	-	N	-	N	N	-	-	-	P
Laud 2009{, #5744}	-	N	-	N	-	-	-	-	+	-	+	+	-	+	-	-	-	+	+	+	-	-	N	N	-	-	N	+	+	+	P
Legoff 2006{, #5558}	+	-	+	N	-	-	-	-	+	+	+	N	N	-	-	-	+	+	+	+	-	+	N	N	-	+	+	+	+	-	P

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Levy 2003{, #942}	+	+	+	+	-	-	-	-	+	+	+	+	+	+	N	+	-	+	+	+	+	-	-	-	-	N	N	+	+	-	F
Lopata 2006{, #2697;, #216}	-	-	-	N	-	-	-	-	+	-	+	+	N	+	+	+	-	+	+	+	-	-	N	N	-	-	N	+	+	-	P
Lopata 2008{, #216;, #2697}	+	+	+	-	-	-	-	+	-	+	+	+	N	+	+	-	-	+	+	+	+	+	+	N	-	N	N	+	+	-	F
Ludlow 2006{, #5711}	-	-	-	N	-	-	-	-	+	+	-	+	N	+	-	-	-	+	+	+	-	+	N	N	-	+	+	-	-	-	P
Ludlow 2008{, #3710}	-	N	-	N	-	-	-	-	+	-	-	+	N	+	-	-	-	+	+	+	-	-	N	N	-	-	N	-	+	-	P
Luiselli 2000{, #3024}	-	-	-	N	-	-	-	-	+	-	-		N	+	-	-	-	+	+	+	-	+	N	N	+	+	+	-	+	-	P

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Magiati 2003{, #916}	-	-	-	N	-	-	-	-	+	+	+	-	N	+	-	-	+	+	+	+	-	+	N	N	+	N	N	-	+	-	P
Magiati 2007{, #288}	+	-	+	N	-	-	-	-	+	+	+	+	N	+	-	-	+	+	+	+	-	+	N	-	-	+	+	-	+	+	F
Mahoney 2005{, #719}	-	-	-	N	-	-	-	+	-	+	-	+	N	+	-	+	-	+	+	+	-	+	N	N	-	N	N	-	+	-	P
Marcus 2009{, #5687}	+	+	+	+	-	+	-	-	-	-	+	+	-	+	N	+	+	+	+	+	+	+	+	N	-	N	N	+	+	-	G
Masi 2003{, #891}	-	-	-	N	-	-	+	-	-	+	+	+	-	+	N	-	-	+	+	+	-	+	N	N	+	N	N	+	-	-	P
McConachie 2005{, #651}	+	-	+	N	-	-	+	-	-	+	+	+	N	+	+	+	+	+	+	+	+	+	N	N	-	N	N	-	+	+	F
Meguid 2008{, #107}	+	-	-	N	-	-	+	-	-	-	+	+	N	+	-	-	+	+	+	+	-	+	N	N	-	N	N	+	+	-	P

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Molloy 2002{, #995}	+	+	+	-	-	-	-	+	-	+	+	+	-	+	N	-	-	+	+	+	+	+	+	+	-	N	N	+	+	-	F
Moore 2000{, #1253}	+	+	+	-	-	-	-	-	+	-	-	+	N	+	+	+	-	+	+	+	-	+	+	N	N	N	N	-	+	-	P
Mousain-Bosc 2006{, #508}	-	-	-	N	-	-	-	+	-	-	-	+	N	+	N	-	+	+	+	+	-	+	N	N	-	N	N	-	-	-	P
Mudford 2000{, #1228}	+	-	-	N	-	-	+	-	-	+	-	+	-	+	-	-	-	+	+	+	+	+	N	N	-	N	N	+	+	+	F
Mukaddes 2004{, #855}	-	-	-	N	-	-	-	+	-	-	-	+	N	+	-	-	-	+	+	+	-	+	N	N	-	N	N	-	+	-	P
Munasinghe 2010{, #5843}	+	+	+	+	-	-	-	+	-	-	+	+	-	+	N	+	+	+	+	+	+	-	-	+	-	N	N	+	+	-	F
Nagaraj 2006{, #475}	+	+	+	+	-	-	-	+	-	+	+	+	-	+	N	-	+	+	+	+	+	-	-	N	-	N	N	+	+	-	F

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Nickels 2008{, #130}	-	N	-	N	-	-	-	+	-	-	+	N	N	+	-	-	-	-	+	+	-	+	N	N	N	+	+	+	+	N	P
Osborne 2008{, #224}	+	-	+	N	-	-	-	-	+	+	+	+	N	+	-	-	-	+	+	+	+	+	N	N	-	+	+	-	+	-	F
Owen 2009{, #5714}	+	+	+	+	-	+	-	-	-	-	+	+	-	+	N	+	+	+	+	+	+	+	+	N	-	N	N	+	+	-	G
Owens 2008{, #116}	+	+	+	-	-	-	-	-	+	+	+	+	-	+	-	-	+	+	+	+	-	-	-	N	-	N	N	+	+	-	P
Owley 2001{, #1142}	+	+	+	+	+	-	-	-	-	+	+	+	N	+	N	+	+	+	+	+	+	+	+	+	-	N	N	+	+	-	G
Owley 2010{, #5841}	-	-	-	N	+	-	-	-	-	+	+	+	-	+	N	-	+	+	+	+	-	+	N	N	N	+	+	+	+	-	F
Pan 2010{, #6030}	-	N	-	N	-	-	-	+	-	-	+	N	N	+	-	+	+	+	+	+	-	-	N	N	+	-	N	+	+	-	P

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Panerai 2009{, #4343}	+	-	+	N	-	+	-	-	-	+	+	+	N	+	-	-	-	+	+	+	+	-	N	N	-	-	N	+	+	-	G
Perry 2008{, #3668}	-	N	-	N	-	-	-	+	-	+	+	N	N	+	-	-	-	+	+	+	-	+	N	N	-	+	+	+	+	-	P
Piravej 2009{, #6031}	+	+	+	+	-	-	-	+	-	-	+	-	-	+	-	+	-	+	+	+	-	-	-	N	-	N	N	+	+	-	P
Posey 2004{, #821}	-	-	-	N	-	-	-	+	-	+	+	N	N	+	N	+	+	+	+	+	-	-	N	N	-	-	N	+	+	N	P
Probst 2008{, #158}	-	-	-	N	-	-	-	+	-	+	+	+	N	+	-	-	-	+	+	+	-	-	N	N	-	-	N	-	+	-	P
Quirmbach 2009{, #84}	+	+	+	-	-	-	-	+	-	+	+	+	N	+	-	-	-	+	+	+	+	+	+	N	-	N	N	+	+	-	F
Reaven 2009{, #3650}	+	-	+	N	-	-	-	+	-	+	+	+	-	+	+	+	+	+	+	+	-	-	N	N	-	N	N	+	+	-	F

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Reed 2006{, #381}	+	-	+	N	-	-	-	-	+	+	+	+	N	+	-	-	+	+	+	+	+	-	N	N	-	-	N	-	+	-	F
Reed 2007{, #3887}	+	-	+	N	-	-	-	-	+	+	+	+	-	+	-	-	-	+	+	+	-	+	N	N	-	+	+	+	+	-	F
Reed 2009{, #5066}	-	N	-	N	-	-	-	+	-	+	+	+	-	+	-	-	+	+	+	+	-	-	N	N	-	-	N	+	+	-	P
Reed 2010{, #5899}	+	-	+	N	-	-	-	-	+	+	+	+	N	+	-	+	+	+	+	+	-	+	N	N	-	+	+	+	+	-	F
Remington 2007{, #240}	+	-	+	N	-	-	-	-	+	+	+	-	N	-	-	-	-	+	+	+	-	-	N	N	-	+	+	-	+	-	P
Rickards 2001{, #278}	+	+	+	+	+	-	-	-	-	+	+	+	-	+	-	-	-	+	+	+	+	-	-	N	-	N	N	-	-	+	G
Roberts 2001{, #1199}	+	+	+	+	+	-	-	-	-	+	+	+	-	+	N	+	+	+	+	+	+	-	-	-	+	N	N	+	+	-	G

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Rossignol 2009{, #4}	+	+	+	+	+	-	-	-	-	+	+	+	+	+	+	-	+	+	+	+	+	+	+	N	-	N	N	+	+	-	G
RUPP 2002{, #1051;, #610;, #704;, #892;, #564;, #539;, #108;, #838;, #691}	+	+	+	+	-	+	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	N	-	N	N	-	-	-	G
RUPP 2005; Posey 2007; Jahromi 2009{, #635;, #363;, #3615}	+	+	+	+	-	+	-	-	-	+	+	+	-	+	N	-	+	+	+	+	+	+	+	N	-	N	N	+	+	-	F

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
RUPP 2005{, #5725}	-	N	-	N	-	+	-	-	-	+	+	+	-	+	+	+	+	+	+	+	+	-	N	N	-	-	N	+	+	-	G
Sallows 2005{, #647}	+	+	+	+	-	+	-	-	-	+	+	+	-	+	+	+	+	+	+	+	+	-	-	N	-	N	N	+	+	+	G
Salt 2002{, #1094}	+	-	+	N	-	-	-	-	+	+	-	+	-	+	-	+	-	+	+	+	-	-	N	N	-	-	N	+	+	-	P
Sams 2006{, #532}	+	-	-	N	-	-	-	-	+	-	-	+	N	+	-	-	-	+	+	+	-	-	N	N	N	-	N	-	+	-	P
Shea 2004; Pandina 2007{, #799;, #458}	+	+	+	-	-	-	+	-	-	+	+	+	-	+	N	+	+	+	+	+	+	+	+	N	-	N	N	+	+	-	F
Silva 2007{, #302}	+	+	+	-	-	-	-	+	-	+	+	+	-	+	-	-	+	+	+	+	+	-	-	N	-	N	N	-	+	-	F

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Silva 2008{, #58}	-	N	-	N	-	-	-	-	+	-	+	+	N	+	+	+	-	+	+	+	-	-	N	N	-	-	N	-	+	-	P
Silva 2009{, #5051}	+	+	+	-	-	-	-	-	+	-	-	+	-	+	+	-	+	+	+	+	-	-	-	N	+	N	N	+	+	+	P
Smith 2000{, #1264}	+	+	+	-	-	-	-	-	+	+	+	+	N	+	+	+	-	+	+	+	+	+	+	N	+	N	N	+	+	-	F
Sofronoff 2002{, #1039}	+	-	+	N	-	-	-	+	-	-	-	-	N	+	-	-	-	+	+	+	-	-	N	N	+	-	N	+	+	-	P
Sofronoff 2003{, #5832}	+	+	+	-	-	-	-	-	+	-	-	+	N	+	+	-	-	-	+	+	-	+	+	N	N	N	N	+	+	-	P
Sofronoff 2004{, #814}	+	+	+	-	-	-	-	-	+	-	-	+	N	+	-	-	-	-	+	+	-	+	+	N	-	N	N	+	+	-	P
Sofronoff 2005{, #644}	+	+	+	-	-	-	+	-	-	+	+	+	+	+	+	-	-	+	+	+	+	-	-	N	+	N	N	+	+	-	F

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Sofronoff 2007{, #417}	+	+	+	-	-	-	+	-	-	+	+	+	N	+	+	+	-	+	+	+	-	+	+	N	-	N	N	+	+	-	F
Solomon 2004{, #756}	+	+	+	-	+	-	-	-	-	+	+	+	N	+	-	-	-	+	+	+	-	+	+	N	-	N	N	+	+	-	F
Solomon 2007{, #3950}	-	N	-	N	-	-	-	+	-	-	+	+	-	+	+	-	-	+	+	+	+	-	N	N	-	-	N	+	+	-	P
Solomon 2008{, #150}	+	+	+	-	+	-	-	-	-	+	+	+	N	+	+	+	-	+	+	+	-	+	N	N	-	N	N	+	+	-	F
Stahmer 2001{, #2999}	+	-	+	N	-	-	-	-	+	+	-	+	N	+	-	+	-	+	+	+	+	+	N	N	-	-	N	+	+	-	P
Stahmer 2004{, #4234}	-	N	-	N	-	-	+	-	-	+	+	+	N	+	-	-	+	+	+	+	-	-	N	N	-	-	N	+	+	-	P
Stigler 2004{, #845}	-	-	-	N	-	-	-	+	-	-	+	N	N	+	N	-	-	+	+	+	-	+	N	N	-	N	N	+	+	-	P

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Tjus 2001{, #1141}	-	-	-	N	-	-	-	-	+	+	-	+	N	+	-	+	-	+	+	+	-	+	N	N	-	+	+	-	+	-	P
Tsang 2006{, #491}	+	-	-	N	-	-	-	+	-	+	+	+	N	+	-	-	-	-	+	+	-	+	N	N	-	N	N	-	+	-	F
Tyminski 2008{, #2539}	-	-	-	N	-	-	-	+	-	-	+	+	-	+	-	+	-	+	+	+	-	+	N	N	-	+	+	+	+	-	P
Unis 2002{, #1024}	+	+	+	-	-	+	-	-	-	+	+	+	-	+	N	-	-	+	+	+	+	-	-	-	-	N	N	+	+	-	F
Vismara 2009{, #5767}	-	N	-	N	-	+	-	-	-	+	+	+	-	+	+	+	-	+	+	+	-	-	N	N	-	-	N	+	+	-	P
Vorgraft 2007{, #245}	-	-	-	N	-	-	-	+	-	-	+	N	N	+	-	-	-	+	+	+	-	-	N	N	+	-	N	+	+	-	P
Wetherby 2006{, #4027}	-	N	-	N	-	+	-	-	-	+	+	+	N	+	+	-	-	+	+	+	-	-	N	N	-	-	N	+	+	-	P

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Whalen 2010{, #6122}	+	+	+	-	-	-	-	-	+	+	+	+	N	+	-	-	-	+	+	+	-	-	+	N	-	N	N	-	+	-	P
Whitaker 2004{, #4176}	-	N	-	N	-	-	-	-	+	+	-	+	N	+	-	-	-	+	+	+	-	-	N	N	N	-	N	-	+	-	P
Whittingham 2009{, #3592;, #3631}	+	+	+	+	-	-	-	+	-	+	-	+	-	+	-	-	-	+	+	+	-	+	+	N	+	N	N	+	+	+	P
Wong 2007{, #3875}	-	-	-	N	-	-	-	+	-	+	+	+	N	+	+	-	-	+	+	+	-	+	N	N	-	+	+	-	+	-	P
Wood 2009{, #3618;, #5523}	+	+	+	+	-	-	+	-	-	+	+	+	-	+	-	-	+	+	+	+	+	+	+	N	-	N	N	+	+	+	F

Study	Group design	Random assignment	Appropriate comparison	RCT: Correct randomization	DSM-IV + ADI-R + ADOS	DSM-IV + ADOS or ADI-R	[DSM-IV + other] or [ADOS + other]	Only DSM-IV or only ADOS	Neither DSM-IV nor ADOS	Sample clearly characterized	Inclusion/Exclusion criteria stated	Reported attrition	Drop-out evaluated for differences	Intervention fully described	Treatment fidelity monitored	Reported adherence	Held steady concomitant interventions	Reliability & validity of measures	Prim. & sec. measures specified	Data collected from approp. sources	Coded by blinded individuals	Appropriate statistical analysis	Intent-to-treat analysis	Power calculation provided	Corrected for multiple testing	Confounders & modifiers captured	Confounders & modifiers handled	Outcomes measured outside tx setting	Outcomes measured in natural environ.	Follow-up at least 3 mos post-tx	Final Score
Yoder 2006, 2009{, #516;, #487;, #5719;, #408}	+	+	+	+	+	-	-	-	-	+	+	+	N	+	+	+	-	+	+	+	+	+	+	N	-	N	N	+	+	-	G
Zachor 2007{, #5652}	+	-	+	N	-	+	-	-	-	+	-	+	N	+	-	-	-	+	+	+	-	+	N	N	-	+	+	-	-	-	F

+ = Yes, - = No or Not Reported, and N = Not applicable
G = Good, F = Fair, and P = Poor

APPENDIX I. Applicability Summary Tables

Behavioral

Early intensive behavioral and developmental interventions: UCLA/Lovaas-based interventions

Domain	Description of applicability of evidence
Population	Studies typically included preschool children (i.e. children from 2-7), baseline cognitive/language and adaptive behavior scores typically falling within the impaired range, but often included children with more intact early cognitive/language skills. Populations generally reflect IQ, language, and adaptive behavior characteristics of preschool children with ASD in the community.
Intervention	Early intensive behavioral intervention (EIBI) approaches ranged in terms scope [i.e., applied behavioral analysis-based (ABA) methods/techniques included] as well as intensity (i.e., from 10-40 hours).
Comparators	Comparators included eclectic interventions, parent-directed EIBI, and varying levels of intensity (e.g. hours of treatment, intensity of supervision of treatment given by parents or treatment given in clinic); comparative interventions were often heterogeneous and may not have employed standardized manuals/protocols.
Outcomes	Studies commonly assessed IQ, language, and adaptive behavior outcomes after approximately 9-months to three years of intervention. Follow-up over the course of years and inclusion of broader adaptive indices for evaluation (i.e., school functioning/placement) suggests that certain cognitive/language and educational gains may be durable. It is less clear that adaptive behavior skills see similar patterns of improvement. Participant groups in many studies included children with ranges of skills which makes group based differences difficult to interpret, particularly as early IQ was found to potentially be a greater predictor of response to intervention.
Setting	Studies were conducted in the US, UK, Norway, and Israel in clinic, school/community, and home settings. Participants were often allocated to early intervention treatment vs. eclectic/community-available treatments based on geography (i.e. location relative to clinic), availability of service, or combined parent and educational system choice.

Early intensive behavioral and developmental interventions: Parent training in social communication

Domain	Description of applicability of evidence compared to question
Population	Studies included preschool-aged children.
Intervention	Parent training interventions included components aimed at social communication including joint attention behaviors, play-based interactions, and pragmatic language approaches; interventions were conducted for approximately 1-4 hours/week with parents asked to introduce learned techniques within natural settings. This approach aligns with several current approaches to ASD treatment.
Comparators	Comparative interventions included eclectic/community-available approaches which may not have employed standardized manuals/protocols.

Early intensive behavioral and developmental interventions: Parent training in social communication (continued)

Domain	Description of applicability of evidence compared to question
Outcomes	Studies assessed language and social outcomes after 12 months of intervention. While some language/communication skills improved with intervention, with lower functioning children at baseline generally showing greater improvement.
Setting	Studies were conducted in clinics in the UK. Participants were recruited from the community and randomly allocated to parent training or locally/community-available treatment.

Early intensive behavioral and developmental interventions: ESDM

Domain	Description of applicability of evidence
Population	Limited studies of Early Start Denver Model (ESDM) have been published to date (i.e., one RCT, one case series). These studies have focused on younger preschool aged children (i.e. mean of 2 years of age), Baseline cognitive/language and adaptive behavior scores fell within the impaired range and are generally reflective of characteristics of preschool children with ASD in the community.
Intervention	The ESDM approach focused on delivering approximately 15 hours of service per week with parents providing substantial intervention at other times. The intervention involves supplying ABA-based intervention within developmentally appropriate patterns of activity for young children.
Comparators	Comparators included eclectic community intervention and intensity/type of supervision provided.
Outcomes	Children demonstrated cognitive, language, and adaptive behavior improvements relative to comparison group over two-years, although adaptive behavior skill improvement appears less robust. The impact of such intervention on core autism symptoms also appears unclear.
Setting	Studies were conducted in the US in home and center/school settings.

Social skills

Domain	Description of applicability of evidence
Population	Most studies of social skills interventions targeted elementary school aged children (between 6 and 13 years old). Only one study targeted younger children (4 to 6 years old). Most of the studies of social skills interventions also excluded children with IQs below 60 (reported mean IQs for these studies ranged from 95 to 119), and 6 of the studies targeted children with high functioning ASD or who were diagnosed with Asperger disorder. Therefore this evidence may not be applicable to children below 6 years old or children with very low cognitive functioning.
Intervention	Interventions in this category were mostly implemented in a small group format. 4 studies looked at interventions that ran concurrent parent training in addition to the small groups for the children. Only 3 studies assessed interventions implemented at an individual level. Very few studies followed a manualized intervention or reported fidelity data.
Comparators	The most common comparison group used was a wait-list control group, however almost half the studies in this category did not have a comparison group.
Outcomes	The most common outcomes used were parental reports of children’s social behaviors. Few studies included direct observation measures of peer interactions in naturalistic settings.

Social skills (continued)

Domain	Description of applicability of evidence
Setting	Most of the social skills interventions were implemented in a clinic setting. Three studies were conducted with interventions in school setting.

Interventions targeting commonly associated conditions

Domain	Description of applicability of evidence
Population	As a whole, studies of interventions targeting commonly associated conditions typically targeted older and higher functioning children, with mean ages ranging from 7-9 in studies of parent training and from 9-11 in studies of cognitive behavioral therapy-based (CBT) interventions; several studies only accepted children with Asperger Disorder and/or excluded for intellectual disabilities.
Intervention	Interventions in this category included individual-based and group-based cognitive behavioral therapy, parent trainings, and teacher trainings, targeting commonly associated conditions including anxiety, anger management, and problem behaviors.
Comparators	Comparison groups in studies of interventions targeting commonly associated conditions most often were waiting list control groups; in the case of parent trainings, several studies compared the same training material presented in multiple formats to each other, as well as to a waiting list control.
Outcomes	Studies of interventions targeting commonly associated conditions measured outcomes including anxiety symptoms, problem behaviors, and anger management, most often using parent and/or teacher report rather than direct assessment or observation.
Setting	Most interventions took place in the clinic setting, with two in the school setting; no studies took place in the home.

Play-/interaction-based - Joint Attention

Domain	Description of applicability of evidence
Population	The majority of the children in these studies was 3-4 years old and diagnosed with autism.
Intervention	The majority of these interventions consisted of a combination of adult-directed behavioral drill (i.e., discrete trial training) and child-directed milieu teaching approach. The child-directed training incorporated ABA and developmental procedures of responsive and interactive methods in a tabletop structured context. One study also included a generalization test of joint attention skills to novel stimuli. These approaches align with several current approaches to ASD treatment.
Comparators	All of these studies compared joint attention interventions to symbolic play interventions, and one included a control group.
Outcomes	The most frequently reported outcomes were those related to joint attention and symbolic play skills. These were most often assessed pre- and post-intervention but one study also included a 6- and 12-month follow up.
Setting	These studies all took place in center-based early intervention programs in the US and likely reflect

Play-/interaction-based - Imitation

Domain	Description of applicability of evidence
Population	The majority of the children included were ages 3 through 6, all of whom were nonverbal and diagnosed with autism or ASD.
Intervention	The primary intervention was adult imitation of the child’s behavior. This approach aligns with current approaches to ASD treatment.

Play-/interaction-based – Imitation (continued)

Domain	Description of applicability of evidence
Comparators	All of these studies used contingent responsiveness as the comparison treatment. Contingently responsive behavior refers to the adult responding to the child's initiations by either commenting back or gesturing within the play context.
Outcomes	The outcomes most frequently assessed were social behaviors (e.g, proximity to adult, looking at adult, touching adult). These outcomes were assessed pre- and post-intervention only.
Setting	These studies were conducted in clinics located in the US and Norway.

Play-/interaction-based - Parent-focused

Domain	Description of applicability of evidence
Population	Children in these studies were diagnosed with ASD and had behavior problems; participants were between the ages of 2 and 12.
Intervention	These interventions generally consisted of ABA-based behavior management strategies taught to and led by parents; these approaches align with several approaches currently used to treat ASD in children.
Comparators	The comparison group was a wait-list control group for both studies.
Outcomes	The most frequent outcome assessed was problem behavior. Both studies included a pre- and post-intervention assessment, and one also conducted a 6-month follow-up.
Setting	These interventions were conducted in clinics in the US and Australia.

Educational

Broad-based approaches

Domain	Description of applicability of evidence
Population	Studies typically included younger preschool children (i.e. children from 2-6), with baseline cognitive/language and autism severity scores typically falling within the impaired range. Populations generally reflect IQ, language, and adaptive behavior characteristics of preschool children with ASD in the community.
Intervention	Approaches included variants of early intensive behavioral and developmental intervention approaches ranging in terms of scope (i.e., applied behavioral analysis-based (ABA) methods/techniques included) as well as intensity (i.e., hours of intervention/week) and eclectic, school- or center-based approaches which employed elements of special nursery, special education, parent training, portage, etc.
Comparators	Comparators included ABA-based approaches compared to eclectic interventions and varying levels of intensity or combinations of center- and home-based treatment; comparative interventions were often heterogeneous and may not have employed standardized manuals/protocols.
Outcomes	Studies commonly assessed developmental functioning, language, ASD severity, and adaptive behavior outcomes with some improvements noted across groups. Few studies assessed longer term outcomes. On study with follow-up at 12 months post-intervention suggests that cognitive gains were sustained while behavioral improvements were not.
Setting	Studies were conducted in the US, UK, and Australia in school/center and home settings. Some participants were allocated to early intervention treatment vs. eclectic/community-available treatments based on geography (i.e. location relative to clinic), availability of service, or combined parent and educational system choice.