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Behavioral Counseling to Promote Physical Activity and a Healthful Diet to Prevent Cardiovascular Disease in Adults: Update of the Evidence for the U.S. Preventive Services Task Force

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Structured Abstract

Purpose: We conducted this systematic evidence review of trials of physical activity and/or dietary counseling to prevent cardiovascular disease (CVD) to assist the U.S. Preventive Services Task Force (USPSTF) in updating its 2002 and 2003 recommendations on counseling to improve physical activity and diet, respectively.

Data Sources: We searched MEDLINE, PsycInfo, and the Cochrane Central Register of Controlled Trials 2001–2009 to locate relevant trials for all key questions published since the previous reviews were conducted. We supplemented our searches with suggestions from experts and reference lists from other publications, including the prior USPSTF reviews and other relevant systematic reviews.

Study Selection: Two investigators independently reviewed 13,562 abstracts and 474 articles against a set of *a priori* inclusion criteria, and also independently critically appraised each study using design-specific quality criteria based on USPSTF methods. Discrepancies were resolved by consensus. In total, 109 articles representing 73 unique studies were included.

Data Extraction and Analysis: One investigator abstracted data from included studies into evidence tables and a second reviewer checked these data. We conducted meta-analyses on 58 trials that provided necessary data to estimate the effect size of counseling on both intermediate health outcomes (adiposity, systolic and diastolic blood pressure, total cholesterol, high-density lipoproteins [HDLs], low-density lipoproteins [LDLs], triglycerides, and glucose) and behavioral outcomes (self-reported physical activity; fitness; intake of total energy, fat, saturated fat, fiber, fruits and vegetables; and urinary sodium as a measure of sodium intake).

Data Synthesis: *Key Question 1: Do healthful diet and/or physical activity interventions improve CVD health outcomes in adults?* One large, good-quality trial evaluating an intensive healthful diet counseling intervention showed no difference in the incidence of coronary heart disease or stroke over a mean of 8 years followup. Observational followup of two hypertension prevention trials evaluating intensive sodium reduction counseling showed a decrease in the incidence of CVD outcomes over 10 to 15 years of followup.

Key Question 2: Do healthful diet and/or physical activity interventions improve intermediate outcomes associated with CVD in adults? Medium- (31 to 360 minutes) to high-intensity (>360 minutes) dietary interventions (with or without concomitant physical activity counseling) decreased body mass index (BMI) approximately 0.3 to 0.7 kg/m^2 at 12 months. The largest reduction in blood pressures occurred in three intensive salt-restriction counseling interventions in persons with mildly elevated diastolic blood pressure, resulting in approximately 1.8 mmHg lower systolic blood pressure and 1.1 mmHg lower diastolic blood pressure at 12 months. Medium- and high-intensity diet and lifestyle interventions decreased systolic blood pressure by 0.9 to 1.4 mmHg and diastolic blood pressure by 0.7 mmHg. Medium- and high-intensity diet and combined lifestyle counseling decreased total cholesterol and LDL. When stratified by intervention intensity, however, this decrease was only significant among the six high-intensity counseling interventions with a reduction in total cholesterol of 0.17 mmol/L (6.56 mg/dL) and

LDL by 0.13 mmol/L (5.02 mg/dL). Overall, few trials provided followup longer than 12 months.

Key Question 3: Do healthful diet and/or physical activity interventions change associated health behaviors in adults? Medium- to high-intensity counseling interventions improved self-reported dietary intake of salt, energy, fats, and fruits and vegetables and self-reported physical activity. The medium-intensity physical activity counseling interventions in this review resulted in an approximately 38-minute increase in physical activity per week. Diet and combined lifestyle counseling interventions decreased total fat and saturated fat intake and increased fruit and vegetable consumption. Although there was significant statistical heterogeneity across interventions, there appeared to be an increasing effect size with intervention intensity. Among low-intensity interventions, there was an approximate 1.5 percent decrease in energy intake from fats; for medium-intensity counseling there was an approximate 3.0 to 4.9 percent decrease in energy intake from fats; and for high-intensity interventions there was an approximate 5.9 to 11 percent decrease in energy intake from total fat. Saturated fat intake was reported less frequently, but effects were generally consistent with the magnitude of effect seen with total fat intake. Counseling interventions increased fruit and vegetable intake by approximately 0.4 to 2 servings per day.

Key Question 4: What are the adverse effects of healthful diet and/or physical activity interventions? We found no studies designed to assess the adverse effects of dietary counseling and none of the included healthful diet counseling trials reported specific adverse events. Two physical activity counseling trials reported common findings of mild muscular fatigue, strain, or soreness. Seven comparative observational studies showed that the risk of a cardiac event is increased during vigorous exertion, with a range of 2- to 17-fold increases in risk.

Limitations: In addition to the large statistical heterogeneity limiting confidence in the pooled estimates of effect sizes for some outcomes, other limitations included: there were only 10 trials with followup beyond 12 months, the fact that most trials relied on self-reported behavioral outcomes subject to bias, potential bias due to including only published data, and possible selective reporting of outcomes.

Conclusions: Medium- to high-intensity dietary behavioral counseling resulted in small but statistically significant changes in adiposity, blood pressure, and cholesterol, as well as medium to large changes in self-reported dietary and physical activity behaviors. Evidence for changes in physiologic outcomes was strongest for high-intensity counseling interventions. Medium- to high-intensity physical activity counseling resulted in increases in self-reported physical activity. However, there was limited evidence for maintenance of behavioral or physiologic effects beyond 12 months. Most trials of high-intensity interventions that had followup beyond 12 months showed persistent beneficial changes in adiposity and lipids, as well as improvements in self-reported behavioral outcomes.

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Chapter 1. Introduction

Scope and Purpose

In 2002 and 2003, the U.S. Preventive Services Task Force (USPSTF) made recommendations on counseling to improve physical activity and healthful diet based on two separate systematic reviews of the literature. We undertook the current review to assist the USPSTF in updating these recommendations. This review combined both topics and evaluates the effectiveness and adverse effects of physical activity and dietary counseling interventions to prevent cardiovascular disease (CVD) in adults. In addition, this review focuses on the effectiveness of behavioral counseling as primary prevention for CVD and therefore does not include counseling interventions targeted to persons with known CVD, diabetes, hypertension, or dyslipidemia. Trials focusing on weight loss or weight management in adults are addressed in a separate USPSTF review on adult obesity, which is currently being updated.

Background

Condition Definition

Physical activity has been defined as "bodily movement produced by the contraction of skeletal muscle that increases energy expenditure above the basal level."[1] This review operationalized this definition to include interventions promoting aerobic- or strength-related physical activity. We did not review interventions focusing primarily on flexibility or balance.

A healthful diet promotes health and reduces risk of chronic disease through nutritious eating patterns. For this review, we considered dietary counseling that promoted a balanced diet (e.g., appropriate energy content); balance of fats (e.g., consumption of mono- and polyunsaturated fats, omega-3 fats, avoidance of excess saturated fat, avoidance of trans fats); increased consumption of fruits and vegetables; increased consumption of legumes; increased consumption of lean proteins; increased consumption of non- or low-fat dairy; diet balanced in carbohydrates (e.g., consumption of whole grain and fiber, avoidance of excess refined carbohydrates, including excess sweetened beverages); and avoidance of excess sodium. We did not review dietary counseling that focused only on micronutrient intake, vitamin and/or antioxidant supplementation, or alcohol moderation.

Burden of Disease

Diseases associated with physical inactivity and poor diet rank among the leading causes of illness and death in the United States,[2,3] and are well established determinants in many chronic diseases, including cardiovascular and cerebrovascular disease, hypertension, dyslipidemia, and type 2 diabetes.[2,4-6]

Convincing evidence suggests that regular physical activity decreases CVD risk[5,6] and numerous studies have shown an inverse relationship between exercise and heart disease mortality.[6,7] Similarly, regular exercise increases high-density lipoprotein (HDL) cholesterol and decreases triglycerides, blood pressure, and risk of CVD events.[6] Studies have also shown that diet clearly affects cardiovascular health. Diets high in fruits and vegetables can decrease CVD.[5] Evidence

also suggests that saturated and trans fatty acids increase CVD while linoleic acid, fish oils, plant sterols and stanols, alpha-linolenic acid, oleic acid, and nuts decrease CVD.[5] Likewise, there is convincing evidence that high sodium intake increases high blood pressure, while potassium can decrease blood pressure.[5]

Available evidence strongly suggests that regular physical activity decreases an individual's risk for type 2 diabetes,[5,6] likely through improving insulin sensitivity and reduced total and abdominal adiposity.[4] Similarly, excess energy intake increases obesity, which may increase the risk for type 2 diabetes. While there is little evidence that total carbohydrate intake is associated with diabetes, high glycemic index of a diet may be a risk factor.[4] Evidence also suggests that saturated fatty acids can increase the risk for type 2 diabetes, while a high intake of fruits, vegetables, and dietary fiber can decrease type 2 diabetes risk.[5]

Prevalence of Physical Activity and Healthful Dietary Behaviors

The U.S. Department of Health and Human Services' (DHHS) 2008 report on physical activity concluded that individuals of all ages benefit from regular exercise, and that substantial health benefits can be obtained from moderate-to-vigorous physical activity. Moderate physical activity is defined as 3.0 to 5.9 metabolic equivalent units (METs) (e.g., walking at a pace of 3 miles per hour).[6] Vigorous physical activity is defined as 6.0 METs or greater (e.g., walking uphill at a pace of 3.5 miles per hour).[6] According to the DHHS Physical Activity Guidelines, adults should engage in at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity aerobic physical activity per week (or an equivalent combination of moderate- and vigorous-intensity aerobic activity) to obtain substantial health benefits, in addition to strengthening activities at least twice per week. The American College of Sports Medicine, the American Heart Association (AHA), and the Centers for Disease Control and Prevention (CDC) have issued very similar guidelines.[8-10] However, Americans generally do not meet these physical activity guidelines. According to the Healthy People 2010 midcourse review,[11] 39 percent of Americans aged 18 years or older reported no leisure time physical activity, while 31 percent met the Healthy People 2010 objectives for moderate or vigorous exercise during 2006. Physical activity declines with age: 38 percent of 18- to 24-year-olds reported regular moderate or vigorous physical activity, while only 29 percent of 45- to 64-year-olds reported this level of activity. Rates were even lower in older adults: 26 percent of 65- to 74-year-olds and 17 percent of persons aged 75 or older reported moderate or vigorous physical activity.

In light of the significant impact diet and nutrition have on health, multiple national and international agencies have developed guidelines for dietary intake of macronutrients, including the Institute of Medicine (IOM), World Health Organization (WHO), DHHS, U.S. Department of Agriculture (USDA), American Dietetic Association, CDC, AHA, American Cancer Society (ACS), and American Diabetes Association (ADA). Although there are subtle differences among these groups' recommendations, they all generally recommended higher consumption of fruits, vegetables, polyunsaturated and monounsaturated fatty acids, fish, whole grains, and fiber. These recommendations also include lower consumption of fat, saturated fatty acids, sodium, and refined sugars. The 2005 Dietary Guidelines for Americans, for example, recommend five to 13 daily servings of fruits and vegetables, depending on caloric needs.[12] It also recommends a diet that acquires less than 10 percent of its total calories from saturated fat, less than 20 to 35 percent from total fat, and a limited amount of trans fatty acids. However, most Americans' diets are drastically out of line with these recommended levels. In 2005, the USDA reported that based on

the Dietary Guidelines for Americans recommendations, Americans over-consumed refined grains, sugars, meats, and fats, and under-consumed whole grains and fruits and vegetables.[13] Data from the 2005 Behavioral Risk Factor Surveillance System indicates that only 33 percent of adults consumed at least two servings of fruits and only 27 percent consumed at least three daily servings of vegetables.[14]

Risk Factors for Poor Diet and Low Physical Activity

People of lower socioeconomic status tend to exercise less and eat fewer fruits, vegetables, and foods rich in dietary fiber, compared with people in a higher socioeconomic position.[15,16] Major barriers to a healthful diet include low income, marketing of unhealthy foods, lack of accessible and accurate information on what constitutes a healthful diet, poor access to affordable healthy foods, lack of opportunity to develop healthy cooking skills, and sociocultural factors (e.g., family or cultural food norms, family resistance, lack of support, and childcare demands).[17] Major barriers to physical activity in adults include the high costs of exercise facilities, equipment, and sports teams; poor access to facilities; unsafe environments for physical activity; and urban designs that discourage walking.[15,18,19] Psychosocial barriers to physical activity include anxiety about unfamiliar settings for physical activity, poor body image, lack of social support for physical activity, low self-efficacy for maintaining a physical activity program, and lack of belief in the benefits of physical activity.[15]

Current Clinical Practice

Although patients perceive family doctors as one of the most reliable sources of information on food and nutrition, data on dietary counseling practices of primary care clinicians indicate that providers pay limited attention to diet modification.[20] In a 1999–2000 survey of U.S. adults, only 33 percent of respondents reported that their physician had advised them to eat more fruits and vegetables during the previous year, and 29 percent reported receiving similar advice to reduce dietary fat.[21] In another recent survey, 25 percent of adult patients from four community-based, family medicine clinics indicated that their physicians had advised them to limit or reduce the amount of fat in their diets.[22] Similarly, 28 percent of respondents to a national household survey reported that their health care provider had advised them to increase their level of physical activity. Only half of those receiving advice, however, also received help in developing physical activity program or followup support.[21]Data from Canada are consistent with these findings: 38 percent of adults reported "often" or "always" receiving advice from their physicians on diet or healthful eating.[23] This survey also reported that 42 percent of respondents received advice on physical activity "often" or "always."

Previous USPSTF Recommendations

In 2002, the USPSTF concluded that there was insufficient evidence to recommend for or against behavioral counseling in primary care settings to promote physical activity **(I recommendation)**. Data included in the 2002 physical activity counseling review[24] were limited to trials conducted, at least in part, by primary care staff. Thus, trials in which research staff conducted the intervention were excluded, even if they were conducted in primary care settings using methods that were feasible for use in primary care.

Available data on the feasibility and potential harms of routine physical activity counseling in primary care settings were also limited in the 2002 review. Only the Activity Counseling Trial

reported rates of physical harm during the 2 years following counseling.[25] Based on this paucity of data, the USPSTF concluded that the balance of benefits and harms, as well as approaches to preventing adverse effects (particularly among older adults and those less fit), needed further exploration.

In 2003, the USPSTF concluded that there was insufficient evidence to recommend for or against routine behavioral counseling to promote a healthful diet in unselected patients in primary care **(I recommendation)**. In addition, the Task Force recommended intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. This intensive counseling could be delivered by primary care clinicians or referral to other specialists, such as nutritionists or dietitians **(B recommendation)**.

The prior evidence review on dietary counseling found that counseling patients can improve dietary behaviors, including reduction in total and saturated fat consumption and increases in fruit and vegetable intake.[26] The previous review found insufficient evidence to determine the effectiveness of counseling in changing consumption of whole grains, fiber, calcium, sodium, or fish. The strength of this evidence was also limited by reliance on self-reported dietary outcomes, limited followup, and enrollment of participants who were not necessarily representative of primary care patients. Intensive interventions were more likely to produce important changes, but lower-intensity interventions did result in smaller positive changes in dietary behavior. Although the largest effect of dietary counseling in asymptomatic adults has been observed with more intensive interventions among patients with risk factors for diet-related chronic disease, it is unknown whether similar approaches are effective among unselected adults. Additionally, because there was little direct evidence regarding the effect of dietary changes on health outcomes, it is unclear if small changes in dietary behavior seen in lower-intensity trials translate into changes in the incidence of chronic disease.

Chapter 2. Methods

The previous USPSTF reviews addressing behavioral counseling for physical activity and healthful diet were independently conducted in 2002[24] and 2003.[26] After consulting with the USPSTF liaisons, we decided to coordinate the update of these two topics due to the significant overlap in literature and their similar implications for clinical practice. This decision also allowed us to review the body of literature that addressed combined physical activity and healthful diet counseling, which was not thoroughly addressed in the previous reviews. To accomplish this, we developed an analytic framework and four key questions (Figure 1) to guide our review. We present the results for each of the key questions according to the intervention's target (i.e., physical activity, healthful diet, or combined physical activity and healthful diet, referred to as combined lifestyle). We reviewed the literature on health outcomes (key question 1 [KQ1]), intermediate outcomes (key question 2 [KQ2]), and harms of the counseling interventions (key question 4 [KQ4]), as opposed to the previous reviews' focus on only behavioral outcomes (key question 3 [KQ3]). Other important differences between these reviews include:

1. For dietary interventions, behavioral outcomes could include: appropriate energy content, balance of fats, increased fruits and vegetables, increased legumes and lean proteins, increased fiber, increased non- or low-fat dairy, balance of carbohydrates, and reduced sodium. The previous dietary counseling review was limited to interventions that primarily focused on fat, fruits and vegetables, and dietary fiber intake.
2. Primary care-relevant counseling interventions that included both diet and physical activity counseling were included. The previous healthy diet review was limited to trials focusing primarily on diet.
3. Both randomized and nonrandomized controlled trial evidence will be included on counseling interventions to improve diet. The previous healthful diet review included only randomized controlled trials, and the previous physical activity review accepted observational designs in addition to controlled trials.
4. The current review included trials that were feasible for primary care or referable from primary care, and did not require that a primary care clinician be directly involved in the intervention delivery. Interventions included in the previous physical activity review were limited to studies in which at least one component was delivered by a primary care clinician.

Data Sources and Searches

In addition to evaluating all trials included in the previous reviews, we searched for systematic reviews from January 2001 through July 2008 in MEDLINE, the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, and publications from IOM, Agency for Healthcare Research and Quality (AHRQ), and National Institute of Health and Clinical Excellence (Appendix B Table 2) to locate trials that were excluded from the prior reviews because they did not report a behavioral outcome. In addition, we searched (Appendix B) MEDLINE, PsycInfo, and the Cochrane Central Register of Controlled Trials to locate

relevant trials for all key questions published since the previous reviews were conducted from January 2001 through the end of 2009. We supplemented our searches with suggestions from experts and a review of reference lists from other relevant publications.

Study Selection

Two investigators independently reviewed 13,562 abstracts and 474 articles (Appendix B Figure 1) against the specified inclusion criteria (Appendix B Table 1). Discrepancies were resolved by consensus. Articles excluded for not meeting inclusion criteria for poor quality are listed in Appendix D Tables 1–5.

The current review targeted behaviorally-based counseling interventions for physical activity, healthful diet, or both. Interventions of primary prevention of obesity, hypertension, hyperlipidemia, diabetes, or CVD were considered to be within scope of this review. Interventions aimed at weight loss were excluded, as were those providing controlled diets or supervised physical activity. We included physical activity interventions that incorporated activities such as walking, cycling, swimming, or resistance training. We included healthful diet interventions aiming to change dietary behavior or improve or maintain cardiovascular health through a balanced diet (e.g., appropriate calorie intake; increased fruits and vegetables, whole grains, and fiber; balanced intake of balanced fats; and decreased sodium).

Study designs were limited to randomized controlled trials or controlled clinical trials comparing an active intervention against a usual-care, a minimal-intervention, or an attention-control group. Studies were considered for key questions addressing efficacy or effectiveness of healthful diet, physical activity, or combined healthy lifestyle counseling (KQ1–KQ3). We also included observational studies reporting serious cardiovascular harms (KQ4), such as acute cardiac events during or immediately after physical activity. Trial participants were limited to unselected adults (i.e., those who were not screened for CVD risk factors) or individuals who were screened and did not meet criteria for hypertension, hyperlipidemia, diabetes, or CVD. We excluded trials in which more than 50 percent of the population had diabetes, hypertension (or using hypertension medications), dyslipidemia (or using dyslipidemia medications), or heart disease. We excluded trials in which the average total cholesterol of participants was >6.21 mmol/L (240 mg/dL), average triglycerides was ≥2.26 mmol/L (200 mg/dL), average LDL was ≥4.14 mmol/L (160 mg/dL), average systolic blood pressure was ≥140 mmHg, or average diastolic blood pressure was ≥90 mmHg. We excluded studies conducted in settings that were not generalizable to primary care, including inpatient care, emergency departments, or occupational settings. We included studies with interventions that were conducted over the phone or electronically. We also included studies that tested interventions that were referable from primary care or considered feasible to conduct within primary care settings (see Appendix B Table 1 for more detail on what is considered primary care-feasible or referable).

We required that duration of followup be 6 months or longer. We examined health outcomes including morbidity or mortality related to CVD. Intermediate health outcomes included blood pressure, total cholesterol, LDL cholesterol, HDL cholesterol, fasting serum glucose, glucose tolerance, hemoglobin A1C, weight, and body mass index (BMI). Consistent with current USPSTF methods, incidence of disease (e.g., diabetes, hypertension) was also considered an intermediate health outcome. We accepted a number of behavioral outcomes, including self-

reported dietary intake, self-reported physical activity, or objectively measured markers of behavior change, such as VO_2max and urinary sodium.

Data Extraction and Quality Assessment

We extracted study setting, population details, intervention details, and outcomes from included studies into standardized evidence tables for each intervention category (Appendix C Tables 1–4). Trials with multiple intervention arms may appear in multiple tables, if appropriate. A second reviewer verified all extracted data.

Articles meeting inclusion criteria were independently critically appraised by two reviewers using the USPSTF's design-specific quality criteria[27] supplemented with the National Institute for Health and Clinical Excellence methodology checklists.[28] Articles were rated as good-, fair-, or poor-quality. In general, a good-quality study met all criteria well. A fair-quality study did not meet, or it was unclear if it met, at least one criterion, but also had no known important limitations that could invalidate its results. A poor-quality study had important limitations. We excluded poor-quality studies from this review.

Data Synthesis and Analysis

We separately synthesized identified evidence for three types of interventions: those focused on increasing physical activity, those focused on eating a healthful diet, and those focused on both physical activity and healthful diet counseling.

We conducted random effects meta-analyses to estimate the effect size of counseling on both intermediate health outcomes (adiposity, systolic and diastolic blood pressure, total cholesterol, HDL, LDL, triglycerides, and glucose) and behavioral outcomes (self-reported physical activity; objectively measured fitness; intake of total energy, fat, saturated fat, fiber, fruits and vegetables; and urinary sodium as a measure of sodium intake). We conducted separate analyses for each of the three intervention categories, and further grouped the dietary trials by intervention target (sodium reduction, fruit and vegetable only focus, or general low-fat/heart-healthy dietary counseling). Analyses were also stratified by intervention intensity. **Low-intensity trials** were estimated to involve 30 minutes or less of contact with providers. These trials generally included only a single contact, two very brief contacts, or mail-only interventions. **Medium-intensity trials** were estimated to involve more than 30 minutes but less than 6 hours of contact with providers (e.g., 1-hour group meeting monthly for up to 6 months). **High-intensity trials** were those that were estimated to involve more than 6 hours of contact. Because many articles did not report detailed information about the time of contact, these categorizations often involved reviewer judgment. As such, at least one other team member reviewed the studies' categorizations, and discrepancies were resolved through discussion. Trials were also categorized by how participants were selected: 1) participants were unselected or selected based on age only; 2) participants were selected for sub-optimal behavior (i.e., sedentary behavior or poor dietary intake); and 3) participants were selected for individual or population risk factor for increased incidence of CVD (e.g., mildly elevated diastolic blood pressure, fasting glucose, serum lipids, increased BMI, poverty or poor access to health care). Details of the meta-analysis and calculations are included in Appendix E. Briefly, we combined intervention arms within trials with multiple active treatment arms meeting our inclusion criteria that were of similar intensity

to calculate standard deviations based on the information provided in the individual articles. We converted measurements into common units using standard conversion factors, which are provided in Appendix E. We also adjusted results for studies that were cluster randomized, but did not report adjusting for the clustering effect.

We assessed the presence of statistical heterogeneity among the studies using standard χ^2 tests and the magnitude of heterogeneity was estimated using the I^2 statistic.[29] With 10 or more studies, we assessed for publication bias and whether the distribution of the effect sizes was symmetric with respect to the precision measure by using funnel plots and Egger's linear regression method.[30,31]

We ran meta-regressions combining all studies included for KQ1–KQ3 (studies reporting treatment efficacy) to examine the effect of four *a priori*-specified primary sources of heterogeneity on effect size: intervention intensity (low, medium, high), intervention target (physical activity, healthful diet, combined lifestyle), study population risk (unselected, selected for behavioral factors, selected for increased cardiovascular risk), and recruitment method (self-identified, such as through media advertisements, vs. study-identified). Two dummy variables were entered for predictors with three levels; reference categories were low intensity, combined lifestyle target, and unselected for risk. In addition, we ran a series of exploratory meta-regressions to examine the effects on effect size of: study design (months of followup, overall methodological quality of the study), year of publication, measurement (type of self-report measure of physical activity, fat intake, and fruit and vegetable intake), degree of estimation (calculation needed to use each study's data in the meta-analysis), setting (United States vs. not United States, whether the sample was selected from primary care or not), and population characteristics (average age, percent male, percent nonwhite, average baseline BMI). To accomplish this, we included a single exploratory factor in each meta-regression model, controlling for the four *a priori* predictors (intensity, target, risk status, and recruitment approach).

All analyses were performed using Stata 10.0 (StataCorp LP, College Station, Texas).

USPSTF Involvement

The authors worked with four USPSTF liaisons at key points throughout the review process to develop and refine the analytic framework and key questions, to address methodological decisions on applicable evidence, and to resolve issues around scope for the final evidence synthesis. This research was funded by AHRQ under a contract to support the work of the USPSTF. AHRQ staff provided oversight for the project, reviewed the draft report, and assisted in external review of the draft evidence synthesis.

Chapter 3. Results

We identified 66 trials reporting the effects of counseling for physical activity, healthful diet, or both. Thirty trials tested the effect of counseling individuals to increase physical activity,[32-76] and 26 of these could be included in the meta-analyses of physical activity counseling.[32-34,36,38,40-42,47,50,52,53,55,56,58-62,64,66,68-70,72,74,75] Twenty-five trials tested the effect of counseling people to eat a healthful diet,[34,35,42,43,47,48,53,77-109] 24 of which could be included in meta-analyses.[42,47,53,77-83,86,87,90-98,101,104,108] Seventeen trials examined the effects of counseling people for both physical activity and healthful diet,[47-49,81,110-132] 15 of which were eligible for inclusion in meta-analyses (Table 1).[47,81,110,112,114,117,119-124,127,130,131] Trials with multiple intervention arms that were applicable to different intervention targets were included in multiple target areas. In addition, seven studies were included to examine the harms of physical activity (Table 1).[133-139]

There was a large variation in the types and intensities in counseling interventions, which ranged from brief single-session counseling to over 20 group sessions over 2 years (Table 2). Twenty-one of the interventions across all three target areas were categorized as low-intensity trials, generally involving a single or two very brief contacts with providers or were limited to mailed or Web-based treatment with little or no direct contact with an intervention provider. These interventions are generally most likely to be feasible for implementation in primary care, and primary care providers played a substantial role in six of these 21 trials. Almost all of the low-intensity trials targeted either physical activity or healthful diet. Only a single trial of combined lifestyle counseling had a low-intensity intervention.[120] Thirty-two of the trials across all three target areas involved medium-intensity interventions. These interventions were quite heterogeneous, and may have involved phone or in-person counseling or both, and sometimes mailed materials as well. The number of phone calls ranged from three to 24 calls, and the number of in-person sessions ranged from one to eight. These interventions were too intensive to conduct in most primary care offices, but primary care providers at least played a role in seven of these trials. In most cases the provider's role was to deliver a brief health promotion message during a primary care visit. Fifteen of the trials across all three target areas included high-intensity interventions. These interventions involved group counseling (range of four to 20 sessions over 1 to 24 months), with or without sporadic maintenance sessions for the trial duration. Only one of these trials involved physical activity counseling alone,[71] the remaining included either healthful diet or combined lifestyle counseling. None of these trials involved the primary care provider.

In addition to the range in intensity of intervention, the distribution of these interventions varied by type of counseling intervention and whom was counseled (i.e., risk of population studied) (Table 2). None of the low-intensity trials were conducted in populations selected for increased risk of CVD. Instead, the healthful diet trials were generally in unselected populations, and the physical activity trials generally targeted people with inadequate levels of physical activity. The medium-intensity combined lifestyle trials were almost all conducted in samples selected for increased risk of CVD, whereas the physical activity trials were primarily conducted in people with inadequate levels of physical activity. The healthful diet trials were roughly evenly divided between being selected for poor diet and for increased CVD risk. The high-intensity healthful diet trials were primarily conducted in samples selected for CVD risk, while most of the combined lifestyle trials were in unselected samples.

Key Question 1. Do primary care-relevant behavioral counseling interventions for healthful diet and/or physical activity improve CVD health outcomes in adults?

We found only three trials evaluating healthful diet counseling that specifically reported CVD-related health outcomes.[106,109] Several trials reported mortality as part of their attrition, but not as a health outcome.[44,71,87,92-94,101,104] In general, there were very few deaths in each trial and mortality was equivalent between the intervention and control groups.

In a very large good-quality trial, the Women's Health Initiative (WHI) Randomized Controlled Dietary Modification Trial (n=48,835), post-menopausal women who were randomly assigned to intensive low-fat dietary counseling had no difference in major coronary heart disease events (hazard ratio [HR], 0.97 [95% CI, 0.90 to 1.06]) or stroke (HR, 1.02 [95% CI, 0.90 to 1.15]) or mortality (HR, 0.98 [95% CI, 0.91 to 1.07]) after approximately 8.1 years of followup, compared with those women who were randomly assigned to the usual-diet group.[105,106] Although this was a good-quality trial, the authors state that the observed incidence rate for major coronary heart disease was 30 percent lower than projected and that the composite CVD outcome in persons without known CVD had a trend towards significance (HR, 0.94 [95% CI, 0.83 to 1.02]).[106] Additionally, authors state that the dietary message focused on overall low-fat message for the primary purpose of breast cancer prevention, but did not include any specific messages about reducing saturated fats.[140]

Two hypertension prevention trials, Trials of Hypertension Prevention (TOHP) I and II, had long-term observation followup for 77 percent of the initial trial participants.[109] In these two trials (n=3,126), pre-hypertensives with mildly elevated diastolic blood pressures who were randomly assigned to intensive sodium restriction counseling had less cardiovascular events and revascularization (n=2,415; HR, 0.70 [95% CI, 0.53 to 0.94]), but no difference in total mortality (n=3,126; HR, 0.80 [95% CI, 0.51 to 1.26]) after 10 to 15 years of followup. A more conservative CVD composite outcome (without revascularization) was not statistically significant, although the point estimate was similar (n=2,415; HR, 0.72 [95% CI, 0.50 to 1.03]). Cumulative incidence of CVD events between intervention and control groups in TOHP I and II appeared to diverge at approximately 8 to 9 years followup.

Key Question 2. Do primary care-relevant behavioral counseling interventions for physical activity and/or healthful diet improve intermediate outcomes associated with CVD (e.g., adiposity, blood pressure, lipids, glucose tolerance) in adults?

Physical Activity

Eight physical activity trials (n=3,731) did not show an impact on adiposity, blood pressure, lipids, or glucose tolerance (Table 3). Seven of eight trials were fair- or good-quality medium-intensity trials.[36,47,50,56,59,62,72] The remaining trial was a low-intensity intervention that found no group differences in BMI at 6 months followup. In addition to the short followup, this trial has limited utility as it used a self-identified (volunteer), male-only sample, and did not examine any other intermediate outcomes.[70] All of these trials were principally conducted in persons selected for sedentary behavior.

Few of the medium-intensity trials found statistically significant between-group differences in intermediate outcomes. All seven medium-intensity trials reported either BMI or weight as a measure of adiposity. Only two of these studies found statistically significant group differences in adiposity,[47,50] and the pooled standardized mean difference (SMD) showed no group differences (-0.09 [95% CI, -0.24 to 0.05]; I^2=72.2%; n=3,490). Six[36,47,50,56,59,72] of the seven medium-intensity trials also reported blood pressure outcomes, with statistically significant effects reported in one study for diastolic blood pressure only.[36] Similarly, six[36,47,50,56,59,72] of the seven medium-intensity studies reported lipid outcomes, but only one[50] reported statistically significant group differences. The participants undergoing a single physician-led group session and one individual counseling session with a health educator reduced their total cholesterol by an average of 0.30 mmol/L after 6 months, compared with an average 0.10 increase among those in the control group (p=0.04). This study, however, did not find group differences in either HDL or LDL cholesterol levels. Also, only one of four trials reporting changes in plasma glucose found a statistically significant group difference, and this was in only one of the two treatment arms in a trial of persons with impaired glucose tolerance.[72] Study participants receiving a pedometer and one 3-hour group session with two brief followup sessions reduced 2-hour fasting glucose by 1.75 mmol/L, compared with a 0.30 mmol/L decline in the control group (p=0.004). The robustness of this result is questionable, however, since the second intervention group, which was not given a pedometer (but otherwise received the same intervention), did not differ from the control group.[72]

Meta-analyses combining data from all eight trials confirmed no effect on intermediate outcomes, with no effect on adiposity (SMD, -0.09 [95% CI, -0.23 to 0.05]; I^2=67.7%; k=8; N=3,555) (Figure 2), systolic blood pressure (weighted mean difference [WMD], -0.57 mmHg [95% CI, -1.89 to 0.74]; I^2=14.0%; k=6; N=2,441) (Figure 3), diastolic blood pressure (WMD, -0.54 mmHg [95% CI, -1.90 to 0.81]; I^2=58.5%; k=5; N=2,354) (Figure 4), lipids (total cholesterol WMD, -0.05mmol/L [95% CI, -0.13 to 0.04]; I^2=23.9%; k=6; N=2,441) (Figure 5), HDLs (WMD, 0.0 [95% CI, -0.04 to 0.03]; I^2=0.0%; k=4; N=1,476) (Figure 6), or LDLs (WMD, -0.02 [95% CI, -0.18 to 0.14]; I^2=31.2%; k=3; N=387) (Figure 7). Thus, while available evidence suggests that counseling interventions of up to 6 hours duration are unlikely to affect intermediate health outcomes after 1 year, most studies did not report intermediate health outcomes. There was no evidence of statistically significant publication bias for any of the intermediate outcomes, based on Egger's test.

Healthful Diet

Trials examining healthful diet counseling were more likely to report intermediate outcomes than trials focused only on physical activity. Of the 25 trials of healthful diet counseling interventions that met our inclusion criteria, 16 reported one or more intermediate health outcomes (e.g., objectively measured weight, blood pressure, cholesterol, and/or glucose tolerance) (Table 4). Three evaluated low-sodium dietary counseling,[87,98,101] one trial evaluated fruits and vegetables only dietary counseling,[90] and 12 trials evaluated general heart-healthy dietary counseling, including low-fat dietary changes.[47,77,78,81,83,91,94-97,104,108]

Low-sodium only dietary counseling. Three fair-to-good-quality trials of high-intensity low-sodium dietary counseling reduced blood pressure in persons with mildly elevated diastolic blood pressure (approximately 80–89 mmHg).[87,98,101] All three trials were conducted in the United States among middle-aged adults. Approximately two thirds of participants were men and

one fifth were nonwhite. Meta-analyses of blood pressure outcomes at 6 to 18 months showed a statistically significant reduction in systolic and diastolic blood pressure of -1.86 mmHg (95% CI, -2.49 to -1.23; I^2=0.0%; k=3; N=2,275) (Figure 8) and -1.05 mmHg (95% CI, -1.55 to -0.54; I^2=0.0%; k=3; N=2,275) (Figure 9), respectively. Reductions in blood pressure were still statistically significant, although slightly attenuated, at up to 36 months.[87,98,101]

These three trials were generally good-quality trials. Although one trial (TOHP I) was considered overall fair-quality because of the lower followup of urinary sodium outcomes, followup for blood pressure outcomes, however, was greater than 90 percent.[98] All three of these trials used a primarily self-identified (volunteer) sample recruited through media or other announcements and involved very intensive counseling, likely over 900 minutes of group counseling, plus ongoing maintenance sessions throughout the study duration.

Fruits and vegetables only dietary counseling. Only one of the three trials evaluating fruits and vegetables dietary counseling reported intermediate outcomes and showed mixed results.[90] This fair-quality trial (n=29) conducted in the United Kingdom evaluated a 25-minute dietary intervention aimed at increasing fruit and vegetable intake for middle-aged adults without chronic diseases. At followup, the intervention group averaged slightly lower systolic (by 4 mmHg [95% CI, 2.0 to 6.0]) and diastolic (by 1.5 mmHg [95% CI, 0.2 to 2.7]) blood pressures than the waitlist control group. However, there were no statistically significant differences in weight or total cholesterol between groups. Although this trial showed a larger effect size than seen in the high-intensity sodium counseling trials, we are not confident that an effect this large could be replicated given that the trial had limitations in its conduct and followup was only 6 months.

Low-fat and general heart-healthy dietary counseling. Nine of the 12 trials evaluating low-fat and general heart-healthy dietary counseling reported weight or BMI as a measure of adiposity, generally demonstrating improvements in adiposity.[47,77,81,83,91,94-96,104] There was a large variation in intervention intensity, which ranged from brief counseling conducted in a single session to high-intensity counseling with up to 20 sessions. Only three of these trials involved low-intensity interventions (i.e., single session or mail-only interventions).[91,94,95] Meta-analyses showed a statistically significant reduction in adiposity, although the statistical heterogeneity was quite high (SMD, -0.30 [95% CI, -0.39 to -0.20]; I^2=78.9%; k=8; N=48,394). Five of these eight trials showed a significant decrease in BMI.[47,83,95,96,104] Stratified meta-analyses by intervention intensity showed statistically significant reductions in adiposity for the medium- and high-intensity counseling interventions. Only two trials were included in the medium-intensity group and a significant amount of heterogeneity remained in the high-intensity counseling trials (I^2=85%) (Figure 10). While included trials were primarily conducted in middle-aged adults, two larger trials were conducted in slightly older, all-female populations with a mean age of about 60 years.[83,104] Both trials showed a statistically significant decrease in BMI at 6 or 12 months.

Six of the 12 trials evaluating low-fat and general heart-healthy dietary counseling reported blood pressure outcomes.[47,83,94-96,104] Meta-analyses pooling blood-pressure outcomes at 6 to 12 months showed a statistically significant reduction in systolic (SMD, -0.88 mmHg [95% CI, -1.67 to -0.08]; I^2=54.2%; k=6; N=48,501) (Figure 11) and diastolic (SMD, -0.72 mmHg [95% CI, -1.29 to -0.16]; I^2=8.1%; k=6; N=48,496) (Figure 12) blood pressure. Statistical heterogeneity appeared to primarily stem from intervention intensity. In stratified meta-analyses, there were statistically significant reductions in systolic and diastolic blood pressures for

medium- and high-intensity interventions, but not for the two low-intensity trials (Figures 11 and 12).[94,95]

Eight of the 12 trials evaluating low-fat and general heart-healthy dietary counseling reported lipids outcomes at 6 to 12 months.[47,77,78,81,94,96,97,104] Meta-analyses showed a statistically significant reduction in total cholesterol (WMD, -0.10 mmol/L [95% CI, -0.17 to -0.02]; I^2=37.6%; k=6; N=1,335) (Figure 13) and LDL cholesterol (WMD, -0.14 mmol/L [95% CI, -0.25 to -0.04]; I^2=33.8%; k=5; N=782) (Figure 14). Again, statistical heterogeneity appears to stem from intervention intensity. There were statistically significant reductions in total cholesterol and LDL for only the two highest-intensity interventions (k=2; N=332).[77,96] There were no statistically significant changes in HDL or triglycerides (Figures 15 and 16).

Only five of the 12 trials evaluating general heart-healthy dietary counseling reported glucose tolerance outcomes.[81,83,96,104,108] Meta-analyses showed a statistically significant reduction in fasting glucose, although statistical heterogeneity was extremely high (WMD, -0.63 mmol/L [95% CI, -1.20 to -0.05]; I^2=98.8%; k=4; N=4,873) (Figure 17). When one outlier trial conducted in Japan was removed, statistical heterogeneity was somewhat reduced, although still substantial (66.7%), and the pooled effect was no longer statistically significant. This fair-quality trial was the only trial conducted in a nonwestern population and included only men with impaired fasting glucose.[108]

The WHI was the largest and best quality study (n=48,835) studying the effects of general low-fat dietary counseling. For this trial, post-menopausal women received 19 counseling sessions aimed at decreasing overall fat consumption and increasing fiber and fruit and vegetable intake to prevent breast cancer and CVD.[104] Although there was a statistically significant difference in change in blood pressure and fasting glucose at 12 months between the intervention and control groups, these differences were no longer statistically significant at 72 months. There were no statistically significant differences in total cholesterol, LDL, or HDL at 12 and 36 months. Change in BMI was the only statistically significant difference at both 12 and 72 months followup (Table 4).

The majority of dietary counseling trials reporting intermediate health outcomes were of fair-quality, and there was significant clinical and statistical heterogeneity. Much, but not all, of this heterogeneity could be attributed to different levels of counseling intensities. However, because intervention intensity generally corresponded with population risk for CVD or how the population was selected for the intervention (e.g., low-intensity interventions were primarily conducted in unselected persons), it is unclear if the heterogeneity was primarily a result of intervention intensity or population CVD risk. In addition, only nine[77,83,87,91,96-98,101,104] of the 16 trials were conducted in the United States, five of which utilized primary care samples.[83,97,98,101,104] Overall, there was no evidence for statistically significant publication bias based on the Egger's test for any of the intermediate outcomes.

Combined Lifestyle

Of the 17 trials of combined lifestyle counseling interventions that met our inclusion criteria, 14 reported intermediate health outcomes of objectively measured weight, blood pressure, cholesterol, and/or glucose tolerance (Table 5). Only two trials were rated as good quality.[124,131] All but one evaluated medium- or high-intensity counseling interventions requiring more than 30 minutes of patient contact, ranging from two to 30 counseling sessions for up to 24 months. Of

these 14 trials reporting intermediate outcomes, seven were conducted in the United States[110,115,120-122,124,127] and five were conducted in unselected adults samples.[110,119,120,124,127]

Thirteen of the 14 trials evaluating lifestyle counseling reported weight or BMI as a measure of adiposity.[47,81,110,112,115,117,119-124,127] Meta-analyses showed a statistically significant reduction in adiposity (SMD, -0.40 [95% CI, -0.62 to -0.18]; k=12; N=3,247), with high statistical heterogeneity (I^2=88%). Six of these 12 trials showed a statistically significant reduction in BMI.[47,81,110,117,119,127] Stratified meta-analyses by intervention intensity (Figure 18) and population risk showed statistically significant reductions in adiposity for both medium- and high-intensity interventions, but statistical heterogeneity remained high within each subset (Figure 18). Longer-term followup from four trials illustrated that statistically significant reductions in BMI persist for up to 54 months.[119,123,124,127]

Twelve of the 14 trials reported blood pressure outcomes.[47,110,112,115,117,119,121-124,127,131] None of these were low-intensity interventions. Meta-analyses showed an average reduction of 1.40 mmHg for systolic blood pressure (95% CI, -2.77 to -0.03; I^2=43.7%; k=10; N=2,592) (Figure 19), but no reduction in diastolic blood pressure (WMD, -0.76 mmHg [95% CI, -1.89 to 0.36]; I^2=58.0%; k=9; N=2,278) (Figure 20). Stratified meta-analysis showed that reductions in systolic blood pressure were only apparent in the high-intensity trials (WMD, -1.87 mmHg [95% CI, -3.24 to -0.50]; I^2=2.7%; k=4; N=1,104). In the three trials (n=850) that reported longer-term followup, changes in systolic blood pressure were no longer statistically significant at 24 and 54 months.[119,124,127]

Thirteen of the 14 trials reported on lipid measures.[47,81,110,112,115,117,119,121-124,127,131] Again, there were no low-intensity interventions. Meta-analyses did not show a statistically significant improvement at 6 to 12 months in total cholesterol (k=11; N=2,637) (Figure 21), LDL (k=10; N=2,312) (Figure 22), HDL (k=11; N=2,634) (Figure 23), or triglycerides (k=9; N=2,110) (Figure 24). Pooled effect sizes for all of these outcomes, however, were very close to being statistically significant when limited to high-intensity trials. In the three trials with longer-term followup, reductions in total cholesterol, LDL, and/or triglycerides were statistically significant at 18 and 54 months.[119,124,127]

Only eight of the 14 trials evaluating combined lifestyle counseling reported glucose tolerance outcome measures.[81,110,112,122-124,127,131] Combined lifestyle counseling did not improve glucose tolerance outcomes (WMD, -0.06 mmol/L [95% CI, -0.11 to 0.00]; I^2=0.0%; k=7; N=1,927) (Figure 25).

The majority of included trials were rated fair quality, and there was significant clinical and statistical heterogeneity amongst the trials. Some of this heterogeneity could be attributed to different levels of counseling intensity or population risk. In addition, only half[110,115,120-122,124,127] of the trials were conducted in the United States, and five studies selected the study population from primary care.[47,112,117,121,122] Overall, there was no evidence for statistically significant publication bias based on the Egger's test for any intermediate outcome.

Exploring Heterogeneity

We conducted meta-regressions examining study characteristics' effects on intermediate health outcomes. These regressions focused on adiposity, blood pressure (systolic and diastolic), and lipids (total cholesterol and LDL) using all data available from the 66 included studies. We ran multivariate models including each of the four primary predictor variables (intervention target,

risk status of the sample, intensity of the intervention, and recruitment strategy) on each of the five outcomes. Intervention intensity and participants' risk group predicted effect size for adiposity and systolic blood pressure. High-intensity interventions were associated with larger than average reductions in adiposity and systolic blood pressure. Paradoxically, medium-intensity interventions had smaller effect sizes than low-intensity interventions on average, although this low-intensity estimate is based on only three trials for this outcome. As such, this result should not be considered robust.

In addition, risk status was a significant predictor of both adiposity and systolic blood pressure. Samples selected for cardiovascular risk or suboptimal behavior showed smaller reductions in adiposity compared with unselected samples. Samples selected for suboptimal behavior showed greater average reductions in systolic blood pressure than other samples. Given the small number of trials in some intensity levels and risk groups, however, these results should be interpreted cautiously.

Further exploratory analyses of additional potential sources of heterogeneity found that the effects on adiposity, systolic and diastolic blood pressure, and total cholesterol were slightly reduced in studies conducted in the United States after adjusting for the four *a priori* predictor variables, compared with those conducted in other countries. More recent publication was associated with reduced average effect sizes for systolic blood pressure, total cholesterol, and LDL. Additionally, percent male, percent nonwhite (among U.S.-based studies only), study quality, and degree of calculation/estimation needed for inclusion in the meta-analysis each predicted one or two intermediate health outcomes. However, due to the exploratory nature of these analyses, the small number of trials in important subgroups, and the number of models run, these effects should be interpreted with great caution. In addition, those exploratory analyses using study-level patient characteristics (i.e., sex, race, and baseline BMI), are vulnerable to ecologic fallacy. Forest plots of meta-analyses combining trials from all three intervention targets and stratified by intervention intensity of the population are provided in Appendix G.

Key Question 3. Do primary care-relevant behavioral counseling interventions for physical activity and/or healthful diet change associated health behaviors in adults?

Physical Activity

Overall, counseling increased participants' physical activity levels, especially in trials that provided at least medium-intensity interventions. All 30 trials of physical-activity interventions meeting our inclusion criteria reported at least one behavioral outcome (Table 6). Eleven of these studies delivered low-intensity interventions,[32,33,38,40,44,52,60,61,66,70,75] 19 delivered medium-intensity interventions,[34,36,41,42,46,47,50,53,55,56,58-60,62,64,68,69,72,74] and one trial delivered a high-intensity intervention.[71] One of these trials included both low- and medium-intensity arms, and, as such, is discussed with each of these bodies of literature.[60] Seven of the included trials were rated as good quality,[36,40,50,58,59,62,64] all but one[40] of which were medium-intensity trials. Nineteen studies recruited from primary care, and an additional three studies recruited from general-risk populations comparable to primary care populations. Sixteen trials were conducted in the United States, [34,38,41,42,52,53,55,60,62,64,66,68,69,71,74,75] nine of which involved primary care populations.[34,38,41,52,62,64,68,69,71] A number of trials focused specifically on middle-aged and/or older adults; seven were limited to adults aged 60 or older.[42,44,50,58,64,69,71] The remaining trials,

which included a wide range of ages, reported average ages in the 40s or 50s. The populations for these trials were approximately one third men and one fifth nonwhite. Individual trial details are summarized in Table 6.

The majority of these trials selected participants who were below some defined threshold of physical activity, usually less than 90 to 150 minutes of medium-intensity physical activity per week. Some studies simply described participants as "sedentary" or "inactive." Only seven trials included participants regardless of their baseline physical activity level.[33,41,52,62,64,68,70] Three trials limited their samples to overweight or obese participants,[50] participants with impaired glucose tolerance,[72] or participants with elevated total cholesterol.[47] Summarizing baseline activity levels over this body of literature as a whole is difficult due to differences in the measurement of physical activity. Only four trials[36,59-61] reported baseline activity levels of 30 minutes per week or less, although not all trials reported baseline levels in minutes per week. Six trials[32,33,53,55,58,68] reported 2 or more hours per week of physical activity (of any kind or limited to moderate-intensity activity or higher) at baseline. One of these was an outlier, reporting an average of over 2,700 minutes/week of physical activity at baseline, including 7 or more hours of moderate-intensity physical activity and 2 hours of walking each week.[33] The remaining trials used various other measures of physical activity and were therefore difficult to compare in terms of baseline activity level.

The data for low-intensity interventions were mixed. Four of the 11 trials of low-intensity interventions increased some measure of physical activity.[40,44,60,70] One of these[40] was a good-quality trial with an effect that was not statistically significant in our meta-analysis, but the original publication reported statistically significant group differences after adjusting for 11 potential confounding variables. The remaining seven trials failed to find group differences in any of the physical activity behavioral outcomes.[32,33,38,52,61,66,75] The meta-analysis of the low-intensity trials with self-reported physical activity (e.g., minutes per week) showed no overall effect (SMD, 0.08 [95% CI, -0.01 to 0.18]; I^2=40.7%; k=8; N=6,288) (Figure 26). The only low-intensity study rated as good quality reported a statistically significant increase of 17.5 minutes/week in the intervention group compared with the control group. Low-intensity interventions generally improved participants' chances of meeting recommended physical activity levels. The three studies reporting sufficient data to be include in the meta-analysis showed that those in the intervention groups were 25 percent more likely to meet physical activity recommendations at 6- to 12-month followup than those in the control groups (pooled risk ratio [RR], 1.25 [95% CI, 1.11 to 1.41]; I^2=0.0%; n=4,289) (Figure 27). This represented an absolute risk difference of four percentage points, which translated to a number-needed-to-treat of 25 for one additional person to meet physical activity guidelines. Low-intensity interventions, as measured by VO_2max, were unlikely to affect fitness. The pooled effect size for VO_2max was 0.05 ml/kg/min (95% CI, -0.11 to 0.20; I^2=26.1%; k=3; N=4,518) (Figure 28).

Only one of the low-intensity trials was rated as good quality. Most of the fair-quality trials failed to report whether allocation and/or assessment were blinded, and many had additional quality issues, such as randomization procedures that were not clearly random,[32] fairly high attrition rates,[33,61] potentially important baseline group differences,[38,60] or no information on baseline comparability.[66]

Medium-intensity interventions increased the level of self-reported physical activity at 6 to 12 months (SMD, 0.19 [95% CI, 0.12 to 0.27]; I^2=49.9%; k=17; N=6,808) (Figure 26). Among the nine studies reporting minutes per week of physical activity (as opposed to measures such as

MET-min or scale scores), this change amounted to 38 additional minutes of physical activity per week for those in the intervention group (WMD, 38.3 minutes [95% CI, 25.9 to 50.7]; I^2=0.0%; k=9; N=3,855). One of these trials examined whether ongoing support improved maintenance of recent physical activity changes. The authors found that participants in the medium-intensity intervention maintained their activity levels, while control-group participants did not.[62] Changes were maintained at the 24-month followup.[76]

Participants in medium-intensity interventions also had a 22 percent greater chance of meeting physical activity guidelines after 6 to 12 months, compared with control participants (pooled RR, 1.22 [95% CI, 1.07 to 1.40]; I^2=59.0%; k=6; N=4,183) (Figure 27). This difference translated to an absolute risk difference of seven percentage points and a number-needed-to-treat of 14 to 15 for one additional person to meet physical activity guidelines. Medium-intensity interventions, however, did not appear to increase fitness (SMD, 0.11 [95% CI, -0.04 to 0.25]; I^2=0.0%; k=3; N=731) (Figure 28), although this outcome was only reported in three of the 17 trials.

Egger's test of small study effects was statistically significant for the medium-intensity trials. The three trials with the largest effect sizes (all rated as fair quality)[47,69,72] were also among the four trials with the fewest participants. We conducted a sensitivity analysis that excluded these three trials from the meta-analysis and the results still showed a statistically significant positive effect of physical activity counseling (SMD, 0.14 [95% CI, 0.9 to 0.20]; I^2=16.9%; k=14). Only one of these three trials reported change in physical activity in minutes per week. Thus, the estimated 38-minute difference appears not to have been substantially biased by the inclusion of these small trials with relatively large effects.

The one physical activity trial using a high-intensity intervention[71] reported an increase in physical activity. This 6-month intervention included monthly group meetings, staff-initiated phone calls, an initial individual session, booklets, and monthly newsletters. Participants in this intervention increased their physical activity by an average of 687 kilocalories per week, while those in the waitlist control group slightly reduced their activity level by 9 kilocalories per week.

Healthful Diet

Overall, dietary counseling improved self-reported dietary intake of energy, fats, fruits and vegetables, and objectively measured urinary sodium. All 25 trials of healthful diet counseling interventions meeting our inclusion criteria reported behavioral health outcomes of dietary intake (Table 7). Three of these trials evaluated low-sodium dietary counseling,[87,98,101] three trials evaluated fruits and vegetables dietary counseling,[42,90,92] and 19 trials evaluated general heart-healthy dietary counseling, including low-fat dietary changes.[34,47,53,77-83,86,91,93-97,104,108]

Low-sodium only dietary counseling. Three fair-to-good-quality trials evaluated intensive low-sodium dietary counseling aimed at persons with mildly elevated diastolic blood pressure.[87,98,101] All three trials were conducted in the United States among middle-aged persons. The populations for these trials were approximately two thirds men and one fifth nonwhite. Meta-analyses pooling objectively measured sodium intake at 6 to 18 months showed a statistically significant reduction in urinary sodium (SMD, -0.53 [95% CI, -0.73 to -0.32]; I^2=79.9%; k=3; N=2,023) (Figure 29). Given the high statistical heterogeneity, the certainty of the pooled estimate for the reduction in urine sodium was not reliable. The reduction in urinary sodium in each of the three trials, however, was consistent with the main outcome—the reduction in blood pressure (refer to Key Question 2).

Fruits and vegetables only dietary counseling. Three fair-quality trials evaluated behavioral counseling interventions designed to increase fruit and vegetable consumption.[42,90,92] These counseling interventions generally included mailed health education, telephone followup, and less than 45 minutes of in-person or phone counseling. One trial targeted older adults with a mean age of 75 years.[42] All the trials included a self-reported measure of fruit and vegetable intake per day. Meta-analyses pooling fruit and vegetable intake at 6 or 12 months showed a statistically significant increase in fruit and vegetable intake (SMD, 0.52 [95% CI, 0.18 to 0.86]; I^2=92.3%; k=3; N=1,922) (Figure 30). Overall, the mean change in fruit and vegetable intake was approximately one serving per day.

These three trials evaluating only fruits and vegetables dietary counseling were only fair quality and did not describe randomization or report if randomization allocation was concealed. One trial did not describe if significant baseline differences were present between groups and had low followup at 24 months.[42] All three trials conducted true intention-to-treat analyses with either imputed values or last observation carried forward. Two trials only had 6-month followup data.[90,92]

Low-fat and general heart-healthy dietary counseling. All 19 trials evaluating low-fat and general heart-healthy dietary counseling reported some type of self-reported dietary intake outcome (Table 7).[34,47,53,77-83,86,91,93-97,104,108] There was a large variation in type of dietary outcome reported, however, and it is not clear if the included dietary outcomes were the primary or secondary outcomes, or if these trials selectively reported outcomes. On occasion, trials were excluded from meta-analyses if they included noncomparable outcome measures or the data reported were not sufficient to enter into the meta-analyses. In addition, there was a large variation in intensity of counseling interventions, which ranged from brief counseling conducted in a single session to counseling conducted over multiple sessions (up to 18 sessions over 12 months). Interventions primarily targeted unselected middle-aged adults, except for four trials that targeted post-menopausal women or older adults,[53,80,83,104] and six trials that targeted persons with slightly elevated cholesterol, glucose tolerance, or high dietary fat intake.[34,47,77,83,97,108]

High-intensity counseling interventions generally reduced caloric intake. Ten of the 19 trials reported some measure of overall energy intake.[34,47,53,77,80,81,83,96,104,108] Only one of these trials was rated as good quality.[104] Meta-analyses pooling all eight of the medium- and high-intensity trials with comparable outcome measures showed no group differences in energy intake at 6 to 12 months, with very high statistical heterogeneity (I^2=91%) (Figure 31). There was a large variation, however, in setting, age, and level of intervention intensity across these trials. While the medium-intensity trials uniformly found no intervention effect, three of the four high-intensity interventions did show a statistically significant reduction in caloric intake. These results are consistent with small but statistically significant reductions seen in adiposity.

Sixteen of the 19 trials reported some measure of total fat or saturated fat intake.[34,47,53,77-83,86,91,94,96,97,104] High-intensity trials were highly variable in effect size and had high statistical heterogeneity, but three of five trials showed statistically significant reductions in total and saturated fat (Figures 32 and 33). Meta-analyses showed statistically significant reductions in self-reported total fat intake in low- (total fat SMD, -0.25 [95% CI, -0.31 to -0.19]; I^2=0.0%; k=5; N=4,357) and medium-intensity interventions (total fat SMD, -0.46 [95% CI, -0.81 to -0.011]; I^2=73.3%; k=5; N=801) (Figure 32). Meta-analyses for self-reported saturated fat intake included only two trials per intervention intensity category. Total fat and saturated fat intake was reported as total intake per day, percent energy from fat or saturated fat, or commonly

recognized fat or saturated fat score. Selected trials also reported measures of cholesterol,[77,80,82,83,96] polyunsaturated fat,[77,78,96,104] monounsaturated fat,[77,81,96] and trans fat intake.[104] While low-intensity interventions appeared to have a statistically significant reduction in self-reported fat intake, there was evidence for publication bias (Eggers p=0.003).

Eleven of the 19 trials reported fruit and vegetable intake, and found that overall the counseling interventions increased fruit and vegetable intake.[34,53,80,82,83,91,93-95,97,104] Only one trial, the WHI, was rated as good quality.[104] Meta-analyses of nine of the trials that reported total fruit and vegetable intake at 6 or 12 months had very high statistical heterogeneity (I^2=98%; n=53,206) (Figure 34). Stratified meta-analyses by intervention intensity accounted for some of the heterogeneity. Low- (low-intensity SMD, 0.19 [95% CI, 0.14 to 0.23]; I^2=0.0%; k=4; N=7,948) and medium-intensity (medium-intensity SMD, 0.65 [95% CI, 0.38 to 0.92]; I^2=44%; k=3; N=691) interventions appeared to generate a statistically significant increase in self-reported fruit and vegetable intake. Overall, the mean change in fruit and vegetable intake ranged from 0.4 to 2 servings per day.

Nine of the 19 trials reported fiber intake.[34,77-81,86,94,104] Only one trial, the WHI, was rated as good quality.[104] Meta-analyses showed a very high statistical heterogeneity (I^2=99%; n=44,892) (Figure 35). None of the low-intensity interventions showed group differences, while four of six medium- or high-intensity trials did improve fiber intake.

The majority of trials were only of fair quality, and there was significant clinical and statistical heterogeneity amongst the trials. Some of this heterogeneity could be attributed to different levels of intensity of counseling. However, because intervention intensity generally corresponded with population risk for CVD or how the population was selected (e.g., low-intensity interventions were generally conducted in unselected persons), it is unclear if the heterogeneity stemmed from intensity or population risk. However, very high statistical heterogeneity was apparent even within intensity categories for self-reported behavioral outcomes. The best evidence for high-intensity counseling on self-reported dietary intake comes from two trials conducted in exclusively post-menopausal women.[83,104] Longer-term evidence for sustained change in dietary behavior was limited to one trial, in which changes in self-reported energy intake, total and saturated fat intake, fruit and vegetable intake, and fiber intake were statistically significant up to 72 months followup.[104] We found evidence for statistically significant publication bias based on the Egger's test for the self-reported total fat intake, but not for the other self-reported measures, including saturated fat intake.

Combined Lifestyle

Overall, combined lifestyle counseling did improve self-reported dietary and physical activity behavior. However, in general, pooled results for dietary outcomes had very high statistical heterogeneity. All 17 trials evaluating combined lifestyle counseling interventions that met our inclusion criteria reported behavioral health outcomes of dietary intake or physical activity outcomes (Table 8). Only three trials were good quality.[122,124,131] Nine were conducted in the United States,[110,114-116,120-122,124,127] seven were conducted in general-risk populations,[110,116,119,120,124,127,130] and seven were conducted in populations with patient populations selected from primary care.[47,112,114,115,117,121,122] Ten of the trials selected patients based on elevated CVD risk.[47,81,112,114,115,117,121-123,131] While most trials were conducted in middle-aged adults, one trial conducted in Japan used a population with a mean age of 64 years,[112] and two trials had a mean age of 20 years.[116,119] There was a very wide range in

intervention intensity, and only one trial was a low-intensity counseling intervention that included monthly mailed newsletters over the 36-month trial.[120] The other trials evaluated counseling interventions with greater than 30 minutes of contact, ranging from two to 30 sessions. Individual trial details are summarized in Table 8.

Dietary intake behavior change. Sixteen of the 17 trials of combined lifestyle counseling provided some type of self-reported dietary behavioral outcome. Nine of the 16 trials reported some measure of overall energy intake.[47,81,110,112,119,120,123,124,127] Meta-analyses showed a statistically significant decrease in energy intake (WMD, -131 kcal/day [95% CI, -224 to -37]; I^2=58.6 %; n=2,226) (Figure 36). However, stratified analyses showed a statistically significant effect only in high-intensity trials (WMD, -192 kcal/day [95% CI, -332 to -52]; k=5; N=1,208) (Figure 36), although statistical heterogeneity was quite high (I^2=70.8%). We found a large variation in setting, age, and level of intervention intensity across these trials. None of the counseling interventions focused on calorie restriction or weight loss, and therefore were not primarily intended to reduce overall energy intake. This change in caloric intake is consistent with the change in adiposity described in Key Question 2.

Twelve trials reported some measure of dietary intake of fat, showing highly variable results.[47,81,110,116,117,119,120,122-124,127,130] Seven of the trials showed statistically significant results, including low-, medium-, and high-intensity interventions. Meta-analyses pooling the 11 trials that reported total fat intake at 6 or 12 months had very high statistical heterogeneity (I^2=94%; n=3,502) (Figure 37). Stratified meta-analyses by intervention intensity and population risk did not reduce the amount of statistical heterogeneity among subgroups.

Only six of the 16 trials reported fruit and vegetable intake, only one of which showed statistically significant group differences.[111,112,116,117,122,127] Meta-analyses pooling the four trials that reported usable total fruit and vegetable intake at 6 or 12 months had very high statistical heterogeneity (I^2=89%; n=1,337) (Figure 38). One fair-quality trial (n=348) showed a statistically significant increase in fruit and vegetable intake at 6 months, a mean difference of 0.9 servings of fruit/day (95% CI, 0.6 to 1.1) and 1.3 servings of vegetable/day (95% CI, 0.9 to 1.9) between groups among unselected middle-aged adults.[111] None of the other trials demonstrated a statistically significant increase in fruit and vegetable intake.

Three trials reported dietary fiber outcomes,[81,122,123] only one of which (n=52) showed a statistically significant increase in fiber intake of about 2.5g/day (95% CI, 1.0 to 4.0) at 12 months.[81] Selected trials also included self-reported measures of protein and carbohydrate intake.[47,81,110,119] Counseling interventions did not generally focus on these types of dietary intake and are briefly discussed in Key Question 4.

The majority of trials were only of fair quality and there was significant clinical and statistical heterogeneity. There was still significant heterogeneity after accounting for differences in intensity of counseling interventions and population risk, and there is limited evidence for behavioral change beyond 12 months. Only two trials (combined n=735), both conducted exclusively in women, showed that decreased energy intake was still statistically significant at 18 months[127] and 54 months[124] followup. Three trials (combined n=813) showed that decreased total fat and saturated fat intake was still statistically significant at 18 and 24 months.[123,124,127]

Physical activity behavior change. Sixteen of the 17 trials evaluating combined lifestyle counseling provided some type of physical activity behavioral outcome. Meta-analyses combining 13 of the 16 trials reporting sufficient data to be included in the analysis of self-

reported amount of physical activity demonstrated a small, but statistically significant, effect (SMD, 0.19 [95% CI, 0.11 to 0.28]; I^2=39.2%; n=4,150) (Figure 39). Only one of these studies provided a low-intensity intervention. This study found no differences between treatment and control group participants at 12-month followup. The combined effects of the medium- and high-intensity trials were both statistically significant (medium-intensity SMD, 0.20 [95% CI, 0.08 to 0.33]; I^2=45.7%; k=8; N=2,189; high-intensity SMD, 0.26 [95% CI, 0.14 to 0.37]; I^2=0.0%; k=4; N=1,152).

It is difficult to interpret these effect sizes due to enormous variability in measures. The standardized effect size of the medium-intensity interventions in these trials, however, is identical to the effect size of medium-intensity interventions that focused solely on physical activity, which were estimated to have resulted in approximately 38 more minutes of physical activity per week among intervention participants than control participants. High-intensity interventions had a slightly larger combined effect size, and thus may have an even larger effect than 38 additional minutes of physical activity per week.

As with the dietary outcomes, the majority of trials were only of fair quality and there was significant clinical heterogeneity amongst the trials. Combined effects were very similar in unselected samples and those selected for either behavioral or physiologic cardiovascular risk factors.

Exploring Heterogeneity

Meta-regressions examining the effects of study characteristics on behavioral outcomes (i.e., self-reported physical activity, fat intake, and fruit and vegetable intake) were conducted using all data available in any of the 66 included studies. As with the intermediate health outcomes, we conducted multivariate meta-regression models including each of the four primary predictor variables (intervention target, risk status of the sample, intensity of the intervention, and recruitment strategy [self-identified vs. study-identified]) for each of the three outcomes.

Both intervention target and intensity predicted fat intake in a multivariate regression model, such that greater effects were seen in high-intensity trials. Exploratory analysis showed that a number of other factors also appeared to modify the size of the effect on fruit and vegetable and/or fat intake after adjusting for the four primary predictors, including: age (trials limited to older adults reported smaller reductions in fat intake); time to followup (fruit and vegetable effect sizes were larger with shorter followup); and race in U.S.-based trials (a higher proportion of nonwhite participants was associated with smaller average effect for both fat and fruit and vegetable intake). Effect sizes were not associated with whether the sample was recruited from primary care, whether it was conducted in the United States, average baseline BMI, percent male, year of publication, or quality of the trial. These effects, however, should be interpreted with caution as they were purely exploratory, and using patient-level characteristics such as percent male and percent nonwhite are subject to the bias of ecological fallacy (i.e., results of analyses of individual patients within trials may show entirely different results). The degree of estimation required for inclusion in the meta-analysis did predict the effect size for fruit and vegetable consumption. Trials requiring a high degree of estimation showed smaller average effects, suggesting that our estimation approach was conservative.

We examined the effects of different types of self-reported outcome measures on effect size to help determine whether it was acceptable to combine disparate self-report measures in the meta-

analyses. For self-reported physical activity, fat intake, and fruit and vegetable intake, we grouped similar types of outcomes and created indicator variables to test differences. For example, for physical activity we combined all trials reporting some measure of minutes per week of physical activity as the first group, trials reporting other measures of amount of physical activity (e.g., sessions per week, MET-minutes per week) as a second group, and trials reporting scores on physical activity scales as a third group, and ran meta-regression with two indicator variables, using the group reporting minutes/week as the reference group. Similar approaches were used for self-reported measures of fat and fruit and vegetable intake. The type of measure did have an impact on both physical activity and fruit and vegetable intake effect sizes. Trials reporting minutes per week generally showed greater average increases in amount of physical activity than trials reporting other measures of physical activity. Trials reporting servings per day reported larger effects than those reporting a score on a constructed scale. However, only three trials reported a scale score rather than servings per day, so these results should also be viewed as purely exploratory.

Finally, as with the intermediate health outcomes, we ran meta-analyses combining trials from all three intervention targets, stratified by intervention intensity to aid visual exploration of these effects. These forest plots are included in Appendix G.

Key Question 4. What are the adverse effects of primary care relevant behavioral counseling interventions for physical activity and/or healthful diet?

Only two of the trials meeting our inclusion criteria for testing the efficacy of physical activity counseling (with or without dietary counseling) reported adverse events.[32,55] Both of these trials reported that mild muscular fatigue, strain, or soreness were relatively common in the intervention groups, occurring in 22 to 24 percent of intervention participants. Three other studies reported falls,[36,58,59] two of which also reported injuries related to falls. All of these studies found physical activity to either have no effect or to have a protective effect on falls and injuries.

We also searched for comparative observational studies demonstrating a link between physical activity and cardiac events. We found seven studies that conducted case-crossover analyses to determine whether cardiac events (sudden death or myocardial infarction) were more likely to occur during periods of vigorous physical exertion.[133-139] Some of these studies also conducted case-control analyses, but the focus of this review remains on the case-crossover analyses due to the difficulty of assembling truly comparable controls and the fact that these studies did not link cardiac events with physical activity at the time of the event.

All seven studies showed that the risk of a cardiac event increased during vigorous exertion, with a range of two- to 17-fold increase in risk (Appendix C Table 4). When analyses were stratified by level of habitual activity, however, this increased risk was much greater for people with low levels of regular activity. In some cases, no increased risk was apparent in people with moderate-to-high levels of usual activity, while the risk of cardiac events were seven to 107 times higher in the presence of vigorous exertion for people with very low levels of habitual activity. Nevertheless, the absolute risk during physical activity was very low. One of these studies[133] estimated that the incidence of sudden death associated with vigorous physical activity was

1/1.42 million person-hours of exertion (based on a study of 21,481 men). This incident was not reported separately by level of habitual activity.

Other harms that may be associated with physical activity are injuries and arthritis. We did not comprehensively search for evidence in these areas as it was beyond the focus of this review. However, we discuss the findings of a recent DHHS report covering these areas in the discussion section of this review.[141]

We found no studies designed to assess the adverse effects of dietary counseling or the adverse effects of increasing fruits and vegetables, increasing fiber, decreasing sodium, or decreasing fat intake. None of the healthful diet counseling trials reported specific adverse events. One potential adverse effect of dietary counseling is unintended changes in other food or nutrient intake, such as low-fat counseling increasing carbohydrate intake. None of the included healthful diet counseling trials showed a statistically significant increase in overall energy intake, decrease in fruit or vegetable, increase in sodium, or increase in fat or saturated fat intake. Very few trials reported monounsaturated fat, polyunsaturated fat, or carbohydrate or sugar intake.[47,77,78,80,81,96,104,110,119] Only two of the eight trials that reported carbohydrate or sugar intake showed a statistically significant increase in carbohydrate intake. One trial showed an increase in self-reported carbohydrate intake at 6 months—an 11.9 percent (95% CI, 10.1 to 13.6) increase in percent energy intake due to carbohydrates.[110] In the WHI, the intervention group had an approximate 10 percent increase in energy from carbohydrates as compared to the control group at 12 and 72 months.[104] In both these trials, however, there was a statistically significant decrease in overall energy intake. In two trials, it appears that low-fat dietary counseling statistically significantly reduced intake of both saturated and unsaturated fats.[96,104] Another trial showed a statistically significant increase in the use of polyunsaturated fats,[78] and a third trial found a nonstatistically significant change in unsaturated fats.[81] It is likely that use of unsaturated fats, both polyunsaturated and monounsaturated, may lower cholesterol when used in place of saturated fats.

Chapter 4. Discussion

Summary of Findings

We conducted this systematic review to assist the USPSTF in updating their 2002 and 2003 physical activity and healthful diet counseling recommendations.[24,26] Our review focused on the effectiveness and harms of primary care relevant counseling interventions across three distinct topics: physical activity, healthful diet, and the combination of these two. We included a total of 66 fair- or good-quality randomized controlled trials published after 1989 that evaluated these counseling interventions.

Building on the 2003 healthful diet review, we found evidence (39 trials; n=76,088) confirming the benefit of medium- or high-intensity dietary counseling interventions, with or without concomitant physical activity counseling. This benefit was apparent despite the fact that we excluded counseling targeted to people with established CVD risk factors and/or those being medically managed for risk factors (e.g., hypertension, dyslipidemia, diabetes). Similar to the prior review, we found that less-intensive dietary counseling interventions did not produce significant behavioral changes. By expanding the scope of this review to include important physiological outcomes, we found small but statistically significant improvements in adiposity, blood pressure, and lipids in high-intensity healthful diet counseling (with or without concomitant physical activity counseling) in 28 trials (n=62,285).

Building on the 2002 physical activity review, we found evidence that contrasts with the results of the prior review, largely based on 28 new trials (only two of the eight trials from the prior review were included). Based on 30 trials targeting physical activity counseling only (n=15,265) and an additional 14 trials (n=5,054) examining combined lifestyle counseling, we found that medium- and high-intensity physical activity counseling interventions (with or without concomitant dietary counseling) improved self-reported physical activity, but only clearly improved adiposity and blood pressure when combined with dietary counseling. However, many physical-activity only trials did not report adiposity, blood pressure, or lipid outcomes. Similar to the previous review, no consistent behavioral benefit was found for low-intensity behavioral counseling to increase physical activity. These data were inconsistent (four of 11 trials showed a benefit), however, suggesting that some low-intensity interventions might be effective.

Magnitude, duration, and clinical interpretation of effects on adiposity, blood pressure, and lipids. High-intensity counseling for healthful diet (with or without concomitant physical activity counseling) results in statistically significant, albeit small, reductions in adiposity, blood pressure, and total and LDL cholesterol. This is based on 16 healthful diet (n=58,557) and 14 combined lifestyle (n=3,855) counseling trials (Table 9, Appendix G, Figures 1, 3, 5,7,9). There is limited evidence suggesting that these reductions in physiologic measures persist beyond 12 months. We found that focused physical activity interventions alone were insufficient to affect adiposity, blood pressure, or lipids, despite increasing physical activity. However, these outcomes were less commonly reported (k=8; N=3,731) (Table 9).

Although the included dietary and combined lifestyle counseling trials did not address weight loss as a direct goal of the intervention, they did have a modest effect on weight. Medium- to high-intensity dietary interventions (with or without concomitant physical activity counseling) decreased BMI approximately 0.3 to 0.7 kg/m^2 at 12 months. Five trials evaluating high-intensity

counseling had followup beyond 12 months and this reduction in BMI persisted up to 72 months, although this result was slightly attenuated.[104,119,123,124,127] These changes may be clinically meaningful since epidemiological data suggest that the risk for both CVD and diabetes increase with each kg/m^2 unit change in BMI.[142] It is unclear, however, if small sustained reductions in BMI after the intervention's conclusion translate into better cardiovascular health outcomes.

Blood pressure was improved in several types of healthful diet and combined lifestyle counseling interventions, at least over the short term. High-intensity diet and lifestyle interventions decreased blood pressure by approximately 1.5 mmHg and 0.7 mmHg systolic and diastolic, respectively, at 12 months (Appendix G, Figures 3 and 5). These changes were persistent although slightly attenuated in the three intensive salt-restriction counseling interventions in persons with mildly elevated diastolic blood pressure.[87,98,143] Four other trials reported followup beyond 12 months, and none of these trials showed a statistically significant reduction by the trial's end.[104,119,124,127] Observational followup of TOHP I and II suggest that these blood pressure reductions could reduce incidence of CVD event in the long term, over 10 to 15 years.[109] However, in the WHI, there were no significant reductions in major CVD events at 8 years followup in post-menopausal women in the intervention group who had blood pressure reductions of less than 1 mmHg, compared with women in the control group.[140] Although these reductions in blood pressure were smaller than those seen in hypertension drug trials and feeding trials (in which participants are fed study-provided diets specifically designed to reduce hypertension),[144,145] epidemiologic data suggest that even small changes in blood pressure (e.g., 2 mmHg systolic blood pressure) can decrease the risk of coronary heart disease by 6 percent or stroke by 16 percent.[146]

High-intensity diet and combined lifestyle counseling decreased total cholesterol by 0.17 mmol/L (6.56 mg/dL) and LDL by 0.13 mmol/L (5.02 mg/dL) (Appendix G, Figure 7).[77,96,110,123,124,127] Of the three trials that reported followup beyond 12 months, two trials conducted exclusively in women demonstrated a persistent decrease in total cholesterol or LDL at 18 or 54 months.[124] There was no statistically significant increase in HDL. Based on randomized controlled trials in primary prevention, a reduction of 0.6 mmol/L (23.17 mg/dL) in total serum cholesterol can reduce coronary heart disease by approximately 25 percent.[147] However, in the WHI, there were no significant reductions in major CVD events at 8 years in post-menopausal women in the intervention group who had small net LDL reductions of approximately 0.09 mmol/L (3.55 mg/dl) at 3 years.[140]

Magnitude, duration, and clinical interpretation of effects on self-reported healthful diet and physical activity behaviors. Based on all the included trials (k=66; N=90,194), medium- to high-intensity counseling interventions improved self-reported dietary intake of energy, fats, and fruits and vegetables, objectively measured urinary sodium, and self-reported physical activity (Table 9). Behavioral changes in these trials were generally consistent in terms of effects on physiologic measures of adiposity, blood pressure, and lipids.

Overall, high-intensity diet-only and combined lifestyle counseling interventions showed a small to moderate reduction in energy consumption, approximately a 7 to 11 percent decrease in kcal/day depending on the baseline caloric intake of trial participants. Three of these trials showed statistically significant reductions in caloric intake up to 72 months.[104,124,127] These changes in caloric intake are consistent with the findings of small reductions in weight. Diet and combined lifestyle counseling interventions also decreased self-reported total fat and saturated fat intake, and increased self-reported fruit and vegetable consumption. Although there was high

statistical heterogeneity amongst pooled trials, there appeared to be a dose effect with intervention intensity (Appendix G, Figures 11 and 13). High-intensity counseling resulted in moderate to large reductions in self-reported fat intake—5.9 to 11 percent decrease in energy from total fat and 2.8 to 3.7 percent decrease in energy from saturated fat. Four trials had longer-term followup, up to 72 months, in which reductions in total fat and saturated fat were still significant.[104,123,124,127] Low- and medium-intensity interventions resulted in smaller reductions in fat intake. None of the low- or medium-intensity counseling trials had followup beyond 12 months. There likely is some publication or selective reporting bias with total dietary fat outcomes, as the Egger's statistical test for small study effects is positive. For low-, medium-, and high-intensity interventions, there was a moderate to large increase in fruit and vegetable intake, approximately 0.4 to 2 servings per day. Only two trials had followup beyond 12 months, which showed a persistent increase in fruit and vegetable intake at 24 and 72 months.[42,104] Although the specific health effects of dietary behavior change are not clear, limited epidemiological data suggest that moderate to large changes in dietary behavior are likely to be associated with lower CVD rates.[26,148,149]

The medium-intensity physical activity counseling interventions resulted in an approximate 38-minute increase in physical activity per week. While baseline activity levels in trials varied, it appeared that most participants in these trials would have received at least 1 hour per week of physical activity if they increased their activity level by 38 minutes per week. One study suggested that support in maintaining recent increases in physical activity improves adherence.[62] While followup beyond 12 months was very rare, changes in activity level were maintained in one moderate-intensity physical activity trial[76] and one high-intensity combined lifestyle counseling trial.[124] Epidemiological evidence suggests that participating in only 60 minutes of physical activity per week can lower the risk of all-cause mortality and coronary heart disease, but benefits are most clearly documented among adults who regularly get at least 150 minutes per week.[6] More physical activity appears to provide more benefit, and it is unclear if there is a ceiling beyond which benefits do not continue to accrue.[6] Other studies of physical activity have shown that at least 1,200 kilocalories per week of physical activity (roughly equivalent to 2.5 hours per week of vigorous physical activity) reduce total cholesterol and triglycerides by 4 to 7 percent.[150] Physical activity changes of these magnitude were not seen in the trials included in this review, and, not surprisingly, blood lipids were unaffected by these interventions.

Adverse effects. There were no increased serious injuries from physical activity or unintended adverse changes in dietary intake, based on available counseling trials. In two trials, there was a paradoxical increase in carbohydrates, but not overall caloric intake. The clinical significance of these dietary changes is unclear. In the WHI, the replacement of fat intake with complex carbohydrates, over 6 years, was not associated with clinical adverse effects on lipid profiles.[151] Seven additional observational studies suggest, however, that there was an increased risk of serious cardiac events during vigorous physical activity, primarily in persons with low levels of habitual activity. However, the absolute risk of serious cardiac events related to physical activity appears to be extremely small. Minor musculoskeletal injuries were fairly common, however, when participants increased their physical activity from habitual levels. Type and total amount of activity, and relative change in activity were all important factors in determining the risk of injury. Non-contact, low-impact activities such as walking, bicycling, and swimming had lower injury rates. Increasing physical activity in a series of small increments, each followed by an adaptation period, resulted in lower rates of injury.[141] Additional information regarding harms of physical activity are detailed in the DHHS 2008 report on physical activity.[141]

Considerations for Applicability of Findings

Distribution of evidence across type of counseling, intervention intensity, and population risk. This review included a body of literature with considerable heterogeneity. The major sources of heterogeneity were type of counseling (physical activity, diet, or both), intervention intensity, and the risk status of the patient. There is substantial evidence supporting the effectiveness of dietary counseling (with or without physical activity counseling) for changing adiposity, blood pressure, and lipids. The physical activity only counseling literature, however, had a smaller proportion of trials that used physiologic outcomes measures. All types of counseling, either alone or in combination, appeared to improve self-reported dietary and physical activity behaviors. The literature, however, did not evenly study all intensities of behavioral counseling interventions (Table 9). For example, only one physical activity counseling trial evaluated a high-intensity intervention, while only one combined lifestyle intervention trial evaluated a low-intensity intervention. The lack of high-intensity physical activity trials is largely due to the fact that we excluded trials providing supervised scheduled physical activity sessions.

Counseling interventions ranged from low-intensity counseling (e.g., conducted in single sessions or by mail alone) to very high-intensity interventions (e.g., up to 20 sessions over a 2-year period). Trials were distributed across three categories of study population risk (unselected, selected for behavioral factors, selected for increased cardiovascular risk) (Table 9). We had difficulty disentangling the effects of intervention intensity from the populations' risk status when attempting to examine whether counseling improved health or behavioral outcomes. Depending on the body of literature, intervention intensity could correlate with population risk or could not. Among the healthful diet counseling trials, low-intensity interventions were almost all conducted in general-risk persons, and medium- to high-intensity interventions were mostly conducted among persons selected for poor dietary intake or with elevated risk for CVD. In contrast, almost all the physical activity counseling trials were conducted in persons not meeting recommended levels of physical activity. These trials were also somewhat evenly distributed between low- and medium-intensity interventions, and there was only one high-intensity counseling intervention. The combined lifestyle counseling interventions showed a very different distribution in that medium-intensity trials tended to target patients selected for risk factors related to CVD while high-intensity trials primary involved unselected populations.

Intervention considerations. Almost all of the effective medium- to high-intensity interventions were delivered by specially trained health educators or nurses, counselors or psychologists, dietitians or nutritionists, or exercise instructors or physiologists. Very few of these interventions involved the primary care physician at all. Interventions with significant benefit beyond 12 months were all high-intensity counseling interventions (up to 20 sessions) with group, phone, or mail contact throughout the trial. Many of the high-intensity interventions trials required resources that are not currently available or paid for in the current health system. Similarly, many of the low-intensity interventions required health system considerations that may not be readily available, such as computer support to generate "tailored" mailed feedback, automated phone calls, or ongoing phone followup. Low-intensity dietary counseling interventions showed small, but statistically significant, improvement in self-reported fat and fruit and vegetable intake. Evidence for low-intensity physical counseling interventions on increasing self-reported physical activity was mixed.

Other population considerations. There were fewer men represented in these trials, with men representing approximately 17 percent of all the trials' participants. This is largely due to the inclusion of the WHI (n=48,835), which enrolled only women. The proportion of males rose to 35 percent when the WHI was excluded. This proportion was adequate to allow application of the overall findings of this review to men. Among the 38 trials conducted in the United States, approximately 18 percent were nonwhite, ranging from 3 to 100 percent. Trials were primarily conducted in middle-aged adults, with a mean age of 59 years, and a range from 20 to 78 years. Based on meta-regressions of these variables, there is no reason to believe that intervention effectiveness would vary significantly by age, sex, or race/ethnicity, although these analyses were purely exploratory and the study-level effects of these variables may not mirror the effects seen within individual trials. Evidence directly applicable to older adults is primarily available for physical activity counseling. Nine of the trials[42,44,50,58,64,69,71,80,92] were explicitly conducted in older adults, selected for age 60 years or older, seven[42,44,50,58,64,69,71] of which involved only physical activity counseling. Each of these seven trials showed that medium- to high-intensity counseling increased physical activity. Fruit and vegetable intake in those targeting dietary change reported results similar to those apparent in other age groups.[80,92]

Limitations

In addition to the heterogeneity of trials limiting confidence in the pooled estimates of effect sizes for some outcomes, there are other limitations to consider for this body of evidence.

This updated review represents only a subset of the diet and physical activity counseling literature. In order to focus the review to support the USPSTF's decisionmaking, we excluded some related bodies of literature, including trials focusing on populations with known disease (including hypertension, dyslipidemia, diabetes, or coronary heart disease); dietary counseling trials to prevent cancer, unless the trial had an explicit objective to reduce both CVD and cancer; and counseling trials that focused on weight loss or weight management. We also excluded trials without a true control arm (e.g., usual care, minimal intervention, attention control, waitlist control). Therefore, we did not address literature that assessed the comparative effectiveness of different types of behavioral counseling and intervention elements. We only included counseling interventions that could be conducted in primary care or referred from primary care. Therefore, worksite, school-based, community-based, public health, economic and policy oriented, or media-based interventions are not addressed in this review. For these types of interventions focused on improving diet and physical activity, we refer to the CDC Community Task Force.[152]

The majority of trials were short term and provided only 6 or 12 months followup. Only 11 of the 66 trials had followup beyond 12 months.[42,59,76,87,98,101,104,119,120,124,127] These trials with longer followup involved high-intensity interventions with ongoing maintenance sessions throughout the trial period. Thus, even with longer-term followup, relatively little is known from this body of evidence about the maintenance of beneficial behavior or physiologic change after an active intervention ceases. Also, given the limited duration of followup, it is not surprising that only three trials reported health outcomes.[98,101,106] Our categorization of counseling interventions primarily addresses the intensity (minutes of in-person contact) rather than duration (period of time over which counseling was delivered) of the intervention. Although most of the high-intensity interventions last over a period of several months, this period ranged from 1 to 24 months.

In addition to the limited duration of followup, many of the trials relied on self-reported behavioral outcome measures. Only 36 percent of trials reported any objectively measured intermediate outcomes. Measurement of behavioral outcomes varied across trials, and both dietary and physical activity behaviors can be difficult to measure validly and reliably. Dietary intake was generally measured by food frequency questionnaires, food diaries, and 24-hour food recalls. Each of these methods can be prone to bias.[153] For physical activity, the various forms of physical activity, the episodic nature of some types of activity, and the subjective nature of people's assessment of intensity make it difficult to get precise information on physical activity levels. Only seven of the studies reporting physical activity outcomes used objective measures (pedometer, accelerometer, actigraph), and this measure was always used in addition to a self-reported measure.[50,53,55,69,72,112,121,124] Results were generally consistent between self-reported and objective measures, although two studies reported no between-group differences in objective measures but found statistically significant differences in self-reported activity.[72,121] It is reassuring that the behavioral outcome results in this review were consistent with results using intermediate outcomes.

There were also limitations posed by the quantitative pooling of results. Six of the 66 trials did not report outcome data necessary to include in any quantitative pooling of results. Of the data included in the meta-analyses, some degree of calculation was necessary to include the majority of trials (86 percent) in the meta-analyses, although only a small percentage (12 percent) required statistical judgment. In these instances, we erred on the side of avoiding a type I error or overestimation of effect size. Sensitivity analysis showed that our methods for calculating missing data for the meta-analyses likely had little effect on overall results, and this effect was attenuated by effect size. In some instances, trials were simply excluded from the meta-analysis if they reported insufficient outcome data or noncomparable outcomes.

Other considerations include risk of bias due to including only published data, potential selective reporting of outcomes, and including trials that used volunteer participants. Egger's statistical test for small study effects was significant only for self-reported total dietary fat intake and self-reported physical activity level among the physical-activity counseling trials. Sensitivity analyses excluding the small studies with large effects, however, still demonstrated a positive effect of physical activity counseling.

Future Research

Although this is a very large body of literature, good-quality trial evidence is still needed to fully evaluate the longer-term health impacts of diet, physical activity, and combined lifestyle counseling interventions across a range of patients using counseling interventions that are most applicable to primary care. More trials are needed to evaluate low-intensity counseling interventions that would be more readily implemented in primary care, or medium-intensity interventions that could be referred to from primary care. Many of the high-intensity interventions would require resources that are not currently available or paid for in the current health system (not to mention issues concerning real-world patient adherence). Many of the high-intensity interventions were conducted among participants selected for increased risk of CVD. It is important to examine if the effectiveness of these interventions is reproducible in more unselected populations, or if counseling should indeed be targeted only to those selected for pre-clinical disease (e.g., impaired fasting glucose, pre-hypertension). In addition, trials with longer-

term followup are crucial to understanding the maintenance effects of behavioral and physiologic changes after an intervention has ended.

This review was unable to address the effectiveness of specific intervention elements, which would likely be helped by more complete and consistent reporting of counseling intervention elements, replication of intervention approaches across different types of patients, and interventions with different behavioral foci. This issue might be best addressed by trials focusing on the comparative effectiveness of different counseling interventions. Comparative effectiveness trials may also be helpful to determine optimal or minimum intensity and duration of effective counseling. In addition to self-reported behavioral outcomes, trials should also collect and report objectively measured physiologic outcomes. Greater use of objective measures to assess physical activity would likely provide more accurate estimates of changes in physical activity level, which is especially important when the changes are small in magnitude. To help interpret the magnitude of effect, epidemiological evidence on the relationship between small to moderate changes in dietary and physical activity and health outcomes is needed.

Conclusions

Medium- to high-intensity dietary behavioral counseling, with or without physical activity counseling, resulted in small, but statistically significant, improvements in adiposity, blood pressure, and cholesterol, as well as moderate to large changes in self-reported dietary and physical activity behaviors. Evidence for changes in physiologic outcomes was strongest for high-intensity counseling interventions. Medium- to high-intensity physical activity counseling resulted in large changes in self-reported physical activity. There was some evidence to suggest that even low-intensity dietary counseling results in moderate increases in fruit and vegetable intake, and small decreases in dietary fat intake. However, there was very limited evidence for maintenance of any behavioral or physiologic effects beyond 12 months, particularly for low- and medium-intensity interventions. Most trials for high-intensity interventions that had followup beyond 12 months showed persistent beneficial changes in adiposity and lipids (but not blood pressure) as well as improvements in self-reported behavioral outcomes. It appears that intervention intensity was the most important factor for differences in effect size among different trials. This literature, however, did not represent a full range of combinations of intensity and population risk. Instead, intensity and population risk were highly correlated in the healthful diet and combined counseling trials, and very few physical activity trials were conducted in those selected for increased CVD, or utilizing a high-intensity approach, so the two factors could not be fully disentangled.

References

1. Caspersen CJ, Powell KE, Christenson GM. Physical activity, exercise, and physical fitness: definitions and distinctions for health-related research. *Public Health Rep.* 1985;100:126-131.

2. Mokdad AH, Marks JS, Stroup DF, Gerberding JL. Actual causes of death in the United States, 2000. *JAMA.* 2004;291:1238-1245.

3. McGinnis JM, Foege WH. Actual causes of death in the United States. *JAMA.* 1993;270:2207-2212.

4. Institute of Medicine. DRI Dietary Reference Intakes: The Essential Guide to Nutrient Requirements. Washington, DC: National Academies Press; 2006.

5. Joint WHO-FAO Expert Consultation. Diet, Nutrition and the Prevention of Chronic Diseases. WHO Technical Report Series No. 916. Geneva, Switzerland: World Health Organization; 2003.

6. Physical Activity Guidelines Advisory Committee. Physical Activity Guidelines Advisory Committee Report, 2008. Washington, DC: U.S. Department of Health and Human Services; 2008.

7. Warburton DE, Katzmarzyk PT, Rhodes RE, Shephard RJ. Evidence-informed physical activity guidelines for Canadian adults. *Can J Public Health.* 2007;98(Suppl 2):S16-S68.

8. Haskell WL, Lee IM, Pate RR, et al. Physical activity and public health: updated recommendation for adults from the American College of Sports Medicine and the American Heart Association. *Med Sci Sports Exerc.* 2007;39:1423-1434.

9. Pate RR, Pratt M, Blair SN, et al. Physical activity and public health: a recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine. *JAMA.* 1995;273:402-407.

10. Nelson ME, Rejeski WJ, Blair SN, et al. Physical activity and public health in older adults: recommendation from the American College of Sports Medicine and the American Heart Association. *Med Sci Sports Exerc.* 2007;39:1435-1445.

11. Centers for Disease Control and Prevention and President's Council on Physical Fitness and Sports. Midcourse Review: Healthy People 2010. Washington, DC: U.S. Department of Health and Human Services; 2006.

12. U.S. Department of Health and Human Services and U.S. Department of Agriculture. Dietary Guidelines for Americans, 2005. 6th edition. Washington, DC: U.S. Government Printing Office; 2005.

13. Wells, HF. Dietary Assessment of Major Trends in U.S. Food Consumption, 1970–2005. Economic Information Bulletin No. 33. Washington, DC: U.S. Department of Agriculture Economic Research Service; 2008.

14. Centers for Disease Control and Prevention. Prevalence of fruit and

vegetable consumption and physical activity by race/ethnicity—United States, 2005. *MMWR*. 2007;56:301-304.

15. Trost SG, Owen N, Bauman AE, Sallis JF, Brown W. Correlates of adults' participation in physical activity: review and update. *Med Sci Sports Exerc.* 2002;34:1996-2001.

16. Stringhini S, Sabia S, Shipley M, et al. Association of socioeconomic position with health behaviors and mortality. *JAMA.* 2010;303:1159-1166.

17. Nelson M, Erens B, Bates B, Church S, Boshier T. Low Income Diet and Nutrition Survey: Summary of Key Findings. Norwich, United Kingdom: The Stationery Office; 2007.

18. Allender S, Cowburn G, Foster C. Understanding participation in sport and physical activity among children and adults: a review of qualitative studies. *Health Educ Res.* 2006;21:826-835.

19. Handy SL, Boarnet MG, Ewing R, Killingsworth RE. How the built environment affects physical activity: views from urban planning. *Am J Prev Med.* 2002;23:64-73.

20. Hiddink GJ, Hautvast JG, van Woerkum CM, Fieren CJ, van 't Hof MA. Consumer's expectations about nutrition guidance: the importance of primary care physicians. Am J Clin Nutr. 1997;65(6 Suppl):S1974-S1979.

21. Glasgow RE, Eakin EG, Fisher EB, Bacak SJ, Brownson RC. Physician advice and support for physical activity: results from a national survey. *Am J Prev Med.* 2001;21:189-196.

22. Kreuter MW, Chheda SG, Bull FC. How does physician advice influence patient behavior? Evidence for a priming effect. *Arch Fam Med.* 2000;9:426-433.

23. Sinclair J, Lawson B, Burge F. Which patients receive advice on diet and exercise? Do certain characteristics affect whether they receive such advice? *Can Fam Physician.* 2008;54:404-412.

24. Eden KB, Orleans CT, Mulrow CD, Pender NJ, Teutsch SM. Clinician Counseling to Promote Physical Activity. Systematic Evidence Review No. 9. Rockville, MD: Agency for Healthcare Research and Quality; 2002.

25. Activity Counseling Trial Research Group. Effects of physical activity counseling in primary care: the Activity Counseling Trial, a randomized controlled trial. *JAMA.* 2001;286:677-687.

26. Ammerman A, Pignone M, Fernandez L, et al. Counseling to Promote a Healthy Diet. Systematic Evidence Review No. 18. Rockville, MD: Agency for Healthcare Research and Quality; 2003.

27. U.S.Preventive Services Task Force. U.S. Preventive Services Task Force Procedure Manual. AHRQ Publication No. 08-05118-EF. Rockville, MD: Agency for Healthcare Research and Quality; 2008.

28. National Institute for Health and Clinical Excellence. The Guidelines Manual. London: National Institute for Health and Clinical Excellence; 2006.

29. Higgins JP, Thompson SG. Quantifying heterogeneity in a meta-analysis. *Stat Med.* 2002;21:1539-1558.

30. Egger M, Davey SG, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *BMJ.* 1997;315:629-634.

31. Terrin N, Schmid CH, Lau J. In an empirical evaluation of the funnel plot, researchers could not visually identify publication bias. *J Clin Epidemiol.* 2005;58:894-901.

32. Aittasalo M, Miilunpalo S, Kukkonen-Harjula K, Pasanen M. A randomized intervention of physical activity promotion and patient self-monitoring in primary health care. *Prev Med.* 2006;42:40-46.

33. De Vet E, Oenema A, Sheeran P, Brug J. Should implementation intentions interventions be implemented in obesity prevention: the impact of if-then plans on daily physical activity in Dutch adults. *Int J Behav Nutr Phys Act.* 2009;6:11.

34. Delichatsios HK, Friedman RH, Glanz K, et al. Randomized trial of a "talking computer" to improve adults' eating habits. *Am J Health Promot.* 2001;15:215-224.

35. Pinto BM, Friedman R, Marcus BH, Kelley H, Tennstedt S, Gillman MW. Effects of a computer-based, telephone-counseling system on physical activity. *Am J Prev Med.* 2002;23:113-120.

36. Elley CR, Kerse N, Arroll B, Robinson E. Effectiveness of counselling patients on physical activity in general practice: cluster randomised controlled trial. *BMJ.* 2003;326:793.

37. Kerse N, Elley CR, Robinson E, Arroll B. Is physical activity counseling effective for older people? A cluster randomized, controlled trial in primary care. *J Am Geriatr Soc.* 2005;53:1951-1956.

38. Goldstein MG, Pinto BM, Marcus BH, et al. Physician-based physical activity counseling for middle-aged and older adults: a randomized trial. *Ann Behav Med.* 1999;21:40-47.

39. Pinto BM, Goldstein MG, DePue JD, Milan FB. Acceptability and feasibility of physician-based activity counseling: the PAL project. *Am J Prev Med.* 1998;15:95-102.

40. Grandes G, Sanchez A, Sanchez-Pinilla RO, et al. Effectiveness of physical activity advice and prescription by physicians in routine primary care: a cluster randomized trial. *Arch Intern Med.* 2009;169:694-701.

41. Green BB, McAfee T, Hindmarsh M, Madsen L, Caplow M, Buist D. Effectiveness of telephone support in increasing physical activity levels in primary care patients. *Am J Prev Med.* 2002;22:177-183.

42. Greene GW, Fey-Yensan N, Padula C, Rossi SR, Rossi JS, Clark PG. Change in fruit and vegetable intake over 24 months in older adults: results of the SENIOR project intervention. *Gerontologist.* 2008;48:378-387.

43. Greaney ML, Riebe D, Ewing GC, et al. Long-term effects of a stage-based intervention for changing exercise

intentions and behavior in older adults. *Gerontologist.* 2008;48:358-367.

44. Halbert JA, Silagy CA, Finucane PM, Withers RT, Hamdorf PA. Physical activity and cardiovascular risk factors: effect of advice from an exercise specialist in Australian general practice. *Med J Aust.* 2000;173:84-87.

45. Halbert JA, Silagy CA, Finucane P, Withers RT, Hamdorf PA. Recruitment of older adults for a randomized, controlled trial of exercise advice in a general practice setting. *J Am Geriatr Soc.* 1999;47:477-481.

46. Harland J, White M, Drinkwater C, Chinn D, Farr L, Howel D. The Newcastle exercise project: a randomised controlled trial of methods to promote physical activity in primary care. *BMJ.* 1999;319:828-832.

47. Hellenius ML, de Faire U, Berglund B, Hamsten A, Krakau I. Diet and exercise are equally effective in reducing risk for CVD: results of a randomized controlled study in men with slightly to moderately raised cardiovascular risk factors. *Atherosclerosis.* 1993;103:81-91.

48. Hellenius ML, Dahlof C, Aberg H, Krakau I, de Faire U. Quality of life is not negatively affected by diet and exercise intervention in healthy men with cardiovascular risk factors. *Qual Life Res.* 1995;4:13-20.

49. Naslund GK, Fredrikson M, Hellenius ML, de Faire U. Effect of diet and physical exercise intervention programmes on coronary heart disease risk in smoking and non-smoking men in Sweden. *J Epidemiol Community Health.* 1996;50:131-136.

50. Kallings LV, Sierra Johnson J, Fisher RM, et al. Beneficial effects of individualized physical activity on prescription on body composition and cardiometabolic risk factors: results from a randomized controlled trial. *Eur J Cardiovasc Prev Rehabil.* 2009;16:80-84.

51. Kallings LV. Physical Activity on Prescription: Studies on Physical Activity Level, Adherence, and Cardiovascular Risk Factors. Stockholm, Sweden: Karolinska Institutet; 2008.

52. Katz DL, Shuval K, Comerford BP, Faridi Z, Njike VY. Impact of an educational intervention on internal medicine residents' physical activity counselling: the Pressure System Model. *J Eval Clin Pract.* 2008;14:294-299.

53. King AC, Baumann K, O'Sullivan P, Wilcox S, Castro C. Effects of moderate-intensity exercise on physiological, behavioral, and emotional responses to family caregiving: a randomized controlled trial. *J Gerontol Series A Biol Sci Med Sci.* 2002;57:M26-M36.

54. Castro CM, Wilcox S, O'Sullivan P, Baumann K, King AC. An exercise program for women who are caring for relatives with dementia. *Psychosom Med.* 2002;64:458-468.

55. King AC, Friedman R, Marcus B, et al. Ongoing physical activity advice by humans versus computers: the Community Health Advice by

Telephone (CHAT) trial. *Health Psychol.* 2007;26:718-727.

56. Kinmonth AL, Wareham NJ, Hardeman W, et al. Efficacy of a theory-based behavioural intervention to increase physical activity in an at-risk group in primary care (ProActive UK): a randomised trial. *Lancet.* 2008;371:41-48.

57. Williams K, Prevost AT, Griffin S, et al. The ProActive trial protocol: a randomised controlled trial of the efficacy of a family-based, domiciliary intervention programme to increase physical activity among individuals at high risk of diabetes. *BMC Public Health.* 2004;4:48.

58. Kolt GS, Schofield GM, Kerse N, Garrett N, Oliver M. Effect of telephone counseling on physical activity for low-active older people in primary care: a randomized, controlled trial. *J Am Geriatr Soc.* 2007;55:986-992.

59. Lawton BA, Rose SB, Elley CR, Dowell AC, Fenton A, Moyes SA. Exercise on prescription for women aged 40–74 recruited through primary care: two year randomised controlled trial. *BMJ.* 2008;337:a2509.

60. Marcus BH, Napolitano MA, King AC, et al. Telephone versus print delivery of an individualized motivationally tailored physical activity intervention: Project STRIDE. *Health Psychol.* 2007;26:401-409.

61. Marshall AL, Bauman AE, Owen N, Booth ML, Crawford D, Marcus BH. Population-based randomized controlled trial of a stage-targeted physical activity intervention. *Ann Behav Med.* 2003;25:194-202.

62. Martinson BC, Crain AL, Sherwood NE, Hayes M, Pronk NP, O'Connor PJ. Maintaining physical activity among older adults: six-month outcomes of the Keep Active Minnesota randomized controlled trial. *Prev Med.* 2008;46:111-119.

63. Sherwood NE, Martinson BC, Crain AL, Hayes MG, Pronk NP, O'Connor PJ. A new approach to physical activity maintenance: rationale, design, and baseline data from the Keep Active Minnesota Trial. *BMC Geriatrics.* 2008;8:17.

64. Morey MC, Peterson MJ, Pieper CF, et al. The Veterans Learning to Improve Fitness and Function in Elders Study: a randomized trial of primary care-based physical activity counseling for older men. *J Am Geriatr Soc.* 2009;57:1166-1174.

65. Morey MC, Peterson MJ, Pieper CF, et al. Project LIFE—Learning to Improve Fitness and Function in Elders: methods, design, and baseline characteristics of randomized trial. *J Rehabil Res Dev.* 2008;45:31-42.

66. Napolitano MA, Whiteley JA, Papandonatos G, et al. Outcomes from the women's wellness project: a community-focused physical activity trial for women. *Prev Med.* 2006;43:447-453.

67. Dutton GR, Napolitano MA, Whiteley JA, Marcus BH. Is physical activity a gateway behavior for diet? Findings from a physical activity trial. *Prev Med.* 2008;46:216-221.

68. Norris SL, Grothaus LC, Buchner DM, Pratt M. Effectiveness of physician-based assessment and counseling for exercise in a staff model HMO. *Prev Med.* 2000;30:513-523.

69. Pinto BM, Goldstein MG, Ashba J, Sciamanna CN, Jette A. Randomized controlled trial of physical activity counseling for older primary care patients. *Am J Prev Med.* 2005;29:247-255.

70. Stensel DJ, Brooke-Wavell K, Hardman AE, Jones PR, Norgan NG. The influence of a 1-year programme of brisk walking on endurance fitness and body composition in previously sedentary men aged 42–59 years. *Eur J Appl Physiol Occup Physiol.* 1994;68:531-537.

71. Stewart AL, Verboncoeur CJ, McLellan BY, et al. Physical activity outcomes of CHAMPS II: a physical activity promotion program for older adults. *J Gerontol A Biol Sci Med Sci.* 2001;56:M465-M470.

72. Yates T, Davies M, Gorely T, et al. Twelve-month follow-up from the PREPARE (Prediabetes Risk Education and Physical Activity Recommendation and Encouragement) programme study: a randomized controlled trial. *Diabet Med.* 2009;26:17.

73. Yates T, Davies M, Gorely T, Bull F, Khunti K. Rationale, design and baseline data from the Prediabetes Risk Education and Physical Activity Recommendation and Encouragement (PREPARE) programme study: a randomized controlled trial. *Patient Educ Couns.* 2008;73:264-271.

74. Connell CM, Janevic MR. Effects of a telephone-based exercise intervention for dementia caregiving wives: a randomized controlled trial. *J Appl Gerontol*. 2009;28:171-194.

75. Pekmezi DW, Neighbors CJ, Lee CS, et al. A culturally adapted physical activity intervention for Latinas: a randomized controlled trial. *Am J Prev Med.* 2009;37:495-500.

76. Martinson BC, Sherwood NE, Crain AL, et al. Maintaining physical activity among older adults: 24-month outcomes of the Keep Active Minnesota randomized controlled trial. *Prev Med.* 2010;51:37-44.

77. Anderson JW, Garrity TF, Wood CL, Whitis SE, Smith BM, Oeltgen PR. Prospective, randomized, controlled comparison of the effects of low-fat and low-fat plus high-fiber diets on serum lipid concentrations. *Am J Clin Nutr.* 1992;56:887-894.

78. Baron JA, Gleason R, Crowe B, Mann JI. Preliminary trial of the effect of general practice based nutritional advice. *Br J Gen Pract.* 1990;40:137-141.

79. Beresford SA, Curry SJ, Kristal AR, Lazovich D, Feng Z, Wagner EH. A dietary intervention in primary care practice: the Eating Patterns Study. *Am J Public Health.* 1997;87:610-616.

80. Bernstein A, Nelson ME, Tucker KL, et al. A home-based nutrition intervention to increase consumption of fruits, vegetables, and calcium-rich foods in community dwelling elders. *J Am Diet Assoc.* 2002;102:1421-1427.

81. Brekke HK, Jansson PA, Lenner RA. Long-term (1- and 2-year) effects of lifestyle intervention in type 2 diabetes relatives. *Diabet Res Clin Pract.* 2005;70:225-234.

82. Carpenter RA, Finley C, Barlow CE. Pilot test of a behavioral skill building intervention to improve overall diet quality. *J Nutr Educ Behav.* 2004;36:20-24.

83. Coates RJ, Bowen DJ, Kristal AR, et al. The Women's Health Trial Feasibility Study in Minority Populations: changes in dietary intakes. *Am J Epidemiol.* 1999;149:1104-1112.

84. Bowen D, Clifford CK, Coates R, et al. The Women's Health Trial Feasibility Study in Minority Populations: design and baseline descriptions. *Ann Epidemiol.* 1996;6:507-519.

85. Hall WD, Feng Z, George VA, et al. Low-fat diet: effect on anthropometrics, blood pressure, glucose, and insulin in older women. *Ethn Dis.* 2003;13:337-343.

86. Fries E, Edinboro P, McClish D, et al. Randomized trial of a low-intensity dietary intervention in rural residents: the Rural Physician Cancer Prevention Project. *Am J Prev Med.* 2005;28:162-168.

87. Hypertension Prevention Trial Research Group. The Hypertension Prevention Trial: three-year effects of dietary changes on blood pressure. *Arch Intern Med.* 1990;150:153-162.

88. Shah M, Jeffery RW, Laing B, Savre SG, Van NM, Strickland D. Hypertension Prevention Trial (HPT): food pattern changes resulting from intervention on sodium, potassium, and energy intake. *J Am Diet Assoc.* 1990;90:69-76.

89. Meinert CL, Borhani NO, Langford HG. Design, methods, and rationale in the Hypertension Prevention Trial. *Control Clin Trials.* 1989;10:1S-29S.

90. John JH, Ziebland S, Yudkin P, Roe LS, Neil HA; Oxford Fruit and Vegetable Study Group. Effects of fruit and vegetable consumption on plasma antioxidant concentrations and blood pressure: a randomised controlled trial. *Lancet.* 2002;359:1969-1974.

91. Kristal AR, Curry SJ, Shattuck AL, Feng Z, Li S. A randomized trial of a tailored, self-help dietary intervention: the Puget Sound Eating Patterns study. *Prev Med.* 2000;31:380-389.

92. Lutz SF, Ammerman AS, Atwood JR, Campbell MK, DeVellis RF, Rosamond WD. Innovative newsletter interventions improve fruit and vegetable consumption in healthy adults. *J Am Diet Assoc.* 1999;99:705-709.

93. Prochaska JO, Velicer WF, Redding C, et al. Stage-based expert systems to guide a population of primary care patients to quit smoking, eat healthier, prevent skin cancer, and receive regular mammograms. *Prev Med.* 2005;41:406-416.

94. Roderick P, Ruddock V, Hunt P, Miller G. A randomized trial to evaluate the effectiveness of dietary advice by practice nurses in lowering diet-related coronary heart disease risk. *Br J Gen Pract.* 1997;47:7-12.

95. Sacerdote C, Fiorini L, Rosato R, Audenino M, Valpreda M, Vineis P. Randomized controlled trial: effect of nutritional counselling in general practice. *Int J Epidemiol.* 2006;35:409-415.

96. Stefanick ML, Mackey S, Sheehan M, Ellsworth N, Haskell WL, Wood PD. Effects of diet and exercise in men and postmenopausal women with low levels of HDL cholesterol and high levels of LDL cholesterol. *N Engl J Med.* 1998;339:12-20.

97. Stevens VJ, Glasgow RE, Toobert DJ, Karanja N, Smith KS. One-year results from a brief, computer-assisted intervention to decrease consumption of fat and increase consumption of fruits and vegetables. *Prev Med.* 2003;36:594-600.

98. The Trials of Hypertension Prevention Collaborative Research Group. The effects of nonpharmacologic interventions on blood pressure of persons with high normal levels: results of the Trials of Hypertension Prevention, phase I. *JAMA.* 1992;267:1213-1220.

99. Kumanyika SK, Hebert PR, Cutler JA, et al. Feasibility and efficacy of sodium reduction in the Trials of Hypertension Prevention, phase I. *Hypertens.* 1993;22:502-512.

100. Satterfield S, Cutler JA, Langford HG, et al. Trials of hypertension prevention: phase I design. *Ann Epidemiol.* 1991;1:455-471.

101. The Trials of Hypertension Prevention Collaborative Research Group. Effects of weight loss and sodium reduction intervention on blood pressure and hypertension incidence in overweight people with high-normal blood pressure: the Trials of Hypertension Prevention, phase II. *Arch Intern Med.* 1997;157:657-667.

102. Hebert PR, Bolt RJ, Borhani NO, et al. Design of a multicenter trial to evaluate long-term life-style intervention in adults with high-normal blood pressure levels: the Trials of Hypertension Prevention Phase II. *Ann Epidemiol.* 1995;5:130-139.

103. Kumanyika SK, Cook NR, Cutler JA, et al. Sodium reduction for hypertension prevention in overweight adults: further results from the Trials of Hypertension Prevention Phase II. *J Hum Hypertens.* 2005;19:33-45.

104. Tinker LF, Bonds DE, Margolis KL, et al. Low-fat dietary pattern and risk of treated diabetes mellitus in postmenopausal women: the Women's Health Initiative randomized controlled dietary modification trial. *Arch Intern Med.* 2008;168:1500-1511.

105. Prentice RL, Caan B, Chlebowski RT, et al. Low-fat dietary pattern and risk of invasive breast cancer: the Women's Health Initiative Randomized Controlled Dietary Modification Trial. *JAMA.* 2006;295:629-642.

106. Howard BV, Van HL, Hsia J, et al. Low-fat dietary pattern and risk of CVD: the Women's Health Initiative Randomized Controlled Dietary Modification Trial. *JAMA.* 2006;295:655-666.

107. Design of the Women's Health Initiative clinical trial and

observational study. *Control Clin Trials.* 1998;19:61-109.

108. Watanabe M, Yamaoka K, Yokotsuka M, Tango T. Randomized controlled trial of a new dietary education program to prevent type 2 diabetes in a high-risk group of Japanese male workers. *Diabet Care.* 2003;26:3209-3214.

109. Cook NR, Cutler JA, Obarzanek E, et al. Long term effects of dietary sodium reduction on CVD outcomes: observational follow-up of the Trials of Hypertension Prevention (TOHP). *BMJ.* 2007;334:885-888.

110. Aldana SG, Greenlaw RL, Diehl HA, et al. The behavioral and clinical effects of therapeutic lifestyle change on middle-aged adults. *Prev Chronic Dis.* 2006;3:A05.

111. Aldana SG, Greenlaw RL, Diehl HA, et al. Effects of an intensive diet and physical activity modification program on the health risks of adults. *J Am Diet Assoc.* 2005;105:371-381.

112. Babazono A, Kame C, Ishihara R, Yamamoto E, Hillman AL. Patient-motivated prevention of lifestyle-related disease in Japan: a randomized, controlled clinical trial. *Dis Manag Health Outcomes.* 2007;15:119-126.

113. Brekke HK, Sunesson A, Axelsen M, Lenner RA. Attitudes and barriers to dietary advice aimed at reducing risk of type 2 diabetes in first-degree relatives of patients with type 2 diabetes. *J Hum Nutr Diet.* 2004;17:513-521.

114. Eakin EG, Bull SS, Riley KM, Reeves MM, McLaughlin P, Gutierrez S. Resources for health: a primary-care-based diet and physical activity intervention targeting urban Latinos with multiple chronic conditions. *Health Psychol.* 2007;26:392-400.

115. Edelman D, Oddone EZ, Liebowitz RS, et al. Multidimensional integrative medicine intervention to improve cardiovascular risk. *J Gen Intern Med.* 2006;21:728-734.

116. Franko DL, Cousineau TM, Trant M, et al. Motivation, self-efficacy, physical activity and nutrition in college students: randomized controlled trial of an internet-based education program. *Prev Med.* 2008;47:369-377.

117. Hardcastle S, Taylor A, Bailey M, Castle R. A randomised controlled trial on the effectiveness of a primary health care based counselling intervention on physical activity, diet and CHD risk factors. *Patient Educ Couns.* 2008;70:31-39.

118. Oldroyd JC, Unwin NC, White M, Mathers JC, Alberti KG. Randomised controlled trial evaluating lifestyle interventions in people with impaired glucose tolerance. *Diabet Res Clin Pract.* 2006;72:117-127.

119. Hivert MF, Langlois MF, Bérard P, Cuerrier JP, Carpentier AC. Prevention of weight gain in young adults through a seminar-based intervention program. *Int J Obes.* 2007;31:1262-1269.

120. Jeffery RW, French SA. Preventing weight gain in adults: the pound of prevention study. *Am J Public Health.* 1999;89:747-751.

121. Keyserling TC, Samuel Hodge CD, Jilcott SB, et al. Randomized trial of a clinic-based, community-supported, lifestyle intervention to improve physical activity and diet: the North Carolina enhanced WISEWOMAN project. *Prev Med.* 2008;46:499-510.

122. Mosca L, Mochari H, Liao M, Christian AH, Edelman DJ, Aggarwal B, Oz MC. A novel family-based intervention trial to improve heart health—FIT Heart: results of a randomized controlled trial. *Circ Cardiovasc Qual Outcomes.* 2008;1:98-106.

123. Oldroyd JC, Unwin NC, White M, Imrie K, Mathers JC, Alberti KG. Randomised controlled trial evaluating the effectiveness of behavioural interventions to modify cardiovascular risk factors in men and women with impaired glucose tolerance: outcomes at 6 months. *Diabet Res Clin Pract.* 2001;52:29-43.

124. Simkin-Silverman LR, Wing RR, Boraz MA, Meilahn EN, Kuller LH. Maintenance of cardiovascular risk factor changes among middle-aged women in a lifestyle intervention trial. *Womens Health.* 1998;4:255-271.

125. Simkin-Silverman L, Wing RR, Hansen DH, et al. Prevention of cardiovascular risk factor elevations in healthy premenopausal women. *Prev Med.* 1995;24:509-517.

126. Simkin-Silverman LR, Wing RR, Boraz MA, Kuller LH. Lifestyle intervention can prevent weight gain during menopause: results from a 5-year randomized clinical trial. *Ann Behav Med.* 2003;26:212-220.

127. Thompson JL, Allen P, Helitzer DL, et al. Reducing diabetes risk in American Indian women. *Am J Prev Med.* 2008;34:192-201.

128. Herman C, Thompson J, Wolfe V, et al. Six-month Results From a Healthy Lifestyles Diabetes Primary Prevention Program Among Urban Native American Women. Boston: American Public Health Association 134th Annual Meeting and Exposition; 2006.

129. Allen P, Thompson JL, Herman CJ, et al. Impact of periodic follow-up testing among urban American Indian women with impaired fasting glucose. *Prev Chronic Dis.* 2008;5:A76.

130. Vandelanotte C, De Bourdeaudhuij I, Sallis JF, Spittaels H, Brug J. Efficacy of sequential or simultaneous interactive computer-tailored interventions for increasing physical activity and decreasing fat intake. *Ann Behav Med.* 2005;29:138-146.

131. Wister A, Loewen N, Kennedy-Symonds H, McGowan B, McCoy B, Singer J. One-year follow-up of a therapeutic lifestyle intervention targeting CVD risk. *CMAJ.* 2007;177:859-865.

132. Kuller LH, Simkin-Silverman LR, Wing RR, Meilahn EN, Ives DG. Women's Healthy Lifestyle Project, a randomized clinical trial: results at 54 months. *Circulation.* 2001;103:32-37.

133. Albert CM, Mittleman MA, Chae CU, Lee IM, Hennekens CH, Manson JE. Triggering of sudden death from cardiac causes by vigorous exertion. *N Engl J Med.* 2000;343:1355-1361.

134. Giri S, Thompson PD, Kiernan FJ, et al. Clinical and angiographic characteristics of exertion-related acute myocardial infarction. *JAMA.* 1999;282:1731-1736.

135. Hallqvist J, Moller J, Ahlbom A, Diderichsen F, Reuterwall C, de Faire U. Does heavy physical exertion trigger myocardial infarction? A case-crossover analysis nested in a population-based case-referent study. *Am J Epidemiol.* 2000;151:459-467.

136. Mittleman MA, Maclure M, Tofler GH, Sherwood JB, Goldberg RJ, Muller JE. Triggering of acute myocardial infarction by heavy physical exertion: protection against triggering by regular exertion. *N Engl J Med.* 1993;329:1677-1683.

137. Siscovick DS, Weiss NS, Fletcher RH, Lasky T. The incidence of primary cardiac arrest during vigorous exercise. *N Engl J Med.* 1984;311:874-877.

138. von KS, Mittleman MA, Dockery DW, et al. Intensity of physical exertion and triggering of myocardial infarction: a case-crossover study. *Eur Heart J.* 2008;29:1881-1888.

139. Willich SN, Lewis M, Lowel H, Arntz HR, Schubert F, Schroder R. Physical exertion as a trigger of acute myocardial infarction. *N Engl J Med.* 1993;329:1684-1690.

140. Anderson CA, Appel LJ. Dietary modification and CVD prevention: a matter of fat. *JAMA*. 2006;295:693-695.

141. U.S. Department of Health and Human Services. 2008 Physical Activity Guidelines for Americans. Washington, DC: U.S. Department of Health and Human Services; 2008.

142. Danaei G, Ding EL, Mozaffarian D, et al. The preventable causes of death in the United States: comparative risk assessment of dietary, lifestyle, and metabolic risk factors. *PLoS Med.* 2009;6:e1000058.

143. Borugian MJ, Sheps SB, Kim-Sing C, et al. Waist-to-hip ratio and breast cancer mortality. *Am J Epidemiol.* 2003;158:963-968.

144. Moore TJ, Vollmer WM, Appel LJ, et al. Effect of dietary patterns on ambulatory blood pressure: results from the Dietary Approaches to Stop Hypertension (DASH) trial. *Hypertens.* 1999;34:472-477.

145. Sacks FM, Svetkey LP, Vollmer WM, et al. Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. *N Engl J Med.* 2001;344:3-10.

146. MacMahon S, Peto R, Cutler J, et al. Blood pressure, stroke, and coronary heart disease. Part 1, prolonged differences in blood pressure: prospective observational studies corrected for the regression dilution bias. *Lancet.* 1990;335:765-774.

147. Law MR, Wald NJ, Thompson SG. By how much and how quickly does reduction in serum cholesterol concentration lower risk of ischaemic heart disease? *BMJ.* 1994;308:367-372.

148. Joshipura KJ, Hu FB, Manson JE, et al. The effect of fruit and vegetable intake on risk for coronary heart

disease. *Ann Intern Med.* 2001;134:1106-1114.

149. Bazzano LA, Li TY, Joshipura KJ, Hu FB. Intake of fruit, vegetables, and fruit juices and risk of diabetes in women. *Diabet Care.* 2008;31:1311-1317.

150. Durstine JL, Grandjean PW, Davis PG, Ferguson MA, Alderson NL, DuBose KD. Blood lipid and lipoprotein adaptations to exercise: a quantitative analysis. *Sports Med.* 2001;31:1033-1062.

151. Howard BV, Curb JD, Eaton CB, et al. Low-fat dietary pattern and lipoprotein risk factors: the Women's Health Initiative Dietary Modification Trial. *Am J Clin Nutr.* 2010;91:860-874.

152. Zaza S, Lawrence RS, Mahan CS, et al. Scope and organization of the Guide to Community Preventive Services. *Am J Prev Med.* 2000;18:27-34.

153. Fowles ER, Sterling BS, Walker LO. Measuring dietary intake in nursing research. *Can J Nurs Res.* 2007;39:146-165.

154. Higgins JP, Green S (eds). Cochrane Handbook for Systematic Reviews of Interventions. Version 5.0.2. London: Cochrane Collaboration; 2009.

155. DerSimonian R, Laird N. Meta-analysis in clinical trials. *Control Clin Trials.* 1986;7:177-188.

156. Laird RD, Studenski S, Perera S, Wallace D. Fall history is an independent predictor of adverse health outcomes and utilization in the elderly. *Am J Manag Care.* 2001;7:1133-1138.

157. Beresford SA, Farmer EM, Feingold L, Graves KL, Sumner SK, Baker RM. Evaluation of a self-help dietary intervention in a primary care setting. *Am J Public Health.* 1992;82:79-84.

158. Campbell MK, DeVellis BM, Strecher VJ, Ammerman AS, DeVellis RF, Sandler RS. Improving dietary behavior: the effectiveness of tailored messages in primary care settings. *Am J Public Health.* 1994;84:783-787.

159. Delichatsios HK, Hunt MK, Lobb R, Emmons K, Gillman MW. EatSmart: efficacy of a multifaceted preventive nutrition intervention in clinical practice. *Prev Med.* 2001;33:91-98.

160. Henderson MM, Kushi LH, Thompson DJ, et al. Feasibility of a randomized trial of a low-fat diet for the prevention of breast cancer: dietary compliance in the Women's Health Trial Vanguard Study. *Prev Med.* 1990;19:115-133.

161. Keyserling TC, Ammerman AS, Davis CE, Mok MC, Garrett J, Simpson R Jr. A randomized controlled trial of a physician-directed treatment program for low-income patients with high blood cholesterol: the Southeast Cholesterol Project. *Arch Fam Med.* 1997;6:135-145.

162. Knutsen SF, Knutsen R. The Tromso Survey: the Family Intervention Study—the effect of intervention on some coronary risk factors and dietary habits, a 6-year follow-up. *Prev Med.* 1991;20:197-212.

163. Lindholm LH, Ekbom T, Dash C, Eriksson M, Tibblin G, Schersten B. The impact of health care advice given in primary care on cardiovascular risk. *BMJ.* 1995;310:1105-1109.

164. Maskarinec G, Chan CL, Meng L, Franke AA, Cooney RV. Exploring the feasibility and effects of a high fruit and vegetable diet in healthy women. *Cancer Epidemiol Biomarkers Prev.* 1999;8:919-924.

165. Mojonnier ML, Hall Y, Berkson DM, et al. Experience in changing food habits of hyperlipidemic men and women. *J Am Diet Assoc.* 1980;77:140-148.

166. Neaton JD, Broste S, Cohen L, Fishman EL, Kjelsberg MO, Schoenberger J. The Multiple Risk Factor Intervention Trial (MRFIT) VII: a comparison of risk factor changes between the two study groups. *Prev Med.* 1981;10:519-543.

167. Ockene IS, Hebert JR, Ockene JK, Merriam PA, Hurley TG, Saperia GM. Effect of training and a structured office practice on physician-delivered nutrition counseling: the Worcester-Area Trial for Counseling in Hyperlipidemia (WATCH). *Am J Prev Med.* 1996;12:252-258.

168. Siero FW, Broer J, Bemelmans WJ, Meyboom-de Jong BM. Impact of group nutrition education and surplus value of Prochaska-based stage-matched information on health-related cognitions and on Mediterranean nutrition behavior. *Health Educ Res.* 2000;15:635-647.

169. Steptoe A, Doherty S, Rink E, Kerry S, Kendrick T, Hilton S. Behavioural counselling in general practice for the promotion of healthy behaviour among adults at increased risk of coronary heart disease: randomised trial. *BMJ.* 1999;319:943-947.

170. Burton LC, Paglia MJ, German PS, Shapiro S, Damiano AM. The effect among older persons of a general preventive visit on three health behaviors: smoking, excessive alcohol drinking, and sedentary lifestyle. *Prev Med.* 1995;24:492-497.

171. Kerse NM, Flicker L, Jolley D, Arroll B, Young D. Improving the health behaviours of elderly people: randomised controlled trial of a general practice education programme. *BMJ.* 1999;319:683-687.

172. Smith BJ, Bauman AE, Bull FC, Booth ML, Harris MF. Promoting physical activity in general practice: a controlled trial of written advice and information materials. *Br J Sports Med.* 2000;34:262-267.

173. Swinburn BA, Walter LG, Arroll B, Tilyard MW, Russell DG. The green prescription study: a randomized controlled trial of written exercise advice provided by general practitioners. *Am J Public Health.* 1998;88:288-291.

174. NIMH Multisite HIV/STD Prevention Trial for African American Couples Group. Eban health promotion intervention: conceptual basis and procedures. *J Acquir Immune Defic Syndr*. 2008;49(Suppl 1):S28-S34.

175. Munakata M, Honma H, Akasi M, et al. Japanese study to organize proper lifestyle modifications for metabolic syndrome (J-STOP-MetS): design and method. *Vasc Health Risk Manag.* 2008;4:415-420.

176. Groeneveld IF, Proper KI, van der Beek AJ, van Duivenbooden C, van Mechelen W. Design of a RCT

evaluating the (cost-) effectiveness of a lifestyle intervention for male construction workers at risk for CVD: the Health Under Construction study. *BMC Public Health.* 2008;8:1.

177. van Keulen HM, Mesters I, Brug J, et al. Vitalum study design: RCT evaluating the efficacy of tailored print communication and telephone motivational interviewing on multiple health behaviors. *BMC Public Health.* 2008;8:216.

178. Hosper K, Deutekom M, Stronks PK. The effectiveness of "Exercise on Prescription" in stimulating physical activity among women in ethnic minority groups in the Netherlands: protocol for a randomized controlled trial. *BMC Public Health.* 2008;8:406.

179. Gine-Garriga M, Martin C, Martin C, et al. Referral from primary care to a physical activity programme: establishing long-term adherence? A randomized controlled trial: rationale and study design. *BMC Public Health.* 2009;9:31.

180. Fitzsimons CF, Baker G, Wright A, et al. The "Walking for Wellbeing in the West" randomised controlled trial of a pedometer-based walking programme in combination with physical activity consultation with 12 month follow-up: rationale and study design. *BMC Public Health.* 2008;8:259.

181. Voils CI, Yancy WS Jr, Kovac S, et al. Study protocol: Couples Partnering for Lipid Enhancing Strategies (CouPLES): a randomized, controlled trial. *Trials.* 2009;10:10.

Table 1. Number of Trials Included in the Review and Meta-Analysis By Key Question

	Physical Activity	Healthful Diet	Lifestyle	Meta-analysis
Key Question 1- Health Outcomes	0	3	0	N/A
Key Question 2- Intermediate Outcomes	8	16	14	33 (n=64,319)
Key Question 3- Behavioral Outcomes	30	25	17	58 (n=87,930)
Key Question 4- Harms*	7	0	0	N/A

* Additional studies identified for harms (not including trials included for key questions 1–3).

Table 2. Counseling Trials By Intervention Intensity and Population Risk

Unselected	Selected for behavioral factors (physical activity or dietary intake)	Selected for increased cardiovascular risk
Low-intensity intervention (estimated 0-30 min)		
4: Beresford 1997 (HD)	**1: Prochaska 2005 (HD)**	
1: Carpenter 2004 (IG1) (HD)	4: Aittasalo 2006 (PA)	
1: Fries 2005 (HD)	**4: Goldstein 1999 (PA)**	
1: John 2002 (HD)	4: Grandes 2009 (PA)	
1: Kristal 2000 (HD)	1: Halbert 2000 (PA)	
1: Lutz 1999 (HD)	**0: Marcus 2007 (IG2) (PA)**	
1: Roderick 1997 (HD)	0: Marshall 2003 (PA)	
4: Sacerdote 2005 (HD)	**0: Napolitano 2006 (PA)**	
0: de Vet 2009 (PA)	**0: Pekmezi 2009 (PA)**	
4: Katz 2008 (PA)		
0: Stensel 1994 (PA)		
0: Jeffery 1999 (HD+PA)		
Moderate-intensity interventions (estimated 31-360 minutes)		
4*:Baron 1990 (HD)	**0: Greene 2008 (HD) (PA)**	0: Brekke 2005 (HD)(HD+PA)
2: Green 2002 (PA)	**0: Bernstein 2002 (HD)**	1: Hellenius 1993 (ALL 3)
0: Martinson 2008 (PA)	**1: Delichatsios 2001 (HD) (PA)**	**1: Stevens 2003 (HD)**
1: Morey 2009 (PA)	**0: King 2002 (HD) (PA)**	0: Watanabe 2003 (HD)
3-4: Norris 2000 (PA)	3:Elley 2003 (PA)	3: Kallings 2009 (PA)
0: Franko 2008 (HD+PA)	1: Harland 1999 (PA)	1: Yates 2009 (PA)
0: Vandelanotte 2005(HD+PA)	**0: King 2007 (PA)**	1: Babazono 2007 (HD+PA)
0: Connell 2009 (PA)	1: Kinmonth 2008 (PA)	**1: Eakin 2007 (HD+PA)**
	1: Kolt 2007 (PA)	1: Hardcastle 2008 (HD+PA)
	4*: Lawton 2008 (PA)	**1: Keyserling 2008 (HD+PA)**
	0: Marcus 2007 (IG1) (PA)	**1: Mosca 2008 (HD+PA)**
	2: Pinto 2005 (PA)	1: Wister 2007 (HD+PA)
High-intensity interventions (>360 minutes)		
0: Carpenter 2004 (IG2) (HD)	**0: Coates 1999 (HD)**	**0: HPT 1990 (HD)**
0: Aldana 2006 (HD+PA)	**0: Tinker 2008 (HD)**	**0: TOHP I 1992 (HD)**
0: Hivert 2007 (HD+PA)	**1: Stewart 2001 (PA)**	**0: TOHP II 1997 (HD)**
0: Simkin-Silverman 1995 (HD+PA)		**0: Stefanick 1998 (HD)**
0: Thompson 2008 (HD+PA)		**0: Anderson 1992 (HD)**
		1: Edelman 2005 (HD+PA)
		1: Oldroyd 2001 (HD+PA)

*Primary care nurse conducted intervention rather than physician; **Bold**=conducted in the United States

Numeric Prefix:

4=primary care provider conducted all or most of the intervention

3=primary care provider played substantial role in intervention (e.g., 1 of 2 visits was with primary care provider)

2=primary care provider played small role (e.g., brief advice followed by more extensive intervention conducted by other providers)

1=primary care provider played no direct role, but study participants were recruited from primary care or health plan rolls. Setting may have been primary care or mail, phone, or e-mail/Internet

0=primary care provider played no role, not conducted in primary care setting

Table 3. Randomized Controlled Trials for Physical Activity Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention description	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Low-intensity interventions (estimated 0-30 minutes)			
Stensel, 1994[70] UK Fair	N=72 100% men Mean age 51 Race/ethnicity NR Selected for sedentary behavior and age 42-59 years	Not described	**N** / **Baseline Mean** / **12 months Mean change (SD)** *BMI, kg/m²* **IG** 42 25.4 0.0 (1.2) **CG** 23 24.8 0.2 (1.5) NS
Medium-intensity interventions (estimated 31-360 minutes)			
Elley, 2003[36] New Zealand Good	N=878 34% men Mean age 58 23% nonwhite Selected for sedentary behavior and age 40-79 years	One brief visit with general practitioner with PA prescription, 3 phone calls from exercise physiologist, quarterly newsletters	**N** / **Baseline Mean** / **12 months Mean change (SD)** *BMI, kg/m²* **IG** 451 30.0 -0.1 (1.5) **CG** 427 29.9 -0.05 (1.3) *SBP, mmHg* **IG** 451 135.1 -2.6 (15.7) **CG** 427 135.4 -1.2 (14.3) *DBP, mmHg* **IG** 451 82.4 -2.6 (10.9) **CG** 427 81.8 -0.8 (10.2) *Cholesterol, mmol/L* **IG** 451 5.78 -0.02 (0.70) **CG** 427 5.64 0.01 (0.58) All NS

Table 3. Randomized Controlled Trials for Physical Activity Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention description	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Hellenius 1993[47] Sweden Fair	N=79 100% men Mean age 45 Race/ethnicity NR Selected for slightly elevated total cholesterol	One counseling visit with physician, offered aerobic exercise class 2-3 times per week (attendance not required)	**Baseline** **6 months** **N** **Mean** **Mean change (SD)** *BMI, kg/m^2* **IG** 39 25.3 -0.3(0.8)* **CG** 39 24.5 0.3(0.6) *SBP, mmHg* **IG** 39 133 -5.0(13.8)* **CG** 39 130 -1.0(11.2) *DBP, mmHg* **IG** 39 82 -4.0(8.0)* **CG** 39 82 -1.0(6.4) *Cholesterol, mmol/L* **IG** 39 5.98 -0.12(0.73) **CG** 39 5.97 -0.13(0.64) * p<0.05 for paired t-test of IG
Kallings 2009[50] Sweden Good	N=101 43% men Mean age NR Selected for age 64-74 years (calc), sedentary behavior, and overweight	One group session with physician, one individual counseling session with specialty provider including PA prescription	**Baseline** **6 months** **N** **Mean** **N** **Mean change (SD)** *BMI, kg/m^2* **IG** 47 29.7 41 -0.6(1.0)* **CG** 54 30.4 50 -0.2(0.7) *SBP, mmHg* **IG** 47 137.6 41 0.2(14.7) **CG** 54 142.3 50 -4.1(12.4) *DBP, mmHg* **IG** 47 79.9 41 -1.0(8.3) **CG** 54 81.6 50 -1.7(9.6) *Cholesterol, mmol/L* **IG** 47 5.6 41 -0.30(0.98)* **CG** 54 5.5 50 0.10(0.36) *Fasting glucose, mmol/L* **IG** 47 5.5 41 -0.2 (0.33) **CG** 54 5.4 50 -0.1 (0.36) * p<0.05

Table 3. Randomized Controlled Trials for Physical Activity Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention description	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Kinmonth 2008[56] UK Fair	N=365 % men NR Mean age NR Race/ethnicity NR Selected for age 30-50 years and a parental history of type 2 diabetes	Four 45-minute and two 15-minute counseling phone calls, postal contact for 7 months	**N** / **Baseline Mean** / **12 months Mean change (SD)** *BMI, kg/m²* **IG** 107 27.8 0.6(2.4) **CG** 111 27.8 0.0(2.3) *SBP, mmHg* **IG** 107 124.2 -3.2(12.2) **CG** 111 122.6 -3.4 (10.7) *DBP, mmHg* **IG** 107 79.1 -1.7 (9.9) **CG** 111 78.2 -3.1 (7.8) *Cholesterol, mmol/L* **IG** 107 5.03 0.10 (0.91) **CG** 111 5.29 0.02 (0.76) *Plasma glucose, mmol/L* **IG** 107 4.8 0.14 (--) **CG** 111 4.9 -0.01 (--) All NS
Lawton 2008[59] New Zealand Good	N=1089 0% men Mean age 59 Race/ethnicity NR Selected for age 40-74 years and sedentary behavior	One brief motivational interview including PA prescription and 30-minute followup visit with primary care nurse; five 15-minute calls from community exercise specialist	**N** / **Baseline Mean** / **12 months Mean change (SD)** / **24 months Mean change** *Weight, kg* **IG** 544 73.2 -0.6 (6.3) -0.6 **CG** 545 72.7 0.0 (6.3) -0.2 *SBP, mmHg* **IG** 544 122.8 -2.2 (14.6) -3.7 **CG** 545 123.4 -1.5 (14.8) -3.9 *DBP, mmHg* **IG** 544 73.8 -2.3 (8.3) -2.2 **CG** 545 74.7 -2.3 (7.8) -3.0 *Cholesterol, mmol/L* **IG** 544 6.10 -0.24 (0.96) -0.45 **CG** 545 6.03 -0.20 (0.91) -0.44 *Glucose, mmol/L* **IG** 544 5.02 -0.05 (--) **CG** 545 4.96 0.0 (--) All NS

Table 3. Randomized Controlled Trials for Physical Activity Counseling Interventions: Intermediate Outcomes

Author, Year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention Description	Intermediate outcomes (adiposity, BP, lipids, glucose)
Martinson 2008[62] US Good	N=1049 28% men Mean age 57 6% nonwhite Selected for age 50-70 years and increasing levels of physical activity	Four lectures, one group orientation, 23 phone calls, library or materials available for use, three motivational contests over 24 months, but not all completed at 6-month assessment	**N** / **Baseline Mean** / **6 months Mean change (SD)** *BMI, kg/m²* **IG** 495 27.5 -0.1 (2.4) **CG** 491 27.7 0.0 (2.5) NS
High-intensity interventions (estimated >360 minutes)			
Stewart, 2001[71] US Fair	N=173 34% men Mean age 74 Race/ethnicity NR Selected for sedentary behavior and Medicare enrollment	11 group sessions, one individual session, booklets, phone calls from counselor, monthly newsletters	Only self-reported BMI available
Yates 2009[72] UK Fair	N=98 66% men Mean age 65 25% nonwhite Selected for BMI and IGT	3-hour group session, two 10-minute followup sessions, and a subset received a pedometer	**N** / **Baseline Mean** / **12 months Mean change (SD)** *Weight, kg* **IG** 58 80.6 -0.03 (3.8) **CG** 29 81.1 -0.7 (3.5) *SBP, mmHg* **IG** 58 142.5 -1.4 (14.9) **CG** 29 141 -3.5 (14.0) *Cholesterol, mmol/L* **IG** 58 4.75 -0.03 (0.69) **CG** 29 4.8 0.11 (0.84) *2-hour glucose, mmol/L* **IG** 58 8.5 -0.78 (2.01) **CG** 29 8.4 -0.30 (2.54) All NS

BMI – body mass index; calc – calculated; CG – control group; DBP – diastolic blood pressure; IG – intervention group; IGT – impaired glucose tolerance; L – liters; mmol – millimole; N – number randomized; NR – not reported; NS – not significant; PA – physical activity; RCT – randomized controlled trial; SBP – systolic blood pressure; SD – standard deviation; UK – United Kingdom; US – United States

Table 4. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Intermediate Outcomes

Reference Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Salt only dietary counseling			
High-intensity interventions (estimated >360 minutes)			
HPT, 1990[87] US Good	N=841 65% men Mean age 39 18% nonwhite Selected for DBP 78-89	12 group sessions in 4 months plus ongoing maintenance	**Baseline** / **6 months** / **36 months** **N** / **Mean** / **N** / **Mean change (SE)** / **N** / **Mean change (SD)** *SBP, mmHg* **IG1+IG2** 392 / 124.05 / 353 / -3.60 (--) / 352 / -3.46 (--) **CG** 196 / 123.9 / 191 / -2.1 (0.6) / 177 / -2.9 (0.7) p IG2 v. IG1 / 0.822 / 0.161 p IG1 v. CG / 0.126 / 0.885 *DBP, mmHg* **IG1+IG2** 196 / 82.6 / 353 / -3.55 (--) / 352 / -3.26 (--) **CG** 196 / 83.0 / 191 / -3.0 (0.5) / 177 / -3.0 (0.5) p IG2 v. IG1 / 0.597 / 0.664 p IG1 v. CG / 0.398 / 0.787
TOHP I, 1992[98] US Fair	N=744 71% men Mean age 43 23% nonwhite Selected for DBP 80-89	10 individual or group sessions in 3 months plus ongoing maintenance	**Baseline** / **12 months** / **18 months** **N** / **Mean** / **N** / **Mean change (SD)** / **N** / **Mean change (SD)** *SBP, mmHg* **IG** 327 / 124.8 / 301 / -5.83 (7.46) / 304 / -5.08 (7.94) **CG** 417 / 125.1 / 392 / -3.93 (7.43) / 395 / -3.02 (8.31) Mean difference (95%CI) at end of study: -1.69 (-2.85, -0.54) *DBP, mmHg* **IG** 327 / 83.7 / 301 / -4.44 (5.38) / 304 / -4.35 (5.65) **CG** 417 / 83.9 / 392 / -3.37 (5.74) / 395 / -3.18 (5.80) Mean difference (95%CI) at end of study: -0.85 (-1.68, -0.02)

Table 4. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Intermediate Outcomes

Reference Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
TOHP II, 1997[101] US Good	N=1190 67% men Mean age 44 20% nonwhite Selected for DBP 83-89	10 group sessions in 3 months plus ongoing maintenance	**Baseline** N / Mean; **18 months** N / Mean change (SD); **36 months** N / Mean change (SD) *SBP, mmHg* **IG** 594 127.7 — 513 -3.8 (8.2) — 515 -0.7 (9.0) **CG** 596 127.3 — 525 -1.8 (7.0) — 514 0.6 (8.5) Mean difference (SE): -2.0 (0.5)* — -1.2 (0.5)# *DBP, mmHg* **IG** 594 86.1 — 513 -4.4 (6.5) — 515 -3.0 (6.5) **CG** 596 85.8 — 525 -3.2 (5.8) — 514 -2.4 (7.0) Mean difference (SE): -1.2 (0.4)† — -0.7 (0.4) * p<0.001 for comparison with CG † p=0.002 for comparison with CG # p=0.02 for comparison with CG
Fruits and vegetables only dietary counseling			
Low-intensity interventions (estimated 0-30 minutes)			
John, 2002[90] UK Fair	N=729 49% men Mean age 46 NR nonwhite Unselected	25-minute session, plus followup phone call and mailed booklet over 3 months	**Baseline** N / Mean; **6 months** N / Mean change (SD) *Weight, kg* **IG** 344 76.1 — 344 0.6 (2.6) **CG** 346 75.6 — 346 0.6 (2.6) Adjusted difference in change (95%CI): 0.1 (-0.4, 0.6) *SBP, mmHg* **IG** 344 130.2 — 344 -2.0 (13.5) **CG** 346 129.3 — 346 1.4 (14.6) Adjusted difference in change (95%CI): 4.0 (2.0, 6.0) *DBP, mmHg* **IG** 344 79.2 — 344 -1.6 (8.7) **CG** 346 79.9 — 346 -0.3 (8.7) Adjusted difference in change (95%CI): 1.5 (0.2, 2.7) *Total cholesterol, mmol/L* **IG** 344 5.037 — 344 -0.018 (0.87) **CG** 346 5.123 — 346 -0.036 (0.56) Adjusted difference in change (95%CI): 0.010 (-0.097, 0.116)

Table 4. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Intermediate Outcomes

Reference Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Fats only dietary counseling			
High-intensity interventions (estimated >360 minutes)			
Stefanick, 1998[96] US Fair	N=377 51% men Mean age 52 NR nonwhite Selected for slightly elevated LDL	9 group/individual sessions in 3 months, plus ongoing maintenance over 8 months	**Women** / **Men** **N** / **Mean change (SD) at 12 mo** / **N** / **Mean change (SD) at 12 mo** *Body weight, kg* **IG** 46 -2.7 (3.5)*** 49 -2.8 (3.5)*** **CG** 45 0.8 (4.2) 46 0.5 (2.7) *** p<0.001 for comparison with the CG *SBP, mmHg* **IG** 46 -3.5 (9.2) 49 -1.7 (6.4) **CG** 45 -2.4 (7.6) 46 0.3 (7.9) *DBP, mmHg* **IG** 46 -1.9 (5.0) 49 -0.3 (5.2) **CG** 45 -0.6 (5.9) 46 1.8 (6.1) *HDL cholesterol, mmol/L* **IG** 46 0.008 (0.489) 49 -0.021 (0.114) **CG** 45 0.026 (0.158) 46 -0.005 (0.111) *LDL cholesterol, mmol/L* **IG** 46 -0.189 (0.489) 49 -0.279 (0.486) **CG** 45 -0.026 (0.504) 46 -0.119 (0.546) *Total cholesterol, mmol/L* **IG** 46 -0.204 (0.533) 49 -0.341 (0.499) **CG** 45 -0.026 (0.504) 46 -0.101 (0.559) *Triglycerides, mmol/L* **IG** 46 -0.047 (0.735) 49 -0.071 (0.674) **CG** 45 0.024 (0.479) 46 0.079 (0.940) *Glucose, mmol/L* **IG** 46 -0.428 (0.367) 49 -0.422 (0.478) **CG** 45 -0.144 (0.844) 46 -0.211 (0.583)
Multiple message or general cardiovascular dietary counseling			
Low-intensity interventions (estimated 0-30 minutes)			
Kristal, 2000[91] US Fair	N=1459 51% men Mean age 45 14% nonwhite Unselected	Mailed materials, plus phone call at 1 month and semi-monthly newsletters over 12 months	*Body weight, kg* **12 month** **N** / **Mean change (SD)** **IG** 601 0.08 (--) **CG** 604 0.39 (--) Adjusted intervention effect: -0.76, p=0.088 Adjusted for age, sex, race, and income

Table 4. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Intermediate Outcomes

Reference Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Roderick, 1997[94] UK Fair	N=956 50% men Mean age 47 NR nonwhite Unselected	Minimum 1 session with nurse, followup session in 1 month if needed	**Baseline** **12 months** **N** **Mean** **N** **Mean change (SD)** *BMI, kg/m^2* **IG** 473 26.3 401 0.01 (1.97) **CG** 483 25.9 352 0.14 (2.10) Mean difference within matched pairs (95%CI): -0.12 (-0.30, 0.05) *SBP, mmHg* **IG** 473 124.4 401 -1.14 (16.10) **CG** 483 125.2 352 -0.39 (13.30) Mean difference within matched pairs (95%CI): -0.59 (-2.43, 1.24) *DBP, mmHg* **IG** 473 77.8 401 -0.19 (10.55) **CG** 483 77.1 352 -0.09 (9.79) Mean difference within matched pairs (95%CI): 0.09 (-4.9, 5.0) *Total cholesterol, mmol/L* **IG** 473 NR 401 -0.23 (--) **CG** 483 NR 352 -0.0007 (--) Mean difference (95%CI): -0.20 (-0.38, -0.03)
Sacerdote, 2005[95] Italy Fair	N=3179 50% men Mean age 44 NR nonwhite Unselected	15-minute session with PCP with brochure	**Baseline** **12 months** **N** **Mean** **N** **Mean change (SD)** *BMI, kg/m^2* **IG** 1592 24.8 1488 -0.4 (1.8) **CG** 1587 24.3 1489 0 (1.57) Adjusted effect of intervention: F=5.42, p=0.02 *SBP, mmHg* **IG** 1592 128.7 1488 0.1 (13.6) **CG** 1587 128.8 1489 -0.20 (13.3) Adjusted effect of intervention: F=0.01, p=0.93 *DBP, mmHg* **IG** 1592 78.5 1488 0.4 (7.6) **CG** 1587 78.7 1489 0.6 (16.2) Adjusted effect of intervention: F=0.03, p=0.85 Adjusted for sex, BMI, education, and time

Table 4. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Intermediate Outcomes

Reference Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Medium-intensity interventions (estimated 31-360 minutes)			
Baron, 1990[78] UK Fair	N=368 51% men Mean age 42 NR nonwhite Unselected	3 individual/group visits over 3 months	**Baseline** **12 months** **N** **Mean** **N** **Mean change (SD)** *Total cholesterol, mmol/L* **IG** 186 4.86 167 -0.20 (0.76) **CG** 181 4.84 178 -0.42 (0.57) *LDL, mmol/L* **IG** 169 2.83 164 -0.30 (0.69) **CG** 167 2.81 164 -0.30 (0.69) *HDL, mmol/L* **IG** 172 149 164 -0.03 (0.26) **CG** 174 1.52 158 -0.02 (0.24) p= NS
Brekke, 2005[81] Sweden Fair	N=77 63% men Mean age 43 NR nonwhite Relative with DM, otherwise unselected	2 individual sessions plus followup phone calls for 8 months	**Baseline** **12 months** **N** **Mean** **N** **Mean change (SD)** *BMI, kg/m^2* **IG** 24 25.0 24 -0.15 (0.87) **CG** 19 26.1 19 0.22 (1.36) *Total cholesterol, mmol/L* **IG** 24 4.84 24 0.10 (0.64) **CG** 19 5.03 19 0.24 (0.58) *HDL, mmol/L* **IG** 24 1.26 24 0.08 (0.26) **CG** 19 1.31 19 -0.04 (0.16) *LDL, mmol/L* **IG** 24 3.06 24 0.01 (0.62) **CG** 19 3.23 19 0.28 (0.49) *Triglycerides, mmol/L* **IG** 24 1.16 24 0.03 (0.42) **CG** 19 1.10 19 0.01 (0.23) *Fasting blood glucose, mmol/L* **IG** 24 4.69 24 -0.33 (0.81) **CG** 19 5.04 19 -0.21 (0.51)

Table 4. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Intermediate Outcomes

Reference Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Hellenius, 1993[47] Sweden Fair	N=158 100% men Mean age 45 NR nonwhite Selected for slightly elevated total cholesterol	1 session with PCP and 1 session with dietitian over 2 weeks	**Baseline** / **6 months** **N** **Mean** / **N** **Mean change (SD)** *BMI, kg/m²* **IG** 40 25.2 / 40 -0.3 (1.02)* **CG** 39 24.5 / 39 0.3 (0.64) *SBP, mmHg* **IG** 40 130 / 40 -7 (11.30) **CG** 39 130 / 39 -1 (11.20) *DBP, mmHg* **IG** 40 82 / 40 -6 (6.40)* **CG** 39 82 / 39 -1 (6.40) *Total cholesterol, mmol/L* **IG** 40 6.08 / 40 -0.19 (0.19) **CG** 39 5.97 / 39 -0.13 (0.21) *LDL, mmol/L* **IG** 40 4.29 / 40 -0.30 (0.77) **CG** 39 4.14 / 39 -0.15 (0.56) *HDL, mmol/L* **IG** 40 1.41 / 40 0.01 (0.77) **CG** 39 1.36 / 39 -0.02 (0.56) *Triglycerides, mmol/L* 40 1.27 / 40 0.03 (0.39) 39 1.33 / 39 0.06 (0.45) * p<0.001
Stevens, 2003[97] US Fair	N=616 0% men Mean age 54 7% nonwhite Selected for age 40-70 and slightly elevated total cholesterol	2 individual sessions over 1 month, plus 2 followup phone calls over 1 month	*Total cholesterol, mmol/L* **Baseline** / **12 months** **N** **Mean** / **N** **Mean change (SD)** **IG** 271 5.98 / 271 -0.19 (0.58) **CG** 277 6.01 / 277 -0.16 (0.60) p=NS

Table 4. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Intermediate Outcomes

Reference Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Watanabe, 2003[108] Japan Fair	N=173 100% men Mean age 55 NR nonwhite Selected for IFG	1 individual session, plus mailed tailored booklet at 1 month	*Fasting plasma glucose, mmol/L* **Baseline** **12 months** **N** **Mean** **N** **Mean % change (SD)** **IG** 79 6.1 79 -0.5 (0.9) **CG** 77 5.5 79 2.2 (0.9) Adjusted mean difference (95%CI): -1.8 (-4.2, 0.6) Adjusted for baseline values
High-intensity interventions (estimated >360 minutes)			
Anderson, 1992[77] US Fair	N=177 60% men Mean age 41 0% nonwhite Selected for slightly elevated total cholesterol	10 group sessions over 2.5 months plus 4 home visits over 12 months	**Baseline** **12 months** **N** **Mean** **N** **Mean change (SD)** *Weight, kg* **IG1+2** 95 71.55 95 -1.04 (3.05) **CG** 51 71.44 51 -0.44 (2.68) p=NS **Baseline** **6 months** **N** **Mean** **N** **Mean change (SE)** *Total cholesterol, mmol/L* **IG1+2** 95 6.09 95 -0.69 (0.62) **CG** 51 5.92 51 -0.42 (0.57) p=0.009 *LDL, mmol/L* **IG1+2** 95 4.16 95 -0.66 (0.56) **CG** 51 4.00 51 -0.40 (0.43) p=0.005 *HDL, mmol/L* **IG1+2** 95 1.29 95 -0.02 (0.14) **CG** 51 1.20 51 0.01 (0.14) p=NS *Log triglyceride* **IG1+2** 95 0.23 95 -0.06 (0.69) **CG** 51 0.36 51 -0.06 (0.71) p=NS

Table 4. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Intermediate Outcomes

Reference Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)				
Coates, 1999[83] US Fair	N=2207 0% men Mean age 60 45% nonwhite Selected for post-menopausal women, and fat >30% energy intake	20 group sessions over 18 months		**Baseline**		**6 months**	
				N	**Mean**	**N**	**Mean change (SD)**
			BMI, kg/m²				
			IG	1324	28.7	1324	-0.7 (2.06)
			CG	883	29.1	883	-0.1* (2.15)
			SBP, mmHg				
			IG	1324	127.1	1324	-3.1 (17.08)
			CG	883	127.3	883	-1.4* (15.31)
			DBP, mmHg				
			IG	1324	76.3	1324	-1.1 (8.68)
			CG	883	76.9	883	-0.6 (7.95)
			Fasting glucose, mmol/L				
			IG	1324	5.3	1324	-0.2 (1.34)
			CG	883	5.3	883	-0.1 (1.34)
			*p<0.05 for differences between IG and CG				

Table 4. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Intermediate Outcomes

Reference Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)						
Tinker, 2008[104] US Good	N=48835 0% men Mean age 62 18% nonwhite Selected for post-menopausal women and dietary fat intake >30%	18 group sessions and 1 individual session over 12 months, plus ongoing maintenance for trial duration		**Baseline**		**12 months**		**72 months**	
				N	**Mean**	**N**	**Mean change (SD)**	**N**	**Mean change (SD)**
			BMI, kg/m²						
			IG	18,291	28.9	17,026	-0.90 (2.59)	14,409	-0.10 (NR)
			CG	27,386	28.9	24,977	-0.20 (2.57)	22,321	0.20 (NR)
			SBP, mmHg						
			IG	18,375	127.1	17,126	-2.70 (15.34)	14,543	-2.60 (NR)
			CG	27,510	127.4	25,173	-2.00 (14.18)	22,532	-2.80 (NR)
			DBP, mmHg						
			IG	18,370	75.9	17,125	-2.00 (8.18)	14,540	-4.20 (NR)
			CG	27,505	76.0	25,169	-1.30 (7.57)	22,532	-4.10 (NR)
				Baseline		**36 months**			
				N	**Mean**	**N**	**Mean change (SD)**		
			(5.8% subsample for lipid measures, N analyzed but not reported)						
			Total cholesterol, mmol/L						
			IG	NR	5.72	NR	-0.25 (NR)		
			CG	NR	5.72	NR	-0.19 (NR)		
			Relative change (95%CI): 0.98 (0.97, 1.00)						
			LDL, mmol/L						
			IG	NR	3.33	NR	-0.26 (NR)		
			CG	NR	3.35	NR	-0.19 (NR)		
			Relative change (95%CI): 0.97 (0.95, 1.00)						
			HDL, mmol/L						
			IG	NR	1.50	NR	-0.01 (NR)		
			CG	NR	1.46	NR	0.00 (NR)		
			Relative change (95%CI): 0.99 (0.98, 1.01)						
			Triglycerides, mmol/L						
			IG	NR	1.57	NR	0.04 (NR)		
			CG	NR	1.59	NR	0.04 (NR)		
			Relative change (95%CI): 1.00 (0.97, 1.04)						
				Baseline		**12 months**		**72 months**	
				N	**Mean**	**N**	**Mean change (SD)**	**N**	**Mean change (SD)**
			(5.8% subsample with analyzed serum samples)						
			Fasting glucose, mmol/L						
			IG	979	5.24	915	-0.11 (--)	760	0.12 (NR)
			CG	1525	5.25	1366	-0.02 (--)	1165	0.09 (NR)

N - number; BP - blood pressure; HPT - Hypertension Prevention Trial; US - United States; IG - intervention group; CG - control group; SE - standard error; SBP - systolic blood pressure; DBP - diastolic blood pressure; mmHg - millimeters of mercury; TOHP - Trial of Hypertension Prevention; CI - confidence interval; SD - standard deviation; min - minutes; NR - not reported; UK - United Kingdom; mmol/L - millimoles per liter; kg - kilograms; NS - not significant; HDL - high density lipoprotein; LDL - low density lipoprotein; PCP - primary care physician; BMI - body mass index; kg/m^2 - kilograms per meters squared

Table 5. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Low-intensity interventions (estimated 0-30 minutes)			
Jeffery, 1999[120] US Fair	N=809 20% men Mean age 38 10% nonwhite Unselected	IG1: 36 monthly newsletters plus additional activities offered every 6 months, over 36 months IG2: IG1 + incentives	**12 months** / **36 months** **N** **Mean Change (SD)** **N** **Mean Change (SD)** *Weight, kg* **IG** 395 0.45 (4.21) 395 1.55 (7.02) **CG** 414 0.6 (4.07) 414 1.8 (6.10) p=NS for all measures Blood pressure: NR Lipids: NR Glucose tolerance: NR

Table 5. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Medium-intensity interventions (estimated 31-360 minutes)			
Babazono, 2007[112] Japan Fair	N=99 42% men Mean age 64 NR nonwhite Selected for SBP 130-159, DBP 85-99, or A1C 5.6+	2 home visits, plus reinforcement at 2 data collection visits over 6 months	**Baseline** **12 months** **N** **Mean** **N** **Mean change (SD)** *BMI, kg/m²* **IG** 46 23.6 46 -0.5 (1.4) **CG** 41 24.0 41 -0.1 (1.1) *SBP, mmHg* **IG** 46 127.6 46 -5.2 (14.3) **CG** 41 132.0 41 -8.7 (14.0) *DBP, mmHg* **IG** 46 78.2 46 -3.7 (8.7) **CG** 41 79.3 41 -3.8 (7.7) *Total cholesterol, mmol/L* **IG** 46 5.28 46 -0.06 (0.74) **CG** 41 5.35 41 0.07 (0.68) *HDL, mmol/L* **IG** 46 1.41 46 0.06 (0.28) **CG** 41 1.44 41 0.02 (0.27) *LDL, mmol/L* **IG** 46 3.13 46 -0.04 (0.66) **CG** 41 3.20 41 0.00 (0.59) *Trigylcerides, mmol/L* **IG** 46 1.97 46 -0.31 (0.94) **CG** 41 1.87 41 0.02 (0.85) **N** **Percent (SD)** **N** **Percent (SD)** *HbA1c* **IG** 46 5.5 46 5.5 (0.4) **CG** 41 5.4 41 5.4 (0.4) **N** **N (Percent)** **N** **N (Percent)** *Diabetic* **IG** 50 10 (20.0) 46 11 (23.9) **CG** 49 7 (14.3) 41 10 (24.4) *Hypertensive* **IG** 50 15 (30.0) 46 10 (21.7) **CG** 49 15 (30.6) 41 6 (14.6) p=NS for all measures

Table 5. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Brekke, 2005[81] Sweden Fair	N=77 63% men Mean age 43 NR nonwhite Relatives with DM, otherwise unselected	2 individual sessions, plus followup phone calls over 8 months	**N** / **Baseline Mean** / **12 months Mean change (SD)** *BMI, kg/m^2* **IG2** 25 26.1 -0.72 (1.20)* **CG** 19 26.1 0.22 (1.36) *Total cholesterol, mmol/L* **IG2** 25 4.74 0.37 (0.73) **CG** 19 5.03 0.24 (0.58) *HDL, mmol/L* **IG2** 25 1.16 0.11 (0.17)* **CG** 19 1.31 -0.04 (0.16) *LDL, mmol/L* **IG2** 25 2.73 0.23 (0.55) **CG** 19 3.23 0.28 (0.49) *Triglycerides, mmol/L* **IG2** 25 1.26 0.08 (0.48) **CG** 19 1.10 0.01 (0.23) *Fasting blood glucose, mmol/L* **IG2** 25 5.13 -0.43 (0.59) **CG** 19 5.04 -0.21 (0.51) Blood pressure: NR

Table 5. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)			
Hardcastle, 2008[117] UK Fair	N=334 NR % men Mean age 50 NR nonwhite Selected for 1 or more CV risk factors (including BMI)	Up to 5 individual sessions (30 minutes each) over 6 months (average 2 sessions)		**N**	**Baseline Mean**	**6 months Mean Change (SD)**
			BMI, kg/m^2			
			IG	203	33.67	-0.21 (1.42)**
			CG	131	34.28	0.15 (1.14)
			SBP, mmHg			
			IG	203	134.05	-2.90 (10.83)
			CG	131	133.29	-0.60 (10.64)
			DBP, mmHg			
			IG	203	83.52	-1.98 (7.27)***
			CG	131	82.41	0.49 (7.21)
			Cholesterol, mmol/L			
			IG	203	5.48	-0.14 (0.71)
			CG	131	5.42	0.00 (0.69)
			HDL, mmol/L			
			IG	203	1.46	-0.05 (0.14)
			CG	131	1.53	-0.07 (0.34)
			LDL, mmol/L			
			IG	203	2.94	0.09 (1.00)
			CG	131	3.03	0.25 (0.92)
			Triglycerides, mmol/L			
			IG	203	1.96	-0.17 (1.14)
			CG	131	1.73	-0.15 (0.92)
			Glucose tolerance: NR			
			** p<0.01 for t-value between IG and CG *** p<0.001 for t-value between IG and CG			

Table 5. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Hellenius, 1993[47] Sweden Fair	N=158 100% men Mean age 45 NR nonwhite Selected for slightly elevated total cholesterol	One session with PCP and one session with dietitian over 2 weeks	**N** / **Baseline Mean** / **6 months Mean change (SD)** *BMI, kg/m^2* **IG** 39 26.1 -0.6 (0.96)* **CG** 39 24.5 0.3 (0.64) *SBP, mmHg* **IG** 39 129 -4 (9.6) **CG** 39 130 -1 (11.2) *DBP, mmHg* **IG** 39 81 -2 (8.0) **CG** 39 82 -1 (6.4) *Total cholesterol, mmol/L* **IG** 39 6.53 -0.45 (1.02) **CG** 39 5.97 -0.13 (0.64) *LDL, mmol/L* **IG** 39 4.66 -0.35 (0.94) **CG** 39 4.14 -0.15 (0.56) *HDL, mmol/L* **IG** 39 1.33 -0.03 (0.21) **CG** 39 1.36 -0.02 (0.21) *Triglycerides, mmol/L* **IG** 39 1.57 -0.12 (0.62) **CG** 39 1.33 0.06 (0.45) Glucose tolerance: NR *p<0.05

Table 5. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Keyserling, 2008[121] US Fair	N=236 0% men Mean age 53 42% nonwhite Selected for at or below 200% FPL	2 individual counseling and 3 group sessions, plus 10 followup phone calls over 10 months	**Baseline** **12 months** **N** **Mean** **N** **Mean change (SD)** *Weight, kg* **IG** 108 82.3 106 -0.06 (4.8) **CG** 110 81.8 106 -0.10 (4.2) *SBP, mmHg* **IG** 107 126 105 0.0 (15.4) **CG** 110 129 105 -4.0 (15.7) *DBP, mmHg* **IG** 107 77 105 2.0 (8.5) **CG** 110 80 106 -1.0 (9.5) *Total cholesterol, mmol/L* **IG** 106 5.30 106 -0.15 (0.86) **CG** 110 5.56 106 -0.41 (0.74) *HDL, mmol/L* **IG** 106 1.47 106 0.0 (0.27) **CG** 110 1.45 106 0.05 (0.25) *LDL, mmol/L* **IG** 102 3.12 103 -0.17 (0.70) **CG** 103 3.36 101 -0.39 (0.66) Glucose tolerance: NR p=NS for all measures

Table 5. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Mosca, 2008[122] US Good	N=501 34% men Mean age 48 36% nonwhite Family with acute CV event, otherwise unselected	5 in-person or phone sessions over 10 months	**N** / **Baseline Mean** / **12 months Mean change (95% CI)** *BMI, kg/m^2* **IG** 232 27.8 -0.1 (2.7) **CG** 232 28.4 0.0 (2.9) *SBP, mmHg* **IG** 232 126.7 3.0 (15.1) **CG** 232 126.4 3.4 (13.9) *DBP, mmHg* **IG** 232 77.9 1.1 (10.3) **CG** 232 77.0 1.9 (9.8) *Total cholesterol, mmol/L* **IG** 232 5.24 -0.01 (0.89) **CG** 232 5.32 -0.07 (0.87) *LDL, mmol/L* **IG** 232 3.32 -0.12 (0.83) **CG** 232 3.38 -0.17 (0.76) *HDL, mmol/L* **IG** 232 1.51 0.01 (0.40) **CG** 232 1.55 -0.06 (0.36) *Triglycerides, mmol/L* **IG** 232 1.30 -0.02 (0.77) **CG** 232 1.33 0.02 (0.70) *Glucose, mmol/L* **IG** 232 5.44 0.01 (0.75) **CG** 232 5.52 -0.04 (0.84) p=NS for all measures

Table 5. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Wister, 2007[131] Canada Good	N=611 42% men Mean age 55 NR nonwhite Selected for Framingham risk score of 10%+ over 10 years	2 individual sessions (30 minutes each) over 1 year plus "annual report card"	**N** / **Baseline Mean** / **12 months Mean Change (SD)** *SBP, mmHg* **IG** 157 139.0 -7.49 (15.85) **CG** 158 136.1 -3.58 (16.03)* *Total cholesterol, mmol/L* **IG** 157 5.8 -0.41 (1.15) **CG** 158 5.6 -0.14 (1.15)* *HDL, mmol/L* **IG** 157 1.3 0.04 (0.19) **CG** 158 1.3 0.03 (0.19) *Glucose, mmol/L* **IG** 157 8.3 -0.37 (3.07) **CG** 158 8.1 0.01 (2.69) *Framingham risk score* **IG** 157 12.5 -3.10 (5.36) **CG** 158 11.0 -1.30 (5.64)* Adiposity: self-reported only * p<0.05

Table 5. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)			
High-intensity interventions (estimated >360 minutes)						
Aldana, 2006[110] US Fair	N=348 28% men Mean age 50 6% nonwhite Unselected	4 group sessions (120 minutes each) over 4 weeks		**N**	**Baseline Mean**	**6 months Mean change (SD)**
			BMI, kg/m^2			
			IG	174	33.3	-1.6 (1.8)*
			CG	174	31.4	-0.3 (1.3)
			SBP, mmHg			
			IG	174	129	-5 (12)
			CG	174	128	-4 (11)
			DBP, mmHg			
			IG	174	78.3	-5.5 (8.7)*
			CG	174	76.7	-3.8 (7.7)
			Total cholesterol, mmol/L			
			IG	174	4.99	0.16 (0.71)
			CG	174	4.91	0.28 (0.78)
			HDL, mmol/L			
			IG	174	1.16	0.04 (0.18)*
			CG	174	1.16	0.05 (0.11)
			LDL, mmol/L			
			IG	174	3.15	0.13 (0.60)
			CG	174	3.13	0.23 (0.74)
			Triglycerides, mmol/L			
			IG	174	1.50	-0.06 (0.81)
			CG	174	1.29	0.02 (0.96)
			Fasting glucose, mmol/L			
			IG	174	5.72	-0.17 (0.79)
			CG	174	5.56	-0.06 (2.53)

Table 5. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)
Edelman, 2005[115] US Fair	N=294 20% men Mean age 53 23% nonwhite Selected for 1 or more CV risk factors (including BMI)	2 individual sessions and 28 group sessions, plus 20 followup phone calls over 10 months	**Baseline** **10 months** **N** **Mean** **N** **Mean Change** *BMI, kg/m²* **IG** 77 33.3 56 -1.2 **CG** 77 34.1 66 -0.6 Blood pressure: data primarily reported in a figure. IG and CG overall decline in SBP of 8 mmHg. Lipids: data primarily reported in a figure. Overall decline in LDL-cholesterol for IG and CG of 7 mg/dL. Difference in change in LDL-cholesterol between baseline and 5 months was statistically significant between IG and CG (p=0.02), but not at 10 months (p=0.25). Glucose tolerance: NR *p<0.05

Table 5. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)				
Hivert, 2007[119] Canada Fair	N=115 18% men Mean age 20 7% nonwhite Unselected	23 group sessions over 2 years		**N**	**Baseline Mean**	**12 months Mean Change (SD)**	**24 months Mean Change (SD)**
			BMI, kg/m^2				
			IG	58	22.4	-0.1 (0.8)	-0.3 (1.5)*
			CG	57	22.4	0.4 (1.5)	0.2 (1.5)
			SBP, mmHg				
			IG	58	111	--	5 (15.2)
			CG	57	110	--	7 (15.1)
			DBP, mmHg				
			IG	58	70	--	2 (7.6)
			CG	57	71	--	0 (7.6)
			Total cholesterol, mmol/L				
			IG	58	4.55	--	0.02 (0.76)
			CG	57	4.33	--	0.26 (0.60)
			HDL, mmol/L				
			IG	58	1.30	--	0.20 (0.23)
			CG	57	1.31	--	0.27 (0.23)
			LDL, mmol/L				
			IG	58	2.68	--	-0.14 (0.53)
			CG	57	2.52	--	-0.06 (0.53)
			Triglycerides, mmol/L				
			IG	58	1.24	--	-0.10 (0.61)*
			CG	57	1.11	--	0.10 (0.45)
			Glucose tolerance: NR				
			* ANOVA p<0.05 for group effect				

Table 5. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)						
				Baseline		12 months		24 months	
				N	Mean	N	Mean Change (SD)	N	Mean Change (SD)
Oldroyd, 2001[123]	N=78	18 individual sessions (20 minutes each) over 24 months	*Weight, kg*						
	57% men		**IG**	35	83.3	35	-1.1 (3.4)*	35	-1.8 (5.9)*
UK	Mean age 58		**CG**	32	85.5	32	1.5 (2.6)	32	1.5 (2.6)
	NR nonwhite		*SBP, mmHg*						
Fair			**IG**	35	137.2	35	-7.9 (17.6)	--	--
	Selected for IFG		**CG**	32	132.8	32	-0.2 (13.0)	--	--
			DBP, mmHg						
			IG	35	77.0	35	-2.9 (10.4)	--	--
			CG	32	75.5	32	1.9 (8.0)	--	--
			Total cholesterol, mmol/L						
			IG	34	5.7	31	-0.12 (0.62)	?	0.04 (0.79)
			CG	31	5.7	29	-0.12 (0.63)	?	-0.06 (0.59)
			HDL, mmol/L						
			IG	32	1.2	--	--	--	--
			CG	31	1.1	--	--	--	--
			LDL, mmol/L						
			IG	33	3.6	30	-0.11 (0.58)		-0.09 (0.71)
			CG	31	3.5	30	-0.13 (0.69)		-0.14 (0.56)
			Triglycerides, mmol/L						
			IG	34	1.9	--	--	--	--
			CG	31	2.2	--	--	--	--
			Fasting plasma glucose, mmol/L						
			IG	35	6.0	32	0.03 (0.60)	30	0.25 (0.77)
			CG	32	6.2	30	0.08 (0.97)	24	0.12 (1.0)
			* p<0.05						

Table 5. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood pressure, lipids, glucose)					
					Baseline	18 months	54 months	
				N	Mean	Mean change (SD)	N	Mean change (SD)
Simkin-Silverman, 1998[124] US Good	N=535 0% men Mean age 47 8% nonwhite Selected for women age 44-50	15 group sessions over 5 months, plus group, mail, or phone followup after initial 5 months	*BMI, kg/m²*					
			IG	236	24.9	-1.1 (1.4)*	--	0.05 (2.0)*
			CG	253	25.1	0.1 (1.5)	--	0.96 (1.8)
			SBP, mmHg					
			IG	236	110.0	-2.7 (11.5)*	--	-0.12 (--)
			CG	253	110.1	-0.5 (10.6)	--	0.20 (--)
			DBP, mmHg					
			IG	236	68.5	1.4 (7.0)	--	1.5 (--)*
			CG	253	67.9	1.9 (7.0)	--	2.2 (--)
			Cholesterol, mmol/L					
			IG	236	4.9	-0.04 (0.62)	--	--
			CG	253	4.9	0.20 (0.57)	--	--
			LDL, mmol/L					
			IG	236	2.97	-0.11 (0.53)*	--	0.09 (--)*
			CG	253	3.01	0.07 (0.52)	--	0.23 (--)
			HDL, mmol/L					
			IG	236	1.54	0.03 (0.25)	--	0.06 (--)
			CG	253	1.51	0.08 (0.23)	--	0.08 (--)
			Triglycerides, mmol/L					
			IG	236	0.93	0.03 (0.40)*	--	0.21 (--)*
			CG	253	0.88	0.09 (0.45)	--	0.34 (--)
			Fasting glucose, mmol/L					
			IG	236	5.45	0.07 (0.43)*	--	0.09 (--)
			CG	253	5.43	0.16 (0.42)	--	0.18 (--)
			* p<0.05					

Table 5. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Intermediate Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Intermediate outcomes (adiposity, blood rpessure, lipids, glucose)				
Thompson, 2008[127] US Fair	N=200 0% men Mean age 29 100% nonwhite Selected for American Indian women	5 group sessions (150 minutes each) over 5 months		**N**	**Baseline Mean**	**12 months Mean change (SD)**	**18 months Mean change**
			BMI, kg/m^2				
			IG	100	29.5	-0.1 (2.7)	-0.1
			CG	100	29.2	0.3 (2.9)	0.4
			SBP, mmHg				
			IG	100	115.8	-1.4 (11.8)	-0.9
			CG	100	116.6	0.1 (10.9)	0.4
			DBP, mmHg				
			IG	100	67.6	0.4 (9.5)	0.3
			CG	100	68.7	0.4 (8.3)	0.1
			Total cholesterol, mmol/L				
			IG	100	4.34	-0.14 (0.72)	-0.16*
			CG	100	4.36	-0.14 (0.56)	-0.09
			LDL, mmol/L				
			IG	100	2.42	-0.16 (0.57)	-0.14*
			CG	100	2.38	-0.15 (0.45)	-0.11
			HDL, mmol/L				
			IG	100	1.26	0.03 (0.25)	0.0*
			CG	100	1.31	0.03 (0.22)	-0.01
			Triglycerides, mmol/L				
			IG	100	1.46	-0.05 (0.56)	-0.06
			CG	100	1.46	-0.06 (0.51)	0.04
			Fasting blood glucose, mmol/L				
			IG	100	5.20	-0.03 (0.43)	-0.08
			CG	100	5.16	-0.01 (0.42)	0.0
			* RM ANOVA effect of visit p<0.05				

BMI – body mass index; CV – cardiovascular; DBP – diastolic blood pressure; DM – diabetes mellitus; FPL – federal poverty level; HD – healthful diet; HDL – high density lipoprotein; IFG – impaired fasting glucose; LDL – low density lipoprotein; NR – not reported; NS – not significant; PA – physical activity; PCP – primary care physician; RM – repeated measures; SBP – systolic blood pressure; SD – standard deviation; US – United States; UK – United Kingdom

Table 6. Randomized Controlled Trials for Physical Activity Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Low-intensity interventions (estimated 0-30 minutes)			
Aittasalo, 2006[32] Finland Fair	N=265 24% men Mean age 47 Race/ethnicity NR Selected for sedentary behavior and age 20-65 years	One counseling session with PCP with a subset receiving a pedometer	**N** / **Baseline Mean** / **6 months Mean change (SD)** *Any physical activity, minutes/week* **IG** 192 368 167 (728) **CG** 73 430 50 (736) p=NS
de Vet, 2009[33] Netherlands Fair	N=709 33% men Mean age 46 Race/ethnicity NR Selected for age 18-65 years	Questionnaire with section encouraging implementation plan for walking or self-selected activity, with a subset receiving 2 followup questionnaires	**N** / **Baseline Mean** / **6 months Mean change (SD)** *Moderate-intensity physical activity, minutes/week* **IG** 397 458 56 (678) **CG** 163 519 43 (800) p=NS

Table 6. Randomized Controlled Trials for Physical Activity Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Grandes, 2009[40] Spain Good	N=4317 34% men Mean age 50 Race/ethnicity NR Selected for sedentary behavior and age 20-80 years	One brief counseling visit with PCP using Web-based software, additional visit offered, printed pamphlet	**Baseline** **6 months** **N** **Mean** **Mean change (SD)** *Moderate and vigorous activity, minutes/week* **IG** 2248 34.4 82.6 (547.8)* **CG** 2069 33.2 65.1 (527.7) *Meeting physical activity recommendation, percent* † **IG** 2248 0 18.8 (--)* **CG** 2069 0 15.0 (--) *VO_2 max, mL/kg/minute* **IG** 2248 24.4 1.2 (8.2) **CG** 2069 24.7 1.1 (8.0) * p<0.05 in multivariate model
Goldstein, 1999[38] US Fair	N=355 35% men Mean age 66 3% nonwhite Selected for age 50 years or older	One brief counseling visit with PCP including PA prescription, followup session scheduled, monthly mailed materials, PCP training and materials	**Baseline** **8 months** **N** **Mean** **N** **Mean change (SD)** *PASE score* **IG** 181 108.5 158 4.1 (96.3) **CG** 174 108.8 154 2.2 (82.8) *Meeting physical activity recommendation, percent* † **IG** 181 15 159 13 (--) **CG** 174 17 157 7 (--) p=NS
Halbert, 2000[44] Australia Fair	N=299 46% male Mean age 68 Race/ethnicity NR Selected for sedentary behavior and age 60 years or older	One visit with exercise physiologist	**Baseline** **12 months** **N** **Median** **Median (IQR)** *Walking frequency, sessions/week* **IG** 149 0 3 (1-4)* **CG** 150 0 2 (1-3) * p<0.05

Table 6. Randomized Controlled Trials for Physical Activity Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Katz, 2008[52] US Fair	N=316 33% men Mean age NR 65% nonwhite Selected for age 18 years or older	Special training for primary care residents	**Baseline** **12 months** **N** **Mean** **N** **Mean change (SD)** *Yale Physical Activity Survey, total index score* **IG** 195 27.1 185 1.9 (14.5) **CG** 121 28.1 117 1.0 (16.4)
Marcus, 2007[60] US Fair	N=159 18% men Mean age 44 14% nonwhite Selected for sedentary behavior and age 18-65 years	Mailed booklets and fourteen tailored reports	**Baseline** **12 months** **N** **Mean** **Mean change (SD)** *Physical activity, minutes/week* **IG** 81 20.2 142.2 (164.6)* **CG** 78 19.4 62.5 (123.3) *VO_2 max, mL/kg/minute* **IG** 81 26.0 1.1 (8.9) **CG** 78 25.6 0.7 (7.0) **N** **Mean** **Mean (SD)** *Meeting physical activity recommendation, percent* † **IG** 81 -- 49 (--)* **CG** 78 -- 17 (--) * p<0.01
Marshall, 2003[61] Australia Fair	N=462 42% men Mean age 49 Race/ethnicity NR Selected for age 40-60 years	Mailed booklets and tailored letter	**Baseline** **6 months** **N** **Mean** **Mean change (SD)** *Total physical activity, minutes/week* **IG** 227 3.0 18 (--) **CG** 235 3.3 -12 (--) *Meeting physical activity recommendation, percent* † **IG** 227 26 14 (--) **CG** 235 28 3 (--)
Napolitano, 2006[66] US Fair	N=280 0% men Mean age NR 5% nonwhite Selected for sedentary behavior	Personalized letter with AHA booklet and another group received 4 tailored reports plus booklets	**Baseline** **12 months** **N** **Mean** **Mean change (SD)** *Total physical activity, minutes/week* **IG** 188 49.6 102.1 (209.1) **CG** 92 33.6 105.9 (182.1) p=NS

Table 6. Randomized Controlled Trials for Physical Activity Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Pekmezi, 2009[75] US Fair	N=93 0% men Mean age 41 100% nonwhite Selected for sedentary behavior	Six monthly mailings including tailored manuals, pedometer, physical activity logs, and tip sheets	**Baseline** **6 months** **N** **Mean** **Mean (SD)** *Moderate- or vigorous-intensity physical activity, minutes/week* **IG** 45 16.56 147.27 (241.55) **CG** 48 11.88 96.79 (118.49) p=NS
Stensel, 1994[70] UK Fair	N=72 100% men Mean age 51 Race/ethnicity NR Selected for sedentary behavior and age 42-59 years	Not described	**Baseline** **12 months** **N** **Mean** **Mean change (SD)** *VO_2, mL/kg/minute at 2.0 mmol/L lactate concentration* IG 23 21.5 1.4 (6.2) CG 18 20.3 -1.5 (4.2) * p<0.05 for change over time
Medium-intensity interventions (estimated 31-360 minutes)			
Connell, 2009[74] US Fair	N=157 0% men Mean age 67 7% nonwhite Unselected	14 individualized counseling phone calls over 6 months, videos, pamphlet, workbooks, and newsletters	**Baseline** **6 months** **12 months** **N** **Mean** **N** **Mean (SD)** **N** **Mean (SD)** *Total exercise/week score** **IG** 74 5.2 74 7.0 (2.7)** 69 6.1 (2.5) **CG** 63 5.4 63 5.8 (2.7) 61 5.9 (2.8) *Time spent in aerobic exercise, stretching, and strengthening was summed to yield a total exercise per week score. Scale values: 1=none, 2=<30 minutes, 3=30-60 minutes, 4=1-3 hours, 5=>3 hours ** p=0.01

Table 6. Randomized Controlled Trials for Physical Activity Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Delichatsios, 2001[34] US Fair	N=298 28% men Mean age 46 55% nonwhite Selected for sedentary behavior and suboptimal diet	18 automated 10-minute phone calls over 6 months using phone-linked expert system	**Baseline** **6 months** **N** **Mean** **N** **Mean change (SD)** *Daily expenditure, kcal/kg/day* **IG** 150 33.2 112 0.6 (3.1) **CG** 148 33.5 131 0.1 (2.5) *Meeting physical activity recommendation, percent* † **IG** 150 16 112 13 (--) **CG** 148 24 131 11 (--) p=NS
Elley, 2003[36] New Zealand Good	N=878 34% men Mean age 58 23% nonwhite Selected for sedentary behavior and age 40-79 years	One brief visit with general practitioner plus PA prescription, 3 phone calls from exercise physiologist, quarterly newsletters	**Baseline** **12 months** **N** **Mean** **Mean change (SD)** *Exercise, minutes/week* **IG** 451 11.3 54.6 (206.6)* **CG** 427 12.0 16.8 (139.2) *Meeting physical activity recommendation, percent* † **IG** 451 18 14 (--)* **CG** 427 21 5 (--) * p<0.05
Green, 2002[41] US Fair	N=316 48% men Mean age 44 8% nonwhite Selected for sedentary behavior and age 20-64 years	Tailored report from PCP, self-help workbook, three 20- to 30-minute phone calls	**Baseline** **6 months** **N** **Mean** **Mean change (SD)** *PACE, score* **IG** 128 5.0 0.4 (1.8) **CG** 128 4.7 0.1 (1.8) p=NS
Greene, 2008[42] US Fair	N=1.280 27% men Mean age 75 20% nonwhite Selected for age 60 years or older	Stage-based manual plus 9 newsletters, 3 phone calls with mailed tailored reports	**Baseline** **12 months** **24 months** **N** **Mean** **Mean change (SD)** **Mean change** *Yale Physical Activity Survey, summary score* **IG** 470 46 0.0 (38.0) 1.0 **CG** 496 46 1.0 (33.0) 1.0 p=NS

Table 6. Randomized Controlled Trials for Physical Activity Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Harland, 1999[46] UK Fair	N=520 42% men Mean age NR Race/ethnicity NR Selected for age 40-64 years	IG1: Report from PCP, 40-minute motivational interview with specialty provider IG2: IG1 + 30 vouchers for community leisure centers IG3: IG1 + 5 additional visits with specialty provider IG4: IG3 + 30 vouchers for community leisure centers	**N** / **Baseline N (percent)** / **12 months N (percent)** *Increased physical activity by one or more levels* **IG1** 96 -- (--) 22 (23) **IG2** 88 -- (--) 22 (26) **IG3** 88 -- (--) 27 (31) **IG4** 79 -- (--) 21 (27) **CG** 91 -- (--) 21 (23) p=NS
Hellenius, 1993[47] Sweden Fair	N=79 100% men Mean age 45 Race/ethnicity NR Selected for slightly elevated total cholesterol	One counseling visit with physician, offered aerobic exercise class 2-3 times per week (attendance not required)	**N** / **Baseline Mean** / **6 months Mean change (SD)** *Exercise sessions, number/month* **IG** 39 5.1 6.6 (9.4)* **CG** 39 5.3 0.1 (8.9) * p<0.05

Table 6. Randomized Controlled Trials for Physical Activity Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Kallings, 2009[50] Sweden Good	N=101 43% men Mean age NR Selected for age 64-74 years (calc), sedentary behavior, and overweight	One group session with physician, 1 individual counseling session with specialty provider including PA prescription	**Baseline** **6 months** **N** **Median** **Median change (IQR)** *Moderate- or vigorous-intensity physical activity, sessions/week* **IG** 41 2 1 (0-430)* **CG** 50 2 -- (--) * p<0.001
King, 2002[53] US Fair	N=100 0% men Mean age 63 14% nonwhite Selected for being post-menopausal, age 50 years or older (46 years or older with a hysterectomy), and sedentary behavior	One 30- to 40-minute counseling session with specialty provider, 14 15- to 20-minute phone calls	**Baseline** **12 months** **N** **Mean** **Mean change (SD)** *Total physical activity, minutes/week* **IG** 45 186 114 (354)* **CG** 40 168 6 (268) * p<0.03
King, 2007[55] US Fair	N=218 30% men Mean age 62 12% nonwhite Selected for age 55 years or older and sedentary behavior	Four 45-minute and two 15-minute counseling phone calls, multiple mailings	**Baseline** **12 months** **N** **Mean** **Mean change (SD)** *CHAMPS moderate- or vigorous-intensity physical activity, minutes/week* **IG** 127 160.0 211.1 (297.0)* **CG** 62 156.3 97.7 (252.4) * p<0.05

Table 6. Randomized Controlled Trials for Physical Activity Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Kinmonth, 2008[56] UK Fair	N=365 % men NR Mean age NR Race/ethnicity NR Selected for age 30-50 years and a parental history of type 2 diabetes	Four 45-minute and two 15-minute counseling phone calls, postal contact for 7 months	**Baseline** **12 months** **N** **Mean** **Mean change (SD)** *Total reported activity, MET hours/week* **IG** 107 89.3 15.9 (69.7) **CG** 111 84.4 17.0 (70.0) *VO_2 max, L/minute* **IG** 107 3.24 0.2 (1.3) **CG** 111 3.16 0.0 (1.1) p=NS
Kolt, 2007[58] New Zealand Good	N=186 44% men Mean age 74 Race/ethnicity NR Selected for age 65 years and older and sedentary behavior	8 phone counseling sessions, mailed materials	**Baseline** **12 months** **N** **Mean** **Mean change (SD)** *Total leisure physical activity, minutes/week* **IG** 83 165.5 78.5 (407.7) **CG** 82 121.0 -3.8 (192.6) *Meeting physical activity recommendation, percent* † **IG** 83 24 11* **CG** 82 21 2 * p<0.05
Lawton, 2008[59] New Zealand Good	N=1089 0% men Mean age 59 Race/ethnicity NR Selected for age 40-74 years and sedentary behavior	1 brief motivational interview including PA prescription and 30-minute followup visit with primary care nurse; five 15-minute calls, from community exercise specialist	**Baseline** **12 months** **24 months** **N** **Median** **Median change (est SD)** **Median change** *Physical activity, minutes/week* **IG** 544 30 90.0 (297.1) 75.0 **CG** 545 30 45.0 (231.3) 60.0 **N** **Mean** **Mean change (SD)** **Mean change** *Meeting physical activity recommendation, percent* † **IG** 544 10.3 32.5 (--) 29.0* **CG** 545 11.4 18.9 (--) 21.4 * p<0.05 for change over time

Table 6. Randomized Controlled Trials for Physical Activity Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention dDetails	Behavioral outcomes (self-reported unless otherwise noted)
Marcus, 2007[60] US Fair	N=159 18% men Mean age 44 14% nonwhite Selected for age 18-65 years and sedentary behavior	Mailed booklets, 14 counseling phone calls	**Baseline** **12 months** **N** **Mean** **Mean change (SD)** *Physical activity, minutes/week* **IG** 80 19.8 80.8 (120.0) **CG** 78 19.4 62.6 (123.3) *VO_2 max, mL/kg/minute* **IG** 80 25.3 1.9 (9.7) **CG** 78 25.6 0.7 (7.0) *Meeting physical activity recommendation, percent* † **IG** 80 0 21 **CG** 78 0 17 p=NS
Martinson, 2008[62] US Good	N=1049 28% men Mean age 57 6% nonwhite Selected for age 50-70 years and increasing levels of physical activity	4 lectures, 1 group orientation, 23 phone calls, library or materials available for use, 3 motivational contests over 24 months, but not all completed at 6-month assessment	**Baseline** **6 months** **N** **Mean** **Mean change (SD)** *Total physical activity, kcal/week* **IG** 495 4643 -94 (3456)* **CG** 491 4781 -673 (3255) *Meeting physical activity recommendation, percent* † **IG** 495 21.4 12.1 (--)* **CG** 491 27.8 0.7 (--) * p<0.004

Table 6. Randomized Controlled Trials for Physical Activity Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Morey, 2009[64] US Good	N=398 100% men Mean age 78 23% nonwhite Selected for age 70 years or older and sedentary behavior	One visit and 13 phone calls with health counselor, workbook, exercise bands, in-person endorsement and individualized automated phone calls from PCP, quarterly tailored mailings	**Baseline** **12 months** **N** **Mean** **N** **Mean change (SD)** *Endurance physical activity, minutes/week* **IG** 199 37.9 178 34.4 (134.7)* **CG** 199 35.8 177 7.9 (113.8) *2-minute walk, meters* **IG** 199 146.0 178 4.9 (50.2) **CG** 199 145.4 177 2.1 (41.4) * p<0.005
Norris, 2000[68] US Fair	N=847 48% men Mean age 55 9% nonwhite Selected for age 30 years or older	Counseling visit with PCP, phone call from research assistant; a subset received 3 additional phone calls	**Baseline** **6 months** **N** **Mean** **N** **Mean change (SD)** *Total physical activity, minutes/week* **IG** 384 240.0 362 91.1 (451.3) **CG** 463 272.2 460 58.5 (431.6) *Meeting physical activity recommendation, percent* † **IG** 384 46.1 362 19.4 **CG** 463 49.8 460 10.6 p=NS
Pinto, 2005[69] US Fair	N=100 36% men Mean age 68 15% nonwhite Selected for age 60 years or older and sedentary behavior	Brief advice by clinician, 3 in-person and 12 phone counseling sessions with health educator; mailed materials	**Baseline** **6 months** **N** **Mean** **Mean change (SD)** *Moderate-intensity physical activity, minutes/week* **IG** 49 38.1 62.8 (84.7)* **CG** 44 45.3 16.6 (84.9) * p<0.05

Table 6. Randomized Controlled Trials for Physical Activity Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details (total n, sex, age, race/ethnicity)	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Yates, 2009[72] UK Fair	N=98 66% men Mean age 65 25% nonwhite Selected for BMI and IGT	3-hour group session, two 10-minute followup sessions and a subset received a pedometer	**Baseline** **12 months** **N** **Median** **N** **Mean change (SD)** *Total moderate- and vigorous-intensity physical activity, MET minutes/week* **IG** 58 2920 50 1491 (3347)* **CG** 29 2335 26 -1377 (3837) * p<0.05
High-intensity interventions (estimated >360 minutes)			
Stewart, 2001[71] US Fair	N=173 34% men Mean age 74 Race/ethnicity NR Selected for sedentary behavior and Medicare enrollment	11 group sessions, one individual session, booklets, phone calls from counselor, monthly newsletters	**Baseline** **12 months** **N** **Mean** **Mean change (SD)** *Total physical activity, kcal/week* **IG** 81 1935 687 (--)* **CG** 83 2057 -9 (--) * p<0.005

AHA – American Heart Association; BMI – body mass index; calc – calculated; CG – control group; CHAMPS – Community Healthy Activities Model Program for Seniors; est – estimated; IG – intervention group; IGT – impaired glucose tolerance; IQR – interquartile range; kcal – kilocalorie; kg – kilogram; L – liter; MET – metabolic equivalent; mL – milliliter; mmol – millimole; N – number randomized; NR – not reported; NS – not significant; PA – physical activity; PACE – Physician-Based Assessment and Counseling for Exercise; PASE – Physical Activity Scale for the Elderly; PCP – primary care practitioner; SD – standard deviation; UK – United Kingdom; US – United States

† Recommendation may be ACSM/CDC guideline, or study-specific recommendation

Table 7. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Salt only dietary counseling			
High-intensity interventions (estimated >360 minutes)			
HPT, 1990[87] US Good	N=841 65% men Mean age 39 18% nonwhite Selected for DBP 78-89	12 group sessions in 4 months, plus ongoing maintenance for trial duration	*Sodium excretion (mmol/8 h)* **Baseline** — **6 months** — **36 months** **N** / **Mean** / **N** / **Mean change (SD)** / **N** / **Mean change (SD)** **IG1+2** 391 / 42.45 / 391 / -10.4 (16.80) / 391 / -5.02 (NR) **CG** 196 / 43.4 / 185 / -3.9 (17.70) / 155 / 0.0 (NR) p IG2 v. IG1: 0.452 / 0.332 p IG1 v. CG: 0.002 / 0.053
TOHP I, 1992[98] US Fair	N=744 71% men Mean age 43 23% nonwhite Selected for DBP 80-89	10 group/individual sessions in 3 months, plus ongoing maintenance for trial duration	*Sodium excretion (mmol/24 h)* **Baseline** — **12 months** — **18 months** **N** / **Mean** / **N** / **Mean change (SD)** / **N** / **Mean change (SD)** **IG** 314 / 154.6 / 244 / -54.4 (66.2)* / 242 / -55.2 (76.9)* **CG** 401 / 156.4 / 342 / -4.3 (68.0) / 341 / -11.3 (77.7) * p<0.01 for the mean difference between IG and CG
TOHP II, 1997[101] US Good	N=1190 67% men Mean age 44 20% nonwhite Selected for DBP 83-89	10 group sessions in 3 months, plus ongoing maintenance for trial duration	**Baseline** — **18 months** — **36 months** **N** / **Mean** / **N** / **Mean change (SD)** / **N** / **Mean change (SD)** *Sodium excretion (mmol/24 h)* **IG** 594 / 186.1 / 450 / -59.5 (91.7)* / 470 / -50.9 (86.3)* **CG** 596 / 188.0 / 467 / -16.8 (94.8) / 482 / -10.5 (88.5) *Calories*** **IG** NR / NR / NR / -284.3 (1002) / NR / -414.9 (907.1) **CG** NR / NR / NR / -113.2 (938) / NR / -162.2 (946.1) * p<0.001 for the mean difference between IG and CG ** Conducted on a random subsample of participants
Fruits and vegetables only dietary counseling			
Low-intensity interventions (estimated 0-30 minutes)			
John, 2002[90] UK Fair	N=729 49% men Mean age 46 NR nonwhite Unselected	25-minute session, plus followup phone call and mailed booklet over 3 months	*Fruits and vegetables, portions/day* **Baseline** — **6 months** **N** / **Mean** / **N** / **Mean change (SD)** **IG** 329 / 3.4 / 329 / 1.4 (1.7)* **CG** 326 / 3.4 / 326 / 0.1 (1.3) * p<0.0001 for mean difference between IG and CG adjusted for baseline value, sex
Lutz, 1999[92] US Fair	N=710 36% men Mean age 39 22% nonwhite Unselected	Four mailed booklets over 4 months IG1: nontailored IG2: tailored, no goal setting IG3: tailored + goal setting	*Fruits and vegetables, servings/day* **Baseline** — **6 months** **N** / **Mean** / **N** / **Mean change (SD)** **IG2+3** 282 / 3.40 / 282 / 0.86 (2.45) **CG** 151 / 3.5 / 151 / 0.10 (1.92)

Table 7. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Medium-intensity interventions (estimated 31-360 minutes)			
Greene, 2008[42] US Fair	N=1280 27% men Mean age 75 20% nonwhite Selected for age 60 years or older	9 mailed newsletters, 3 tailored reports, and 3 phone calls over 12 months	*Fruits and vegetables, servings/day* **Baseline** **12 months** **24 months** **N** **Mean** **N** **Mean change (SD)** **N** **Mean change (SD)** **IG** 410 8.0 410 2.10 (4.15) 410 2.20 (NR) **CG** 424 7.7 424 0.80 (3.03) 424 1.60 (NR) p<0.001
Fats only dietary counseling			
High-intensity interventions (estimated >360 minutes)			
Stefanick, 1998[96] US Fair	N=377 51% men Mean age 52 NR nonwhite Selected for slightly elevated LDL	9 group/individual sessions in 3 months, plus ongoing maintenance over 8 months	**N** **Mean change (SD) at 12 months** *Calories from total fats, percent* **IG** 95 -6.90 (7.80) **CG** 91 -0.40 (6.30) *Calories from saturated fats, percent* **IG** 95 -2.92 (3.00) **CG** 91 0.10 (2.60) *Cholesterol intake, mg/day* **IG** 95 -85.09 (NR) **CG** 91 3.91 (NR) *Calories* **IG** 95 -253.70 (459.20) **CG** 91 -21.9 (426.40)

Table 7. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Multiple message or general cardiovascular dietary counseling			
Low-intensity interventions (estimated 0-30 minutes)			
Beresford, 1997[79] US Fair	N=4778 32% men 26% age 65+ 9% nonwhite Uselected	3-minute session with PCP with self-help booklet, plus followup mail reminder	**Baseline** **12 months** **N** **Mean*** **N** **Mean change (SD)** *Calories from fat, percent* **IG** 859 37.6 859 -1.54 (5.16) **CG** 959 37.5 959 -0.34 (5.13) Intervention effect (95% CI): -1.20 (-1.68, -0.73)** *Fiber, g/1000 kcal* **IG** 859 10 859 0.55 (0.27, 0.83) **CG** 959 10 959 0.22 (-0.03, 0.49) Intervention effect (95% CI): 0.32 (-0.06, 0.70) *Adjusted for clinic and practice effects, age, and gender ** p<0.01
Fries, 2005[86] US Fair	N=754 36% men Mean age 47 40% nonwhite Unselected	Mailed tailored report, plus phone call at 2 weeks and five booklets over 5 weeks	**Baseline** **12 months** **N** **Mean** **N** **Mean change (SD)** *Dietary Fat Behavior score* **IG** 280 2.03 238 -0.16 (0.25) **CG** 342 2.05 278 -0.10 (0.27) ANCOVA p= 0.0027* *Dietary Fiber Behavior score* **IG** 280 2.24 238 -0.12 (0.26) **CG** 342 2.24 278 -0.08 (0.30) ANCOVA p=0.0862* *Adjusted for physician practice and baseline value
Kristal, 2000[91] US Fair	N=1459 51% men Mean age 45 14% nonwhite Unselected	Mailed materials, plus phone call at 1 month and semi-monthly newsletters over 12 months	**Baseline** **12 months** **N** **Mean** **N** **Mean change (SD)** *Fat-related score (1.0 low fat to 4.0 high fat)* **IG** 601 2.29 604 -0.09 (0.38) **CG** 604 2.30 604 -0.00 (0.40) Intervention effect: -0.10 (0.2)* *Fruits and vegetables, servings/day* **IG** 604 3.62 604 0.47 (1.83) **CG** 604 3.47 604 0.14 (1.80) Intervention effect: 0.46 (0.10)* Intervention effect adjusted for baseline value, age, sex, race, BMI, and income * p<0.0001

Table 7. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Prochaska, 2005[93] US Fair	N=5407 30% men Mean age 45 3% nonwhite Selected for suboptimal dietary behavior	3 mailed tailored reports over 12 months	**Baseline** **12 months** **24 months** **N** **Mean** **N** **Mean change (SD)** **N** **Mean change (SD)** *Fruit and Vegetable Subscale of the Dietary Behavior Questionnaire* **IG** 1781 22.5 1781 1.00 (4.70) 1781 1.00 (NR) **CG** 1920 22.2 1920 0.20 (3.91) 1920 0.20 (NR)
Roderick, 1997[94] UK Fair	N=956 50% men Mean age 47 NR nonwhite Unselected	Minimum one session with nurse, followup session in 1 month if needed	**Baseline** **12 months** **N** **Mean** **N** **Mean change (SD)** *Calories from fat, percent* **IG** 473 34.3 401 -2.4 (6.90) **CG** 483 34.2 352 -0.9 (6.70) Mean difference (95% CI): -1.4 (-2.2, -0.7) *Calories from saturated fat, percent* **IG** 473 13.7 401 -1.5 (3.94) **CG** 483 14.0 352 -0.6 (3.90) Mean difference (95% CI): -0.09 (-1.15, -0.2) *Fiber, g/day* **IG** 473 23.3 401 0.86 (8.76) **CG** 483 23.2 352 -0.19 (9.30) Mean difference (95% CI): 1.02 (-0.20, 2.23) *Fruits, portions/week* **IG** NR NR 401 0.76 (--) **CG** NR NR 352 0.28 (--) Mean difference (95% CI): 0.44(-0.24, 1.11) *Vegetables, portions/week* **IG** NR NR 401 0.33 (--) **CG** NR NR 352 0.33 (--) Mean difference (95% CI): 0.50 (-0.9, 1.9)
Sacerdote, 2005[95] Italy Fair	N=3179 50% men Mean age 45 NR nonwhite Unselected	15-minute session with PCP with brochure	**Baseline** **12 months** **N** **Mean** **N** **Mean change (SD)** *Fruits and vegetables, servings/week* **IG** 1592 19.1 1488 2.90 (7.24) **CG** 1587 19.3 1489 1.60 (6.58) Intervention effect: F=2.88, p=0.09 Intervention effect adjusted for sex, BMI, education, and time

Table 7. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Medium-intensity interventions (estimated 31-360 minutes)			
Baron, 1990[78] UK Fair	N=368 51% men Mean age 42 NR nonwhite Unselected	3 individual/group visits over 3 months	**Baseline** **12 months** **N** **Mean** **N** **Mean** *Dietary fiber, g/day* **IG** 186 19.68 121 2.37 (NR) **CG** 181 35.17 137 -17.40 (NR) **Baseline** **12 months** **N** **Percent** **N** **Percent** *Using saturated fat for frying* **IG** 187 23 160 8 **CG** 181 21 164 20 *Using saturated fat for spreading* **IG** 187 36 166 4 **CG** 181 30 168 30
Bernstein, 2002[80] US Fair	N=70 20% men Mean age 78 3% nonwhite Selected for age 70+ and sedentary behavior	8 home visits over 6 months, plus bi-weekly phone calls and monthly newsletters	**Baseline** **6 months** **N** **Mean** **N** **Adjusted mean change (SD)** *Fat, g/day* **IG** 38 56 38 5 (18.00) **CG** 32 61 32 -0.8 (22.80) *Fiber, g/day* **IG** 38 17 38 4 (5.00) **CG** 32 18 32 2 (4.00) *Cholesterol, mg* **IG** 38 203 38 17 (NR) **CG** 32 200 32 -2 (NR) *Fruits and vegetables servings/day* **IG** 38 5.1 38 2.2 (2.13) **CG** 32 5.8 32 0.2 (1.81) *Calories* **IG** 38 1620 38 218 (400.10) **CG** 32 1708 32 31 (446.90) Adjusted for age, sex, and BMI

Table 7. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Brekke, 2005[81] Sweden Fair	N=77 63% men Mean age 43 NR nonwhite Relative with DM, otherwise unselected	2 individual sessions plus followup phone calls for 8 months	**Baseline** **12 months** **N** **Mean** **N** **Mean change (SD)** *Calories from fat, percent* **IG** 24 35.8 24 -5.3 (6.40)* **CG** 19 34.7 19 -0.5 (7.20) *Calories from saturated fat, percent* **IG** 24 15.0 24 -4.7 (3.50)* **CG** 19 14.1 19 -0.6 (3.70) *Fiber, g/1000 kcal* **IG** 24 9.3 24 3.5 (4.60)* **CG** 19 9.7 19 -0.5 (2.60) *Calories* **IG** 24 2547 24 -505 (632.40) **CG** 19 2482 19 -243 (620.60) * p<0.05
Delichatsios, 2001[34] US Fair	N=298 28% men Mean age 46 55% nonwhite Selected for suboptimal diet	~24 phone calls over 6 months	**Baseline** **6 months** **N** **Mean** **N** **Mean change (SD)** *Fruits and vegetables, serving/day* **IG** 148 1.1 148 0.6 (NR) **CG** 150 1.2 150 0.2 (NR) *Mean intake dietary fiber, g* **IG** 148 6.2 148 1.10 (NR) **CG** 150 6.0 150 0.20 (NR) Adjusted difference (95% CI): 1.0 (0.4, 1.6) *Calories from saturated fat, percent* **IG** 148 12.6 148 -1.90 (NR) **CG** 150 12.2 150 -0.70 (NR) Adjusted difference (95% CI): -1.0 (-1.9, -0.2)
Hellenius, 1993[47] Sweden Fair	N=158 100% men Mean age 45 NR nonwhite Selected for slightly elevated total cholesterol	One session with PCP and one session with dietitian over 2 weeks	**Baseline** **6 months** **N** **Mean** **N** **Mean change (SD)** *Calories from fat, percent* **IG** 34 37 34 -3.00 (4.30)* **CG** 33 36 33 -3.00 (4.30)* *Calories* **IG** 34 1950 34 -87.20 (392.24) **CG** 33 2244 33 -152.4 (550.53) *p<0.05

Table 7. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
King, 2002[53] US Fair	N=100 0% men Mean age 63 14% nonwhite Selected for post-menopausal women and sedentary lifestyle	One individual session plus 14 phone calls and food logs mailed monthly over 12 months	**Baseline** **12 months** **N** **Mean** **N** **Adjusted mean change (SD)** *Calories from fat, percent* **IG** 45 33.3 45 -3.70 (8.41) **CG** 40 31.6 40 0.20 (6.02) p<0.01 *Calories from saturated fat, percent* **IG** 45 10.9 45 -1.40 (3.07) **CG** 40 10.2 40 0.10 (2.25) p<0.01 *Fruits and vegetables, servings/day* **IG** 45 4.20 45 0.70 (1.66) **CG** 40 4.70 40 0.10 (1.58) *Calories* **IG** 45 1700 45 -267.80 (574.56) **CG** 40 1757 40 -57.5 (508.81) Adjusted for baseline values
Stevens, 2003[97] US Fair	N=616 0% men Mean age 54 7% nonwhite Selected for age 40-70 and slightly elevated cholesterol	Two individual sessions over 1 month, plus 2 followup phone calls over 1 month	**Baseline** **12 months** **N** **Mean** **N*** **Adjusted mean (SD)** *Calories from fat, percent* **IG** 308 40.60 274 -5.74 (7.59)** **CG** 308 39.41 262 -0.80 (6.43) *Fruits and vegetables, servings/day* **IG** 308 3.09 274 1.24 (1.74)** **CG** 308 3.21 262 0.19 (1.50) Adjusted for baseline values *Present at 12-month data collection (N analyzed at 12 months NR) ** p<0.001
Watanabe, 2003[108] Japan Fair	N=173 100% men Mean age 55 NR nonwhite Selected for IFG	One individual session, plus mailed tailored booklet at 1 month	*Daily "overintake/underintake fraction" for total energy intake, percent* **Baseline** **12 months** **N** **Mean** **N** **Adjusted mean change (SD)** **IG** 78 21.6 78 -1.8 (1.5) **CG** 77 19.9 77 4.0 (1.4) Adjusted mean difference (95% CI): -6.0 (-9.8, -2.2) p=0.002 for the adjusted difference between groups at 12 months Adjusted for baseline value

Table 7. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
High-intensity interventions (estimated >360 minutes)			
Anderson, 1992[77] US Fair	N=177 60% men Mean age 41 0% nonwhite Selected for slightly elevated total cholesterol	10 group sessions over 2.5 months plus 4 home visits over 12 months	**Baseline** / **12 months** **N** **Mean** **N** **Mean change (SD)** *Calories from fat, percent* **IG1+2** 95 33.99 95 -5.30 (7.60) **CG** 51 33 51 -2.51 (7.90) *Calories from saturated fat, percent* **IG1+2** 95 11 95 -2.51 (3.15) **CG** 51 11 51 -1.00 (3.57) *Dietary cholesterol, mg* **IG1+2** 95 254.07 95 -67.99 (NR) **CG** 51 267 51 -48.00 (NR) *Total fiber, g* **IG1+2** 95 18 95 4.31 (11.30) **CG** 51 17 51 0.10 (10.00) *Calories* **IG1+2** 95 2020 95 -59.21 (503.60) **CG** 51 2177 51 -166.0 (620.60)
Carpenter, 2004[82] US Fair	N= 98 36% men Mean age 50 13% nonwhite Unselected	IG1: 20 group sessions over 6 months IG2: 24 mailed curricula over 6 months, with reminders	**Baseline** / **6 months** **N** **Mean** **N** **Adjusted mean change (SD)** *Fruits and vegetables score* **IG1+2** 60 5.9 60 0.89 (2.36) **CG** 33 7.8 33 -1.12 (2.42) *Total fat score* **IG1+2** 60 6.41 60 -1.96 (3.44) **CG** 33 5.6 33 -0.39 (3.53) *Saturated fat score* **IG1+2** 60 7.30 60 -1.24 (3.36) **CG** 33 6.8 33 -0.59 (3.44) *Cholesterol score* **IG1+2** 60 7.51 60 0.58 (NR) **CG** 33 8.2 33 0.88 (NR) Adjusted for baseline measurement, age, gender, education, and baseline caloric intake

Table 7. Randomized Controlled Trials for Healthful Diet Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)
Coates, 1999[83] US Fair	N=2207 0% men Mean age 60 45% nonwhite Selected for post menopausal women, and fat >30% energy intake	20 group sessions over 18 months	**Baseline** / **6 months** **N** **Mean** **N** **Mean change (SD)** *Calories from fat, percent* **IG** 1324 39.7 1324 -13.3 (7.78) **CG** 883 39.1 883 -2.3 (7.00) *Calories from saturated fat, percent* **IG** 1324 13.26 1324 -4.21 (3.11) **CG** 883 12.97 883 -0.71 (2.82) *Cholesterol, mg/day* **IG** 1324 273.3 1324 107.0 (NR) **CG** 883 260.2 883 -28.6 (NR) *Fruits and vegetables, servings/day* **IG** 1324 3.15 1324 0.66 (1.82) **CG** 883 3.17 883 0.05 (1.46) *Calories* **IG** 1324 1834 1324 -538 (927) **CG** 883 1766 883 -171 (747)
Tinker, 2008[104] US Good	N=48,835 0% men Mean age 62 18% nonwhite Selected for postmenopausal women and dietary fat intake >30%	18 group sessions and one individual session over 12 months, plus ongoing maintenance for trial duration	**Baseline** / **12 months** / **72 months** **N** **Mean** **N** **Mean change (SD)** **N** **Mean change (SD)** *Calories from fat, percent* **IG** 18,306 37.7 17,117 -13.50 (7.08) 14,117 -9.10 (NR) **CG** 27,435 37.7 25,182 -2.70 (6.17) 21,759 -0.80 (NR) *Calories from saturated fat, percent* **IG** 18,306 12.7 17,117 -4.70 (2.91) 14,117 -3.20 (NR) **CG** 27,435 12.7 25,182 -1.00 (2.72) 21,759 -0.30 (NR) *Vegetables or fruits, servings/day* **IG** 18,306 3.6 17,117 1.50 (1.99) 14,117 1.40 (NR) **CG** 27,435 3.6 25,182 0.30 (1.48) 21,759 0.20 (NR) *Fiber, g/1000 kcal* **IG** 18,306 8.8 17,117 3.5 (3.44) 14,117 3.20 (NR) **CG** 27,435 8.8 25,182 0.90 (2.82) 21,759 0.80 (NR) *Calories* **IG** 18,306 1790 17,117 -288.0 (641.71) 14,117 -355 (NR) **CG** 27,435 1788 25,182 -194.0 (601.14) 21,759 -240 (NR) p<0.001

ID - identification; HPT - Hypertension Prevention Trial; US - United States; N - number; mmol - millimoles; h - hour; IG - intervention group; CG - control group; SE - standard error; SD - standard deviation; TOHP - Trial of Hypertension Prevention; UK - United Kingdom; NR - not reported (or only noncomparable behavioral outcomes reported); mo - month; CI - confidence interval; PCP - primary care physician; BMI - body mass index

Table 8. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)	
			Dietary	**Physical activity**
Low-intensity interventions (estimated 0-30 minutes)				
Jeffery, 1999[120] US Fair	N=809 20% men Mean age 38 10% nonwhite Unselected	36 monthly newsletters plus additional activities offered every 6 months over 36 months	**N** / **Baseline Mean** / **12 months Mean change (SD)** / **36 months Mean change (SE)** *Energy intake, kcal/day* **IG** 395 1717 -143 (1068) -198 (1095) **CG** 414 1702 -122 (1058) -130 (1099) *Fat intake, % of energy* **IG** 395 34.0 -1.75 (7.0) -1.35 (8.4) **CG** 414 34.0 -0.6 (8.1) -1.1 (8.1) p=NS	**N** / **Baseline Mean** / **12 months Mean change (SD)** / **36 months Mean change (SE)** *Exercise, metabolic equivalent units* **IG** 395 45.5 0.55 (30.9) -0.70 (29.5) **CG** 414 46.6 -1.2 (31.5) -4.5 (30.5) p=NS
Medium intensity interventions (estimated 31-360 minutes)				
Babazono, 2007[112] Japan Fair	N=99 42% men Mean age 64 NR nonwhite Selected for SBP 130-159, DBP 85-99, or A1c 5.6+	2 home visits, plus reinforcement at 2 data collection visits over 6 months	**N** / **Baseline Number (%)** / **12 months Number (%)** *≥2 meals/day with vegetable servings* **IG** 46 34 (73.9) 40 (87.0) **CG** 41 29 (70.7) 30 (73.2) **N** / **Mean** / **Mean change (SD)** *Energy intake, kcal* **IG** 46 1931 -63 (497) **CG** 41 1859 -44 (407) p=NS	**N** / **Baseline Mean** / **12 months Mean change (SD)** *Number of steps* **IG** 46 7345 3028 (5355) **CG** 41 7196 -381 (4355) p<0.001

Table 8. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)	
			Dietary	**Physical activity**
Brekke, 2005[81] Sweden Fair	N=77 63% men Mean age 43 NR nonwhite Relatives with DM, otherwise unselected	2 individual sessions, plus followup phone calls over 8 months	**Baseline** **12 months** **N** **Mean** **Mean change (SD)** *Total energy intake, kcal* **IG** 25 2341 -323 (522) **CG** 19 2482 -243 (608) *Fat, % intake* **IG** 25 34.9 -5.1 (6.4)* **CG** 19 34.7 -0.5 (7.2) *Saturated fatty acids, % intake* **IG** 25 13.8 -3.9 (4.0)* **CG** 19 14.1 -0.6 (3.7) *Monounsaturated fatty acids, % intake* **IG** 25 13.3 -1.6 (2.3)* **CG** 19 12.6 0.4 (3.1) *Fiber, g/1000 kcal* **IG** 25 8.6 2.5 (3.8)* **CG** 19 9.7 -0.5 (2.6) * p<0.05	NR
Eakin 2007[114] US Fair	N=200 22% men Mean age 50 85% nonwhite Selected for one or more chronic conditions (including BMI or non-CV conditions)	2 individual sessions, plus 3 followup phone calls over 3 months	**Baseline** **6 months** **N** **Mean** **Mean change (SD)** *Dietary behavior†* **IG** 84 2.47 -0.23 (--)* **CG** 78 2.48 -0.05 (--) † Lower scores indicate better dietary behavior change, range 1-4 * p<0.05	**Baseline** **6 months** **N** **Median** **Mean change (SD)** *Total walking, minutes/week* **IG** 101 60 16 (183) **CG** 99 70 -11 (203)
Franko, 2008[116] US Fair	N=476 43% men Mean age 20 41% nonwhite Unselected	IG1: 2 Web sessions (45 minutes each) over 2 weeks IG2: 3 Web sessions (45 minutes each) over 5 weeks	**Baseline** **6 months** **N** **Mean** **N** **Mean change** *Fruit and vegetables, servings/day* **IG** 329 5.3 287 -0.25 **CG** 147 5.1 135 -0.18 *Energy from fat, percent* **IG** 329 31.1 287 -0.02 **CG** 147 31.9 135 -0.46	**Baseline** **6 months** **N** **Mean** **N** **Mean change** *Total MET minutes/week* **IG** 329 1798 287 123.4 **CG** 147 1820 135 -68.0

Table 8. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)	
			Dietary	**Physical activity**
Hardcastle, 2008[117] UK Fair	N=334 NR % men Mean age 50 NR nonwhite Selected for 1 or more CV risk factors (including BMI)	Up to 5 individual sessions (30 minutes each) over 6 months (average 2 sessions)	**N** **Baseline Mean** **6 months Mean change (SD)** *Fat intake, % fat intake per day* **IG** 203 23.85 -0.92 (6.13)** **CG** 131 23.72 -2.92 (6.87) *Fruit and vegetable intake, portions per day* **IG** 203 6.41 1.05 (4.27) **CG** 131 6.88 0.73 (5.04) ** p<0.01 for t-value between IG and CG	**N** **Baseline Mean** **6 months Mean change (SD)** *Total physical activity, MET-min/week* **IG** 203 2039 245 (1482)* **CG** 131 2320 -122 (1808) * p<0.05 for t-value between IG and CG ** p<0.01 for t-value between IG and CG
Hellenius, 1993[47] Sweden Fair	N=158 100% men Mean age 45 NR nonwhite Selected for slightly elevated total cholesterol	One session with PCP and one session with dietitian over 2 weeks	**N** **Baseline Mean** **6 months Mean change (SD)** *Total energy intake, kcal* **IG** 39 2064 -222 (452)* **CG** 39 2245 -153 (551) *Fat, % intake* **IG** 39 36 -3 (5.6)* **CG** 39 36 0 (5.9) *p<0.05	**N** **Baseline Mean** **6 months Mean change (SD)** *Number of exercise sessions/month* **IG** 39 5.1 4.8 (9.5)* **CG** 39 5.3 0.1 (8.9) *p<0.01
Keyserling, 2008[121] US Fair	N=236 0% men Mean age 53 42% nonwhite Selected for at or below 200% FPL	2 individual counseling and 3 group sessions, plus 10 followup phone calls over 10 months	**N** **Baseline Mean** **N** **12 months Mean change (SD)** *Dietary risk assessment, total score* **IG** 102 34.2 85 5.0 (--)* **CG** 108 34.2 89 -1.4 (--)	**N** **Baseline Mean** **N** **12 months Mean change (SD)** *Physical activity assessment (self-reported), all activity* **IG** 107 29.4 86 0.4 (9.3) **CG** 111 29.2 90 -0.6 (8.3) * p<0.05
Mosca, 2008[122] US Good	N=501 34% men Mean age 48 36% nonwhite Family with acute CV event, otherwise unselected	5 in-person or phone sessions over 10 months	**N** **Baseline Mean** **12 months Mean change (SD)** *Total fat, % total intake* **IG** 232 37.7 -0.90 (7.7) **CG** 232 37.8 -1.3 (7.0) *Fruit/vegetables, servings/day* **IG** 232 4.8 -0.1 (2.2) **CG** 232 4.9 0.0 (2.1) p= NS	**N** **Baseline Mean** **12 months Mean change (SD)** *Activity, days/week* **IG** 232 1.9 0.6 (2.9) **CG** 232 1.6 0.4 (2.4) p=NS

Table 8. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)	
			Dietary	**Physical activity**
Vandelanotte, 2005[130] Belgium Fair	N=1023 36% men Mean age 39 NR nonwhite Unselected	1 computer session (50 minutes) IG1: HD and PA counseling at one time IG2: PA then HD counseling IG3: HD then PA counseling	**N** **Baseline Mean** **6 months Mean change (SD)** *Total fat intake, g/day* **IG** 370 114 -14.7 (39.7) **CG** 195 101 -7.0 (36.4) *Energy from fat, %* **IG** 370 34.8 -1.3 (--) **CG** 195 35.3 -2.1 (--) p<0.001 for time x group for both	**N** **Baseline Mean** **6 months Mean change (SD)** *Total physical activity, minutes/week* **IG** 369 523 193 (643) **CG** 204 720 14 (613) p=NS
Wister, 2007[131] Canada Good	N=611 42% men Mean age 55 NR nonwhite Selected for Framingham risk score of 10%+ over 10 years	2 individual sessions (30 minutes each) over 1 year plus "annual report card"	**N** **Baseline Mean** **12 months Mean change (95% CI)** *Nutrition level (ordinal measure treated continuously)* **IG** 157 -- 0.30 (0.13, 0.47) **CG** 158 -- -0.05 (-0.22, 0.12)* * p<0.01	**N** **Baseline Mean** **12 months Mean change (95% CI)** *Physical activity (ordinal measure treated continuously)* **IG** 157 -- 0.17 (-0.06, 0.40) **CG** 158 -- 0.16 (-0.08, 0.40)
High-intensity interventions (estimated >360 minutes)				
Aldana, 2006[110] US Fair	N=348 28% men Mean age 50 6% nonwhite Unselected	Four group sessions (120 minutes each) over 4 weeks	**N** **Baseline Mean** **6 months Mean Change (SD)** *Kcal intake/day* **IG** 174 2092 -558 (779)* **CG** 174 1919 -63 (497) *Fat, % intake* **IG** 174 36.7 -8.2 (7.7)* **CG** 174 34.6 1.0 (6.9) *Fruit and vegetable, servings/day* **IG** 174 4.6 2.3 (3.3)* **CG** 174 5.0 0.1 (3.2) *p<0.01	**N** **Baseline Mean** **6 months Mean change (SD)** *Total steps/day* **IG** 174 5797 1767 (2559)* **CG** 174 6267 809 (2589) *p<0.0002

Table 8. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)	
			Dietary	**Physical activity**
Edelman 2005[115] US Fair	N=294 20% men Mean age 53 23% nonwhite Selected for 1 or more CV risk factors (including BMI)	2 individual sessions and 28 group sessions, plus 20 followup phone calls over 10 months	NR	Data primarily reported in a figure. Days of exercise were significantly increased in IG compared with CG (3.7 v. 2.4 days, p=0.002).
Hivert, 2007[119] Canada Fair	N=115 18% men Mean age 20 7% nonwhite Unselected	23 group sessions over 2 years	**N** / **Baseline Mean** / **12 months Mean change (SD)** / **24 months Mean change (SD)** *Total caloric intake, kcal/day* **IG** 58 2051 -194 (503) -224 (556) **CG** 57 2016 -112 (506) -229 (604) *% of lipids* **IG** 58 29.5 -0.9 (7.6) 0.6 (9.1) **CG** 57 30.1 -1.4 (7.6) 0.0 (7.6) p=NS	**N** / **Baseline Mean** / **12 months Mean change (SD)** / **24 months Mean change (SE)** *Physical activity, kcal/kg/year* **IG** 58 1216 -81 (701) -89 (967) **CG** 57 1378 -260 (838) -292 (830) *VO_2 max* **IG** 58 39.0 -0.31 (2.6) 0.28 (2.6) **CG** 57 38.8 -0.96 (3.5) 0.31 (3.2) p=NS
Oldroyd, 2001[123] UK Fair	N=78 57% men Mean age 58 NR nonwhite Selected for IFG	18 individual sessions (20 minutes each) over 24 months	**N** / **Baseline Mean** / **12 months Mean change (SD)** / **24 months Mean change (SD)** *Energy, kcal/day* **IG** 33 1988 -199 (580) -- **CG** 32 2137 7 (582) -- *Total fat, g/day* **IG** 33 85.4 -16.7 (26.5)* -24.4 (24.5)* **CG** 32 84.7 -0.43 (33.5) -6.5 (30.9) * p<0.05	**N** / **Baseline Percent** / **12 months Percent (SD)** / **24 months Percent (SD)** *Regular activity at least once per week* **IG** 30 25.0 -- 57.1 (16)* **CG** 24 50.0 -- 45.8 (11) * p<0.05

Table 8. Randomized Controlled Trials for Combined Lifestyle Counseling Interventions: Behavioral Outcomes

Author, year Country Quality	Population details	Intervention details	Behavioral outcomes (self-reported unless otherwise noted)											
			Dietary						Physical activity					
				N	Baseline Mean	18 months Mean change (SD)	54 months N	54 months Mean change		N	Baseline Mean	18 months Mean change (SD)	54 months N	54 months Mean change
Simkin-Silverman, 1998[124] US Good	N=535 0% men Mean age 47 8% nonwhite Selected for women age 44-50	15 group sessions over 5 months, plus group, mail or phone followup after initial 5 months	*Total energy intake, kcal*						*Total physical activity, kcal*					
			IG	236	1492	-189 (514)*	246	-160*	**IG**	236	1217	432(1647)*	246	275*
			CG	253	1427	-79 (456)	263	-25	**CG**	253	1389	43 (1677)	263	-113
			Fat, %						* p<0.05					
			IG	236	32.5	-9.2 (7.2)*	--	--						
			CG	253	32.4	-1.8 (7.6)	--	--						
			* p<0.05											
Thompson, 2008[127] US Fair	N=200 0% men Mean age 29 100% nonwhite Selected for American Indian women	5 group sessions (150 minutes each) over 5 months		N	Baseline Mean	12 months Mean change (SD)	18 months Mean change			N	Baseline Mean	12 months Mean change (SD)	18 months Mean change	
			Total energy intake, kcal/day						*Total leisure-time activity, minutes/week*					
			IG	96	2201.3	-355.1 (871.1)	-318.0*		**IG**	100	303.6	1.2 (397)	-7.2	
			CG	95	2191.8	-215.6 (827.5)	-497.0		**CG**	100	366.0	-48.6 (421)	-52.8	
			Total fat intake, g/day						*Peak VO_2, L/minute*					
			IG	96	94.9	-14.7 (44.4)	-13.9*		**IG**	98	2.08	-0.02 (--)	-0.03	
			CG	95	96.6	-8.8 (47.1)	-10.3		**CG**	99	1.20	0.78 (--)	0.74	
			Fruit and vegetable intake, servings/day						p=NS					
			IG	96	3.93	0.11 (2.09)	0.55							
			CG	95	3.85	-0.09 (1.73)	0.1							
			* RM ANOVA effect of visit p<0.001											

BMI – body mass index; CV – cardiovascular; DBP – diastolic blood pressure; DM – diabetes mellitus; FPL – federal poverty level; A1c – hemoglobin A1c; HD – healthful diet; IFG – impaired fasting glucose; NR – not reported; NS – not significant; PA – physical activity; PCP – primary care physician; SBP – systolic blood pressure; SD – standard deviation; US – United States; UK – United Kingdom

Table 9. Summary of Evidence By Key Question

No. of studies (k)	Design	Major limitations	Consistency	Applicability	Overall quality	Summary of findings
KQ1. Do primary care-relevant behavioral counseling interventions for physical activity and/or healthful diet reduce cardiovascular disease (CVD) in adults?						
k=3 n=50,769	RCT	Only 3 HD trials. Two trials with observational followup after trials were completed.	Fair. Trials evaluated different interventions in different populations.	Fair. Largest trial in post-menopausal women. Two trials in pre-HTN.	Fair-Good	In the WHI, high-intensity general low-fat counseling did not statistically significantly decrease major CVD events at 8.1 years. Observational followup of TOHP I and II showed that high-intensity sodium reduction counseling in pre-HTN decreased CVD events and revascularization at 10-15 years.
KQ2. Do primary care-relevant behavioral counseling interventions for physical activity and/or healthful diet improve intermediate outcomes (e.g., adiposity, blood pressure, lipids) in adults?						
Evidence for physical activity counseling alone						
PA only: k=8, n=3731	RCT	Intermediate outcomes not commonly reported.	Good.	Fair. Only one trial conducted in the US. Only one low-intensity trial.	Fair-Good	Sparsely reported. Pooled estimates showed that mostly medium-intensity counseling did not improve adiposity, blood pressure, or lipids. Two trials did show statistically signficant group differences in adiposity, blood pressure, or lipids; however, the remaining trials did not.
Evidence for healthful diet counseling with or without physical activity counseling						
HD only: k=16 n=58,557 CL: k=14 n=3,855 Meta-analysis: k=28 n=60,799	RCT	Very high I^2 for adiposity meta-analyses. Limited evidence beyond 12 months.	Fair. HD and CL trials were not distributed consistently by intervention intensity and population risk.	Good.	Fair	High-intensity counseling for healthful diet results in statistically significant reductions in adiposity, blood pressure, and total and LDL cholesterol. BMI was reduced by approximately 0.3 to 0.7 kg/m^2. Systolic and diastolic blood pressures were reduced by 1.5 and 0.7 mmHg. Total and LDL cholesterol were reduced by 0.17 and 0.13 mmol/L (6.56 and 5.02 mg/dL), respectively. No statistically significant changes were seen for HDL and triglycerides.

Table 9. Summary of Evidence By Key Question

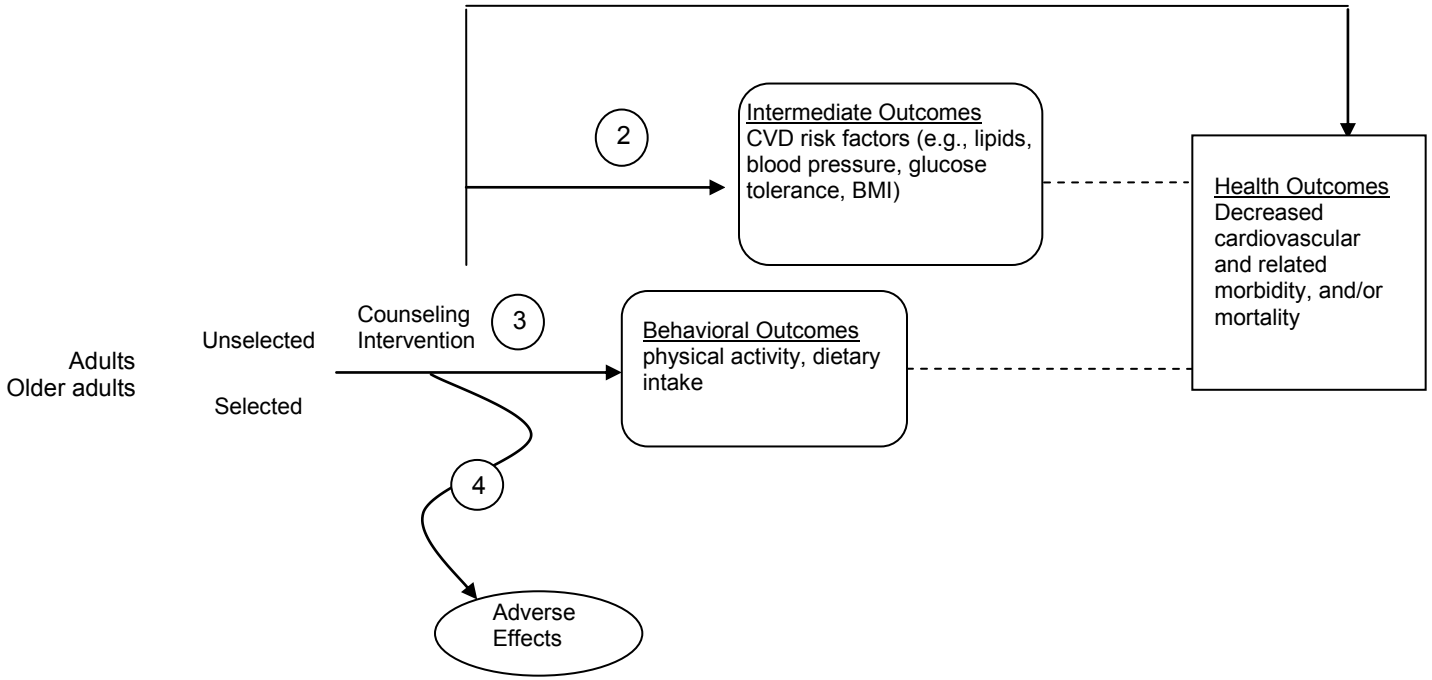
No. of studies (k)	Design	Major limitations	Consistency	Applicability	Overall quality	Summary of findings
KQ3. Do primary care-relevant behavioral counseling interventions for physical activity and/or healthful diet change associated health behaviors in adults?						
Evidence for change in physical activity						
PA only: k=30 n=15,265 CL: k=15 n=4,975 Meta-analysis: k=39 n=18,517	RCT	Wide variety in measurement of physical activity. Mostly self-reported measures. Egger test positive. Limited evidence beyond 12 months.	Fair. PA and CL trials were not distributed consistently by intervention intensity and population risk.	Good. Most trials conducted in persons selected for sedentary behavior or some increased risk for CVD.	Fair	Medium- to high-intensity interventions improved self-reported measures of physical activity, by approximately 38 minutes per week. Although baseline levels of physical activity varied across trials, this modest increase meant that most persons exercised for at least 1 hour per week. Results for the effectiveness of low-intensity counseling were mixed. Although the pooled estimate was not statistically significant, 4 trials (2 of which were not in the meta-analysis) showed statistically significant improvements in self-reported activity levels.
Evidence for change in dietary intake						
HD only: k=25 n=71,267 CL: k=16 n=4,951 Meta-analysis: k=34 n=74,152	RCT	High I^2 for all dietary intake meta-analyses. Mostly self-reported measures. Egger test positive for total fat dietary intake. Limited evidence beyond 12 months.	Fair. HD and CL trials were not distributed consistently by intervention intensity and population risk.	Good.	Fair	High-intensity counseling showed an approximate 7-11% decrease in total energy consumption. Although there was high statistical heterogeneity amongst pooled trials, there appeared to be a dose effect with intervention intensity. High-intensity counseling resulted in moderate to large reductions in self-reported fat intake, 5.9-11% decrease in energy from total fat, and 2.8-3.7% decrease in energy from saturated fat. Low- to medium-intensity interventions resulted in smaller changes. For low- to high-intensity counseling, there were moderate to large increases in fruit and vegetable intake, about 0.4-2 servings/day.

Table 9. Summary of Evidence By Key Question

No. of studies (k)	Design	Major limitations	Consistency	Applicability	Overall quality	Summary of findings
KQ4. What are the adverse effects of primary care-relevant behavioral counseling interventions for physical activity and/or healthful diet in adults?						
Evidence for harms of physical activity or counseling to improve physical activity						
Trials: k=2, n=483 Observational studies: k=7, n=4,354 cases	RCT Case-crossover	Adverse events only reported in 2 of 30 trials. Case-crossover design; difficult to measure habitual PA.	Good.	Fair. Observational studies often limited to nonfatal cases, cases primarily in men (range 57-100% male). Only 1 trial reported absolute risk of cardiac event during vigorous physical activity.	Fair	In 2 trials, almost 25% of participants reported mild muscular fatigue, strain, or soreness. In observational studies, risk of serious cardiac event was increased during vigorous physical activity. This increased risk was much greater in people with low levels of habitual physical activity. However, the absolute risk of cardiac event was very small.
Evidence for harms of healthful diet or counseling to improve diet						
HD only: k=25 n=71,267 CL: k=16 n=4,951	RCT	Explicit adverse events not reported in trials.	Good.	Good.	Fair	No specific examination of adverse effects, but two trials showed an increased intake of carbohydrates, although no increase in overall energy intake. Overall, few trials reported dietary intake of mono- or polyunsaturated fats, carbohydrates, or sugars.

CL – counseling; CV – cardiovascular; CVD – cardiovascular disease; HD – healthful diet; HDL – high-density lipoprotein; HTN – hypertension; LDL – low-density lipoprotein; PA – physical activity; TOHP – Trial of Hypertension Prevention; US – United States; WHI – Women's Health Initiative

Figure 1. Analytic Framework and Key Questions

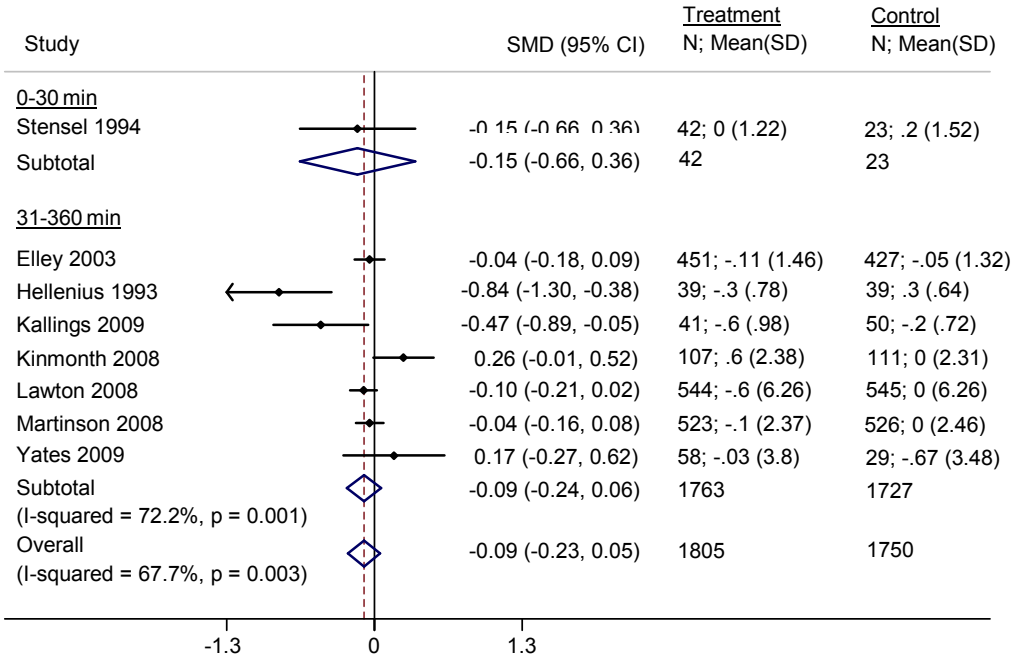


Key Questions

1. Do primary care-relevant behavioral counseling interventions for physical activity and/or healthful diet improve cardiovascular disease (CVD) health outcomes (e.g., prevent morbidity and mortality) in adults?
2. Do primary care-relevant behavioral counseling interventions for physical activity and/or healthful diet improve intermediate outcomes associated with CVD (e.g., lipids, blood pressure, glucose tolerance, weight, body mass index [BMI]) in adults (including older adults)?
3. Do primary care-relevant behavioral counseling interventions for physical activity and/or healthful diet change associated health behaviors in adults?
4. What are the adverse effects of primary care-relevant behavioral counseling interventions for physical activity and/or healthful diet in adults?

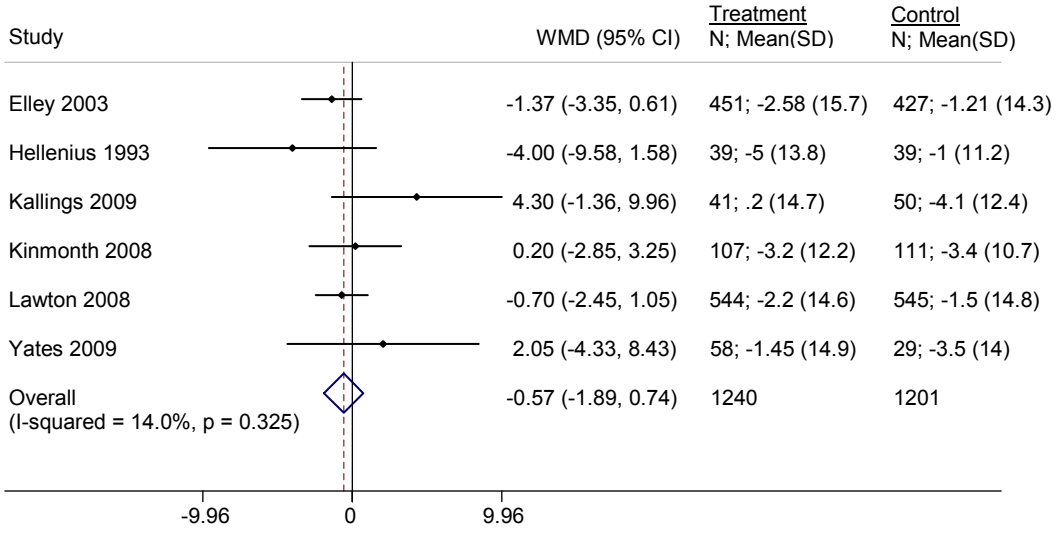
Contextual Questions: How are adults and older adults selected for physical activity and/or dietary counseling interventions? What primary care-feasible assessment tools, if any, are used to identify adults and older adults in need of physical activity and/or dietary counseling interventions?

Figure 2. Meta-Analysis of Physical Activity Trials (KQ2): Adiposity



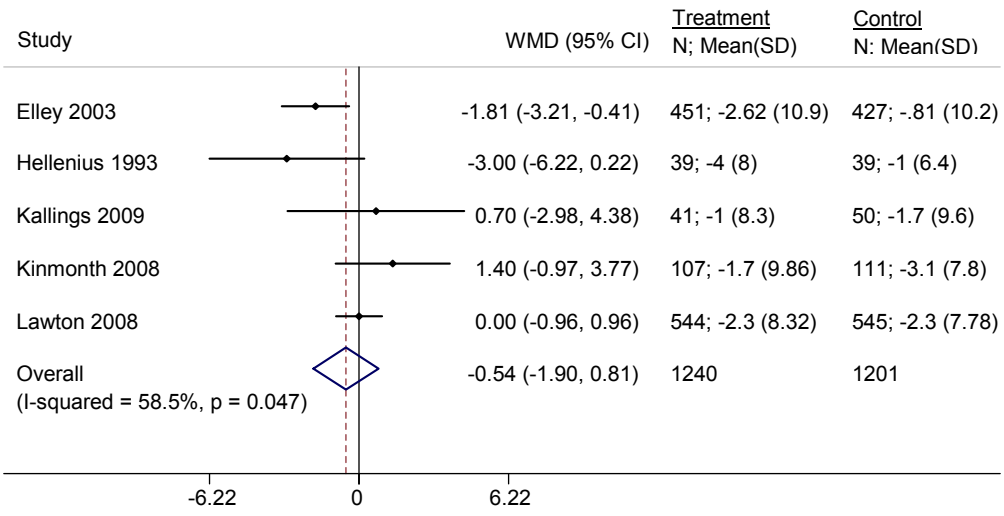
SMD – standardized mean difference; 95% CI – 95% confidence interval

Figure 3. Meta-Analysis of Physical Activity Trials (KQ2): Systolic Blood Pressure



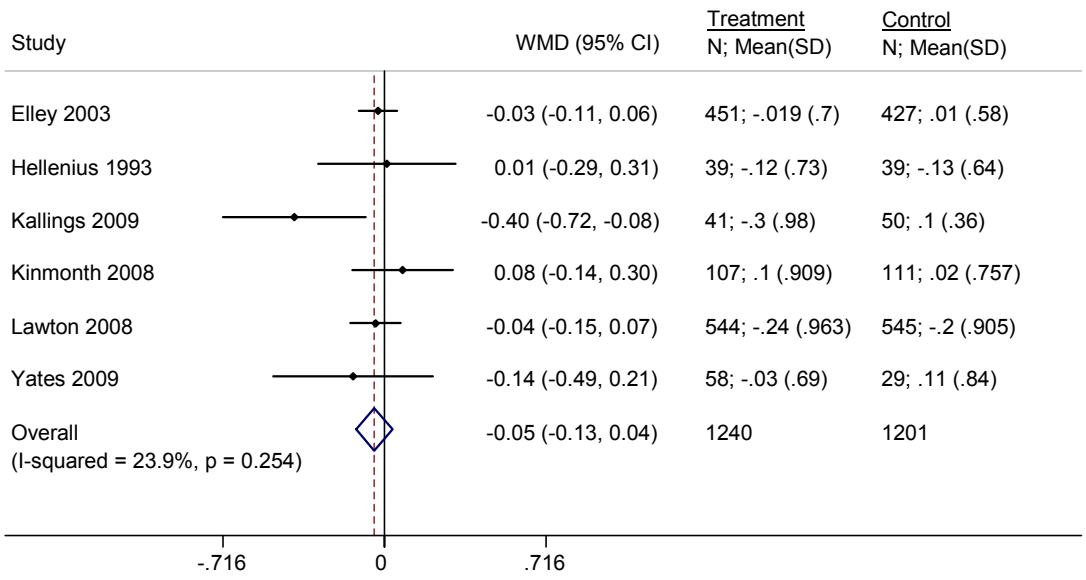
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 4. Meta-Analysis of Physical Activity Trials (KQ2): Diastolic Blood Pressure



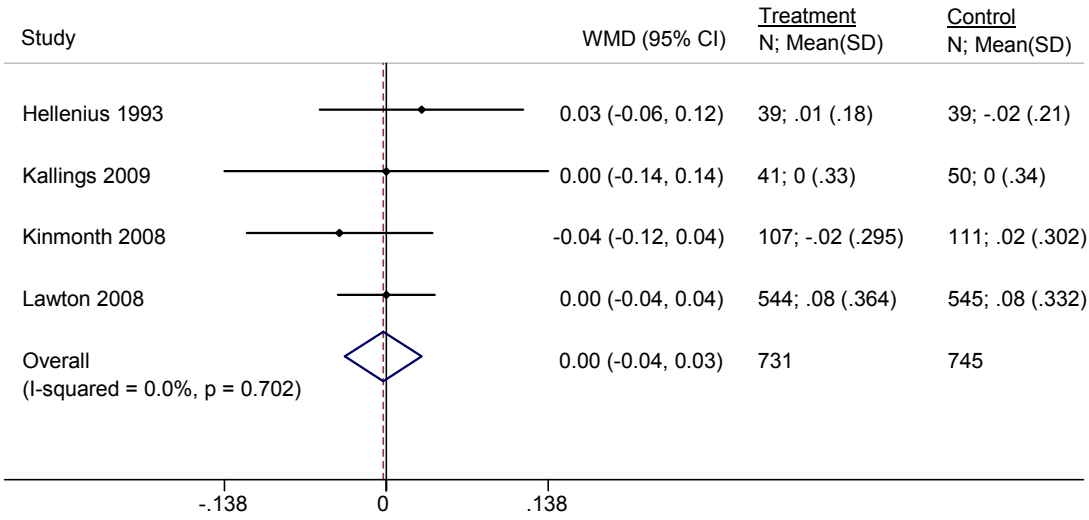
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 5. Meta-Analysis of Physical Activity Trials (KQ2): Total Cholesterol



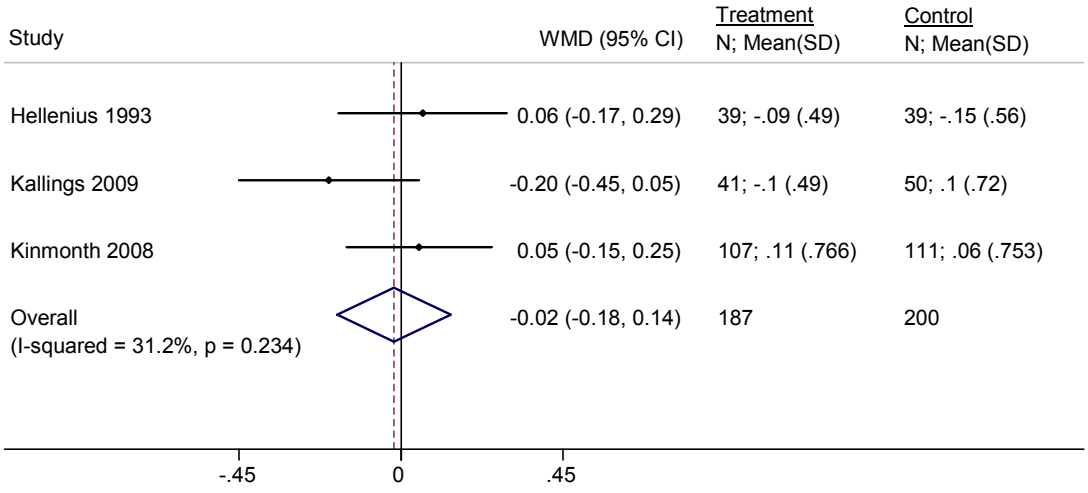
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 6. Meta-Analysis of Physical Activity Trials (KQ2): High-Density Lipoproteins



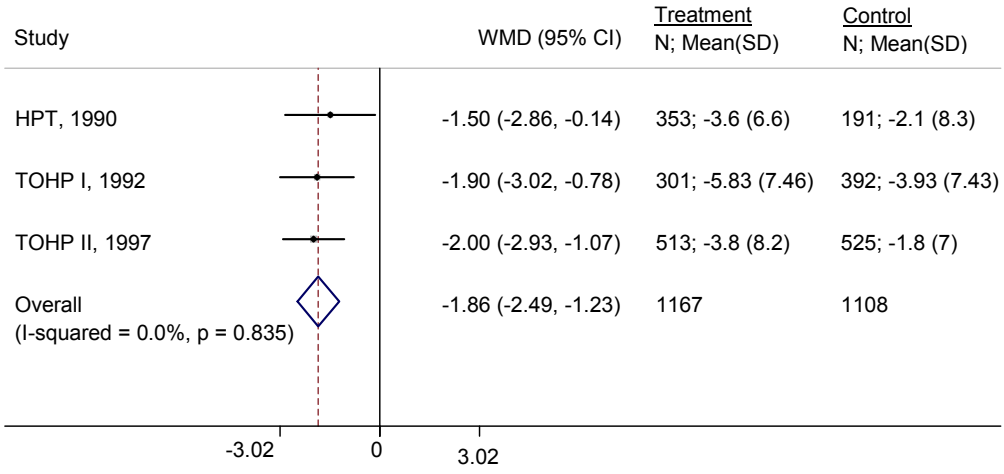
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 7. Meta-Analysis of Physical Activity Trials (KQ2): Low-Density Lipoproteins



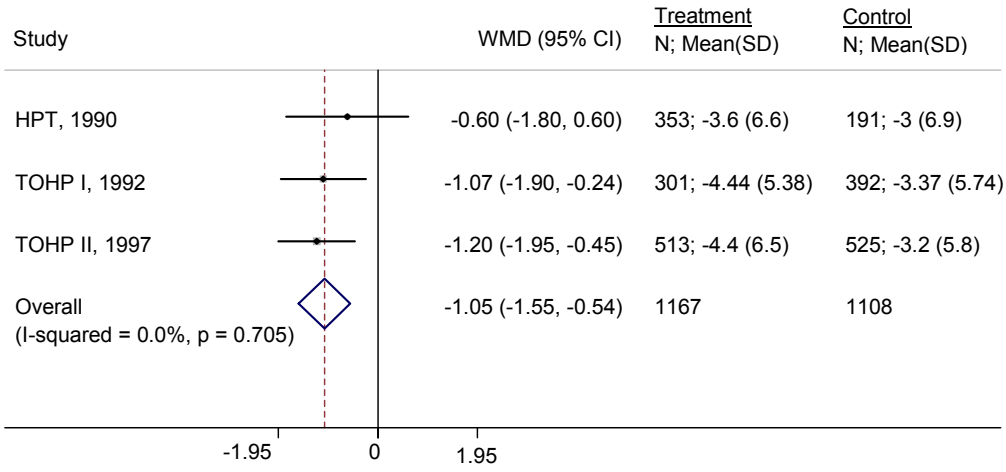
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 8. Meta-Analysis of Healthful Diet Trials, Salt Reduction Counseling (KQ2): Systolic Blood Pressure



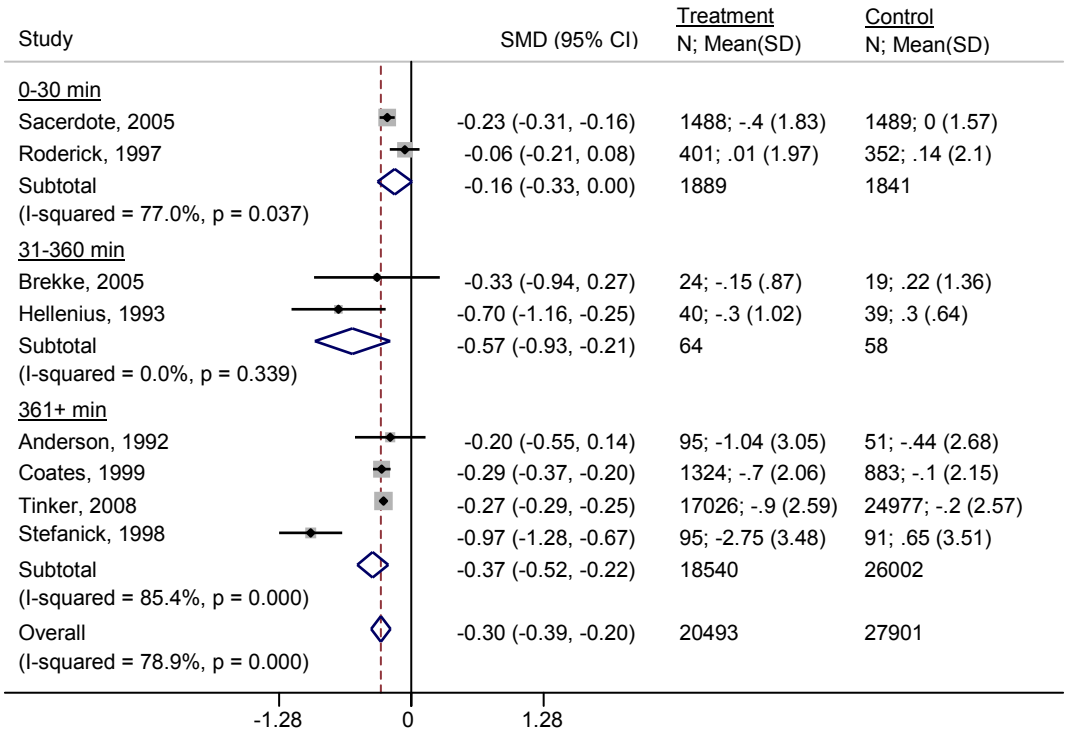
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 9. Meta-Analysis of Healthful Diet Trials, Salt Reduction Counseling (KQ2): Diastolic Blood Pressure



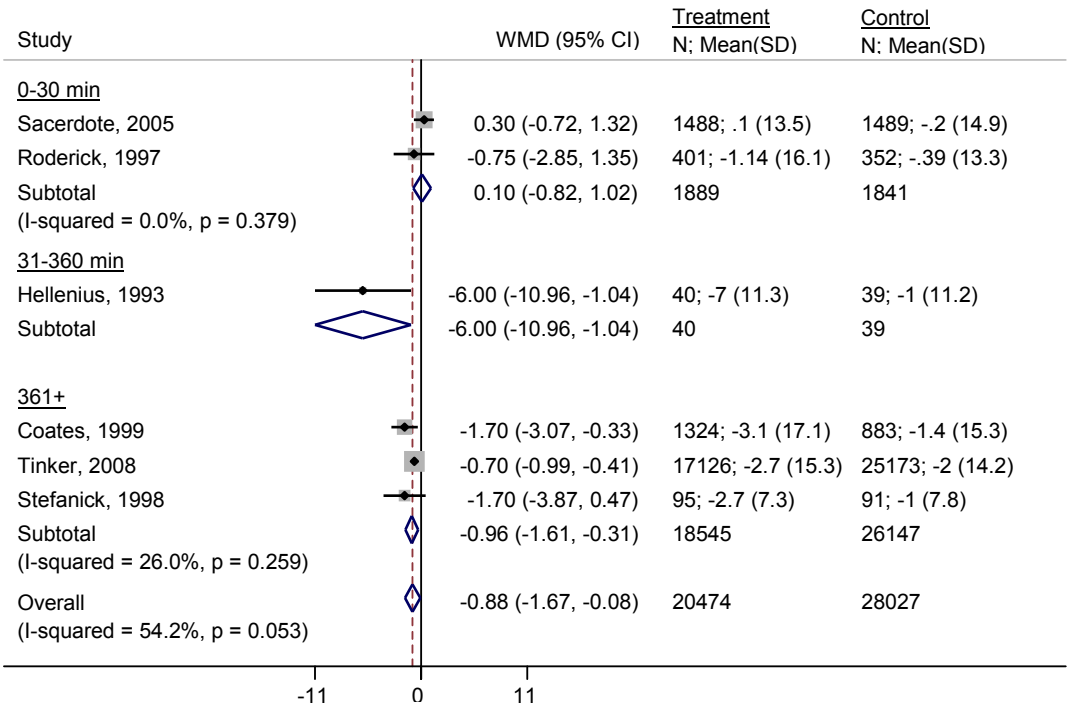
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 10. Meta-Analysis of Healthful Diet Trials, General Counseling (KQ2): Adiposity



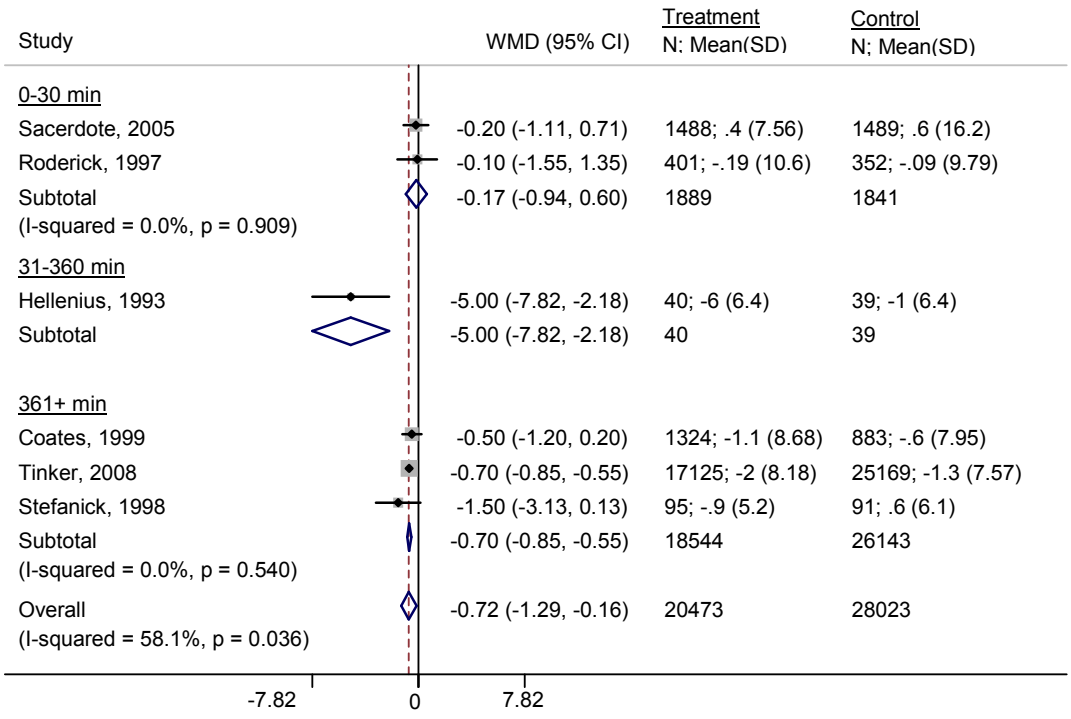
SMD – standardized mean difference; 95% CI – 95% confidence interval

Figure 11. Meta-Analysis of Healthful Diet Trials, General Counseling (KQ2): Systolic Blood Pressure



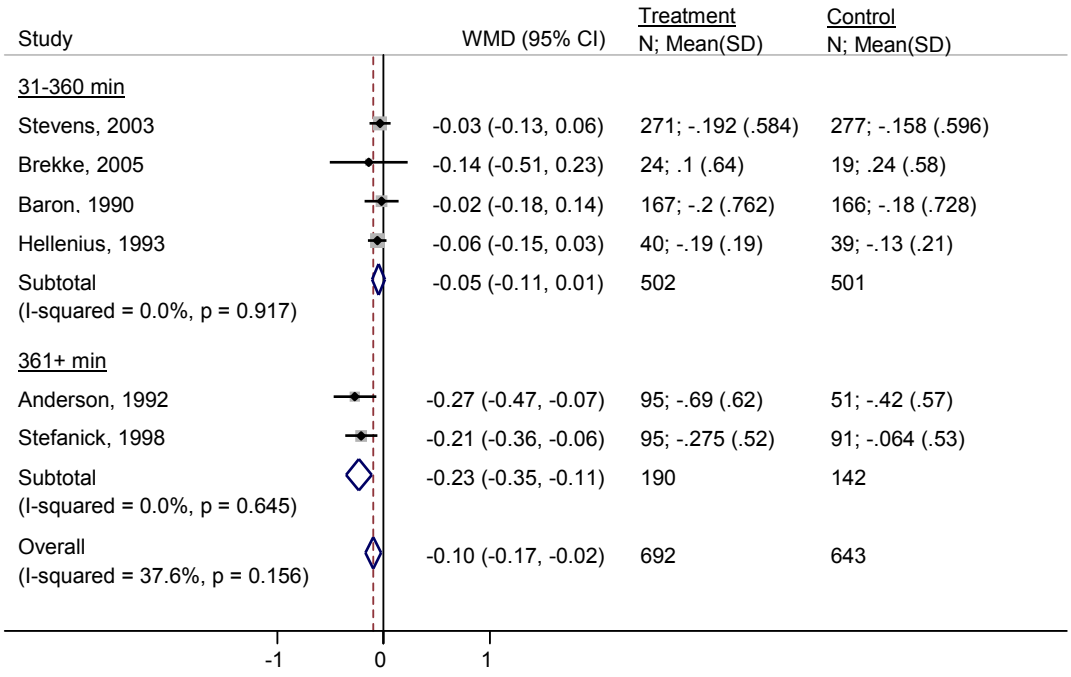
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 12. Meta-Analysis of Healthful Diet Trials, General Counseling (KQ2): Diastolic Blood Pressure



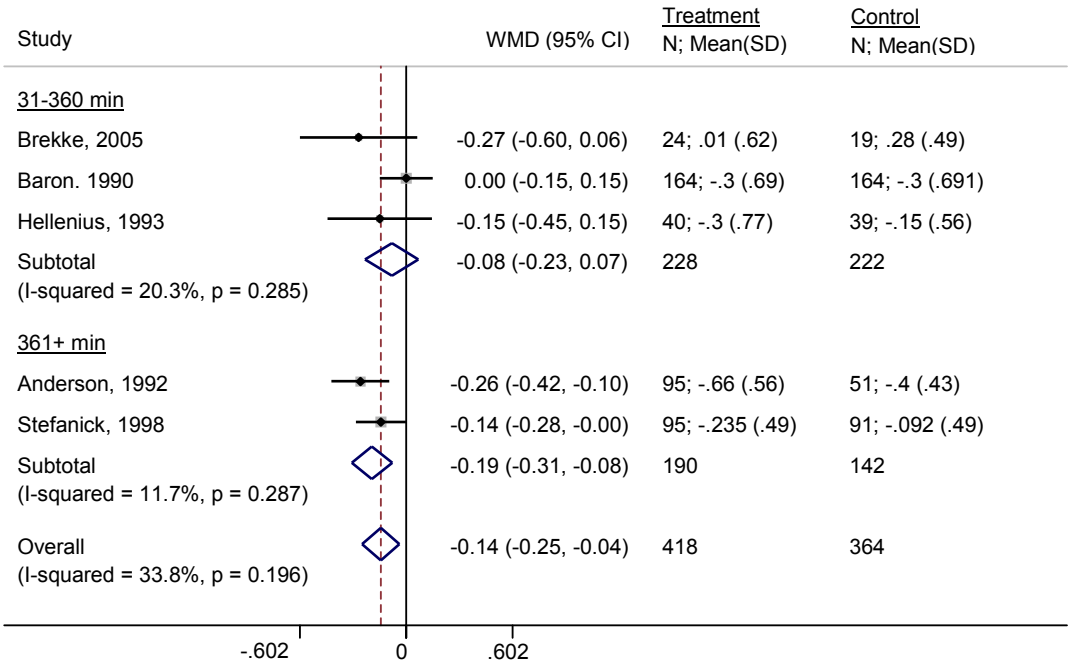
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 13. Meta-Analysis of Healthful Diet Trials, General Counseling (KQ2): Total Cholesterol



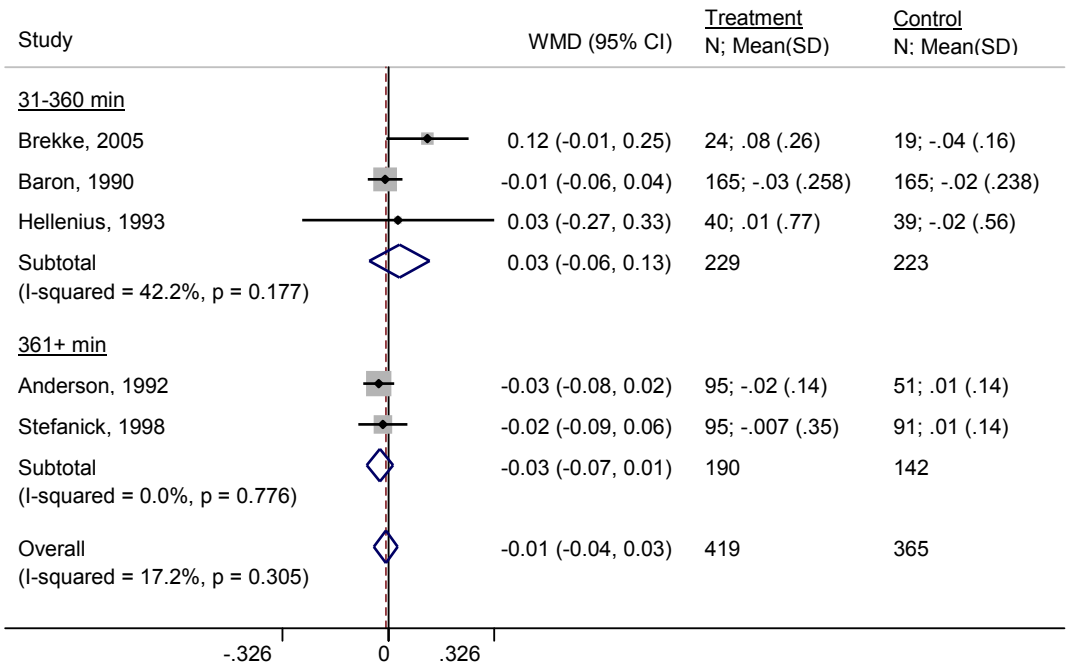
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 14. Meta-Analysis of Healthful Diet Trials, General Counseling (KQ2): Low-Density Lipoproteins



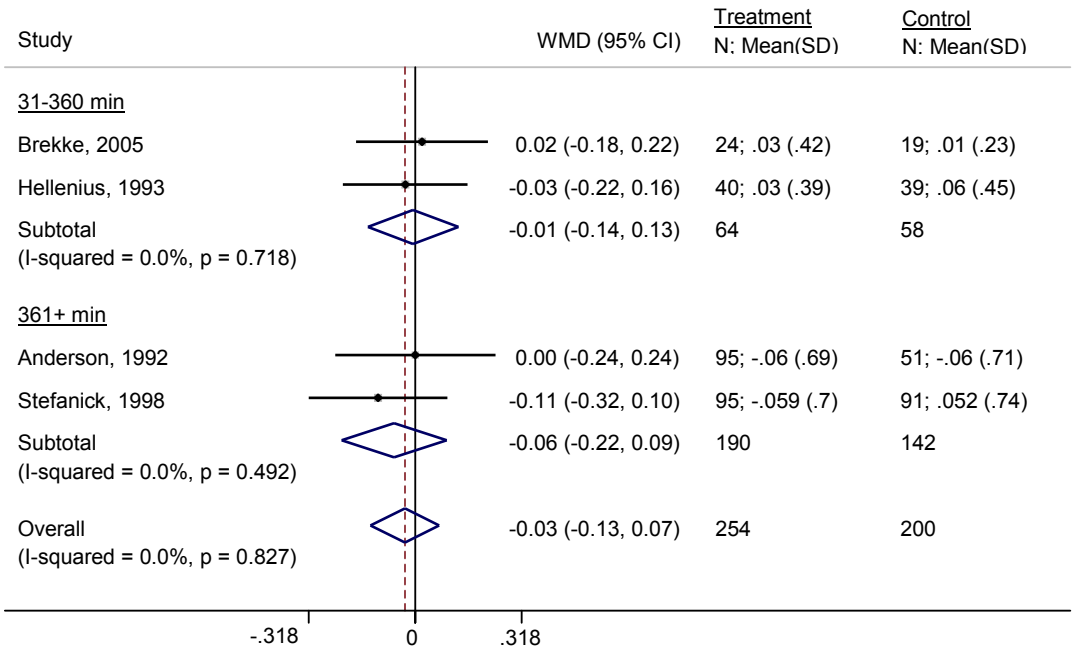
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 15. Meta-Analysis of Healthful Diet Trials, General Counseling (KQ2): High-Density Lipoproteins



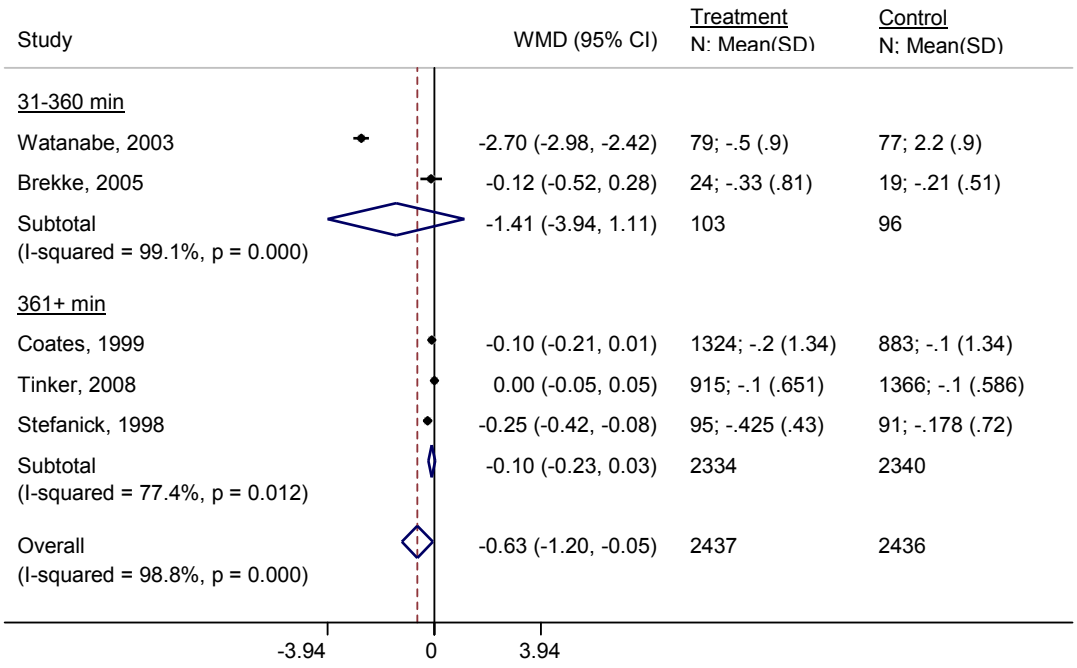
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 16. Meta-Analysis of Healthful Diet Trials, General Counseling (KQ2): Triglycerides



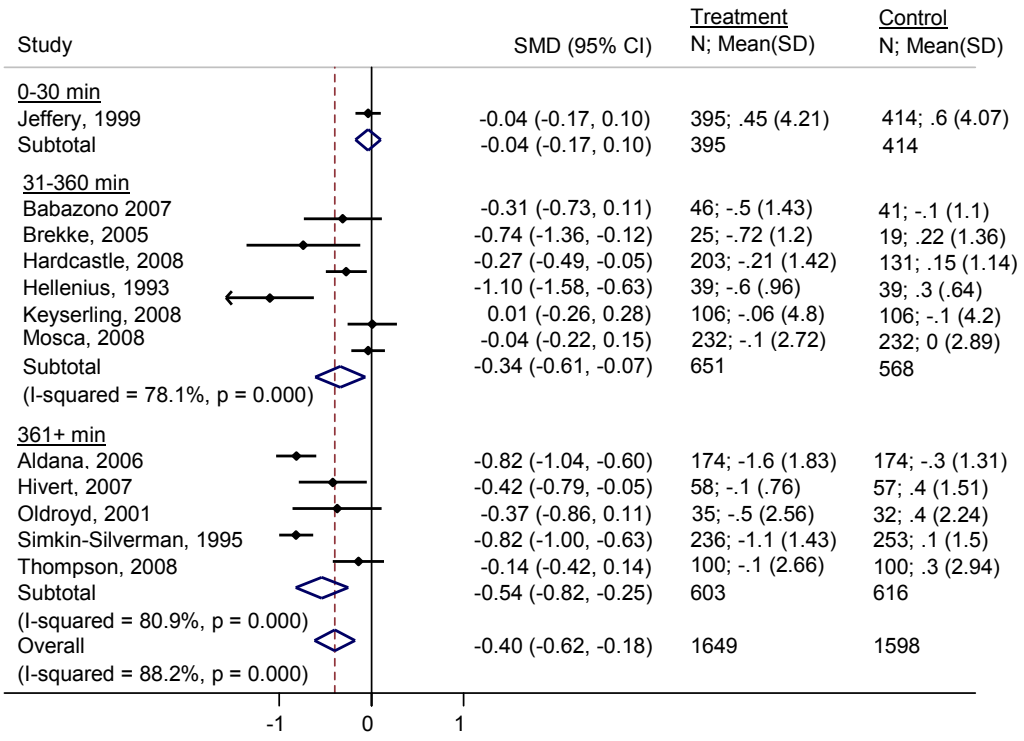
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 17. Meta-Analysis of Healthful Diet Trials, General Counseling (KQ2): Glucose



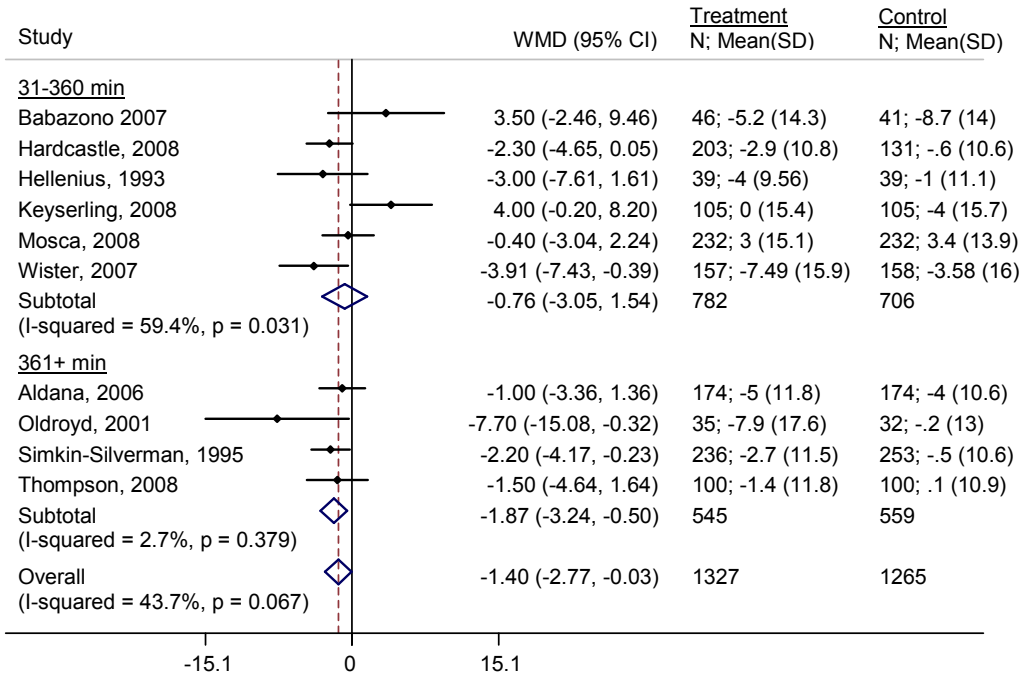
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 18. Meta-Analysis of Combined Lifestyle Trials (KQ2): Adiposity



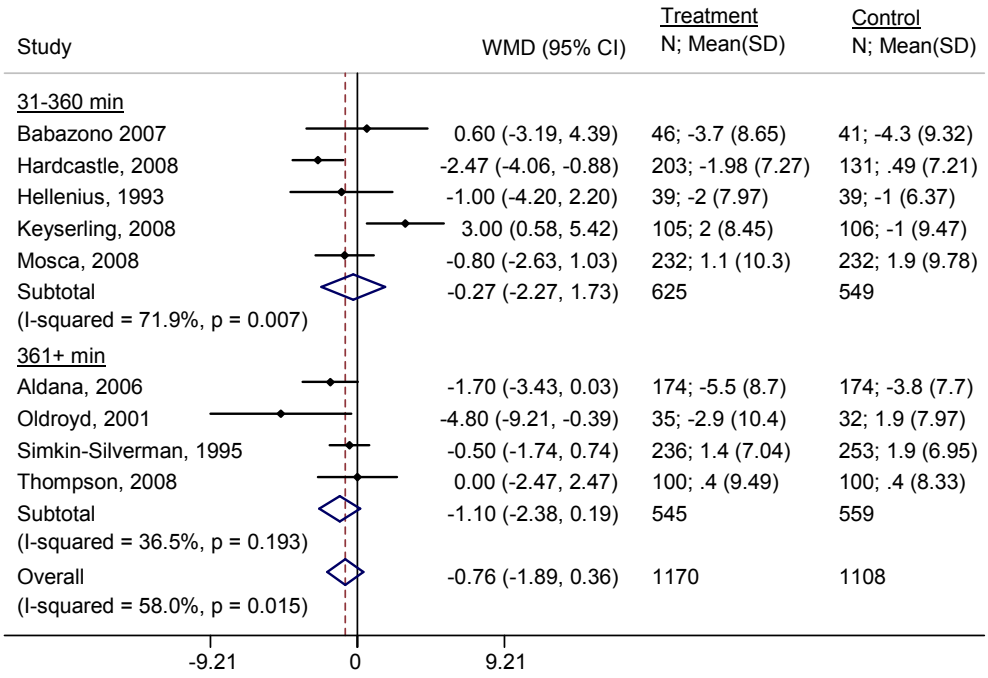
SMD – standardized mean difference; 95% CI – 95% confidence interval

Figure 19. Meta-Analysis of Combined Lifestyle Trials (KQ2): Systolic Blood Pressure



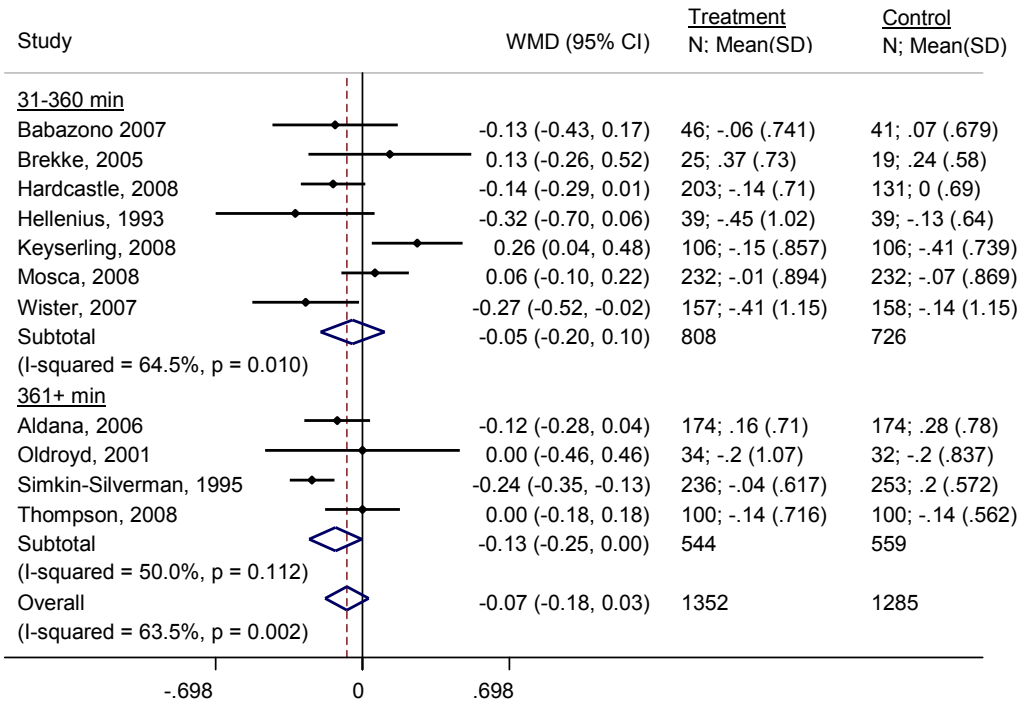
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 20. Meta-Analysis of Combined Lifestyle Trials (KQ2): Diastolic Blood Pressure



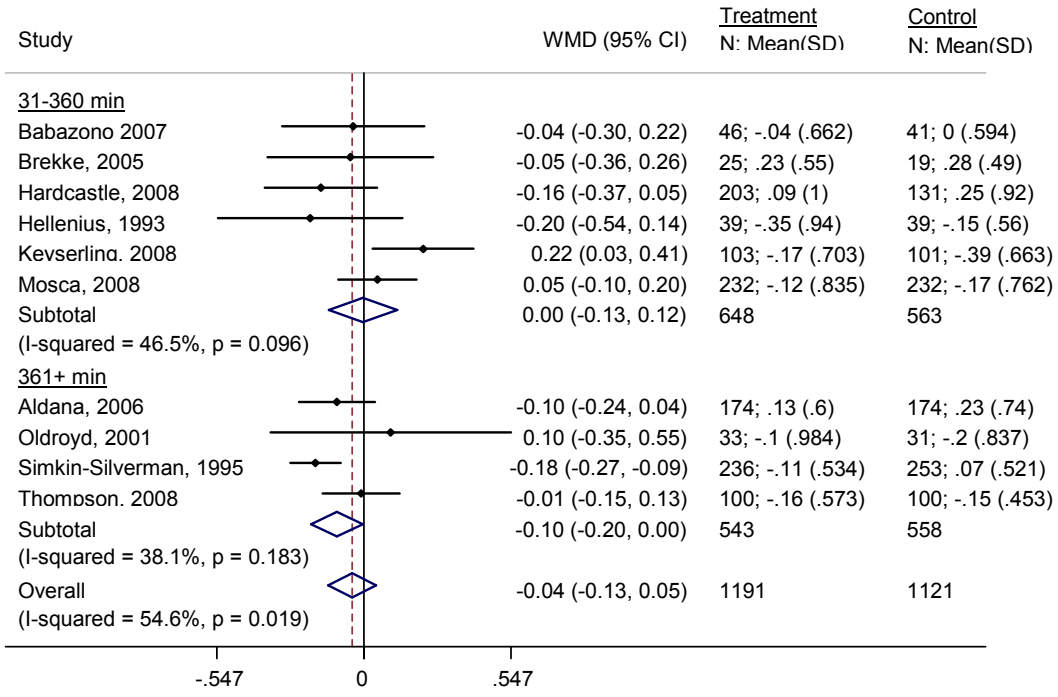
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 21. Meta-Analysis of Combined Lifestyle Trials (KQ2): Total Cholesterol



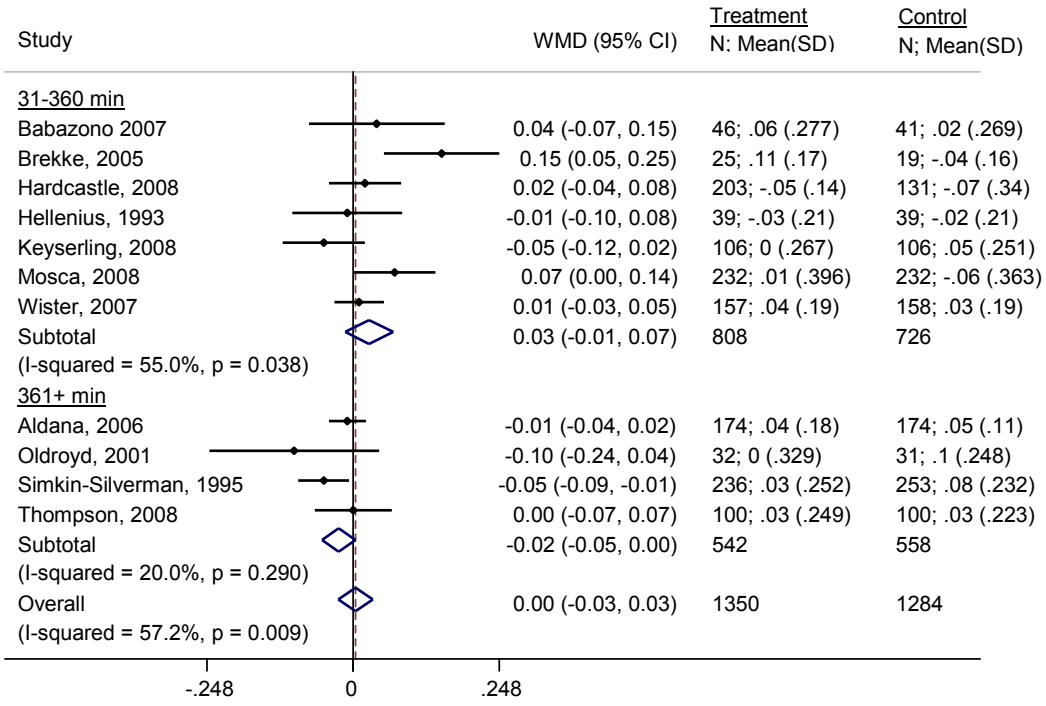
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 22. Meta-Analysis of Combined Lifestyle Trials (KQ2): Low-Density Lipoproteins



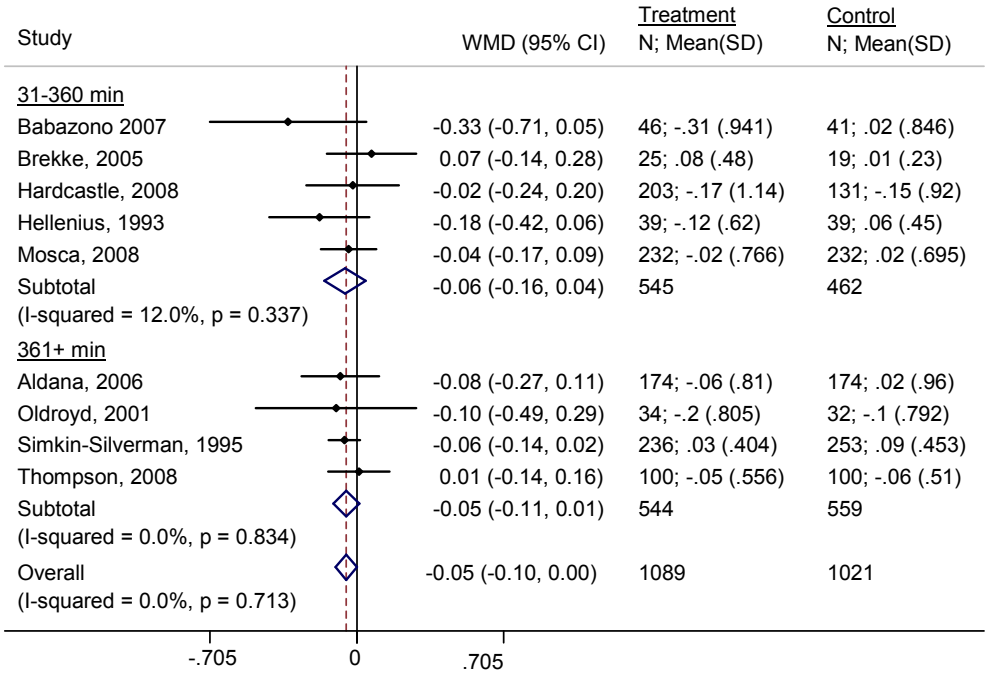
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 23. Meta-Analysis of Combined Lifestyle Trials (KQ2): High-Density Lipoproteins



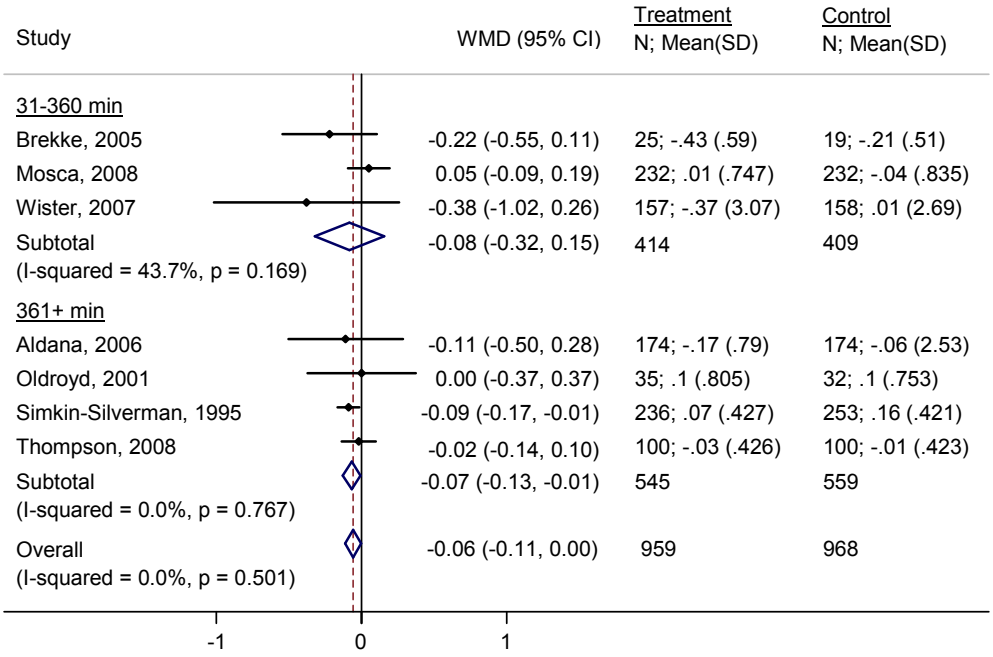
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 24. Meta-Analysis of Combined Lifestyle Trials (KQ2): Triglycerides



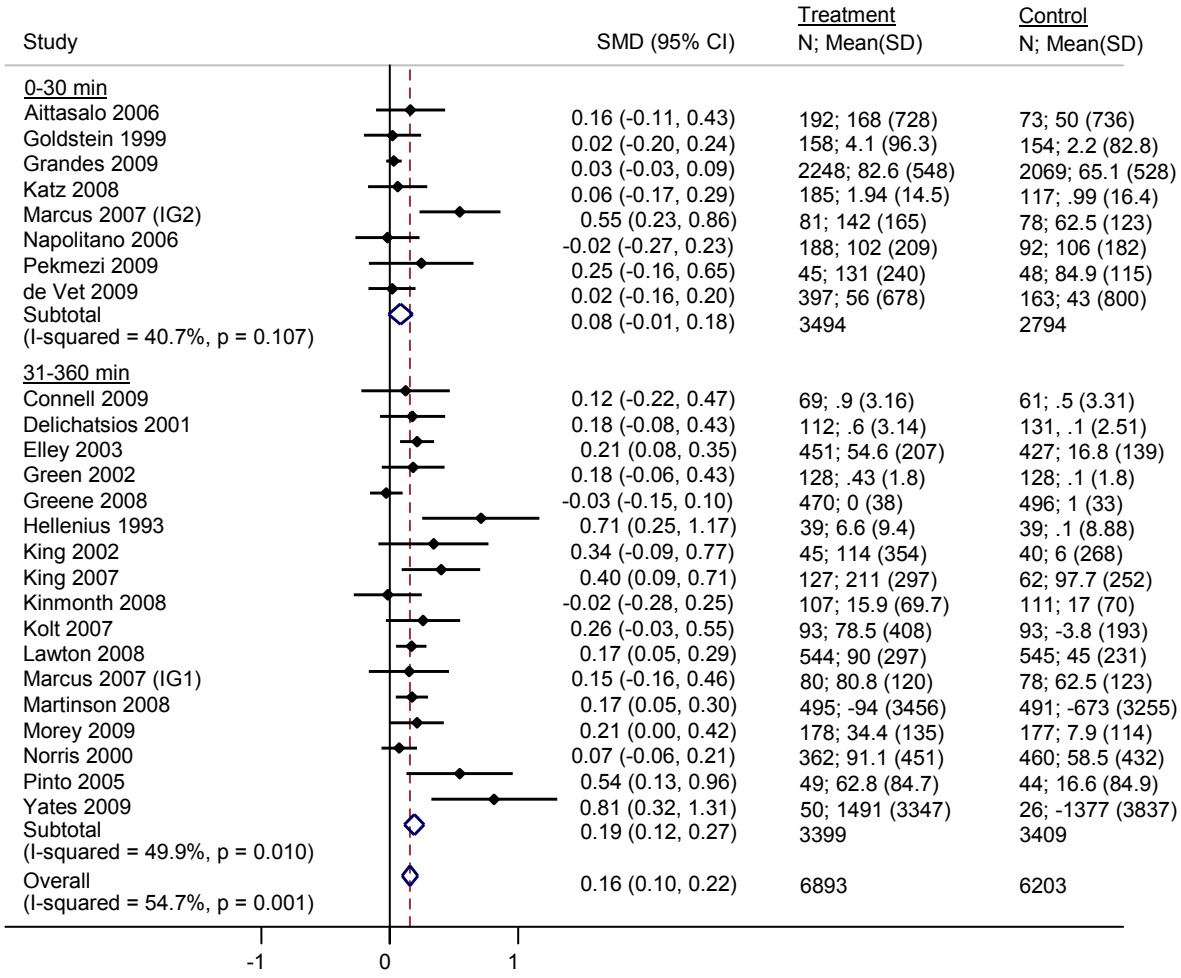
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 25. Meta-Analysis of Combined Lifestyle Trials (KQ2): Glucose



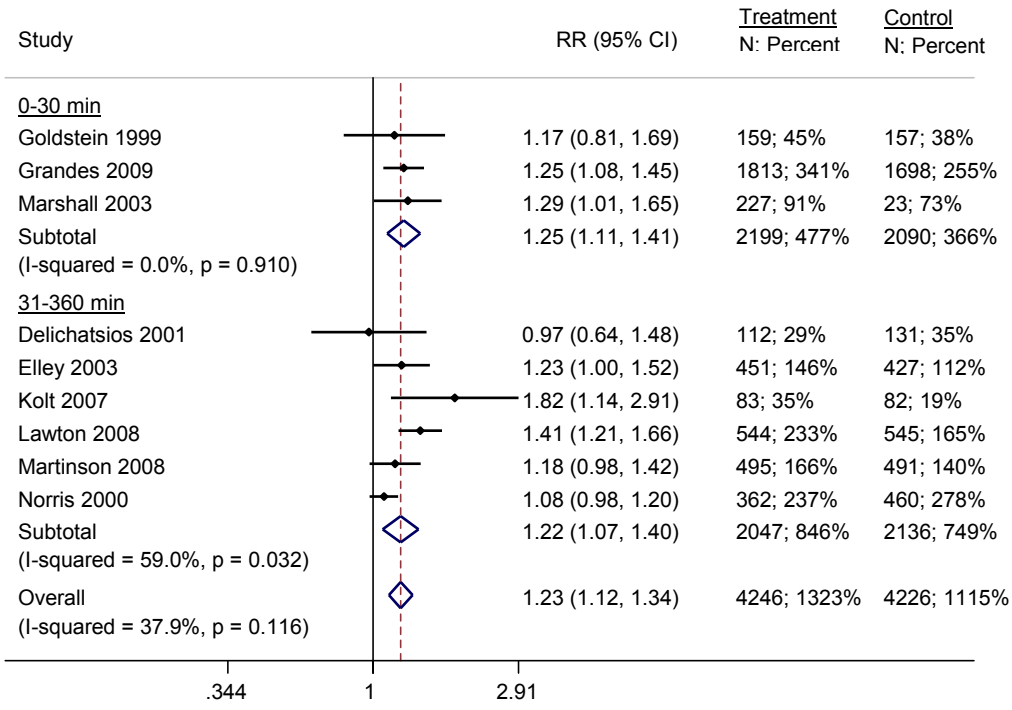
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 26. Meta-Analysis of Physical Activity Trials By Intensity of Counseling (KQ3): Self-Reported Physical Activity



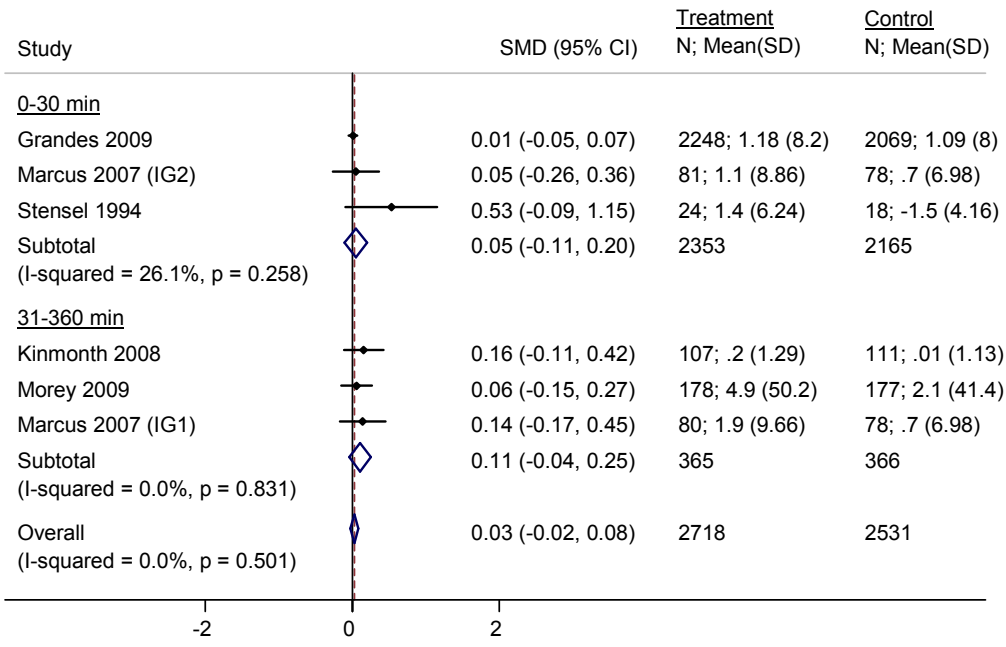
SMD – standardized mean difference; 95% CI – 95% confidence interval

Figure 27. Meta-Analysis of Physical Activity Trials By Intensity of Counseling (KQ3): Percent Meeting Physical Activity Recommendations



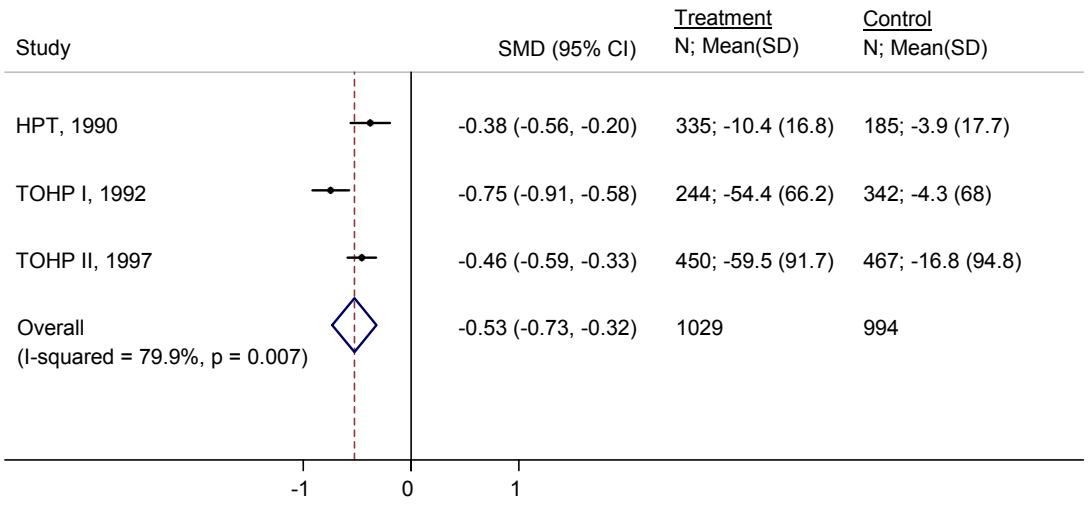
RR – relative risk; 95% CI – 95% confidence interval

Figure 28. Meta-Analysis of Physical Activity Trials By Intensity of Counseling (KQ3): Fitness Measures



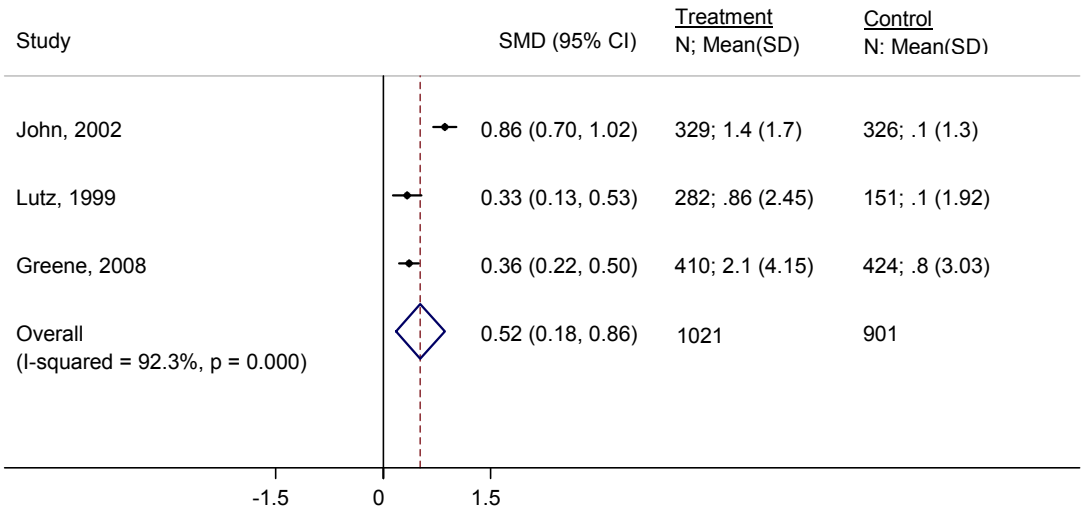
SMD – standardized mean difference; 95% CI – 95% confidence interval

Figure 29. Meta-Analysis of Healthful Diet Trials, Salt Reduction Counseling (KQ3): Urinary Sodium



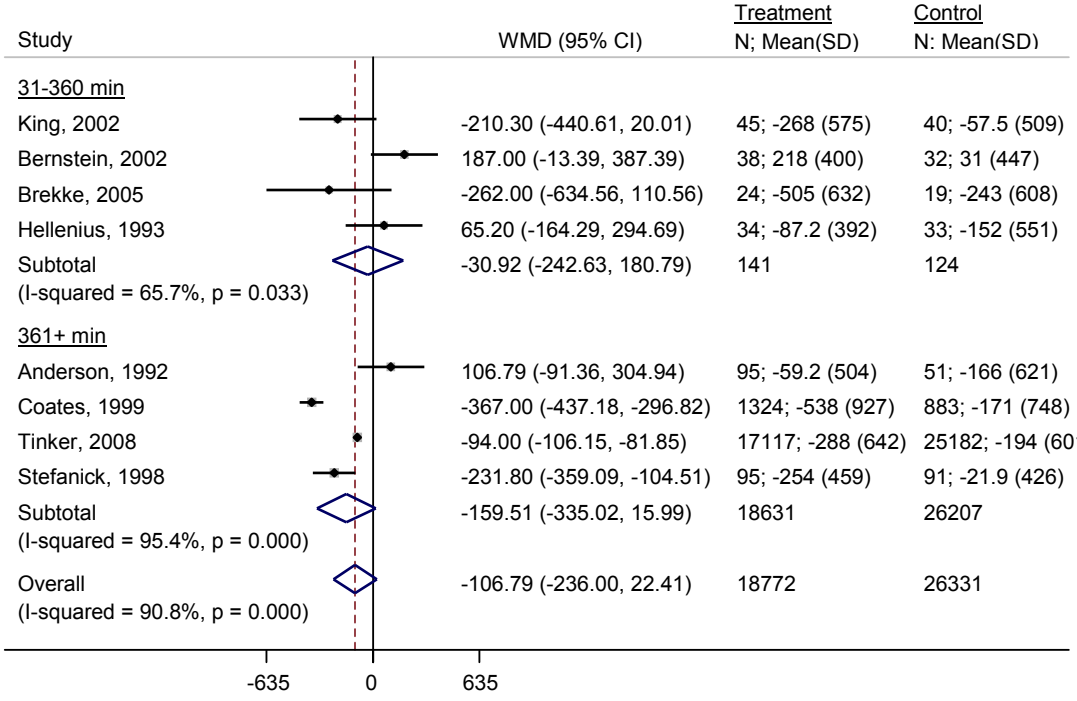
SMD – standardized mean difference; 95% CI – 95% confidence interval

Figure 30. Meta-Analysis of Healthful Diet Trials, Fruits and Vegetables Counseling (KQ3): Fruits and Vegetables



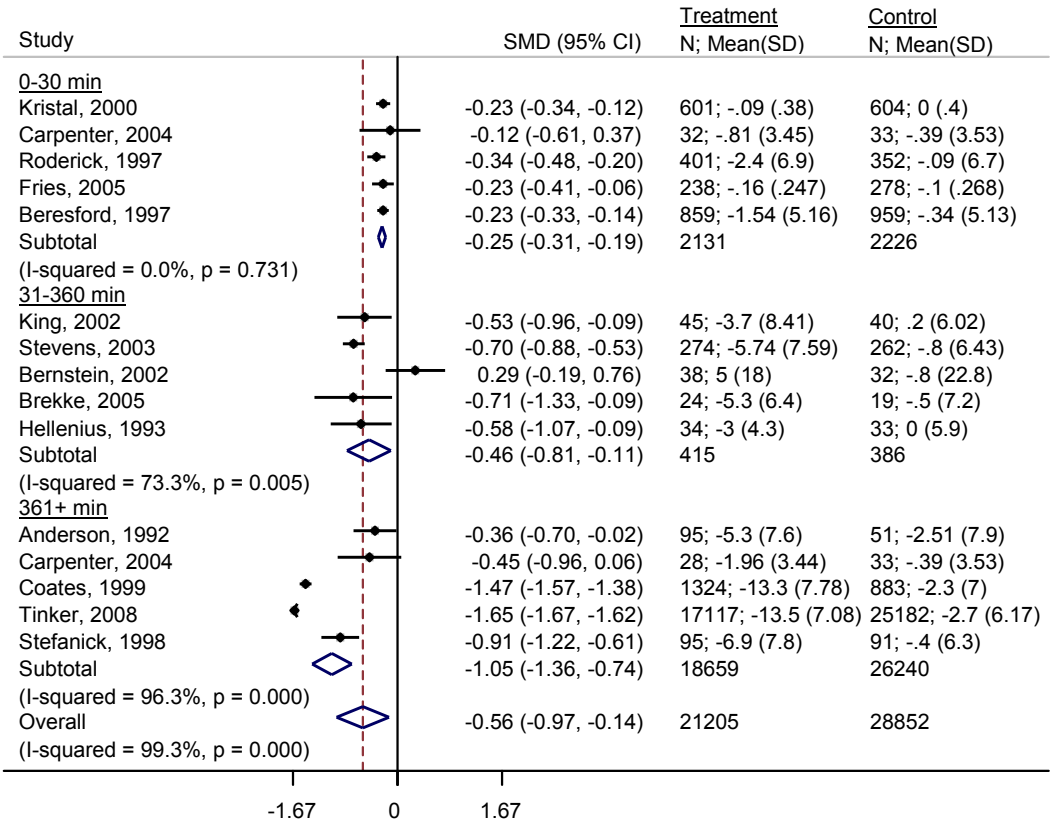
SMD – standardized mean difference; 95% CI – 95% confidence interval

Figure 31. Meta-Analysis of Healthful Diet Trials, General Counseling (KQ3): Energy



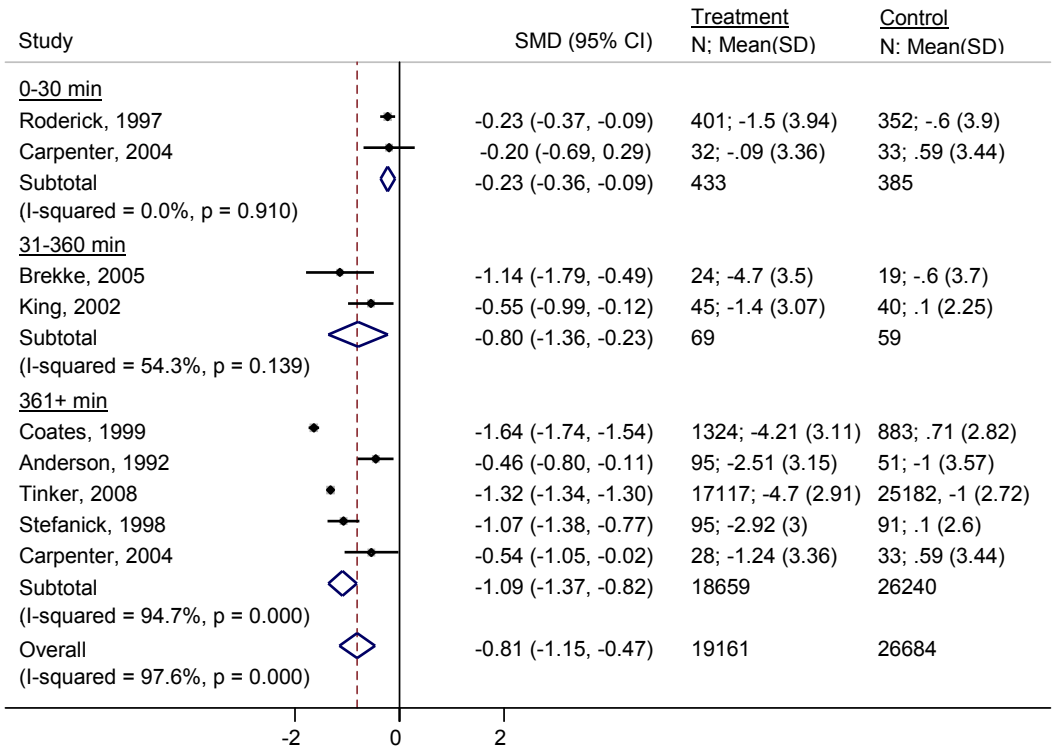
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 32. Meta-Analysis of Healthful Diet Trials, General Counseling (KQ3): Fat



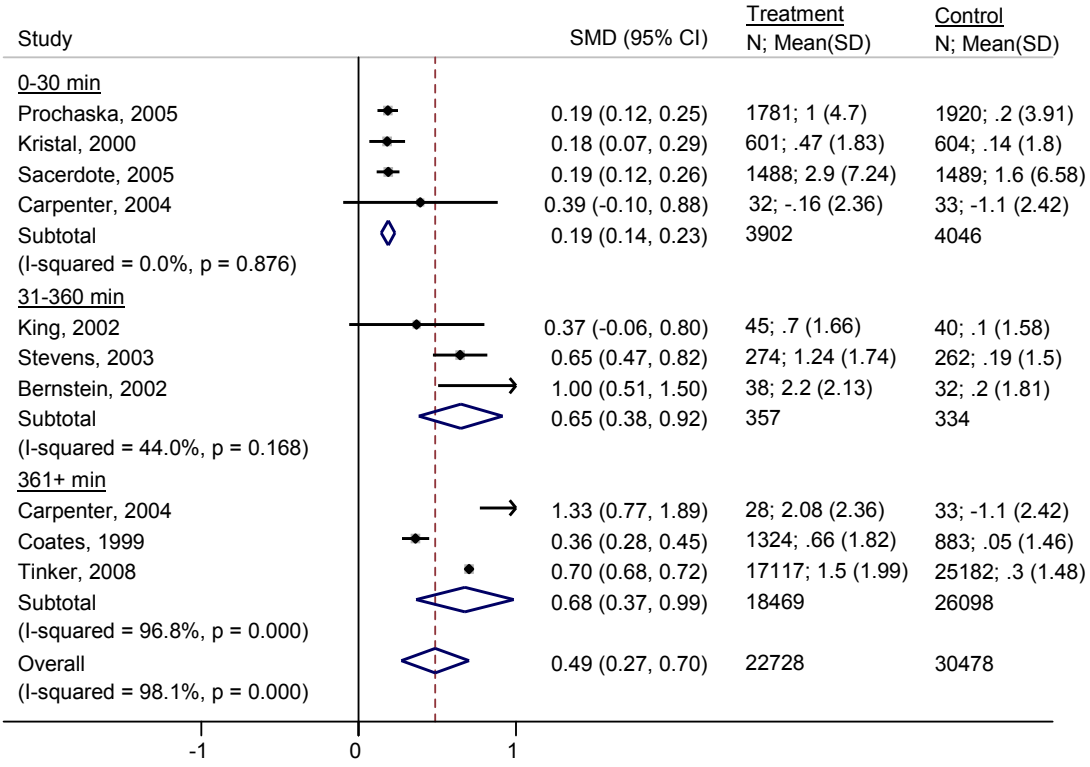
SMD – standardized mean difference; 95% CI – 95% confidence interval

Figure 33. Meta-Analysis of Healthful Diet Trials, General Counseling (KQ3): Saturated Fat



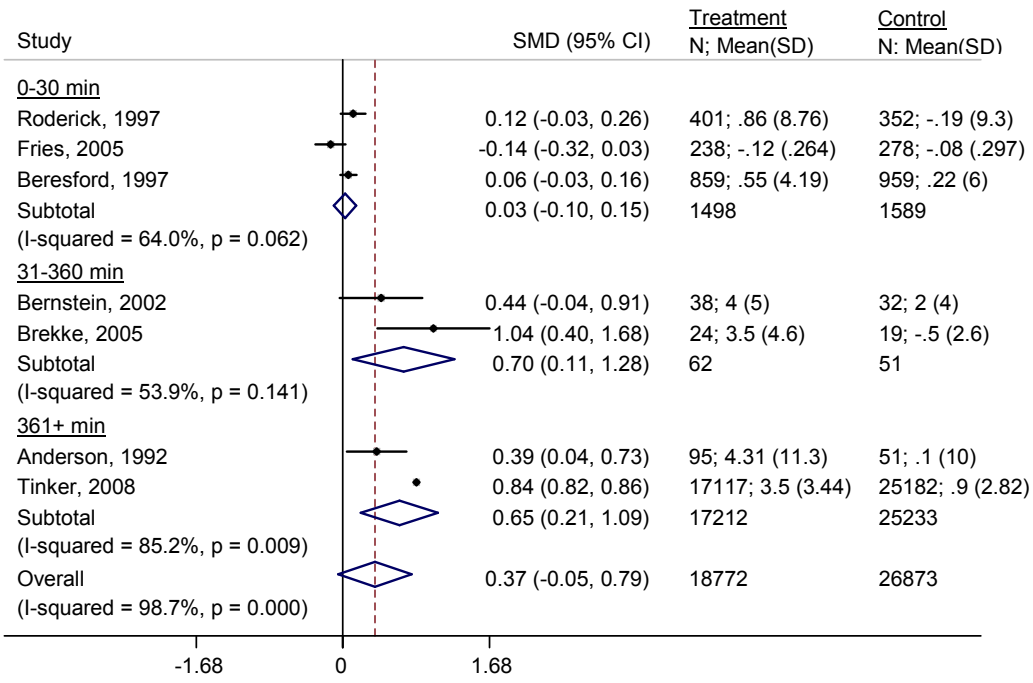
SMD – standardized mean difference; 95% CI – 95% confidence interval

Figure 34. Meta-Analysis of Healthful Diet Trials, General Counseling (KQ3): Fruits and Vegetables



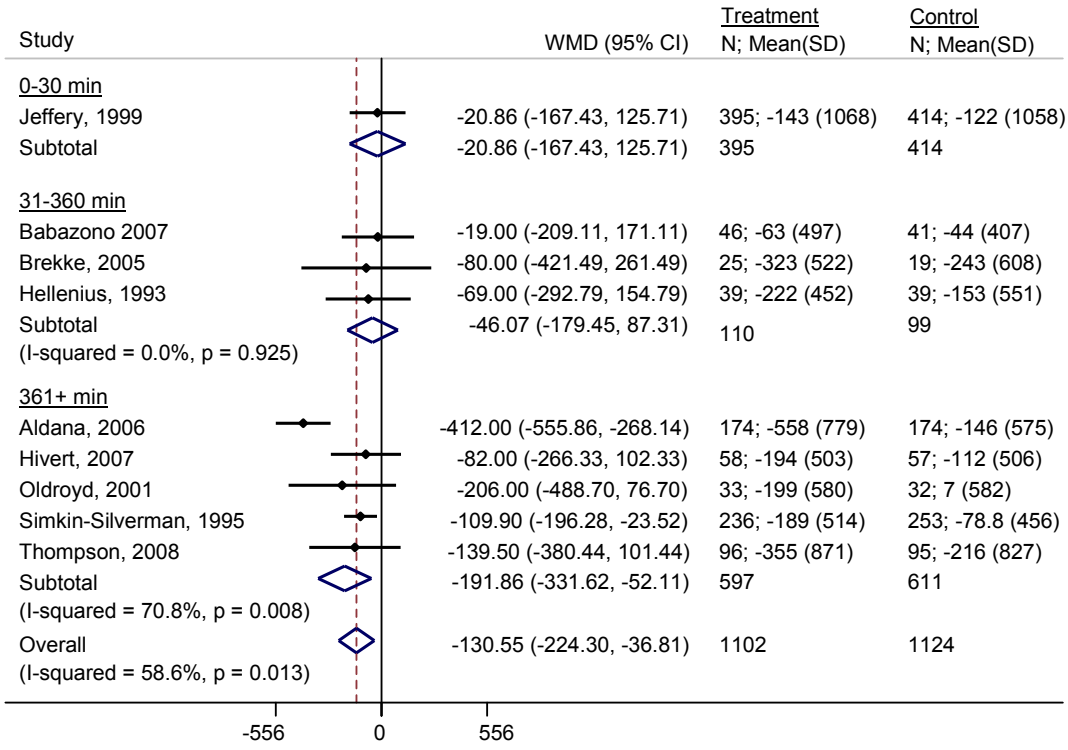
SMD – standardized mean difference; 95% CI – 95% confidence interval

Figure 35. Meta-Analysis of Healthful Diet Trials, General Counseling (KQ3): Fiber



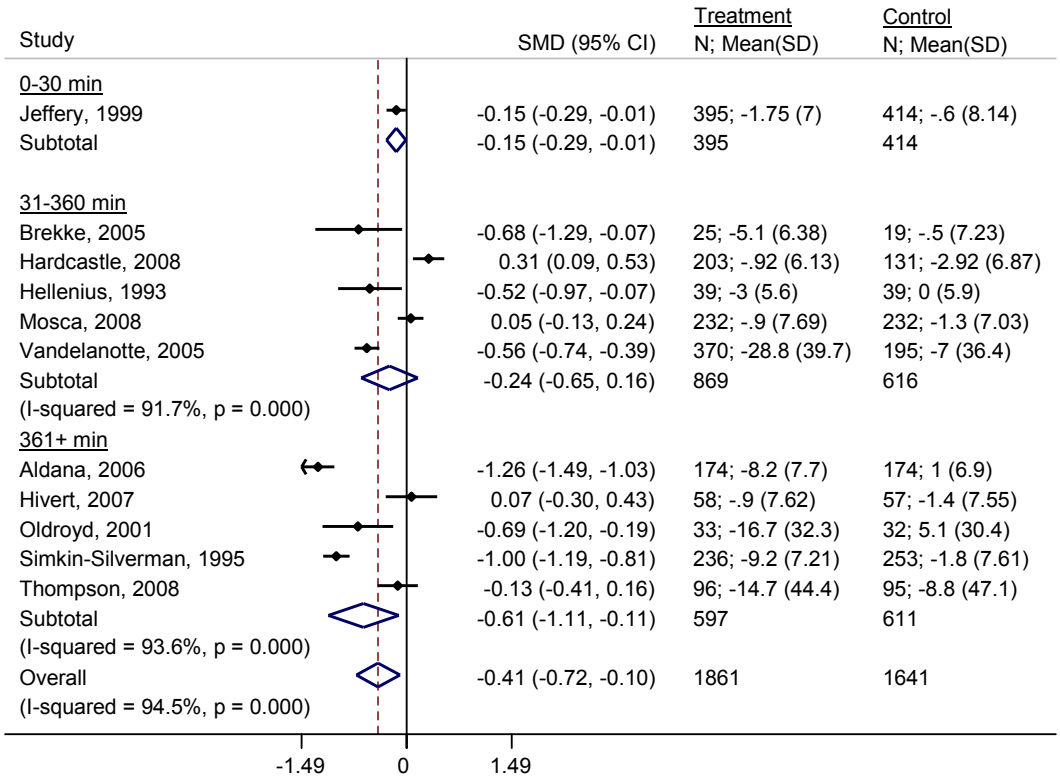
SMD – standardized mean difference; 95% CI – 95% confidence interval

Figure 36. Meta-Analysis of Combined Lifestyle Trials (KQ3): Energy



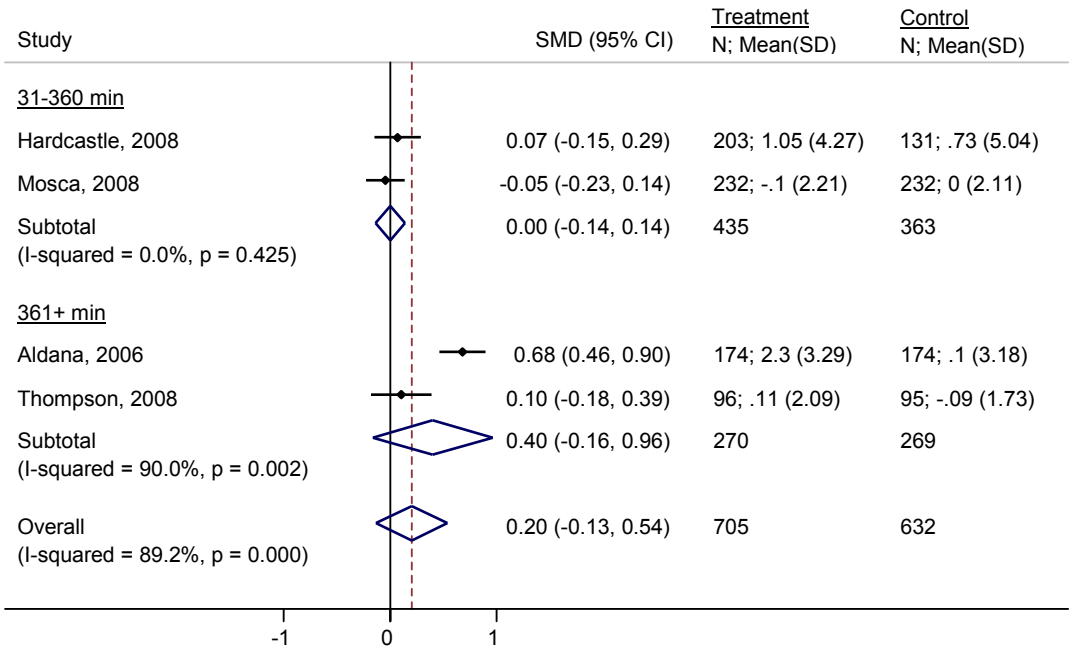
WMD – unstandardized weighted mean difference; 95% CI – 95% confidence interval

Figure 37. Meta-Analysis of Combined Lifestyle Trials (KQ3): Dietary Fat



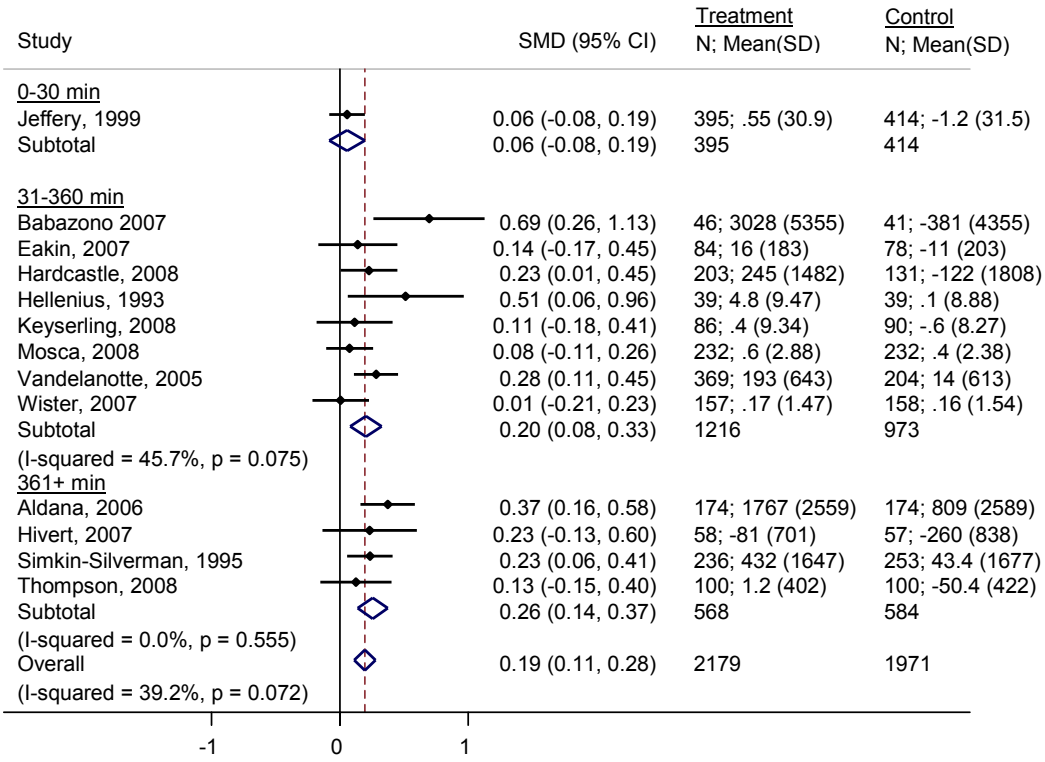
SMD – standardized mean difference; 95% CI – 95% confidence interval

Figure 38. Meta-Analysis of Combined Lifestyle Trials (KQ3): Fruits and Vegetables



SMD – standardized mean difference; 95% CI – 95% confidence interval

Figure 39. Meta-Analysis of Combined Lifestyle Trials (KQ3): Self-Reported Physical Activity



SMD – standardized mean difference; 95% CI – 95% confidence interval

Abbreviations

AARP	American Association of Retired Persons
ACSM	American College of Sports Medicine
AHA	American Health Association
AHSPAQ	Auckland Heart Study Physical Activity Questionnaire
BMI	Body Mass Index
CG	Control Group
CHAMPS	Community Healthy Activities Model Program for Seniors
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
DBP	Diastolic Blood Pressure
FAD	5 A Day for Better Health Program
HDL	High-Density Lipoproteins
IG	Intervention Group
IPAQ	International Physical Activity Questionnaire
LDL	Low-Density Lipoproteins
MET	Metabolic Equivalent
MI	Motivational Interview
NCIF	National Cancer Institute Fruit and Vegetable Screener, All Day
NCIP	National Cancer Institute Fruit and Vegetable Screener, By Meal
NIA	National Institute on Aging
NR	Not Reported
NS	Not Significant
PAR	(Stanford 7-Day) Physical Activity Recall
PACE	Physician-Based Assessment and Counseling for Exercise
PASE	Physical Activity Scale for the Elderly
RCT	Randomized Controlled Trial
SD	Standard Deviation
SE	Standard Error
SBP	Systolic Blood Pressure
YPAS	Yale Physical Activity Survey

Search Strategies

Systematic Reviews

Databases: CDSR, DARE, PubMed, IOM, NICE, AHRQ, Clinical Evidence
Search Dates: 2001 to July 2008

Healthy diet counseling
1. diet[ti] OR dietary[ti]
2. "Food Habits"[Mesh] OR "Diet, Reducing"[Mesh] OR "Diet"[Mesh:NoExp] OR "Diet, Fat-Restricted"[Mesh]
3. "Fruit"[Mesh:NoExp] OR "Vegetables"[Mesh:NoExp]
4. "Dietary Fats"[Mesh:NoExp]
5. #1 OR #2 OR #3 OR #4
6. "Health Behavior"[Mesh:NoExp] OR "Health Promotion"[Mesh:NoExp] OR "Health Education"[Mesh:NoExp]
7. counsel*[tiab]
8. "Patient Education as Topic"[Mesh] OR "Counseling"[Mesh:NoExp] OR "Directive Counseling"[Mesh]
9. "Behavior Therapy"[Mesh:NoExp]
10. interventions[tiab] AND behavi*[tiab]
11. #6 OR #7 OR #8 OR #9 OR #10
12. #5 AND #11
13. "dietary education"[tiab]
14. "diet education"[tiab]
15. nutrition education"[tiab]
16. #12 OR #13 OR #14 OR #15
17. #16 AND systematic[sb]
18. diet[tiab] OR dietary[tiab]
19. counsel*[tiab] OR (behavi*[tiab] AND change*[tiab]) OR motivational*[tiab] OR (behavi*[tiab] AND interventions[tiab])
20. #18 AND #19
21. "diet interventions"[tiab]
22. "dietary interventions"[tiab]
23. "nutrition interventions"[tiab]
24. "obesity prevention interventions"[tiab]
25. #20 OR #21 OR #22 OR #23 OR #24
26. #25 AND systematic[sb]
27. #26 AND (in process [sb] OR publisher [sb] OR pubmednotmedline [sb])
28. #17 OR #27
29. #28 AND (Limits: Publication Date from 2001 to 2008, English)

Physical activity counseling
1. "physical activity"[ti]
2. "Exercise"[Mesh:NoExp] OR "Motor Activity"[Mesh:NoExp] OR "Physical Fitness"[Mesh]
3. #1 OR #2
4. ("Health Behavior"[Mesh:NoExp] OR "Health Promotion"[Mesh:NoExp]) OR "Health Education"[Mesh:NoExp]
5. ("Patient Education as Topic"[Mesh] OR "Counseling"[Mesh:NoExp]) OR "Directive Counseling"[Mesh]
6. counsel*[tiab]
7. "Behavior Therapy"[Mesh:NoExp]
8. interventions[tiab] AND behavi*[tiab]
9. #4 OR #5 OR #6 OR #7 OR #8
10. #3 AND #9
11. #10 AND systematic[sb]
12. "physical activity"[tiab] OR exercise[tiab]

13. counsel*[tiab] OR (behavi*[tiab] AND change*[tiab]) OR motivational*[tiab] OR (behavi*[tiab] AND interventions[tiab])
14. #12 AND #13
15. "physical activity interventions"[tiab]
16. "obesity prevention interventions"[tiab]
17. #14 OR #15 OR #16
18. #17 AND systematic[sb]
19. #18 AND (in process [sb] OR publisher [sb] OR pubmednotmedline [sb])
20. #11 OR #19
21. #20 AND (Limits: Publication Date from 2001 to 2008, English)

Full Literature Search

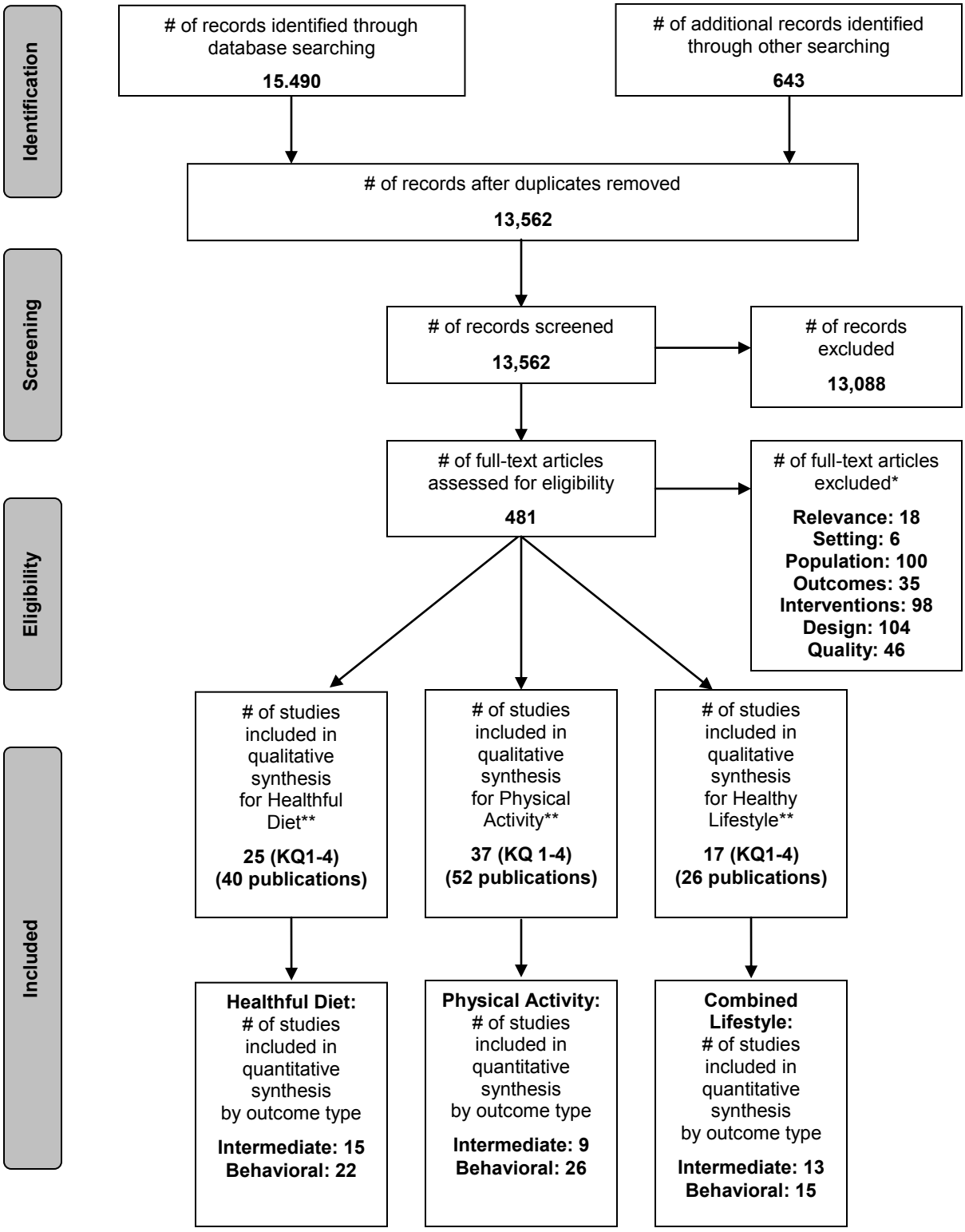
Databases: MEDLINE, CCRCT, PsycINFO
Search Dates: 2001 through January 2010

1. Diet, Reducing
2. Diet, Fat-Restricted
3. Diet, Mediterranean
4. Diet, Sodium-Restricted
5. Diet, Carbohydrate-Restricted
6. Caloric Restriction
7. Fruit
8. Vegetables
9. Diet Therapy
10. Food Habits
11. Exercise
12. Exercise Therapy
13. Motor Activity
14. Physical Fitness
15. Walking
16. physical activit$.ti.
17. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18. Counseling
19. Directive Counseling
20. "Behavior-Therapy"
21. Cognitive Therapy
22. counsel?ing.ti,ab.
23. advice.ti,ab.
24. behavio?r$ change$.ti,ab.
25. behavio?r$ modification$.ti,ab.
26. "Referral and Consultation"
27. Persuasive Communication
28. Social Control, Informal
29. Risk Reduction Behavior
30. Life Style
31. Motivation
32. Social Support
33. Feedback, Psychological
34. Self Efficacy
35. Health Knowledge, Attitudes, Practice
36. Health Behavior
37. Health Education
38. Health Promotion
39. Patient Education as Topic

40. insulin.ti,ab,hw.
41. lipid$.ti,ab,hw.
42. cardiovascular.ti,ab,hw.
43. glucose.ti,ab,hw.
44. body mass index.ti,ab,hw.
45. bmi.ti,ab,hw.
46. coronary.ti,ab,hw.
47. Hemoglobin A, Glycosylated
48. hemoglobin a1c.ti,ab.
49. lipoprotein$.ti,ab,hw.
50. triglyceride$.ti,ab,hw.
51. hypertension.ti,ab,hw.
52. body weight.ti,ab,hw.
53. hyperlipidemia$.ti,ab,hw.
54. blood pressure.ti,ab,hw.
55. cholesterol$.ti,ab,hw.
56. diabet$.ti,ab,hw.
57. 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56
58. 17 and 57 (42846)
59. limit 58 to (clinical trial or controlled clinical trial or meta analysis or randomized controlled trial)
60. clinical trials as topic/ or controlled clinical trials as topic/ or randomized controlled trials as topic/
61. Meta-Analysis as Topic
62. (control$ adj3 trial$).ti,ab.
63. random$.ti,ab.
64. clinical trial$.ti,ab.
65. 60 or 61 or 62 or 63 or 64
66. 58 and 65
67. 59 or 66
68. limit 67 to "all child (0 to 18 years)"
69. limit 67 to "all adult (19 plus years)"
70. 68 not 69
71. 67 not 70
72. limit 71 to animals
73. limit 71 to humans
74. 72 not 73
75. 71 not 74
76. limit 75 to english language
77. limit 76 to yr="2001 - 2009"
78. (harm or harms or harmful or harmed).ti,ab.
79. (risky behavior$ or risky behaviour$).ti,ab.
80. (adverse effects or mortality).fs.
81. Mortality
82. Morbidity
83. death
84. Athletic injuries
85. Malnutrition
86. nutritional defici$.ti,ab.
87. (death or deaths).ti,ab.
88. fracture$.ti,ab,hw.
89. cardiovascular.ti,ab,hw.
90. 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89
91. 58 and 90
92. case-control studies/ or cohort studies/ or longitudinal studies/ or follow-up studies/ or prospective studies/

93. case control$.ti,ab.
94. cohort.ti,ab.
95. longitudinal.ti,ab.
96. (follow-up or followup).ti,ab.
97. prospective$.ti,ab.
98. (comparison group$ or control group$).ti,ab.
99. observational.ti,ab.
100. retrospective studies
101. retrospective$.ti,ab.
102. database$.ti,ab.
103. nonrandomi$.ti,ab.
104. population$.ti,ab.
105. 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104
106. 91 and 105
107. limit 106 to "all child (0 to 18 years)"
108. limit 106 to "all adult (19 plus years)"
109. 107 not 108
110. 106 not 109
111. limit 110 to animals
112. limit 110 to humans
113. 111 not 112
114. 110 not 113
115. limit 114 to english language
116. limit 115 to yr="2001 - 2010"
117. 77 or 116

Appendix B Figure 1. PRISMA Flow Diagram



* 28 articles were excluded for different reasons in different areas; 7 were excluded for one area and included for another.
** 8 studies were included in more than one area.

Appendix B Table 1. Review Inclusion and Exclusion Criteria

Condition Definition	Include	Healthy diet (HD) is one designed to improve or maintain optimal health, which includes: • Appropriate calorie content • Balance of fats (consumption of mono- and polyunsaturated fats, omega-3 fats, avoidance of excess saturated fat, avoidance of trans fat) • Fruits and vegetables • Legumes • Lean proteins • Non- or low-fat dairy • Balance of carbohydrates (consumption of whole grain and fiber, avoidance of excess refined carbohydrates, including excess sweetened beverages) • Balance of sodium (avoidance of excess sodium) Physical activity (PA) may involve either: • Aerobic activities that involve repeated use of large muscles, such as walking, cycling, and swimming, OR • Resistance training designed to improve physical strength
	Exclude	Aspects of a healthy diet that are out of scope include: • Dietary calcium and other vitamin, micronutrient, and antioxidant supplementation; alcohol moderation Aspects of physical activity that are out of scope include: • Balance, flexibility, gait, and sedentary behaviors
Populations	Include	• Adults • Unselected or low-risk patients similar to those seen in primary care (which may include some [<50% altogether] with cardiovascular disease [CVD], diabetes, hypertension, and/or hyperlipidemia) OR asymptomatic persons with increased CVD risk due to obesity; family history of CVD or a risk factor; or slightly elevated cholesterol, blood pressure, or glucose tolerance levels, but without a diagnosis of CVD, diabetes, hyperlipidemia, or hypertension
	Exclude	Studies *limited to*: • Children and adolescents • Parents (if intended behavior change is directed toward children) • Persons with any acute disease • Persons with symptomatic disease • Persons with known coronary heart disease, diabetes (coronary heart disease equivalent), hypertension, or hyperipidemia • Pregnant women • Institutionalized persons • Persons with severe and persistent mental illness • Persons with cognitive impairment HD only: persons requiring a specialized diet (e.g., kidney disease) PA only: persons with specific physical activity requirements or limitations for health reasons (e.g., cardiac or physiotherapeutic rehabilitation patients, physically disabled patients)
Settings	Include	Primary care (including obstetrics/gynecology, internal medicine, family practice, military health clinics) or otherwise generalizable to primary care; trials conducted in developed countries (Human Development Index >0.9) as defined by the United Nations (see below)
	Exclude	Settings not generalizable to primary care (e.g., inpatient hospital units, emergency departments, nursing home and other institutionalized settings, school-based programs, occupational settings, and other community-based settings); dental clinics
Interventions	Include	Behaviorally-based counseling intervention on healthy diet and nutrition, physical activity, or both, including one or more of the following elements: assessment with feedback, advice, collaborative goal-setting, assistance, or arranging further contacts. Behaviorally-based counseling intervention targeting primary prevention of obesity, hypertension, hyperlipidemia, diabetes, or CVD. Either conducted in a primary care setting or judged to be feasible in primary care: 1. Involve individual-level identification of being a patient or in need of intervention 2. Usually involve primary care physicians, other physicians, nurses, nurse practitioners, physician assistants, or related clinical staff (e.g., health educators, other counselors), or the intervention will be seen as connected to the health care system by the participant

Appendix B Table 1. Review Inclusion and Exclusion Criteria

		3. Individual or small group format (15 persons or less, generally no more than 8 group sessions over 12 months) 4. Located anywhere, as long as linked to primary care OR may be conducted entirely online or through the mail without an explicit link to health care system. OR must be primary care referable such that intervention needs to be conducted as part of a health care setting, or be available for referral in most communities. PA only: interventions evaluating referral by primary care provider (or health care system) to community exercise facilities or programs. (this addresses the question of whether patients would follow through on primary care referral)
	Exclude	• Non-counseling interventions (e.g., use of incentives, supervised exercise with the goal of assessing effects of exercise) • Interventions providing controlled diets • Counseling interventions aimed at weight loss, falls prevention, depression, cognitive functioning, or disease prevention other than diabetes, hypertension, hyperlipidemia, or CVD • Prenatal or postnatal dietary counseling • Ccounseling interventions that are primarily community, nonreferral (e.g., occupational/worksite or school-based); or ocial marketing (e.g., media campaigns) • Policy (e.g., local or state public/health policy) • Interventions focused exclusively on reducing sedentary behavior
Comparisons	Include	Control arm with no intervention (e.g., waitlist control, usual care), minimal intervention (e.g., usual care limited to no more than 15 minutes of information), or attention control (e.g., similar format and intensity intervention on a different content area)
	Exclude	Comparative effectiveness trials without a true control; PA only: studies in which the control group is instructed *not* to exercise
Outcomes	Include	KQ1: Distal health outcomes (i.e., morbidity related to CVD, diabetes, hypertension, hyperlipidemia, and mortality) KQ2: Intermediate health outcomes (i.e., blood pressure, hypertension, total cholesterol, LDL cholesterol or ratio of total/HDL cholesterol, serum fasting glucose or glucose tolerance, hemoglobin A1C, incidence of diabetes, weight, body mass index [BMI], overweight [BMI 25-29], obesity [BMI≥30]) KQ3: Behavioral outcomes, self-reported or objective measures of overall endurance-related fitness, such as VO2max, walk time, or treadmill test KQ4: Adverse outcomes include any harms requiring medical attention (e.g., nutritional deficiencies, musculoskeletal injuries, cardiovascular events)
	Exclude	Knowledge, attitudes, self-efficacy, functioning, quality of life PA only: studies limited to balance or flexibility outcomes, sedentary behavior Less than 6 months or 60% followup **Excluded self-reported weight**
Study Designs	Include	KQ1, 2, 3: systematic reviews, randomized controlled trials, controlled clinical trials KQ4: systematic reviews, randomized controlled trials, controlled clinical trials; for cardiovascular-related harms also include cohort, case-control, and case-crossover studies
	Exclude	KQ1, 2, 3: any observational studies KQ4: ecological studies, case-series, case reports

Appendix B Table 2. Quality Rating Criteria

Design	U.S. Preventive Services Task Force quality rating criteria[27]	National Institute for Health and Clinical Excellence methodology checklists[28]
Systematic reviews and meta-analyses	• Comprehensiveness of sources considered/search strategy used • Standard appraisal of included studies • Validity of conclusions • Recency and relevance; especially important for systematic reviews	• Study addresses an appropriate and clearly focused question • Description of the methodology used is included • Literature search is sufficiently rigorous to identify all the relevant studies • Study quality is assessed and taken into account • There are enough similarities between the studies selected to make combining them reasonable
Case-control studies	• Accurate ascertainment of cases • Nonbiased selection of cases/controls with exclusion criteria applied equally to both • Response rate • Diagnostic testing procedures applied equally to each group • Measurement of exposure accurate and applied equally to each group • Appropriate attention to potential confounding variables	• Study addresses an appropriate and clearly focused question • Cases and controls are taken from comparable populations • Same exclusion criteria are used for both cases and controls • Percentage of each group (cases and controls) that participated in the study is reported • Comparison is made between participants and nonparticipants to establish their similarities or differences • Cases are clearly defined and differentiated from controls • It is clearly established that controls are non-cases • Measures have been taken to prevent knowledge of primary exposure influencing case ascertainment • Exposure status is measured in a standard, valid, and reliable way • Main potential confounders are identified and taken into account in the design and analysis • Confidence intervals are provided
Randomized controlled trials	• Initial assembly of comparable groups employs adequate randomization, including first concealment and whether potential confounders were distributed equally among groups • Maintenance of comparable groups (includes attrition, crossovers, adherence, contamination) • Important differential loss to followup or overall high loss to followup • Measurements are equal, reliable, and valid (includes masking of outcome assessment) • Clear definition of the interventions • All important outcomes are considered	• Study addresses an appropriate and clearly focused question • Assignment of subjects to treatment groups is randomized • Adequate concealment methods are used • Subjects and investigators are kept blind about treatment allocation • Treatment and control groups are similar at the start of the trial • Only difference between groups is the treatment under investigation • All relevant outcomes are measured in a standard, valid, and reliable way • Percentage of the individuals or clusters recruited into each treatment arm of the study that dropped out before the study was completed are reported • All subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention-to-treat analysis) • When the study is carried out at more than one site, results are comparable for all sites

Appendix B Table 2. Quality Rating Criteria

Design	U.S. Preventive Services Task Force quality rating criteria[27]	National Institute for Health and Clinical Excellence methodology checklists[28]
Cohort studies	• Initial assembly of comparable groups employs consideration of potential confounders with either restriction or measurement for adjustment in the analysis; consideration of inception cohorts • Maintenance of comparable groups (includes attrition, crossovers, adherence, contamination) • Important differential loss to followup or overall high loss to followup • Measurements are equal, reliable, and valid (includes masking of outcome assessment) • Clear definition of the interventions • All important outcomes are considered	• Study addresses an appropriate and clearly focused question • Groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation • Study indicates how many of the people asked to take part did so, in each of the groups being studied • Likelihood that some eligible subjects might have the outcome at the time of enrollment is assessed and taken into account in the analysis • Percentage of individuals or clusters recruited into each arm of the study that dropped out before the study was completed are reported • Comparison is made between full participants and those lost to followup, by exposure status • Outcomes are clearly defined • Assessment of outcome is made blind to exposure status • When blinding is not possible, some recognition is made that knowledge of exposure status could have influenced the assessment of outcome • Measure of assessment of exposure is reliable • Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable • Exposure level or prognostic factor is assessed more than once • Main potential confounders are identified and taken into account in the design and analysis • Confidence intervals are provided
Diagnostic accuracy studies	• Screening test relevant, available for primary care, adequately described • Study uses a credible reference standard, performed regardless of test results • Reference standard interpreted independently of screening test • Handles indeterminate results in a reasonable manner • Spectrum of patients included in study • Sample size • Administration of reliable screening test	• Nature of the test being studied is clearly specified • Test is compared with an appropriate gold standard • Where no gold standard exists, a validated reference standard is used as a comparator • Patients for testing are selected either as a consecutive series or randomly, from a clearly defined study population • Test and gold standard are measured independently (blind) of each other • Test and gold standard are applied as close together in time as possible • Results are reported for all patients that are entered into the study • A prediagnosis is made and reported

Appendix B Table 2. Quality Rating Criteria

Hierarchy of research design

I	Properly conducted randomized controlled trial
II-1:	Well-designed controlled trial without randomization
II-2:	Well-designed cohort or case-control analytic study
II-3:	Multiple time series with or without the intervention; dramatic results from uncontrolled experiments
III:	Opinions of respected authorities, based on clinical experience; descriptive studies or case reports; reports of expert committees

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Aittasalo, 2006[32] Fair	**Design:** CCT (self-describe as RCT, but while PCPs randomly assigned to interv or control group, the control group participants were further divided non-randomly (every-other person assigned to alternate control group) **Location:** Finland **Setting:** Primary health care centers and occupational outpatient health care units **Volunteer:** No	**Inclusion:** Aged 20-65 years; appointment with study physician; 30 minutes of moderate-intensity PA on fewer than 4 days/week; no perceived obstacles to PA **Exclusion:** NR	**N recruited or assessed for eligibilty** 67 PCPs enrolled/randomized 992 patients (from 45 PCPs) **N eligible:** 535 **N enrolled:** 265 **N randomized** IG1: 130 IG2: 62 CG: 73 *For MA:* IG (comb): 192 **Follow-up (6-mo):** IG1: 96 (74%) IG2: 49 (79%) CG: 58 (79%) **Cluster information**: Number of clusters: 45 Avg cluster size: 11.9 Inter-cluster correlation: NR Analysis controlled for clustering: No	**Age (mean):** 47 **Sex (% men):** 24 **Race/ethnicity:** NR **SES:** NR **Obesity:** NR	**Dietary factors:** None **Physical activity:** Moderate intensity PA, type tailored to participant

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Aittasalo, 2006[32] Fair	**Intervention description** CG: Usual care IG1: Counseling session with PCP using 5 A's; option of PA log for self-monitoring; option of referral to PA experts; arranged followup visit to discuss PA IG2: Pedometer and PA log for monitoring 5 days of activity; feedback and personal PA recommendations based on PA log by mail **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual; face-to-face IG2: Individual; mail **Intensity (total min) and duration (weeks)** IG1: 1 session with 1 more possible; 5-10 minutes each; weeks NR IG2: 1 letter **Provider type** IG1: Physician IG2: Physical therapist	**Physical Activity:** Modified International Physical Activity Questionnaire	Mean (SE) **BL** **6 mo*** *Any PA, minutes/week* **IG1** 344 (29) 526 (43) **IG2** 419 (65) 555 (66) **CG** 430 (82) 480 (54) **Difference in change (95% CI) †:** IG1 vs CG: 79 (-28, 186), p=0.15 IG2 vs CG: 79 (-46, 205), p=0.22 *Moderate intensity PA, minutes/week* **IG1** 69 (5) 99 (8) **IG2** 84 (7) 94 (9) **CG** 81 (6) 88 (8) **Difference in change (95% CI) †:** IG1 vs CG: 16 (-6, 37), p=0.15 IG2 vs CG: 6 (-20, 31), p=0.67 *For MA:* Mean (SD) *Any PA, minutes/week* **IG1** -- (331) -- (490) **IG2** -- (512) -- (433) **CG** -- (701) -- (461) **IG1&2** 368.2 (399) 535.8 (471) ** Missing data imputed* *† Adjusted for baseline PA, age, sex, presence of chronic illness, reason for appointment* **IG1 n analyzed:** 130 **IG2 n analyzed:** 62 **CG n analyzed:** 73

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Aittasalo, 2006[32] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	24% reported some adverse effects caused by PA, mostly musculoskeletal pain, but no statistically significant differences were found between the groups	**Degree of estimation required for MA:** 2

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Connell, 2009[74] **Health First** Fair	**Design:** RCT **Location:** Michigan, US **Setting:** Primarily telephone **Volunteer:** Mixed	**Inclusion:** Female; primary caregiver for a spouse with dementia; living with their spouse at home; interested in increasing their physical activity **Exclusion:** NR	**N recruited or assessed for eligibilty:** NR **N eligible:** NR **N randomized** Total: 157 IG: 86 CG: 71 **Followup (12-mo):** IG: 80.2% CG: 87.3% **Cluster information:** NA	**Age (mean):** 66.8 **Sex (% men):** 0 **Race/ethnicty:** % White: 92.7 **SES:** *% Education* ≤High school: 34.3 Some college: 41.6 ≥College degree: 24.1 **Obesity:** NR	**Dietary factors:** None **Physical activity:** Low-to-moderate intensity aerobic exercise at least 30 min/day 3x/week supplemented by stretching and strength training

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Connell, 2009[74] **Health First** Fair	**Intervention description** CG: Written materials about physical activity at the end of the study period IG: Individualized counseling including short- and long-term goal-setting, problem-solving, and encouragement to keep exercise logs. Participants also received a video discussing strategies for fitting PA into their daily routine; a choice of exercise videos; "Pep Up Your Life" AARP pamphlet containing information on flexibility, strength, and balance exercises for older adults; workbook explaining each step of the program and includes forms to track goals; and 2 motivational newsletters **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; primarily phone; mailed newsletters **Duration and Intensity (total min)** IG: 6 months, 14 phone calls, time NR **Provider type** IG: Counselors, trained behavior-change	**Physical Activity:** Time spent in aerobic exercise, stretching, and strengthening over the past week (Lorig et al. 1996)	Mean (SD) **BL** / **6 mo** / **12 mo** *Total exercise/week score** **IG** 5.2 (2.2) / 7.0 (2.7)** / 6.1 (2.5) **CG** 5.4 (2.6) / 5.8 (2.7) / 5.9 (2.8) ** Time spent in aerobic exercise, stretching, and strengthening was summed to yield a total exercise per week score. Scale values: 1=none, 2=<30 mins, 3=30-60 mins, 4=1-3 hours, 5=>3 hours* *** p=0.01* **IG n analyzed:** 74 (BL, 6 mo), 69 (12 mo) **CG n analyzed:** 63 (BL, 6 mo), 61 (12 mo)

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Connell, 2009[74] **Health First** Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	**Degree of estimation required for MA:**

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
de Vet, 2009[33] Fair	**Design:** RCT **Location:** Netherlands **Setting:** Mailings **Volunteer:** Yes	**Inclusion:** 18-65 years **Exclusion:** NR	**N recruited or assessed for eligibilty:** 709 **N eligible:** 709 **N randomized** Total: 709 IG1 (walking): 161 IG2 (self-selected): 172 IG3 (repeated): 170 CG: 206 *For MA:* IG (comb): 503 **Followup (6-mo):** All: 79% *For MA:* IG (comb): 397 (calc) CG: 163 (calc) **Cluster information:** NA	**Age (mean):** 45.9 **Sex (% men):** 33 **Race/ethnicty:** % Dutch: 90 **SES:** % Higher vocational training/college education: 66 **Obesity:** % Overweight: 37	**Dietary factors:** None **Physical activity:** Increase activity by 2 hours/week

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
de Vet, 2009[33] Fair	**Intervention description** CG: Questionnaire with information about benefits of exercise and recommendation to increase activity level by 2 hours/week IG1: Same as CG with additional section to make implementation intention (when, where, how long) at baseline for an assigned activity (walking). IG2: Same as CG with additional section to make implementation intention (when, where, how long) at baseline for self-selected activity. IG3: Same as CG with additional section to make implementation intention (when, where, how long) at baseline and 2 followup times for self-selected activity. **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1-3: Individual; mail **Duration and Intensity (total min)** IG1-3: 6 months, time NR **Provider type** IG1-3: NR	**Physical Activity:** Dutch Short Questionnaire to Assess Health-enhancing physical activity	Mean (SD) **BL** **6 mo** *Activity, minutes/week* **IG1** 2748 (1076) 2745 (1240) **IG2** 2777 (1118) 2707 (1240) **IG3** 2745 (1237) 2729 (1254) **CG** 2789 (1163) 2870 (1482) *Moderate-intensity PA, minutes/week* **IG1** 500 (490) 562 (516) **IG2** 441 (544) 465 (458) **IG3** 435 (475) 518 (542) **CG** 519 (657) 562 (650) *Walking, minutes/week* **IG1** 146 (232) 172 (236) **IG2** 140 (208) 189 (538) **IG3** 127 (226) 131 (169) **CG** 124 (161) 183 (391) *For MA:* *Moderate-intensity PA, minutes/week* **IG (comb)** 457.9 (504.1) 513.9 (506.4) All NS **IG (combined) n analyzed:** 397 **CG n analyzed:** 163

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
de Vet, 2009[33] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	Entered a raffle for 20 euros if completed study Did not abstract self-reported BMI (weight & height) **Degree of estimation required for MA:** 3

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Delichatsios, 2001[34] **Pinto, 2002**[35] **(Dietary behavioral outcomes in Healthy Diet table)** Fair	**Design:** RCT **Location:** Massachusetts, US **Setting:** Recruited from group practice, Home and phone visits **Volunteer:** No	**Inclusion:** Sedentary and suboptimal diet (suboptimal intake of one of fruits, vegetables, red and processed meats, whole fat dairy foods, or whole grain foods) **Exclusion:** Younger than 25 years; medical conditions that would limit ability to participate in the study, such as dementia and severe psychiatric disorders; engaging in moderate PA > 5 days/week for ≥ 30 minutes/day or vigorous PA > 3 days/week for ≥ 20 minutes/day	**N recruited or assessed for eligibilty:** 2884 **N eligible:** 609 **N randomized** Total: 298 IG: 150 CG: 148 **Followup (6-mo):** IG: 112 (74.7%) CG: 131 (88.5%) **Cluster information:** NA	**Age (mean):** 45.9 **Sex (% men):** 28 **Race/ethnicity:** % White: 45 % Black: 45 **SES:** % ≥ 12 years education: 71 % Married: 59 **Obesity:** Mean (SD) BMI: 28.7 (7.0)	**Dietary factors:** See Delichatsios in Healthy Diet table **Physical activity:** Moderate intensity physical activity ≥ 5 times/week for ≥ 30 minutes

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Delichatsios, 2001[34] **Pinto, 2002**[35] **(Dietary behavioral outcomes in Healthy Diet table)** Fair	**Intervention description** CG: Telephone linked communication system providing automated counseling on healthy eating behaviors IG: Telephone linked communication system that is set up to provide automated physical activity counseling. The system asked questions and modified the counseling based on responses and kept a cumulative database of responses. **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; phone **Duration (weeks) and Intensity (total min)** IG: 6 months; weekly for 3 months, biweekly for 3 months, estimated 18 calls total; 10 minutes/call; 18*10=180 minutes total **Provider type** IG: Expert system with digitized human speech	**Physical Activity:** 7-day Physical Activity Recall	Mean (SD) **BL** **6 mo** *Daily Expenditure, kcal/kg/day* **IG** 33.2(1.9) 33.8 (2.7) **CG** 33.5(2.0) 33.6 (2.1) p = 0.34 N* (percent) *Meeting ACSM criteria* **IG** 16 (10.7) 29 (25.9) **CG** 24 (16.2) 35 (26.7) **OR (95% CI):** 1.11 (0.60, 2.06) p = 0.73 ** n calculated* **IG n analyzed:** 150 (BL), 112 (6 mo) **CG n analyzed:** 148 (BL), 131 (6 mo)

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Delichatsios, 2001[34] **Pinto, 2002**[35] **(Dietary behavioral outcomes in Healthy Diet table)** Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	Very low adherence: 33% never called the system; 33% called 1-5 times; 13% called 6-10 times; 17% called 11-20 times; 4% called > 20 times **Degree of estimation required for MA:** 1 for percent meeting recommendation, 0 for energy expenditure

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Elley, 2003[36] **Kerse, 2005**[37] **(for 65+ subgroup)** Good	**Design:** RCT, randomization at clinic level **Location:** New Zealand **Setting:** Primary care **Volunteer:** No	**Inclusion:** Age 40-79 years; attended participating practices during their recruitment week; answered "no" to question "As a rule, do you do at least half an hour of moderate or vigorous exercise (such as walking or a sport) on five or more days of the week?" **Exclusion:** Providers considered too unwell; debilitating medical condition or known unstable cardiac condition; did not understand English; expecting to leave the region	**N recruited or assessed for eligibilty** **N eligible:** 1364 **N randomized:** 878 IG: 451 CG: 427 **N analyzed:** IG: 451 CG: 427 **Followup,12-mo:** IG: 389 (86.3%) CG: 361 (84.5%) **Cluster analysis:** Number of clusters: 42 (physicians) Avg cluster size: 21 (calc) Inter-cluster correlation: NR Analysis controlled for clustering: Yes	**Age (mean):** 57.9 (calc) **Sex (% men):** 33.7 **Race/ethnicity:** % European origin: 77.2 **SES:** % Lower economic status: 47.4 **Obesity:** 42.6%	**Dietary factors:** None **Physical activity:** 30 minutes of moderate or vigorous activity 5 days/week

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Elley, 2003[36] **Kerse, 2005**[37] **(for 65+ subgroup)** Good	**Intervention description** CG: Usual care IG: "Green prescription" from GP at initial meeting, followed up by 3 phone calls from exercise physiologist, with quarterly newsletters containing information about community exercise initiatives and motivational material **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; face-to-face, phone, mail **Duration and Intensity (total min)** IG: 3 months; 4 contacts: initial 7-13 minutes; phone contacts 10-20 minutes; total possible range 37-73 minutes **Provider type** IG: Primary Care Provider; exercise physiologist	**Physical Activity:** Questionnaire from the Auckland heart study	Mean (SD) at BL, Mean change (95% CI) at 12 mo **BL** **12 mo** *Exercise, minutes/week* **IG** 11.3 (21.7) 54.6 (41.4, 68.4) **CG** 12.0 (20.5) 16.8 (6.0, 32.4) **Diff between groups:** 33.6 (2.4, 64.2), p=0.04 *Leisure Physical activity, kcal/kg/week* **IG** 6.0 (12.2) 4.32 (3.26, 5.38) **CG** 6.5 (11.1) 1.29 (0.11, 2.47) **Diff between groups:** 2.67 (0.48, 4.86), p=0.02 *Total energy expenditure, kcal/kg/week* **IG** 237.5 (42.2) 9.76 (5.85, 13.68) **CG** 235.7 (45.3) 0.37 (-3.39, 4.14) **Diff between groups:** 9.38 (3.96, 14.81), p=0.001 N (percent) *Proportion achieving 2.5 hours/week activity (raw proportion at each time)* **IG** 80 (18) 146 (32.4) **CG** 91 (21) 112 (26.2) p=0.003 *Notes: All unadjusted (except for nesting within practice)* *Subgroup of 65+ available* **IG n analyzed:** 451 **CG n analyzed:** 427 *For MA (calc):* SD *Exercise, minutes/week* **IG** -- 146.3 **CG** -- 139.2

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Elley, 2003[36] **Kerse, 2005**[37] **(for 65+ subgroup)** Good	Mean (SD) at BL, Mean change (95% CI) at 12 mo **Adiposity:** **BL** **12 mo** *BMI, kg/m*^{2} **IG** 30.0 (6.7) -0.11 (-0.25, 0.02) **CG** 29.9 (6.4) -0.05 (-0.18, 0.07) **Diff between groups:** -0.06 (-0.24, 0.12), p=0.50 **Blood pressure:** **BL** **12 mo** *Systolic blood pressure, mmHg* **IG** 135.1 (19.6) -2.58 (-4.02, -1.13) **CG** 135.4 (17.9) -1.21 (-2.57, 0.15) **Diff between groups:** -1.31 (-3.51, 0.89), p=0.20 *Diastolic blood pressure, mmHg* **IG** 82.4 (12.2) -2.62 (-3.62, -1.61) **CG** 81.8 (12.1) -0.81 (-1.77, 0.16) **Diff between groups:** -1.4 (-3.35, 0.56), p=0.20 **Lipids:** *Cholesterol, mmol/L* **IG** 5.78 (1.0) -0.019 (-0.08, 0.05) **CG** 5.64 (1.0) 0.01 (-0.05, 0.06) **Diff between groups:** -0.02 (-0.12, 0.09), p=0.70 **Glucose tolerance:** NR *Note: All unadjusted (except for nesting within practice)* **IG n analyzed:** 451 **CG n analyzed:** 427	NR	OR (95% CI) *Falls* **IG** 1.19 (0.82, 1.72) **CG** 1.22 (0.85, 1.75) *Injury* **IG** 0.63 (0.44, 0.896) **CG** 0.70 (0.48, 1.02) *Admission to hospital* **IG** 0.77 (0.60, 0.996) **CG** 1.02 (0.796, 1.33) *All NS*	**Degree of estimation required for MA:** 1

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Elley, 2003[36] **Kerse, 2005**[37] **(for 65+ subgroup)** Good					

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Elley, 2003[36] **Kerse, 2005**[37] **(for 65+ subgroup)** Good			

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Elley, 2003[36] **Kerse, 2005**[37] **(for 65+ subgroup)** Good	*For MA (calc):* SD *BMI, kg/m*^{2} **IG** -- 1.46 **CG** -- 1.32 **Diff between groups:** 0.09 *Systolic blood pressure, mmHg* **IG** -- 5.7 **CG** -- 4.3 **Diff between groups:** 1.12 *Diastolic blood pressure, mmHg* **IG** -- 10.9 **CG** -- 10.2 **Diff between groups:** 1.0 *Cholesterol, mmol/L* **IG** -- 0.70 **CG** -- 0.58 **Diff between groups:** 0.054			

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Goldstein, 1999[38] **Pinto, 1998**[39] **(used for quality rating)** **(PAL)** Fair	**Design:** RCT **Location:** Massachusetts, US **Setting:** Primary care office practices **Volunteer:** No	**Inclusion:** Age 50 years or older; ambulatory; scheduled for routine visit during 4-7 week intervention period **Exclusion:** Unable to provide information over the phone; already participating in ≥ 30 minutes of moderate activity 5 days/week or ≥ 20 minutes of vigorous activity 3 days per week per phone screen	**N recruited or assessed for eligibilty:** 34 PCPs; 2,674 patients **N eligible:** 444 **N randomized:** 355 IG: 181 CG: 174 **Followup (8-mo):** IG: 159 (87.8%) CG: 157 (90.2%) **Cluster information:** Number of clusters: 34 Avg cluster size: 10 (calc) Inter-cluster correlation: NR Analysis controlled for clustering: Yes	**Age (mean):** 65.6 **Sex (% men):** 35 **Race/ethnicity:** % White: 97 **SES:** Mean Education (years): 12.3 % Married: 66 "Majority middle income" **Obesity:** NR	**Dietary factors:** None **Physical activity:** ≥ 30 minutes of moderate activity 5 days per week or ≥ 20 minutes of vigorous activity 3 days per week

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Goldstein, 1999[38] **Pinto, 1998**[39] **(used for quality rating)** **(PAL)** Fair	**Intervention description** CG: Usual care, no materials or training provided. IG: Brief patient-centered counseling based on TTM, utilizing "5 As" with written exercise prescription and patient manual; follow-up visit scheduled to discuss PA; mailed materials monthly for 5 months; Physician training manual, desk prompt, and office poster; 1-hour physician training session, chart prompts for individual patients **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; face-to-face **Intensity** IG: 5-minutes x2, plus extensive written materials **Provider** IG: Physician	**Physical Activity:** Physical Activity Scale for the Elderly	Mean (SE) **BL** **8 mo** *PASE Score* **IG** 108.5 (5.26) 112.6 (5.79) **CG** 108.82 (5.02) 111.0 (5.55) p=0.74 **IG n analyzed:** 181 (BL), 158 (8 mo) **CG n analyzed:** 174 (BL), 154 (8 mo) Percent (SE) **BL** **8 mo** *Meeting CDCP/ACSM recommendations* **IG** 15 (3) 28 (4) **CG** 17 (3) 24 (3) p=0.27 **IG n analyzed:** 181 (BL), 159 (8 mo) **CG n analyzed:** 174 (BL), 157 (8 mo) *Note: Adjusted for nested practice, plus other factors* *For MA (calc):* SD *PASE Score* **IG** 70.8 72.8 **CG** 66.2 68.9 N *Meeting CDCP/ACSM recommendations* **IG** 27 45 **CG** 30 38

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Goldstein, 1999[38] **Pinto, 1998**[39] **(used for quality rating)** **(PAL)** Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	**Degree of estimation required for MA:** 1

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Grandes, 2009[40] Good	**Design:** RCT-cluster **Location:** Spain **Setting:** Primary care health centers **Volunteer:** No	**Inclusion:** 20-80 years; did not meet physical activity levels of moderate activity ≥ 30 minutes 5 days/week or vigorous activity ≥ 20 minutes 3 days/week **Exclusion:** Unstable or chronic conditions that would preclude safe participation in regular physical activity; severe emotional distress; complicated pregnancy; followup difficulties	**N assessed for eligibilty:** 16,663 **N eligible:** 10,450 **N randomized** Total: 4317 IG: 2248 CG: 2069 **Followup (6-mo):** IG: 1813 (80.6%) CG: 1698 (82.1%) **Cluster information:** Number of clusters: 29 (IG), 27 (CG) Avg cluster size: 77.1 (calc) Inter-cluster correlation: NR Analysis controlled for clustering: Yes *Randomized physicians, stratified by health center; clusters nested within centers*	**Age (mean):** 50.0 **Sex (% men):** 34.4 **Race/ethnicity:** NR **SES:** % Employed: 50.6 % >High school education: 16.8 **Obesity:** 25.9%	**Dietary factors:** None **Physical activity:** ≥ 30 minutes 5 days/week or vigorous activity ≥ 20 minutes 3 days/week

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Grandes, 2009[40] Good	**Intervention description** CG: Usual care IG: Brief advice from PCP using web-based software, 4-page pamphlet, offered additional 15-minute visit to develop action plan **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; face-to-face, written **Duration (weeks) and Intensity (total min)** IG: Weeks NR; 15 or 30 minutes if participant chose to attend followup visit (30%) **Provider type** IG: Primary care physician	**Physical Activity:** PAR VO_2 max measured	Mean (SD) at BL, Adjusted Change (95% CI) at 6 mo **BL** **6 mo** *Moderate and vigorous activity, minutes/week* **IG** 34.4 (90.9) 82.58 (59.94, 105.23) **CG** 33.2 (79.5) 65.14 (42.40, 87.88) **Difference:** 18.15 (5.66, 30.65) *Moderate and vigorous activity, MET-hour/week* **IG** 2.37 (5.96) 5.70 (4.07, 7.32) **CG** 2.36 (5.94) 4.42 (2.78, 6.05) **Difference:** 1.27 (0.38, 2.16) *VO_{2max}, mL/kg/minute* **IG** 24.37 (8.10) 1.18 (0.84, 1.52) **CG** 24.66 (8.41) 1.09 (0.74, 1.43) **Difference:** 0.11 (-0.20, 0.43) *Change in Proportion meeting PA recommendations, %* **IG** -- 18.8 (13.8, 25.0) **CG** -- 15.0 (10.8, 20.3) **Difference:** 3.9 (1.2, 6.9) **IG n analyzed:** 2248 **CG n analyzed:** 2069 *For MA (calc):* SD *Moderate and vigorous activity, minutes/week* IG -- 547.8 CG -- 527.7 *VO_{2max}, mL/kg/minute* IG -- 8.2 CG -- 8.0 N *Meeting PA recommendations* IG 0 341 CG 0 255

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Grandes, 2009[40] Good	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	**Degree of estimation required for MA:** 1 Subgroup analysis available for >50 years and those attending follow-up

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Green, 2002[41] Fair	**Design:** RCT **Location:** Washington, US **Setting:** Primary care **Volunteer:** No	**Inclusion:** Age 20-64 years; assigned to study provider; inactive (<15 minutes PA/day); expressed interest in increasing PA **Exclusion:** Heart disease; diabetes; enrolled in Group Health Cooperative; medications or medical conditions contraindicating PA increase (e.g., chest pain, syncope, dizziness, bone or joint conditioned that PA could exacerbate)	**N recruited or assessed for eligibilty:** 1330 **N eligible:** 361 **N randomized** Total: 316 IG: 159 CG: 157 **Followup (6-mo):** IG: 128 (80.5%) CG: 128 (81.5%) **Cluster information:** NA	**Age (median):** 44 (est) ≤ 30: 15% 31-50: 54% 51+: 31% **Sex (% men):** 48 **Race/ethnicity:** % White: 92 African American: 1.6 % Asian Pacific: 4.5 % Hispanic: 0.6 % Other: 2.2 **SES:** NR **Obesity:** NR	**Dietary factors:** NR **Physical activity:** Increase PA

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Green, 2002[41] Fair	**Intervention description** CG: Tailored "health improvement" report on preventive practices (including PA), pamphlets on relevant topics, phone number for further resources, summaries sent to PC physician IG: Letter from provider encouraging PA, mailed self-help workbook, three 20- to 30-minute scripted phone calls **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; phone, mail **Duration and Intensity (total min)** IG: 3 months, 3*25 minutes = 75 minutes **Provider type** IG: Health behavior specialist (at least bachelor's degree)	**Physical Activity:** PACE	Mean (SD) at BL, Mean (SE) at 6 mo, Mean change score (SE) at 6 mo **BL** / **6 mo** / **6 mo change score** *PACE Score (range 1-11)* **IG** 5.03 (2.01) 5.37 (0.14) 0.43 (0.16) **CG** 4.73 (2.11) 4.98 (0.14) 0.10 (0.16) **p** -- 0.049 0.145 **IG n analyzed:** 128 **CG n analyzed:** 128 *For MA (calc):* SD *PACE Score (range 1-11)* **IG** -- -- 1.8 **CG** -- -- 1.8

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Green, 2002[41] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	**Degree of estimation required for MA:** 1

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Greene, 2008[42] **Greaney, 2008**[43] Fair	**Design:** RCT **Location:** Rhode Island, US **Setting:** Home (assessment), mail, phone **Volunteer:** Yes	**Inclusion:** Community dwelling; age 60 years or older; English or Portuguese language **Exclusion:** NR	**N recruited or assessed for eligibilty:** NR **N eligible:** NR **N randomized** Total: 1280 IG: NR CG: NR **Followup (12, 24-mo):** IG: 470 CG: 496 Overall: 966 (75.5%) **Cluster information**: NA	**Age (mean):** 74.7 **Sex (% men):** 27.1 **Race/ethnicity:** % White: 79.5 % Hispanic: 13.2 % Other: 7.3 **SES:** % Annual income <$20,000: 57 % No college: 58 **Obesity:** NR *Note: From HD sample (Greene)*	**Dietary factors:** Daily servings of fruits and vegetables **Physical activity:** Moderate-vigorous activity 3-5 times/week for at least 20 minutes per session; flexibility exercises 2 times/week; strengthening 2-3 times/week

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Greene, 2008[42] **Greaney, 2008**[43] Fair	**Intervention description** IG=One group that received physical activity counseling and one group that received physical activity and dietary counseling CG=one group that received dietary counseling and one group that was a control CG: One group received falls prevention manual. The second group received stage-based fruit and vegetable manual; 9 stage-based fruit and vegetable newsletters; 3 reports from expert system tailored current stage of change variables and baseline information; 3 15-minute coaching calls IG: Two groups received stage-based PA manual; 9 stage-based PA newsletters; 3 reports from expert system tailored current stage of change variables and baseline information; 3 15-minute coaching calls. The second group also received dietary counseling **Format and Delivery** IG: Individual; phone, mail **Duration (weeks) and Intensity (total min)** IG: 52 weeks, 45 minute phone calls **Provider type** IG: NR, "trained counselors"	**Physical Activity:** PA summary score of the Yale Physical Activity Survey	Adjusted mean (SE) **BL 12 mo 24 mo** *Yale Physical Activity Survey summary score* **IG** 46 (1.4) 46 (1.2) 47 (1.3) **CG** 46 (1.3) 47 (1.1) 47 (1.2) Both NS *For MA (calc):* SD *Yale Physical Activity Survey summary score* **IG** 30.4 26.0 -- **CG** 29.0 24.5 -- **IG n analyzed:** 470 **CG n analyzed:** 496

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Greene, 2008[42] **Greaney, 2008**[43] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	**Degree of estimation required for MA:** 1

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Halbert, 2000[44] **Halbert, 1999**[45] Fair	**Design:** RCT **Location:** Australia **Setting:** Primary care **Volunteer:** No	**Inclusion:** Community-dwelling patients of two general practices; aged 60 years or older; sedentary (less than three 20 minute brisk PA episodes/week) **Exclusion:** History of stroke, MI, or admission for transient ischemic episode or angina in previous 6 months; malignancy or other life-threatening disease; condition for which PA was contraindicated; taking beta-blocker medication	**N recruited or assessed for eligibilty:** 2878 **N attended screening appointment:** 913 **N eligible:** 351 **N randomized** Total: 299 IG: 149 CG: 150 **Followup (12-mo):** IG: 123 (82.6%) CG: 141 (94.0%) **Cluster information:** NA	**Age Mean:** 67.6 (calc) **Sex (% men):** 46 (calc) **Race/ethnicity:** NR **SES:** % Current Employment: 38 (calc) **Obesity:** Mean weight, kg: 74.9 (calc)	**Dietary factors:** NR **Physical activity:** Minimum of 3 sessions of moderate aerobic activity for at least 20 minutes

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Halbert, 2000[44] **Halbert, 1999**[45] Fair	**Intervention description** CG: Visit with exercise physiologist discussing nutrition pamphlet IG: Visit with exercise physiologist discussing benefit of PA, individualized advice, pamphlet containing a PA plan for next 3 months. The focus was on incorporating physical activity into the individuals's usual activities and on increasing self-efficacy **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; face-to-face **Duration (weeks) and Intensity (total min)** IG: Single interview, 20 minutes **Provider type** IG: Exercise physiologist	**Physical Activity:** NR	Median (IQR) **BL** **12-mo** *Walking Frequency, sessions/week* **IG** 0 (0-1) 3(1-4)* **CG** 0 (0-2) 2(1-3) *Walking Time, minutes/session* **IG** 0 (0-25) 30(10-60) **CG** 0 (0-20) 30(10-60) *Vigorous PA Frequency, sessions/week* **IG** 0 (0-0) 2(0-3)* **CG** 0 (0-0) 0(0-1) *Vigorous PA Time, minutes/session* **IG** 0 (0-0) 20(0-35)* **CG** 0 (0-0) 0(0-15) ** Sigificantly higher for IG compared with CG, p<0.05* **IG n analyzed:** 149 **CG n analyzed:** 150

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Halbert, 2000[44] **Halbert, 1999**[45] Fair	**Adiposity:** (Not used, since control group=nutrition counseling) **Blood pressure:** (Not used, since control group=nutrition counseling) **Lipids:** (Not used, since control group=nutrition counseling) **Glucose tolerance:** (Not used, since control group=nutrition counseling)	NR	NR	**Degree of estimation required for MA:** NA, not included in MA

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Harland, 1999[46] Fair	**Design:** RCT **Location:** UK **Setting:** Urban general practice **Volunteer:** No	**Inclusion:** Aged 40-64 years; attending routine surgeries or identified from the practice register **Exclusion:** Unable to complete a submaximal exercise test (cardiovascular or respiratory disease, acute MI in past 12 months, triple therapy for angina, arythmia, angioplasty or cardiac surgery, severe cardiac failure, aortic valve disease, cardiomyopathy or myocarditis, stroke or transient ischemic attack in past 12 months, pulmonary embolism or venous thrombosis in past 6 months, blood pressure 180/105 mmHg, taking beta-blockers, asthma or chronic obstructive airways disease, severe anemia, other serious morbidity, orthopedia or rheumatic conditions, aspergillosis); severe mental illness; known terminal illness; already exercising sufficiently	**N recruited or assessed for eligibilty:** 734 **N eligible:** NR **N randomized** Total: 523 (Figure 1 reports 520) IG1(brief): 105 IG2(brief + vouchers): 106 IG3(intensive): 104 IG4(intensive + vouchers): 103 (102 reported in Figure 1) CG: 105 (103 reported in Figure 1) **Followup (12-mo):** IG1: 96 (91.4%) IG2: 88 (83.0%) IG3: 88 (84.6%) IG4: 80 (77.7%) CG: 91 (86.7%) **Cluster information:** NA	**Age (n (%)):** 40-49 years: 248 (47) (calc) 50-59 years: 177 (34) (calc) 60-64 years: 98 (19) (calc) **Sex (% men):** 41.7 (calc) **Race/ethnicity:** NR **SES:** % Manual occupation class: 70.4 (calc) **Obesity:** NR	**Dietary factors:** None **Physical activity:** "Promoted safe, effective PA but did not prescribe particular activities"

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Harland, 1999[46] Fair	**Intervention description** CG: Assessment results, written information on: benefits of PA and other lifestyle factors), leisure facilities and activities, and recommended PA level; brief tailored advice on several lifestyle factors, and leaflets for 19 local leisure facilities IG1: CG materials, one 40-minute motivation interview promoting PA IG2: IG1 + 30 vouchers for free admission to community leisure centers IG3: CG materials, six 40-minute motivational interviews promoting PA IG4: IG3 + 30 vouchers for free admission to community leisure centers **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1-4: Individual; face-to-face **Duration (weeks) and Intensity (total min)** IG1 and IG2: Single interview, 40 minutes IG3 and IG4: 12 weeks, 40 minutes*6 interviews = 240 minutes **Provider type** IG1-4: Health visitor	**Physical Activity:** National Fitness Survey (shortened version)	N (%) **12 mo** *Increased PA Score by one or more levels* **IG1** 22 (23) **IG2** 22 (26) **IG3** 27 (31) **IG4** 21 (27) **CG** 21 (23) p=0.73 *Increased total session vigorous activity* **IG1** 17 (28) **IG2** 19 (22) **IG3** 19 (22) **IG4** 14 (18) **CG** 11 (12) p=0.43 **IG1 n analyzed:** 96 **IG2 n analyzed:** 88 **IG3 n analyzed:** 88 **IG4 n analyzed:** 79 **CG n analyzed:** 91

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Harland, 1999[46] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	**Degree of estimation required for MA:** NA, not included in MA+M18

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Hellenius, 1993[47] **Hellenius, 1995**[48] **Nasland, 1996**[49] Fair	**Design:** RCT **Location:** Sweden **Setting:** Primary care health center and hospital **Volunteer:** No	**Inclusion:** No history of cardiovascular disease, diabetes, or other severe illnesses; no regular use of drugs; serum cholesterol 5.2-7.8 mmol/l; fasting triglycerides ≤ 5.6 mmol/l; fasting blood glucose ≤ 6.7 mmol/l; and diastolic blood pressure ≤ 100mmHg **Exclusion:** NR	**N recruited or assessed for eligibilty:** 187 **N responded:** 160 **N eligible:** 158 **N randomized** Total: 158 IG1 (D): 40 IG2 (E): 39 IG3 (DE): 39 CG: 40 **Followup (6-mo):** IG1(D): 40 (100%) IG2 (E): 39 (100%) IG3 (DE): 39 (100%) CG: 39 (98%) **Cluster information:** NA	**Age (mean):** 45 **Sex (% men):** 100 **Race/ethnicity:** NR **SES:** NR **Obesity:** Mean (SD) BMI: 25.3 (3.2)	**Dietary factors:** Of total energy intake: total fat < 30%; saturated fat < 10%; polyunsaturated fat ≤ 10%; monounsaturated fat 10-15%; carbohydrates 50-60%; protein 10-20%; cholesterol < 300 mg/day **Physical activity:** Aerobic exercise at 60-80% max for 30-45 minutes, 2-3 times/week

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Hellenius, 1993[47] **Hellenius, 1995**[48] **Nasland, 1996**[49] Fair	**Intervention description** CG: Told to maintain normal diet and activity IG1: Received written and verbal dietary advice from physician at baseline and advice from dietician after approximately 2 weeks IG2: Received verbal and written information regarding physical activity from physician at baseline, offered aerobic exercise sessions 2-3 times per week IG3: Same as IG1 and IG2 **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1-3: indiv, face-to-face **Duration (weeks) and Intensity (total min)** IG1: 2 weeks, intensity NR IG2: 1 time, intensity NR IG3: 2 weeks, intensity NR **Provider type** IG1: Dietician IG2: Physician IG3: Dietician, physician	**Physical Activity:** Exercise minutes obtained in structured interview	Mean (SD) **BL** **6 mo** *Exercise sessions, number/month* **IG2(E)** 5.1 (7.3) 11.7 (6.7)* **CG** 5.3 (7.1) 5.4 (7.4) *Duration of sessions, minutes* **IG2(E)** 39 (50) 53 (27) **CG** 30 (32) 29 (30) **p<0.05* **IG2 n analyzed:** 39 **CG n analyzed:** 39

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Hellenius, 1993[47] **Hellenius, 1995**[48] **Nasland, 1996**[49] Fair	Mean (SD) at BL, Mean change (95% CI) at 6 mo **Adiposity:** **BL** **6 mo** *BMI, kg/m^2* **IG2(E)** 25.3 (2.9) -0.3 (-0.5, -0.01)* **CG** 24.5 (3.0) 0.3 (0.1, 0.5) **Blood pressure:** *SBP, mmHg* **IG2(E)** 133 (18.0) -5 (-9, -0.3)* **CG** 130 (12.2) -1 (-3, 4) *DBP, mmHg* **IG2(E)** 82 (9.6) -4 (-7, -2)* **CG** 82 (8.3) -1 (-3, 1) **Lipids:** *Total Cholesterol, mmol/L* **IG2(E)** 5.98 (0.64) -0.12 (-0.35, 0.11) **CG** 5.97 (0.90) -0.13 (-0.33, 0.07) *LDL, mmol/L* **IG2(E)** 4.05 (0.66) -0.09 (-0.24, 0.07) **CG** 4.14 (0.75) -0.15 (-0.33, 0.02) *HDL, mmol/L* **IG2(E)** 1.34(0.23) 0.01(-0.04, 0.07) **CG** 1.36(0.28) -0.02(-0.08, 0.05) **Glucose Tolerance:** NR ** p<0.05* **IG2 n analyzed:** 39 **CG n analyzed:** 39	NR	NR	**Degree of estimation required for MA:** 1

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Hellenius, 1993[47] **Hellenius, 1995**[48] **Nasland, 1996**[49] Fair					

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Hellenius, 1993[47] **Hellenius, 1995**[48] **Nasland, 1996**[49] Fair			

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Hellenius, 1993[47] **Hellenius, 1995**[48] **Nasland, 1996**[49] Fair	*For MA (calc):* SD *BMI, kg/m²* **IG2(E)** -- 0.78 **CG** -- 0.64 *SBP, mmHg* **IG2(E)** -- 13.8 **CG** -- 11.15 *DBP, mmHg* **IG2(E)** -- 8.0 **CG** -- 6.4 *Total Cholesterol, mmol/L* **IG2(E)** -- 0.73 **CG** -- 0.64 *LDL, mmol/L* **IG2(E)** -- 0.49 **CG** -- 0.56 *HDL, mmol/L* **IG2(E)** -- 0.18 **CG** -- 0.21			

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Kallings, 2009[50] **Kallings, 2008**[51] Good	**Design:** RCT **Location:** Sweden **Setting:** Primary care **Volunteer:** No	**Inclusion:** Born between 1937 and 1928; healthy but insufficiently physically active; overweight (BMI 25-40 kg/m^2) and abdominal obesity (≥88 cm for women, ≥102 cm for men) **Exclusion:** Self-reported current heart disease, pharmacological treatment for hypertension, hyperlipidemia, or type-2 diabetes; cancer or other serious chronic illness	**N recruited or assessed for eligibilty:** 407 **N eligible:** 116 **N randomized** Total: 101 IG: 47 CG: 54 **Followup (6-mo):** IG: 41 (87.2%) CG: 50 (92.6%) **Cluster information:** NA	**Age (mean):** NR **Sex (% men):** 43 **Race/ethnicity:** NR **SES:** NR **Obesity:** Mean BMI: 30.1 (calc)	**Dietary factors:** NR **Physical activity:** Gradually increase to 30 minutes or more of moderate-intensity PA on most, preferably all, days of the week and include both aerobic and strength training as well as exercises for flexibility and balance. Encouraged to reduce sedentary behavior

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Kallings, 2009[50] **Kallings, 2008**[51] Good	**Intervention description** CG: Usual care, which is a one-page written general information about the importance of PA for health IG: In addition to usual care, received 30-minute patient-centered motivational counseling with individualized written PA prescription and a group session on PA and health **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Group, individual; face-to-face **Duration (weeks) and Intensity (total min)** IG: Single individual session, 30 minutes; Single group session, intensity NR **Provider type** IG: Physician (group session) and health care professional (counseling)	**Physical Activity:** 7-day diaries; sitting time item of the short version of the International Physical Activity Questionnaire last 7 days; pedometer (7 days)	Median (IQR) at BL, Median change at 6 mo **BL** **6 mo** *At least moderate intensity, sessions/week* **IG** 2 (1-5) 3 (0-5)***†† **CG** 2 (1-5) -- *At least moderate intensity, minutes/week* **IG** 120 (0-220) 159 (0-430)***† **CG** 130 (40-215) -- Mean (SD) **BL** **6 mo** *Steps/day* **IG** 5390 (2791) 1663 (--)** **CG** 4980 (2763) 871 (--)* **Difference in change score (95%CI):** 791 (-571, 2154), SD (calc) = 695 *** p<0.001 difference from BL ** p<0.01 difference from BL * p<0.05 difference from BL †† p<0.001 difference between IG and CG at 6 mo † p<0.05 difference between IG and CG at 6 mo **IG n analyzed:** 41 **CG n analyzed:** 50

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Kallings, 2009[50] **Kallings, 2008**[51] Good	Mean (SD) at BL, Mean change (95%CI) at 6 mo **Adiposity:** **BL** **6 mo** *BMI, kg/m*^{2} **IG** 29.7(3.4) -0.6 (-0.9, -.03)* **CG** 30.4 (2.9) -0.2 (-0.4, 0.0) *Waist circumference, cm* **IG** 105.2 (9.2) -2.3 (-3.5, -1.1) **CG** 106.4 (7.8) -1.4 (-2.2, -0.6) **Blood pressure:** *Systolic Blood Pressure, mmHg* **IG** 137.6 (2.2) 0.2 (-4.3, 4.7) **CG** 142.3 (2.6) -4.1 (-7.5, -0.6) *Diastolic Blood Pressure, mmHg* **IG** 79.9 (1.5) -1.0 (-3.5, 1.6) **CG** 81.6 (1.3) -1.7 (-4.4, 0.9) **Lipids:** *Cholesterol, mmol/L* **IG** 5.6 (0.1) -0.3 (-0.6, 0.0)* **CG** 5.5 (0.1) 0.1 (-0.1, 0.1) *Triglycerides, mmol/L* **IG** 1.4 (0.1) -0.2 (-0.3, 0.0) **CG** 1.3 (0.1) 0.0 (-0.1, 0.1) *HDL, mmol/L* IG 1.7 (0.07) 0.0 (-0.1, 0.1) CG 1.7 (0.05) 0.0 (-0.1, 0.1) *LDL, mmol/L* IG 3.4 (0.12) -0.1 (-0.2, 0.1) CG 3.2 (0.09) 0.1 (-0.1, 0.3)	NR	NR	**Degree of estimation required for MA:** 0

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Kallings, 2009[50] **Kallings, 2008**[51] Good					

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Kallings, 2009[50] **Kallings, 2008**[51] Good			

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Kallings, 2009[50] **Kallings, 2008**[51] Good	**Glucose tolerance:** *Fasting Glucose, mmol/L* **IG** 5.5 (0.1) -0.2 (-0.3, -0.1) **CG** 5.4 (0.1) -0.1 (-0.2. 0.0) ** p<0.05 for difference between IG and CG* **IG n analyzed:** 47 (BL), 41 (6 mo) **CG n analyzed:** 54 (BL), 50 (6 mo) *For MA (calc):* SD *BMI, kg/m^2* **IG** -- 0.98 **CG** -- 0.72 *Systolic Blood Pressure, mmHg* **IG** -- 4.7 **CG** -- 12.4 *Diastolic Blood Pressure, mmHg* **IG** -- 8.3 **CG** -- 9.6 *Cholesterol, mmol/L* **IG** -- 0.98 **CG** -- 0.36 *HDL, mmol/L* IG -- 0.33 CG -- 0.36 *LDL, mmol/L* IG -- 0.49 CG -- 0.72			

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Katz, 2008[52] Fair	**Design:** Cluster RCT **Location:** Connecticut, US **Setting:** Primary care **Volunteer:** No	**Inclusion:** *For residents:* First year internal medicine resident at study hospitals; not trained in dual specialties *For participants:* Considered study resident to be PCP; averaged at least 3 non-acute visits over the last 2 years; visited at least once before the start of the intervention; aged 18 years or older **Exclusion:** *For participants:* Contraindications to moderate PA	**N recruited or assessed for eligibilty:** NR **N eligible:** NR **N randomized** Total: 316 patients (65 residents) IG: 195 (29 residents) CG: 121(36 residents) **Followup (12-mo):** IG: 185 (94.9%) CG: 117 (96.7%) Cluster information: Number of clusters: 65 Avg cluster size: 4.86 (calc) Inter-cluster correlation: NR Analysis controlled for clustering: No	**Age (mean):** NR **Sex (% men):** 33 **Race/ethnicity:** % White: 35 % African American: 29 % Hispanic: 21 **SES:** % Some college or higher: 30 **Obesity:** NR	**Dietary factors:** NR **Physical activity:** Increase PA

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Katz, 2008[52] Fair	**Intervention description** CG: Usual residency curriculum IG: Special training for residents on the Pressure System Model, covering a decision algorithm, motivational interviewing techniques, decisional balance, strategies for overcoming barriers, role-playing. Also instructed to plan followup visits **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.) to participants:** IG: Individual; face-to-face **Duration (weeks) and Intensity (total min)** IG: Varied, initial counseling session part of existing appointments, followup recommended at discretion of patient and resident **Provider type** IG: Resident physician	**Physical Activity:** Yale Physical Activity Survey	Baseline Mean (SE) at BL, Mean change (SE) at 6, 12 mo **BL 6 mo 12 mo** *Vigorous activity index score, kcal/minute* **IG** 9.94 (1.09) 1.47 (0.77) 2.29 (0.94)* **CG** 9.25 (1.48) 0.57 (0.94) 1.75 (1.41) *Leisurely walking index score, kcal/minute* **IG** 11.38 (0.97) -0.20 (0.72) 0.22 (0.91) **CG** 13.39 (1.18) -1.36 (0.77) -1.75 (0.97) *Total Index Score* **IG** 27.09 (1.35) 1.77 (0.84)* 1.94 (0.98)* **CG** 28.12 (1.75) 0.35 (1.00) 0.99 (1.52) **IG n analyzed:** 195 (BL), 185 (6, 12 mo) **CG n analyzed:** 121 (BL), 117 (6, 12 mo) ** p<0.05 for paired t-test* *Between-group differences all NS* *Note: Analyses not adjusted for clustering* *For MA (calc):* SD *Total Index Score* IG 18.9 -- 13.3 CG 19.2 -- 16.4 *(a) estimate the cluster size as 316/65=4.86;* *(b) calculate an design effect as 1+(cluster size-1) *r, where r is the assumed correlation between patients of the same resident (in this case, a very low correlation would be appropriate--0.05); = 1+3.86*0.05 = 1.193* *(c) divide n by the design effect:* *IG: 185/1.193=155.07* *CG: 117/1.193=98.07*

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Katz, 2008[52] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	**Degree of estimation required for MA:** 1

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
King, 2002[53] **Castro, 2002**[54] **(Diet behavior outcomes available in Healthy Diet Table)** Fair	**Design:** RCT **Location:** US **Setting:** Home, community recruitment **Volunteer:** Yes	**Inclusion:** Postmenopausal; age 50 years or older (46 years or older if postmenopausal due to hysterectomy); caregiver to relative with dementia; providing at least 10 hours of unpaid care/week; not planning of moving out of the area in next year; free from medical conditions contraindicating PA increase; not participating in a regular program of PA; stable on all medications for at least 3 months **Exclusion:** Evidence of ischemia	**N recruited or assessed for eligibilty:** 574 **N eligible:** NR **N randomized** Total: 100 IG: 51 CG: 49 **Followup (12-mo):** IG1: 45 (88.2%) CG: 40 (81.6%) **Cluster information:** NA	**Age (mean):** 62.7 **Sex (% men):** 0 **Race/ethnicity:** % White: 86 % African American: 5 % Hispanic: 4 % Asian/Pacific Islander: 3 **SES:** Mean (SD) years of education: 15.0 (2.5) **Obesity:** Mean BMI: 27.4	**Dietary factors:** **Physical activity:** Four or more 30- to 40-minute exercise sessions/week of primarily brisk walking

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
King, 2002[53] **Castro, 2002**[54] **(Diet behavior outcomes available in Healthy Diet Table)** Fair	**Intervention description** CG: Attention-placebo, nutrition target. Baseline face-to-face counseling session, 14 phone calls IG: 30-40-minute counseling session in home where initial PA plan developed; 14 15-20-minute phone calls; daily activity logs **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; face-to-face, phone **Duration (weeks) and Intensity (total min)** IG: 52 weeks, 35+17.5*14 = 280 minutes **Provider type** IG: Health educator	**Physical Activity:** CHAMPS; 20% sample wore microprecessors recording heart rate and body movement for 3-day period	Mean (SD) **BL** **12 mo (unadjusted)** **12 mo (adjusted)** *Total energy expenditure, kcal/kg/day* **IG** 1.4 (1.9) 2.2 (2.2) 2.1 (NR) **CG** 1.2 (1.7) 1.2 (1.6) 1.3 (NR) p<0.03 (minimally adjusted), p<0.02 (fully adjusted) *Total time spent in any PA, hours/week* **IG** 3.1 (3.8) 5.0 (4.9) -- **CG** 2.8 (3.6) 2.9 (3.7) -- p<0.03 **IG n analyzed:** 45 **CG n analyzed:** 40 *For MA (calc):* Mean (SD) *Total time spent in any PA, minutes/week* **IG** 186(228) 300(294) -- **CG** 168(216) 174(222) --

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
King, 2002[53] **Castro, 2002**[54] **(Diet behavior outcomes available in Healthy Diet Table)** Fair	Mean(SD) **Adiposity:** **BL** **12 mo** *BMI* **IG** 27.8(4.8) 27.9(5.2) **CG** 26.9(5.6) 26.9(5.3) NS **Blood pressure:** *SBP, mmHg* **IG** 117.3(13.8) 118.0(15.2) **CG** 123.2(14.0) 121.6(15.0) NS *DBP, mmHg* **IG** 69.6(6.7) 68.8(8.6) **CG** 68.0(7.4) 66.5(9.3) NS **Lipids:** NR **Glucose tolerance:** NR **IG n analyzed:** 45 **CG n analyzed:** 40	NR	NR	**Degree of estimation required for MA:** 1 for minute/week, 0 for intermediate outcomes

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
King, 2007[55] **(CHAT)** Fair	**Design:** RCT **Location:** US **Setting:** Phone, computer, community recruitment of caregivers **Volunteer:** Yes	**Inclusion:** Aged 55 years or older; not engaged in more than 60 minutes/week of moderate- or vigorous-intensity PA over the previous 6 months; BMI ≤40; average alcohol intake ≤3 drinks/day; able to speak and understand English sufficiently for consent, intervention, and assessment procedures; regular access to a touch-tone phone; not planning to move out of the area over the study period **Exclusion:** Medical condition that would limit participants in moderate-intensity PA	**N recruited or assessed for eligibilty:** NR **N eligible:** 370 **N randomized** Total: 218 IG1: 73 IG2: 75 CG: 70 **Followup (6, 12-mo):** IG1(Human): 66 (90.4%) IG2(Automated): 61 (81.3%) CG: 62 (88.6%) **Cluster information:** NA	**Age (mean):** 60.8 (calc) **Sex (% men):** 30.2 **Race/ethnicity:** % White: 87.3 **SES:** % Employed: 64.0 (calc) **Obesity:** Mean BMI, kg/m^2: 29.5 (calc) *Note: Baseline characteristics for participants that were still present at 12 months*	**Dietary factors:** **Physical activity:** Gradually increase to 30 minutes or more of moderate-intenstiy PA on most days of the week

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
King, 2007[55] **(CHAT)** Fair	**Intervention description** CG: Asked not to change usual PA patterns; offered weekly health education classes that focused on non-PA topics (e.g., nutrition, home safety) IG1 (Human advice): 30-40 minute session with health educator to develop an individualized plan to increase activity; ~15 10-15 minute telephone contacts over one year with individualized information, support, and problem-solving around PA barriers; Informational mailings; Pedometer; Activity log IG2 (Automated advice): Same as IG1, except the telephone contacts were provided using an automated phone system **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual; Face-to-face, phone, mail IG2: Individual; Face-to-face, automated phone system, mail **Duration (weeks) and Intensity (total min)** IG1&2: 12 months, 35 minutes + (15*12.5 minutes) = 222.5 minutes (estimate) **Provider type** IG1: Health educator IG2: Health educator and automated telephone-linked computer system	**Physical Activity:** Stanford 7-day physical activity recall (PAR); CHAMPS physical activity questionnaire for older adults; 7-day accelerometer (25.7% random subsample, n=56)	Mean (SD) at BL, Mean change (SD) at 6, 12 mo **BL** **6 mo** **12 mo** *PAR energy expenditure, moderate or vigorous intensity PA, kcal/kg/day* **IG1** 0.85(1.0) 0.84(1.3)* 0.79(1.5)* **IG2** 0.80(1.2) 0.73(1.6)* 0.76(1.8)* **CG** 0.95(1.3) 0.04(1.4) 0.26(1.5) *PAR moderate or vigorous intensity PA, minutes/week* **IG1** 99.7(147.6) 71.0(170.8)* 78.1(195.3)* **IG2** 78.4(113.3) 101.6(253.7)* 78.9(175.6) **CG** 92.2(126.7) 8.4(144.4) 26.2(151.6) *CHAMPS moderate or vigorous intensity PA, kcal/kg/day* **IG1** 1.5(1.8) 2.1(2.4)* 2.1(2.6)* **IG2** 1.4(1.5) 1.3(2.5)* 2.0(3.0)* **CG** 1.5(1.5) 0.5(2.6) 0.9(2.5) *CHAMPS moderate or vigorous intensity PA, minutes/week* **IG1** 166.1(210.9) 217.3(252.3)* 216.7(272.2)* **IG2** 154.0(164.0) 138.5(258.0)* 205.0(323.9)* **CG** 156.3(152.9) 44.5(248.3) 97.7(252.4) **IG1&2** 160.0(188.0) -- 211.1(297.0) **p<0.05 for differences between IG and CG* **IG1 n analyzed:** 66 **IG2 n analyzed:** 61 **CG n analyzed:** 62

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
King, 2007[55] **(CHAT)** Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	No PA-related cardiac events. No group differences in non-cardiac injuries (p>0.10). Of non-cardiac injuries, 31/141 experienced mild muscular fatigue, strain, or soreness during initial 3-4 months in IG1 and IG2.	**Degree of estimation required for MA:** 2

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Kinmonth, 2008[56] **Williams, 2004**[57] Fair	**Design:** RCT **Location:** UK **Setting:** General practice clinics **Volunteer:** No	**Inclusion:** Aged 30-50 years; parental history of type 2 diabetes without known diabetes **Exclusion:** Highly active; prescribed beta-blockers; unable to walk briskly across flat terrain for 15 minutes; lived farther than 30 minutes by car from the coordinating center; illness or social obligations that prevented participation	**N recruited or assessed for eligibilty:** 1521 **N eligible:** 434 **N randomized** Total: 365 IG1: 124 IG2: 120 CG: 121 **Followup (12-mo):** IG1(Phone): 107 (86.3% (calc)) IG2(In person): 103 (85.8% (calc)) CG: 111 (91.7% (calc)) **Cluster information:** Number of clusters: 331 Avg cluster size: 1.1 (calc) Inter-cluster correlation: NR Analysis controlled for clustering: Yes *Clustered in families*	**Age (mean):** 40.6 **Sex (% men):** 38 **Race/ethnicity:** Primarily white **SES:** % Owned their homes: 89 % Managerial or professional jobs: 55 **Obesity:** Mean BMI, kg/m^2: 27.8	**Dietary factors:** NR **Physical activity:** Increase PA

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Kinmonth, 2008[56] **Williams, 2004**[57] Fair	**Intervention description** CG: Received a leaflet by mail with brief motivational advice on PA benefits IG1 (telephone): Focused on goal-setting, action-planning, self-monitoring, using rewards, goal-review, using prompts, building support, and preventing relapses. 4 45-minute and 2 15-minute support calls in first 5 months, postal contact for subsequent 7 months; Received a leaflet by mail with brief motivational advice on PA benefits IG2 (home): Same focus as IG1. 2 1-hour home visits, 2 15-minute calls in first 5 months, monthly 30-minute calls for subsequent 7 months; Received a leaflet by mail with brief motivational advice on PA benefits **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual; phone, mail IG2: Individual; face-to-face, phone, mail **Duration (weeks) and Intensity (total min)** IG1: 12 months, 180+30=210 minutes IG2: 12 months 120+30+210=360 minutes **Provider type** IG1-2: "Facilitators," which were from "a range of health professions"	**Physical Activity:** Energy expenditure ratio (daytime energy expenditure/resting energy expenditure as measured by 3-day heart rate monitoring); VO_2 max from the EPIC-Norfolk Physical Activity Questionnaire	Mean (SD) **BL** **6 mo** **12 mo** *Energy expenditure ratio* **IG1** 1.83 (0.62) -- 1.95(0.72) **IG2** 1.91 (0.96) -- 1.94(0.58) **CG** 1.85 (0.54) -- 2.00(0.57) **Diff in change score (95%CI), IG1&2 vs. CG:** -0.04 (-0.16, 0.08) *VO_2 max* **IG1** 3.24 (1.00) -- 3.38(1.00) **IG2** 3.15 (0.91) -- 3.24(0.93) **CG** 3.16 (0.92) -- 3.17(0.93) **Diff in change score (95%CI), IG1&2 vs. CG:** 0.10 (-0.001, 0.21) *Total reported activity, MET hours/week* **IG1** 89.3(52.1) 104.2 (51.9) 105.2(51.8) **IG2** 87.4(47.2) 97.8 (47.9) 97.1(45.7) **CG** 84.4(55.7) 99.1 (56.9) 101.4(58.6) **Diff in change score (95%CI), IG1&2 vs. CG:** -0.23 (-9.68, 9.23) **IG1 n analyzed:** 107† **IG2 n analyzed:** 103 **CG n analyzed:** 111 *† For total reported activity, 324 participants were analyzed at BL and 12 mo and 301 at 6 mo (not provided by IG and CG). For the MA, assume n analyzed to be the same as evergy expenditure and VO2 max. Only IG1 was included in MA.*

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Kinmonth, 2008[56] **Williams, 2004**[57] Fair	Mean (SD) **Adiposity:** **BL 12-mo** *BMI, kg/m²* **IG1** 27.8 (5.2) 28.4 (5.4) **IG2** 27.7 (4.6) 27.7 (4.5) **CG** 27.8 (5.2) 27.8 (5.1) **Difference (95%CI)†:** -0.04 (-0.35, 0.27) *Waist circumference, cm* **IG1** 92.7 (13.4) 94.6 (13.9) **IG2** 92.4 (12.8) 93.6 (13.0) **CG** 93.0 (13.9) 93.8 (13.5) **Difference (95%CI)†:** -0.10 (-1.20, 1.00) **Blood pressure:** *Systolic Blood Pressure, mmHg* **IG1** 124.2 (13.0) 121.0 (14.1) **IG2** 122.6 (12.6) 119.6 (12.5) **CG** 122.6 (12.6) 119.2 (13.0) **Difference (95%CI)†:** -0.30 (-2.33, 1.74) *Diastolic Blood Pressure, mmHg* **IG1** 79.1 (10.6) 77.4 (11.4) **IG2** 77.9 (9.0) 76.2 (9.7) **CG** 78.2 (9.0) 75.1 (9.6) **Difference (95%CI)†:** 0.98 (-0.56, 2.53) **Lipids:** *Total Cholesterol, mmol/L* **IG1** 5.03 (0.95) 5.09 (1.00) **IG2** 5.13 (1.03) 5.36 (1.06) **CG** 5.29 (0.91) 5.31 (0.90) **Difference (95%CI)†:** 0.09 (-0.05, 0.24)	NR	NR	**Degree of estimation required for MA:**3

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Kinmonth, 2008[56] **Williams, 2004**[57] Fair					

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Kinmonth, 2008[56] **Williams, 2004**[57] Fair			

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Kinmonth, 2008[56] **Williams, 2004**[57] Fair	*Triglycerides, mmol/L* **IG1** 1.35 (0.80) 1.31(0.84) **IG2** 1.23 (0.63) 1.29(0.77) **CG** 1.35 (0.82) 1.23(0.73) **Difference (95%CI)†:** 0.09 (-0.03, 0.21) *LDL, mmol/L* **IG1** 3.05 (0.85) 3.15(0.86) **IG2** 3.14 (0.99) 3.33(1.00) **CG** 3.22 (0.85) 3.27(0.89) **Difference (95%CI)†:** 0.10 (-0.03, 0.23) *HDL, mmol/L* **IG1** 1.40 (0.37) 1.37 (0.35) **IG2** 1.46 (0.41) 1.46 (0.38) **CG** 1.46 (0.41) 1.48 (0.44) **Difference (95%CI)†:** -0.04(-0.09, 0.02) **Glucose tolerance:** *Plasma glucose, mmol/L* IG1 4.80 (0.51) 4.94 (0.51) IG2 4.84 (0.54) 4.88 (0.54) CG 4.89 (0.57) 4.88 (0.52) **Difference (95%CI)†:** 0.06 (-0.03, 0.15) *† Difference in change score, IG1 and IG2 combined versus CG* **Total n analyzed:** 327 (BMI),330 (SBP, waist circumference), 331 (DBP), 324 (triglycerides), 328 (LDL), 329 (HDL, total cholesterol), 322 (glucose) *For MA (assumed):* **IG1 n analyzed:** 107 **IG2 n analyzed:** 103 **CG n analyzed:** 111			

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Kolt, 2007[58] Good	**Design:** RCT **Location:** New Zealand **Setting:** Primary care **Volunteer:** No	**Inclusion:** Aged 65 and older; in practice database; participated in less than 30 minutes of activity on 5 or more days per week for 6 months or longer; no unstable major health problems (e.g., unstable heart condition, respiratory conditions) contraindicating increased PA; not moving in the next 12 months; sufficient English to participate in phone counseling **Exclusion:** NR	**N recruited or assessed for eligibilty:** 831 **N agreed to participate:** 333 **N eligible:** 186 **N randomized** Total: 186 IG: 93 CG: 93 **Followup (12-mo):** IG: 83 (89.2%) CG: 82 (88.2%) **Cluster information:** NA	**Age (mean):** 74.2 (calc) **Sex (% men):** 34 (calc) **Race/ethnicity:** NR **SES:** % University or other post-high school qualification: 44 (calc) **Obesity:** NR	**Dietary factors:** None **Physical activity:** Increase all forms of physical activity

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Kolt, 2007[58] Good	**Intervention description** CG: No intervention IG: 8 personallized TTM-based phone counseling sessions where the participant set PA goals with the counselor, walking log, mailed materials to support counseling **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; phone, mail **Duration (weeks) and Intensity (total min)** IG: 12 weeks, 10-16 minutes/call. Total minutes = 8*13 = 104 minutes **Provider type** IG: Exercise counselor	**Physical Activity:** Auckland Heart Study Physical Activity Questionnaire (AHSPAQ)	Adjusted Mean(SD)* **BL** **6 mo** **12 mo** *Total leisure activity, minutes/week* **IG** 165.5 (220.4) 199.1 (221.2) 244.0(365.7) **CG** 121.0 (172.6) 119.2 (147.7) 117.3(138.8) Time*group p=0.05 *Moderate leisure activity, minutes/week* **IG** 108.6 (163.8) 153.9 (203.4) 197.7 (323.4) **CG** 88.6 (168.2) 97.4 (149.6) 83.3 (129.9) Time*group p=0.007 *Walking leisure activty, minutes/week* **IG** 72.4 (85.3) 88.6 (88.1) 91.4 (91.9) **CG** 59.2 (74.6) 63.9 (83.0) 63.7 (87.7) Time*group p=0.68 N (percent) *150+ minutes of moderate or vigorous PA/week, percent* **IG** 24 (28.9) -- 35 (42.2) **CG** 21 (25.6) -- 19 (23.2) **OR (95%CI):** 2.90 (1.33,6.32), p=0.007 * *Adjusted for age, sex, clinic, and baseline value* **IG n analyzed:** 83 **CG n analyzed:** 82

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Kolt, 2007[58] Good	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	N (percent) **BL** **12 mo** *Falls in previous 12 mo* **IG** 12 (12.9) 9 (10.8) **CG** 11 (11.8) 12 (14.6) NS	**Degree of estimation required for MA:** 0

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Lawton, 2008[59] **(Women's Lifestyle Study)** Good	**Design:** RCT **Location:** New Zealand **Setting:** Primary care **Volunteer:** No	**Inclusion:** Women aged 40-74 years; physically inactive **Exclusion:** Medical condition contraindicating increased PA	**N recruited or assessed for eligibilty:** 5913 **N assessed for eligibility:** 2357 **N eligible:** NR **N randomized** Total: 1089 IG: 544 CG: 545 **Followup (12, 24-mo):** *12 mo* IG: 501 (92.1%) CG: 507 (93.0%) *24 mo* IG: 487 (89.5%) CG: 487 (89.4%) **Cluster information:** NA	**Age (mean):** 58.9 (calc) **Sex (% men):** 0 **Race/ethnicity:** % European: 78 (calc) **SES:** % Lower SES: 15 **Obesity:** Mean BMI: 29.2	**Dietary factors:** None **Physical activity:** 30 minutes of moderate or vigorous PA on 5 days or more per week

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Lawton, 2008[59] **(Women's Lifestyle Study)** Good	**Intervention description** CG: Usual care from PCP IG: 7-13 minute motivation interview; "green prescription" given to participant recommending moderate intensity brisk walking or equivalent at a duration and frequency suitable for the individual; avg of 5 15-minute calls to provide support; 30-minute followup visit to monitor progress and provide additional support **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; face-to-face, phone **Duration (weeks) and Intensity (total min)** IG: 9 months, 10 minutes + 75 minutes + 30 minutes = 115 minutes **Provider type** IG: Primary care nurse, exercise facilitator	**Physical Activity**: New Zealand physical activity questionnaire long form (NZPAQ-LF)	Median (IQR) **BL** **12 mo** **24 mo** *Physical Activity, minutes/week* **IG** 30 (0-90) 120 (0-210) 105 (0-205) **CG** 30 (0-90) 75 (0-170) 90 (0-190) p=0.01 (data was log transformed) N (percent) *150+ minutes of PA/week, percent* **IG** 56 (10.3) 233 (42.8) 214 (39.3) **CG** 62 (11.4) 165 (30.3) 179 (32.8) p≤0.001 **IG n analyzed:** 544 **CG n analyzed:** 545 *For MA:* Mean (SD) *Physical Activity, minutes/week* IG 30 (121.5) 120 (283.5) -- CG 30 (121.5) 75 (229.5) --

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Lawton, 2008[59] **(Women's Lifestyle Study)** Good	Mean (SE)* **Adiposity:** **BL 12 mo 24 mo** *Weight, kg* **IG** 73.2 (0.6) 72.6 (0.6) 72.6 (0.6) **CG** 72.7 (0.6) 72.7 (0.6) 72.5 (0.6) *Waist circumference, cm* **IG** 86.7(0.6) 87.3 (0.5) 88.7 (0.6) **CG** 86.2(0.6) 87.3 (0.5) 88.7 (0.6) **Blood pressure:** *Systolic Blood Pressure, mmHg* **IG** 122.8 (0.7) 120.6 (0.7) 119.1 (0.7) **CG** 123.4 (0.8) 121.9 (0.7) 119.5 (0.7) *Diastolic Blood Pressure, mmHg* **IG** 73.8 (0.4) 71.5 (0.4) 71.6 (0.4) **CG** 74.7 (0.4) 72.4 (0.4) 71.7 (0.4) **Lipids:** *Total Cholesterol, mmol/L* **IG** 6.10 (0.05) 5.86 (0.04) 5.65 (0.04) **CG** 6.03 (0.05) 5.83 (0.04) 5.59 (0.04) *HDL, mmol/L* **IG** 1.65 (0.02) 1.73 (0.02) 1.66 (0.02) **CG** 1.63 (0.02) 1.71 (0.02) 1.66 (0.02) **Glucose tolerance:** *Glucose, mmol/L* **IG** 5.02 (0.03) 4.97 (0.03) 4.92 (0.03) **CG** 4.96 (0.02) 4.96 (0.03) 4.87 (0.02) *All NS*	NR	**BL 12 mo 24 mo** *Falls, percent* **IG** 25 32 37 **CG** 29 25 29 p<0.001 *Injuries, percent* **IG** 14 18 19 **CG** 19 17 14 p=0.03 (ns available if needed)	**Degree of estimation required for MA:** 3 for minutes/week, 1 for intermediate outcomes

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Lawton, 2008[59] **(Women's Lifestyle Study)** Good					

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Lawton, 2008[59] **(Women's Lifestyle Study)** Good			

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Lawton, 2008[59] **(Women's Lifestyle Study)** Good	** Adjusted for repeated measures and baseline values* **IG n analyzed:** 544 **CG n analyzed:** 545 *For MA:* SD *Weight, kg* **IG** 14.0 14.0 -- **CG** 14.0 14.0 -- *Systolic Blood Pressure, mmHg* **IG** 16.3 6.3 -- **CG** 18.7 16.3 -- *Diastolic Blood Pressure, mmHg* **IG** 9.3 9.3 -- **CG** 9.3 9.3 -- *Total Cholesterol, mmol/L* **IG** 1.17 0.93 -- **CG** 1.17 0.93 -- *HDL, mmol/L* **IG** 0.47 0.47 -- **CG** 0.47 0.47 --			

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Marcus, 2007[60] **(STRIDE)** Fair	**Design:** RCT **Location:** US **Setting:** Home/phone or mail **Volunteer:** Yes	**Inclusion:** Aged 18-65 years; healthy; participating in 90 minutes or less of moderate or vigorous PA per week **Exclusion:** BMI>35; asthma, emphysema; chronic bronchitis, hypertension, heart disease, abnormal electrocardiogram, stroke, medication that might impair PA performance (e.g., beta blockers), chronic infectious disease, significant musculoskeletal problems, or any other condition that contraindicates PA; pregnancy or plan to attempt pregnancy; self-report more than 3 alcoholic drinks/day; hospitalized for psychiatric disorder in past 6 months; currently suicidal, bipolar, or psychotic	**N recruited or assessed for eligibilty:**1700 **N eligible:** 837 **N refused:** 598 **N randomized** Total: 239 IG1(phone): 80 IG2(mail): 81 CG: 78 **Followup (12-mo):** IG1(phone): 70 (87.5%) IG2(mail): 66 (81.5%) CG: 69 (88.5%) **Cluster information:** NA	**Age (mean):** 44.5 (calc) **Sex (% men):** 18 (calc) **Race/ethnicity:** % Caucasian: 86 (calc) **SES:** % College graduate (or postgrad work): 70 (calc) **Obesity:** Mean BMI: 28.5 (calc)	**Dietary factors:** None **Physical activity:** To meet or exceed at least 5 days per week for a total of 30 minutes each

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Marcus, 2007[60] **(STRIDE)** Fair	**Intervention description** CG: Mailed general health information pamphlets (e.g., stress management, cancer prevention, health nutrition, back health) on same scheule as IGs received PA information; offered IG after 1 year IG1(phone): Individually-tailored messages; stage-targeted booklets; PA tip sheets over 14 phone contacts, average length of calls 13.0 minutes IG2(mail): Individually-tailored messages; stage-targeted booklets; PA tip sheets over 14 mailings **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual; phone IG2: Individual; mail **Duration (weeks) and Intensity (total min)** IG1: 52 weeks, 14*13 minutes = 182 minutes IG2: 52 weeks, minutes NA **Provider type** IG1: Health educator IG2: Computer expert system	**Physical Activity**: Physical Activity Recall (PAR); VO_2 max at 85% of predicted maximal heart rate and treadmill duration (functional capacity)	Mean(SD) **BL** **6 mo** **12 mo** *PA, minutes/week* **IG1** 19.8 (26.6) 123.3 (97.6) 100.6 (119.7) **IG2** 20.2 (24.2) 129.5 (156.5) 162.4 (165.2) **CG** 19.4 (24.5) 77.7 (101.8) 81.9 (127.1) 6-mo p=0.025(IG1,IG2>CG), 12-mo p=0.001(IG2>IG1,CG) *Exercise test, minutes* **IG1** 7.54 (3.85) 8.66 (4.01) 8.64 (4.14) **IG2** 7.96 (3.45) 8.81 (3.95) 8.70 (3.87) **CG** 7.65 (3.08) 8.37 (3.54) 8.16 (3.25) NS *VO2max, mL/kg/minute* **IG1** 25.32 (7.02) 27.13 (7.39) 27.17 (7.40) **IG2** 25.97 (6.38) 27.29 (7.34) 27.13 (6.85) **CG** 25.57 (5.62) 26.85 (6.45) 26.33 (5.85) NS *150+ min of PA/week, percent** **IG1** -- 42 21 **IG2** -- 40 49 **CG** -- 18 17 6-mo p<0.001(IG1,IG2>CG), 12-mo p<0.001(IG2>IG1,CG) OR (95%CI)† *150+ minutes of PA/week, IG v. CG* **IG1** -- 3.30 (1.66, 7.22) 1.50 (0.67, 3.33) **IG2** -- 2.95 (1.41, 6.19) 5.31 (2.47, 11.39) ** Estimated from figure* *† Unclear if adjusted* **IG1 n analyzed:** 80 **IG2 n analyzed:** 81 **CG n analyzed:** 78

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Marcus, 2007[60] **(STRIDE)** Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	Financial incentives for assessment completion **Degree of estimation required for MA:** 0

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Marshall, 2003[61] Fair	**Design:** RCT **Location:** Australia **Setting:** Mail, recruited from respondents to population-based survey **Volunteer:** No	**Inclusion:** Completed population-base survey 2 years prior to current study start; household member aged 40-60 years whose birthday occurred next **Exclusion:** In maintenance stage for PA in previous survey and current study survey	**N recruited or assessed for eligibilty:** 927 **N eligible:** NR **N randomized** Total: 462 IG: 227 CG:235 **Followup (6-mo):** IG: 175 (77.1%) CG: 181 (77.0%) **Cluster information:** NA	**Age (mean):** 49.0 (calc) **Sex (% men):** 42.4 (calc) **Race/ethnicity:** NR (95% English-speaking) **SES:** % ≥10 years education: 50.0 (calc) *Obesity:* Mean BMI, kg/m^2: 26.4 (calc)	**Dietary factors:** NR **Physical activity:** Meet ACSM guidelines for PA

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Marshall, 2003[61] Fair	**Intervention description** CG: No intervention IG: Mailed individualized, stage-targeted letter, booklets corresponding to participants stage of change and all later stages **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; mail **Duration (weeks) and Intensity (total min)** IG: Single mailing, minutes NA **Provider type** IG: NA	**Physical Activity:** 2-week physical activity recall questions	Mean (SD) **BL** **6 mo** *Total PA, hours/week (6 mo estimated from figure)* **IG** 3.0 (3.4) 3.3 (NR) **CG** 3.3 (4.1) 3.1 (NR) group*time p=0.03 (including 2-mo results) Percent *Meeting ACSM guideline, all participants, percent* **IG** 26 40 **CG** 28 31 **OR(95%CI):** 1.46 (0.98, 2.18) *Meeting ACSM guideline, subgroup inactive at baseline, percent* **IG** 0 31 **CG** 0 22 **OR (95%CI):** 1.59 (0.95, 2.67) *For MA:* Mean (SD) *Total PA, minutes/week* **IG** 180 (204) 198 (NR) **CG** 198 (246) 186 (NR) N *Meeting ACSM guideline* **IG** -- 91 **CG** -- 73 **IG n analyzed:** 227, 168 (inactive subgroup) **CG n analyzed:** 235, 168 (inactive subgroup)

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Marshall, 2003[61] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	**Degree of estimation required for MA:** 0

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Martinson, 2008[62] **Sherwood, 2008**[63] **Martinson, 2010**[76] **(Keep Active Minnesota)** Good	**Design:** RCT **Location:** Minnesota, US **Setting:** Phone and mail, recruited health plan enrollees **Volunteer:** Mixed	**Inclusion:** Aged 50-70 years; enrolled in health plan for at least 11 of past 12 months prior to screening; getting 30 minutes or more of moderate or vigorous PA at least 2 days per week for the past 4 weeks and had increased to this level of PA over the past year **Exclusion:** In same household as enrolled participant; Charlson comorbidity score >3; diagnoses of chronic heart disease, congestive heart failure, atrial or ventricular arrhythmias, cardiac arrest, or implantable defibrillator	**N recruited or assessed for eligibilty:** 6452 **N eligible:** 2098 **N randomized** Total: 1049 IG: 523 CG: 526 **Followup:** *6 mo* IG: 495 (94.6%) CG: 492 (93.5%) *12 mo* IG: 495 (95%) CG: 487 (93%) *24 mo* IG: 491 (94%) CG: 475 (90%) **Cluster information:** NA	**Age (mean):** 57.1 **Sex (% men):** 27.6 **Race/ethnicity:** % White: 94.0 % African American: 3.3 % American Indian: 0.2 % Asian: 0.9 % Hispanic/Latino: 1.8 **SES:** % 4-year degree or more: 66.7 **Obesity:** Mean (SE) BMI: 27.6 (0.17)	**Dietary factors:** NR **Physical activity:** Maintain recent PA increases

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Martinson, 2008[62] **Sherwood, 2008**[63] **Martinson, 2010**[76] **(Keep Active Minnesota)** Good	**Intervention description** CG: Usual care; information about 10,000 steps PA program offered by healthplan, 4 newsletters focused on general health and wellness over 2 years IG: Strategies focused on maintenance. 1 face-to-face group orientation; workbook; weekly activity logs; pedometer; 7-session course (20 minutes/session) delivered via phone by activity coaches; monthly calls for 10 months after end of course, bimonthly called for subsequent year; lending library of PA materials, books, videos, and DVDs; 3 motivational contests; 4 in-person support sessions with outside speakers over 24-months. (Outcomes are only reported at 6 months, before full intervention is completed) **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual, group; face-to-face, phone, mail **Duration (weeks) and Intensity (total min)** IG: 24 months, total minutes NR **Provider type** IG: Activity coach (Study staff for orientation)	**Physical Activity**: CHAMPS instrument	Mean(SE) **BL** **6 mo** *Total kcal/week* **IG** 4643 (109.2) 4549 (119.2)* **CG** 4781 (114.0) 4108 (121.9) *Moderate kcal/week* **IG** 2730 (83.4) 2680 (90.6)* **CG** 2898 (93.7) 2287 (92.0) Percent *Maintaining PA* **IG** -- 50.9* **CG** -- 36.3 *Moderate PA 5+ days/week* **IG** 21.4 33.5* **CG** 27.8 28.5 *Vigorous PA 3+ days/week* **IG** 36.7 47.3 **CG** 35.0 42.5 **BL** **12 mo** **24 mo** *All PA kcal/week, mean (SE)* **IG** 2822 (85) 4163 (99) 4309 (112)* **CG** 3998 (95) 3941 (94) 3904 (102) *Maintaining moderate and vigorous activity* **IG** -- 48.6* 50.1* **CG** -- 40.7 34.5 ** p<0.005 for group*time* **IG n analyzed:** 495 **CG n analyzed:** 491 *For MA:* SD *Total kcal/week* **IG** 2497 2652

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Martinson, 2008[62] **Sherwood, 2008**[63] **Martinson, 2010**[76] **(Keep Active Minnesota)** Good	Mean (SE) **Adiposity:** **BL** **6 mo** *BMI, kg/m²* **IG** 27.5 (0.23) 27.4 (0.24) **CG** 27.7 (0.24) 27.7 (0.25) Group*time p=.54 **IG n analyzed:** 495 **CG n analyzed:** 491 *For MA (calc):* SD *BMI, kg/m²* **IG** 5.3 5.3 **CG** 5.5 5.5 **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	**Degree of estimation required for MA:** 1

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Morey, 2009[64] **Morey, 2008**[65] **(Project LIFE)** Good	**Design:** RCT **Location:** North Carolina, US **Setting:** VA primary care **Volunteer:** No	**Inclusion:** Aged 70 years or older; followed at Durham VAMC; could walk 30 feet without human assistance; did not engage in regular PA **Exclusion:** Terminal diagnosis; condition contraindicating PA increase; dementia; severe hearing or visual loss	**N recruited or assessed for eligibilty:** 3995 **N eligible:** 2375 **N randomized** Total: 398 IG: 199 CG: 199 **Followup (6, 12-mo):** *6 mo* IG: 181 (91.0%) CG: 181 (91.0%) *12 mo* IG: 178 (89.4%) CG: 177 (88.9%) **Cluster information:** NA	**Age (mean):** 77.6 (calc) **Sex (% men):** 100 **Race/ethnicity:** % White: 77.4 (calc) **SES:** % College graduate or more: 26.9 (calc) **Obesity:** Mean BMI: 29.0 (calc)	**Dietary factors:** None **Physical activity:** Walk or perform lower extremity PA 30 minutes or more on 5 or more days/week and perform 15 minutes of lower extremity strength training 3 days each week

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Morey, 2009[64] **Morey, 2008**[65] **(Project LIFE)** Good	**Intervention description** CG: Usual care; Asked to continue normal activities and would be offered a short, 3-month version of the intervention at conclusion of study IG: Face-to-face visit with health counselor using protocol adapted from PACE project; NIA exercise workbook; Elastic bands of different resistances and poster with instructions; Pedometer; 13 counseling phone calls; Endorsement of LIFE program by PCP at visit closest to study enrollment; Individualized automated phone messages from PCP encouraging PA; Quarterly report mailed to participants including graph of minutes of PA over time **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; face-to-face, phone, mail **Duration (weeks) and Intensity (total min)** IG: 52; minutes NR **Provider type** IG: Lifestyle health counselor	**Physical Activity**: CHAMPS	Mean(SD) **BL 6 mo 12 mo** *Exercise frequency/week* **IG** 15.9 (9.4) 22.7 (9.9) 22.4 (12.0) **CG** 16.8 (9.8) 17.4 (10.0) 16.8 (9.2) p<0.001 *Endurance PA, minutes/week* **IG** 37.9 (82.8) 69.3 (85.7) 72.3 (114.8) **CG** 35.8 (88.4) 48.5 (100.1) 43.7 (97.1) p=0.002 *Strength PA, minutes/week* **IG** 18.5 (43.4) 58.4 (62.9) 54.9 (54.9) **CG** 23.2 (54.7) 24.7 (54.0) 25.4 (57.4) p<0.001 *2-minute walk, meters* **IG** 146.0 (36.3) 151.4 (39.1) 150.9 (38.5) **CG** 145.4 (32.8) 146.2 (34.3) 147.5 (34.7) p=0.08 **IG n analyzed:** 199 (BL), 181 (6 mo), 178 (12 mo) **CG n analyzed:** 199 (BL), 181 (6 mo), 177 (12 mo)

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Morey, 2009[64] **Morey, 2008**[65] **(Project LIFE)** Good	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	**Degree of estimation required for MA:** 0

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Napolitano, 2006[66] **Dutton, 2008**[67] Fair	**Design:** RCT **Location:** Massachusetts, US **Setting:** Mail **Volunteer:** Yes	**Inclusion:** Female; not participating in more than 90 minutes of purposeful moderate-intensity or 60 minutes or more of vigorous-intensity PA per week **Exclusion:** Medical problems that could potentially impede or be exacerbated by PA (e.g, asthma, severe osteoarthritis, cardiovascular disease)	**N recruited or assessed for eligibilty:** 660 **N eligible:** NR **N randomized** Total: 280 IG1(CTM): 93 IG2(Jumpstart): 95 CG: 92 **Followup (12-mo):** Overall: 260 (92.9%) **Cluster information:** NA	**Age (mean):** 47.1 **Sex (% men):** 0 **Race/ethnicity:** % White: 94.6 %Hispanic/ Portuguese/ Cape Verdean: 28.0 **SES:** % College grad or higher: 54.5 (calc) % Income > $60,000: 50.7 (calc) **Obesity:** Mean (SD) BMI: 28.7 (5.2)	**Dietary factors:** None **Physical activity:** Increase PA

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Napolitano, 2006[66] **Dutton, 2008**[67] Fair	**Intervention description** CG: 1 mailing of women's health information (e.g. sleep, cancer prevention, nutrition) IG1: 1 mailing of AHA CTM booklet that covers 12-week PA program targeting women and a letter describing how to utilize materials IG2: 65-item questionnaire used to tailor feedback. Tailored feedback letters from expert system computer software and stage-matched booklets at BL, 1, 3, and 6 months and a letter explaining how to utilize materials, all by mail **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1-2: Individual; Mail **Duration (weeks) and Intensity (total min)** IG1: 1-time mailing IG2: 26 weeks (4 mailings), minutes NA **Provider type** IG1: NA IG2: Expert computer system	**Physical Activity:** 7-day physical activity recall (PAR)	Mean (SD) at BL, Mean (SE) at 12 mo **BL** **12 mo** *Total PA, minutes/week* **IG1** 50.7 (79.4) 154.5 (19.5) **IG2** 48.6 (141.2) 148.9 (19.1) **CG** 33.6 (51.2) 139.5 (19.6) NS *For MA:* Mean (SD) *Total PA, minutes/week* **IG1** 50.7 (79.4) 154.5 (188.1) **IG2** 48.6 (141.2) 148.9 (186.2) **CG** 33.6 (51.2) 139.5 (188.0) **IG1&2** 49.6 (114.6) 151.7 (186.7) **IG1 n analyzed:** 93 **IG2 n analyzed:** 95 **CG n analyzed:** 92

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Napolitano, 2006[66] **Dutton, 2008**[67] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	**Degree of estimation required for MA:** 2

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Norris, 2000[68] Fair	**Design:** RCT **Location:** Washington, US **Setting:** Primary care **Volunteer:** No	**Inclusion:** Aged 30 years or older; scheduled well-visit appointment with PCP **Exclusion:** Significant cognitive impairment; non-English speaking; pregnant; cardiovascular, respiratory, or metabolic disease; significant lower extremity musculoskeletal impairment; terminal illness	**N recruited or assessed for eligibilty** 34 PCPs, 1920 patients **N eligible:** NR **N randomized** Total: 847 IG: 384 CG: 463 **Followup (6-mo):** IG: 362 (94%) CG: 460 (99%) **Cluster information:** Number of clusters: 34 Avg cluster size: NR Inter-cluster correlation: NR Analysis controlled for clustering: Yes	**Age (mean):** 54.9 (calc) **Sex (% men):** 48 (calc) **Race/ethnicity:** % White: 91 (calc) **SES:** % Some college: 82 (calc) **Obesity:** NR	**Dietary factors:** None **Physical activity:** Individually tailored PA goals

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Norris, 2000[68] Fair	**Intervention description** CG: Usual care IG: PCP-delivered TTM-based PACE protocol, including goal-setting, identifying barriers, problem-solving, contracting, exercise prescription, addressing barriers and benefits of PA, self-efficacy, and social support. Followup phone counseling at 4-weeks by research assistant. A subset received 2, 3, and 4-month booster calls and 4 postcard reminders **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; face-to-face, phone, postcards (for subset) **Duration (weeks) and Intensity (total min)** IG: NR **Provider type** IG: PCP	**Physical Activity:** PACE; PASE, selected subscales; Paffenbarger's physical activity index; total time spent walking; total PA in minutes/week	Mean (SD) **BL** **6 mo** *Paffenbarger PA Index, kcal/week* **IG** 1571.9(2422.1) 2108.1 **CG** 1681.2(2470.3) 2047.6 *PASE leisure score (range 0-130)* **IG** 19.0(28.5) 25.4 **CG** 20.2(27.7) 24.7 *Total PA, minutes/week* **IG** 240.0(336.4) 331.1† **CG** 272.2(352.4) 330.7† *Total walking time, minutes/week* **IG** 148.1(206.5) 186.9 **CG** 163.1(232.2) 201.8 *PACE score (range 1-11)* **IG** 5.2(2.7) 6.2* **CG** 5.5(2.7) 5.7 *Active (per PACE), percent* **IG** 46.1 65.5 **CG** 49.8 60.4 **OR:** 1.65, p=0.08 ** p=0.0004* *† Followup SD is estimated to be same as baseline SD* **IG n analyzed:** 384 (BL), 362 (6 mo) **CG n analyzed:** 463 (BL), 460 (6 mo) *For MA:* N *Active (per PACE)* **IG** 177 237 **CG** 231 278

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Norris, 2000[68] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	**Degree of estimation required for MA:** 3

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Pekmezi, 2009[75] Fair	**Design:** RCT **Location:** Rhode Island, US **Setting:** Mailings **Volunteer:** Yes	**Inclusion:** Spanish-speaking women aged 18-65 years; self-identified as Latina/Hispanic and underactive (participating in moderate or vigorous physical activity ≤2 days/week for ≤30 minutes each) **Exclusion:** Any serious medical condition that would make physical activity unsafe (history of coronary heart disease, diabetes, stroke, osteoarthritis, osteoporosis, orthopedic problems); current or planned pregnancy; BMI >40; consuming ≥3 alcoholic drinks/day on ≥5 days/week; current suicidal ideation or psychosis; current clinical depression; hospitalization due to a psychiatric disorder in the past 3 years; taking medication that may impair physical activity tolerance or performance (e.g. β blockers)	**N recruited or assessed for eligibilty:** 315 **N eligible:** NR **N randomized** Total: 93 IG: 45 CG: 48 **Followup (6-mo):** IG: 37 (82.2%) (calc) CG: 41 (85.4%) (calc) **Cluster information:** NA	**Age (mean):** 41.37 **Sex (% men):** 0 **Race/ethnicity:** Latina/Hispanic: 100% **SES:** *% Education level* ≤High school: 48 Some college/technical school: 28 ≥College graduate: 24 (calc) *% Yearly household income** <$10,000: 24 $10,000-19,999.99: 35 $20,000-29,999.99: 23 $30,000-39,999.99: 8 ≥$40,000: 11 **Obesity:** *% BMI* ≥30: 47 25-29.9: 32 18.5-24.9: 20 ** 1 participant refused to answer*	**Dietary factors:** None **Physical activity:** Increase physical activity level

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Pekmezi, 2009[75] Fair	**Intervention description** CG: Mailed health information on nutrition and other factors associated with CVD other than physical activity; at same intervals as IG IG: Culturally- and linguistically-adapted physical activity manuals matched to current level of motivational readiness and individually tailored computer expert-system feedback reports; stages of process change and self-efficacy measures administered and used for tailoring mailings; received pedometers, physical activity logs, and tip-sheets **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual mailings **Duration (weeks) and Intensity (total min)** IG: 26 weeks, 6 monthly mailings, time NA **Provider type** IG: NA (expert system)	**Physical Activity:** 7-Day Physical Activity Recall (PAR)	Mean (SD) **BL** **6 mo** *Moderate or vigorous intensity PA, minutes/week* **IG** 16.56 (25.76) 147.27 (241.55) **CG** 11.88 (21.99) 96.79 (118.49) p=0.25 **IG n analyzed:** 45 **CG n analyzed:** 48

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Pekmezi, 2009[75] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	**Degree of estimation required for MA:**

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Pinto, 2005[69] **(PAL2)** Fair	**Design:** RCT **Location:** Rhode Island, US **Setting:** Primary care **Volunteer:** No	**Inclusion:** Age 60 years or older; 60 minutes or less per week of moderate-vigorous PA; able to live independently; fully ambulatory; presenting for a nonurgent PC appointment; able to read and write English or Spanish **Exclusion:** NR	**N recruited or assessed for eligibilty:** 264 **N eligible:** 148 **N randomized** Total: 100 IG: 52 CG: 48 **Followup (6-mo):** IG: 46 (88.5%) CG: 44 (91.7%) **Cluster information:** NA	**Age (mean):** 68.5 **Sex (% men):** 36.4 **Race/ethnicity:** % White: 85.3 **SES:** % Some college or more: 57.9 **Obesity:** Mean (SD) BMI: 29.2(5.28)	**Dietary factors:** None **Physical activity:** PA meeting ACSM recommendations

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Pinto, 2005[69] **(PAL2)** Fair	**Intervention description** CG: Brief advice by clinician (3-5 minutes) IG: Brief advice by clinician (3-5 minutes); 3 30-45 minute face-to-face counseling sessions with health educator; PA prescription tailored to participant's readiness; 12 10-15 minute PA counseling phone calls; 12 PA tip sheets by mail **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; face-to-face, phone, mail **Duration (weeks) and Intensity (total min)** IG: 26 weeks, 4 + (3*37.5) + (12*12.5) = 266.5 minutes **Provider type** IG: Health educator	**Physical Activity:** PAR, accelerometer	Mean (SD), Mean (SE) 6-mo change* **BL** **6 mo change** *Moderate intensity PA, minutes/week* **IG** 38.1 (64.8) 62.8 (12.1) **CG** 45.3 (74.6) 16.6 (12.8) p<0.05 *Total kcal/day* **IG** 32.2 (0.9) -0.84 (0.71) **CG** 32.1 (1.1) -0.08 (0.75) NS *Accelerometer mean counts (weight adjusted)* **IG** 245.6(116.9) 42.4(16.3) **CG** 277.4(139.3) -24.2(16.9) p<0.01 *For MA:* Mean change (SD) *Moderate intensity PA, minutes/week* **IG** -- 62.8 (84.7) **CG** -- 16.6 (84.9) ** Article says Mean (SD) are reported for 6-mo change also, but believe this is an error, as the SDs would be extremely small and inconsistent with other results in the article* **IG n analyzed:** 49 **CG n analyzed:** 44

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Pinto, 2005[69] **(PAL2)** Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	Participants received incentives for completing assessment and for attending second in-person counseling appointment. Clinicians compensated for providing brief advice. **Degree of estimation required for MA:** 0

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Stensel, 1994[70] Fair	**Design:** RCT **Location:** UK **Setting:** University **Volunteer:** Yes	**Inclusion:** Male; aged 42-59 years; sedentary **Exclusion:** NR	**N recruited or assessed for eligibilty:** NR **N eligible:** NR **N randomized** Total: 72 IG: 48 CG: 24 **Followup (6, 12-mo):** IG: 42 (87.5%) CG: 23 (95.8%) **Cluster information:** NA	**Age (mean):** 50.7(calc) **Sex (% men):** 100 **Race/ethnicity:** NR **SES:** Majority skilled non-manual occupational class **Obesity:** Mean weight: 78.7 kg	**Dietary factors:** None **Physical activity:** Increase PA to reach goal of brisk walking 40-45 minutes daily

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Stensel, 1994[70] Fair	**Intervention description** CG: Asked to maintain their habitual lifestyle IG: Given walking targets of 20-25 minutes/day in first 3 months, 40-45 minutes/day by 6 months; details of meetings NR **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: NR **Duration (weeks) and Intensity (total min)** IG: NR **Provider type** IG: NR	**Physical Activity:** Walking speed, VO_2 at a blood lactate concentration of 2 mmol/l, walking diaries	Mean (SE) **BL 6 mo 12 mo** *VO_2, mL/kg/minute at 2.0 mmol/L lactate concentration* **IG** 21.5(0.7) 24.7(0.7) 22.9(0.7)* **CG** 20.3(0.6) 20.4(0.9) 18.8(0.8) ** p<0.05 for comparison between IG and CG over time* **IG n analyzed:** 24 **CG n analyzed:** 18 *For MA:* SD *VO2, mL/kg/minute at 2.0 mmol/L lactate concentration* **IG** 4.8 -- 4.5 **CG** 2.9 -- 3.8

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Stensel, 1994[70] Fair	Mean(SE) **Adiposity:** **BL** **6 mo** **12 mo** *BMI, kg/m*^{2} **IG** 25.4(0.4) 25.4(0.4) 25.4(0.4) **CG** 24.8(0.7) 25.1(0.7) 25.0(0.7) NS *% Body fat* **IG** 28.7(0.8) -- 27.6(0.7) **CG** 29.5(1.5) -- 29.3(1.5) NS **IG n analyzed:** 42 **CG n analyzed:** 23 *For MA (calc):* SD *BMI, kg/m*^{2} IG 2.8 -- 2.6 CG 3.4 -- 3.4 **Blood pressure:** NR	NR	NR	**Degree of estimation required for MA:** 1

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Stewart, 2001[71] **(CHAMPS II)** Fair	**Design:** RCT **Location:** State NR, US **Setting:** HMO/Group practice enrollees **Volunteer:** No	**Inclusion:** Medicare enrollee in study HMO/practice; sedentary or underactive (<3 20-minute sessions/week for the past 3 months); no serious medical condition that could limit PA participation (unstable angina, uncontrolled hyptertension, type I diabetes mellitus, diagnosed or hospitalized for chest pain, heart attack, or heart surgery in past 6 months); no severe functional limitations due to multiple medical or psychiatric diseases; not planning on moving from the area within 2 years; English-speaking and cognitively intact; not a CHAMPS I participant; living in community near the group practice **Exclusion:** Other member of household enrolled in study	**N recruited or assessed for eligibilty:** 1381 **Directly contacted:** 1134 **Eligible for Survey:** 1053 **Responded:** 893 **N eligible:** 524 (calc) **N randomized** Total: 173 IG: 85 CG: 88 **Followup (12-mo):** IG: 81 (95.3%) CG: 83 (94.3%) **Cluster information:** NA	**Age (mean):** 74.5 **Sex (% men):** 34.1 (calc) **Race/ethnicity:** % Minority: 8.5 **SES:** % College degree or more: 56.1 **Obesity:** NR *Note: Baseline characteristics are for sample present at 12 months*	**Dietary factors:** NR **Physical activity:** Goal 30 minutes or more of moderate-intensity PA most or all days of the week; also encouraged a balanced program (endurance, strength, flexibility, balance, and coordination)

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Stewart, 2001[71] **(CHAMPS II)** Fair	**Intervention description** CG: Wait list, program offered after one year IG: Group informational meeting; individual planning session included discussion of participant's readiness to increase PA, general safety, disease-specific precautions, and PA options and preferences; 10 monthly group workshops, for those not able to attend, information was provided by phone and handouts were mailed; PA diaries; phone calls from counselor; monthly newsletters; functional fitness assessments; 2 booklets ("Pep Up Your Life" and "Exercise and Your Heart") **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual, group; face-to-face, phone, mail **Duration (weeks) and Intensity (total min)** IG: Duration NR, intensity NR **Provider type** IG: Program staff	**Physical Activity:** CHAMPS Physical Activity Questionnaire for Older Adults	Mean (SD) **BL** **12-mo** *Moderate-intensity PA, kcal/week* **IG** 1052 (NR) 1539 (NR)* **CG** 1185 (NR) 1190 (NR) *All PA, kcal/week* **IG** 1935 (NR) 2622 (NR)* **CG** 2057 (NR) 2048 (NR) ** p=0.003 from F-test* **IG n analyzed:** 81 **CG n analyzed:** 83

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Stewart, 2001[71] **(CHAMPS II)** Fair	**Adiposity:** (Self-report only; BMI reduction of 0.496 for IG, p=0.001) **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR by group	NR	40% of sample hypertension 16% "cardiovascular problems" 65% arthritis or joint problems **Degree of estimation required for MA:** NA, not included in MA

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Yates, 2009[72] **Yates, 2008**[73] **(PREPARE)** Fair	**Design:** RCT **Location:** UK **Setting:** NR (recruited from lists of on-going diabetes screening programs) **Volunteer:** No	**Inclusion:** Overweight or obese (BMI ≥ 25, or BMI ≥ 23 for South Asians); screen-detected impaired glucose tolerance **Exclusion:** Taking steroids; diagnosed diabetes	**N recruited or assessed for eligibilty:** NR **N eligible:** 326 **N randomized** Total: 103 IG1(PREPARE): 31 IG2(PREPARE+): 33 CG: 34 **Followup (12-mo):** IG1: 28 (90.3%) IG2: 29 (87.9%) CG: 26 (76.5%) **Cluster information:** NA	**Age (Mean):** 65 **Sex (% men):** 66 **Race/ethnicity:** % White: 75 % African American: 1 % South Asian: 24 **SES:** NR **Obesity:** Mean (SD) BMI: 29.2 (4.7)	**Dietary factors:** NR **Physical activity:** Increase PA, emphasis on walking 30 minutes/day

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Yates, 2009[72] **Yates, 2008**[73] **(PREPARE)** Fair	**Intervention description** CG: Brief information sheet on IGT, including how PA can be used to treat/control IGT IG1: 3-hour group session covering info about IGT (including diet) and promoting exercise, PA diary, 2 10-minute followup sessions at 3- and 6-months IG2: Same as IG1 and given a pedometer **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1&2: Group, individual; face-to-face **Duration (weeks) and Intensity (total min)** IG1&2: 6 months, 180 + 20 = 200 minutes **Provider type** IG1&2: Trained educators	**Physical Activity:** Sealed pedometer, IPAQ	Median (IQR) at BL, Mean change (95% CI) at 6 and 12 mo **BL** **6 mo** **12 mo** *Total moderate or vigorous PA, MET minutes/week* **IG1** 2359 (947,3989) 1533 (-254,3320) 1459 (327,2571) **IG2** 3480 (1524,6339) 3830 (1637,6024) 1589 (48,3130) **CG** 2335 (923,3921) 340 (-1048,1729) -1377 (-2852,98) **IG1 Diff from CG** 928(-2008,3242) 2364(513,4214)* **IG2 Diff from CG** 3557(1126,5987)* 1150(428,1872)* **IG1 n analyzed:** 29 (BL), 24 (6 mo), 23 (12 mo) **IG2 n analyzed:** 29 (BL), 28 (6 mo), 27 (12 mo) **CG n analyzed:** 29 (BL), 25 (6 mo), 26 (12 mo) *Total walking, MET minutes/week* **IG1** 891(297,2079) 154(-582,889) 421(-224,1067) **IG2** 1386 (594,2772) 1083(517,1649) 708(72,1344) **CG** 801 (292,2161) 123(-619,864) -361(-849,127) **IG1 Diff from CG** -23 (-889,842) 764(14,1515)* **IG2 Diff from CG** 1031 (206,1755)* 1150(428,1872)* **IG1 n analyzed:** 29 (BL), 24 (6 mo), 23 (12 mo) **IG2 n analyzed:** 29 (BL), 28 (6 mo), 27 (12 mo) **CG n analyzed:** 29 (BL), 24 (6 mo), 26 (12 mo)

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Yates, 2009[72] **Yates, 2008**[73] **(PREPARE)** Fair	Mean (SD) at BL, Mean change (95% CI) at 6 and 12 mo **Adiposity:** **BL** **6 mo** **12 mo** *Weight, kg* **IG1** 81.9(14.2) -0.16(-1.29,0.98) -0.54(-1.86,0.878) **IG2** 79.4(16.4) -0.61(-1.84,0.61) 0.49(-0.91,1.89) **CG** 81.1(15.0) -0.45(-1.28,0.38) -0.67(-1.93,0.60) **Adjusted diff in change from CG at12 mo:** IG1 p=0.894; IG2 p=0.207 **IG1 n analyzed:** 29 (BL, 6, 12 mo) **IG2 n analyzed:** 29 (BL, 6, 12 mo) **CG n analyzed:** 29 (BL, 6, 12 mo) **Blood pressure:** *Systolic blood pressure, mmHg* **IG1** 144(17) 0.5(-4.8, 5.8) -2.5(-8.5,3.4) **IG2** 139(15) -3.3(-10.0,3.3) -0.4(-5.3,4.4) **CG** 141(15) -2.6(-6.7,1.4) -3.5(-8.6,1.6) **Adjusted diff in change from CG at 12 mo:** IG1 p=0.437; IG2 p=0.263 **IG1 n analyzed:** 29 (BL, 6, 12 mo) **IG2 n analyzed:** 29 (BL, 6, 12 mo) **CG n analyzed:** 29 (BL, 6, 12 mo)	NR	NR	**Degree of estimation required for MA:** 2

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Yates, 2009[72] **Yates, 2008**[73] **(PREPARE)** Fair					

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Yates, 2009[72] **Yates, 2008**[73] **(PREPARE)** Fair			*Ambulatory activity (steps/day)* **IG1** 6560 (4424) 870 (-54,1793) 549 (-290,1390) **IG2** 6600 (2402) 2039 (944,3242) 1039 (135,1943) **CG** 6873 (3537) -152 (-778,573) -940 (-1574,-307) **IG1 Diff from CG** 968(-297,2234) 1401(417,2385)* **IG1 Diff from CG** 2207(989,3426)* 1902(954,2859)* **IG1 n analyzed:** 29 (BL), 25 (6, 12 mo) **IG2 n analyzed:** 29 (BL, 6, 12 mo) **CG n analyzed:** 29 (BL), 28 (6, 12 mo) ** p<0.05* *For MA (calc):* Mean change (SD) *Total moderate or vigorous PA, MET minutes/week* **IG1** -- -- 1459 (3029) **IG2** -- -- 1589 (4234) **CG** -- -- -1377 (3837) **IG1&2** -- -- 1491(3347)

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Yates, 2009[72] **Yates, 2008**[73] **(PREPARE)** Fair	**Lipids:** *Total cholesterol, mmol/L* **IG1** 4.8(1.0) 0.06(-0.21,0.34) -0.02(-0.18,0.22) **IG2** 4.7(1.1) -0.26(-0.47,-0.06) -0.04(-0.34,0.25) **CG** 4.7(0.9) 0.04(-0.25,0.33) 0.11(-0.19,0.42) **Difference†:** IG1 p=0.647; IG2 p=0.347 Mean (95% CI) at BL, Mean change (95% CI) at 6 and 12 mo *HDL, mmol/L* **IG1** 1.3(1.1,1.5) -0.08(-0.18,0.03) -0.00(-0.07,0.06) **IG2** 1.2(1.1,1.4) -0.08(-0.14,-0.02) -0.03(-0.13,0.02) **CG** 1.3(1.1,1.5) -0.04(-0.10,0.02) 0.02(-0.04,0.08) **Difference†:** IG1 p=0.634; IG2 p=0.927 Mean (SD) at BL, Mean change (95% CI) at 6 and 12 mo *Triglycerides, mmol/L* **IG1** 1.3(0.9, 1.7) 0.23(-0.01,0.47) 0.08(-0.17,0.34) **IG2** 1.4(0.8, 1.9) -0.02(-0.19,0.15) 0.03(-0.18,0.23) **CG** 1.2(1.0, 1.7) 0.11(-0.08,0.30) 0.04(-0.13,0.21) **Difference†:** IG1 p=0.945; IG2 p=0.822 **IG1 n analyzed:** 29 (BL, 6, 12 mo) **IG2 n analyzed:** 29 (BL, 6, 12 mo) **CG n analyzed:** 29 (BL, 6, 12 mo) **Glucose tolerance:** *2-hour glucose, mmol/L* **IG1** 8.1(1.8) 0.09(-0.58,0.75) 0.19(-0.41,0.80) **IG2** 8.8(2.2) -1.40(-2.26,-0.54) -1.75(-2.57,-0.94) **CG** 8.4(2.1) -0.58(-1.23,0.06) -0.30(-1.40,0.45) **Difference†:** IG1 p=0.450; IG2 p=0.004			

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim
Yates, 2009[72] **Yates, 2008**[73] **(PREPARE)** Fair					

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)	PA Behavioral Outcomes (include baseline values)
Yates, 2009[72] **Yates, 2008**[73] **(PREPARE)** Fair			

Appendix C Table 1. Physical Activity Counseling Evidence Table

Study Reference Quality Rating	Intermediate Outcomes (include baseline values)	Health Outcomes	Adverse Effects	Comment
Yates, 2009[72] **Yates, 2008**[73] **(PREPARE)** Fair	**IG1 n analyzed:** 29 (BL, 6, 12 mo) **IG2 n analyzed:** 29 (BL, 6, 12 mo) **CG n analyzed:** 29 (BL, 6, 12 mo) *Fasting glucose, mmol/l* **IG1** 5.6(0.6) -0.19(-0.33,-0.05) -0.03(-0.18,0.12) **IG2** 5.6(0.5) -0.35(-0.57,-0.13) -0.20(-0.40,-0.01) **CG** 5.7(0.5) -0.08(-0.30,0.15) 0.10(-0.15,0.34) **Difference†:** IG1 p=0.336; IG2 p=0.028 **IG1 n analyzed:** 29 (BL, 6, 12 mo) **IG2 n analyzed:** 29 (BL), 28 (6, 12 mo) **CG n analyzed:** 29 (BL, 6, 12 mo) *† Adjusted difference in change from CG at 12 mo* *For MA (calc):* SD 12 mo *Weight, kg* **IG1** -- -- 3.76 **IG2** -- -- 3.85 **CG** -- -- 3.48 *Systolic blood pressure, mmHg* **IG1** -- -- 16.4 **IG2** -- -- 13.3 **CG** -- -- 14.0 *Total cholesterol, mmol/L* **IG1** -- -- 0.55 **IG2** -- -- 0.81 **CG** -- -- 0.84			

Appendix C Table 1. Physical Activity Counseling Evidence Table

5 A's – assessment, advice, agreement, assistance, arrangements; ACSM – American College of Sports Medicine; AHA – American Heart Association; avg – average; BL – baseline; BMI – body mass index; calc – calculated; CCT – cluster controlled trial; CDCP – Centers for Disease Control and Prevention; CHAMPS – Community Healthy Activities Model Program for Seniors; CG – control group; CHAT – Community Health Advice by Telephone; CI – confidence interval; cm – centimeters; comb – combined; CONSORT – Consolidated Standards of Reporting Trials; CTM – Choose to Move; D – diet; DBP – diastolic blood pressure; DE – diet and exercise; diff – difference; E – exercise; e.g. – exempli gratia; EPIC – European Prospective Investigation into Cancer and Nutrition; GP – general practitioner; grad – graduate; HD – healthy diet; HDL – high-density lipoprotein; HMO – health maintenance organization; IG – intervention group; IGT – impaired glucose tolerance; indiv – individual; IPAQ – International Physical Activity Questionnaire; IQR – interquartile range; kcal – kilocalorie; kg – kilogram; kg/m^2 – kilograms per meter squared; LDL – low-density lipoprotein; LIFE – Learning to Improve Fitness and Function in Elders; MA – meta-analysis; MET – metabolic equivalent; MI – myocardial infarction; mo – month; n – number; max – maximum; min – minute; mL – milliliter; mmHG – millimeters of mercury; mmol/L – millimoles per liter; NA – not applicable; NIA – National Institute on Aging; NR – not reported; NS – not significant; p – p value; PA – physical activity; PACE – Physician-based Assessment and Counseling for Exercise; PAL – Physically Active for Life; PAR – physical activity recall; PASE – Physical Activity Scale for the Elderly; PC – primary care; PCP – primary care practitioner; postgrad – postgraduate; PREPARE – Pre-diabetes Risk Education and Physical Activity Recommendation and Encouragement; RCT – randomized controlled trial; RM – reference manager; SD – standard deviation; SE – standard error; SES – socioeconomic status; SBP – systolic blood pressure; TTM – trans-theoretical model; UK – United Kingdom; US – United States; v – versus; VA – Veterans Affairs; VAMC – Veterans Affairs Medical Center; vs – versus

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Anderson, 1992[77] Fair	**Design:** RCT **Location:** Kentucky, US **Setting:** Location NR for 10 educational seminars and consultations with dietitian. Dietitians also made 4 home visits during the year **Volunteer:** Yes	**Inclusion:** Serum cholesterol 5.18-7.76 mmol/L and serum triglyceride <5.65 mmol/L after a 12 hour fast on 2 screenings 2 weeks apart; free of types III and IV hyperlipoproteinemia; no hsitory of lipid-modifying diets; aged 30-50 years; between 80-120% of ideal body weight **Exclusion:** Types III and IV hyperlipoproteinemia; history of lipid-modifying diets; hypertension (BP >160/90); DM (FPG>140); known coronary; renal; COPD; malignant, or other potentially life-shortening diseases; persons taking steroid, hormones, or cholesterol medications	**N recruited or assessed for eligibilty:** 3401 **N eligible:** 199 **N randomized:** Total: 177 IG1 (AHA): NR IG2 (HCF): NR CG: NR **Followup (12 mo):** Total: 146 (82.5%) IG1 (AHA): 47 (% NR) IG2 (HCF): 48 (% NR) CG: 51 (% NR) **Cluster information:** NA	**Age (mean):** 40.55 (calc) **Sex (% men):** 59.6 (calc) **Race/ethnicity:** % White: 100 **SES :** Mean years of education: 16.39 (calc) **Obesity:** NR	**Dietary factors:** Low-fat and low-fat + high fiber diets, based on AHA Phase II guidelines **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Anderson, 1992[77] Fair	**Intervention description** IG1 (AHA): 55% carb, 20% protein, 25% fat, ≤200 mg dietary cholesterol/day, approx 15g dietary fiber/day. General daily guidelines of 3 servings each of fruits and vegetables; 4 servings of bread or non-starch foods; 2 low-fat dairy items; ≤198.45g lean meat, poultry, or seafood; no egg yolk; and fat servings based on energy content. Optional patterns including a serving of sweets and alcohol were also available. Directed not to change body weight IG2 (HCF): Same as above, but 50g dietary fiber/day; additional 1+ serving of beans and 1+ serving of cereal chosen from the HCF exchange groups. The use of soluble-fiber-rich cereals such as oat bran were encouraged CG: Directed to maintain current dietary habits **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1 (AHA) and IG2 (HCF): Phase I: Weekly group educational seminars, weekly consultation with a partner (spouse or friend), and 1 individual home visit, all face-to-face; Phase II: Individual home visits at 4, 8, and 12 months CG: NR **Duration (weeks) and Intensity (total min)** IG1 (AHA) and IG2 (HCF): Phase I: 10 weeks, ~900 total minutes (educational seminars one hour per week for 10 weeks (600 mins), consultation 30 minutes per week for 10 weeks (300 mins), one indiv home visit duration NR; Phase II: 42 weeks, minutes NR CG: NR **Provider type** IG1 (AHA) and IG2 (HCF): Same "instructor" for both groups' educatio seminars, dietitians for consultations and home visits CG: NR	**Dietary:** 3-day food-consumption diaries completed on 2 weekdays and 1 adjacent weekend day. Foods-on-hand survey to validate 3-day diaries. **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes					PA Behavioral Outcomes
Anderson, 1992[77] Fair	Mean (SE)					NR
		BL	**4 mo**	**8 mo**	**12 mo**	**Change**
	Energy, kJ					
	IG (AHA)	8221 (824)	7196 (306)	7288 (289)	7878 (318)	-343 (280)
	IG (HCF)	8678 (335)	8188 (356)	8234 (399)	8523 (314)	-155 (331)
	CG	9109 (393)	--	--	8414 (310)	-695 (364)
	p-value	NS	0.037	0.037	NS	NS
	Carbohydrate, percent					
	IG (AHA)	48 (1.3)	54 (1.2)	52 (1.2)	53 (1.3)	4.5 (1.2)**
	IG (HCF)	50 (0.9)	55 (1.0)	55 (1.0)	55 (1.0)*	5.3 (1.1)**
	CG	48 (1.3)	--	--	50 (1.1)	1.4 (1.3)
	p-value	NS	NS	0.048	0.004	NS
	Fat, percent					
	IG (AHA)	35 (1.0)	27 (1.1)	29 (1.0)	30 (1.1)	-5.0 (1.0)**
	IG (HCF)	33 (0.9)	27 (0.9)	26 (0.9)	27 (0.9)**	-5.6 (1.2)**
	CG	33 (1.0)	--	--	31 (0.8)**	-2.0 (1.1)†
	p-value	NS	NS	NS	0.022	0.040
	Saturated fatty acid, percent					
	IG (AHA)	11 (0.5)	8 (0.4)	9 (0.4)	9 (0.4)	-2.0 (0.4)**
	IG (HCF)	11 (0.4)	8 (0.4)	8 (0.6)	8 (0.4)	-3.0 (0.5)**
	CG	11 (0.5)	--	--	10 (0.4)†	-1.0 (0.5)†
	p-value	NS	NS	NS	0.001	0.013
	Monounsaturated fatty acid, percent					
	IG (AHA)	12 (0.5)	10 (0.5)	10 (0.4)	11 (0.5)	-2.0 (0.5)**
	IG (HCF)	12 (0.4)	9 (0.4)	10 (0.6)	10 (0.4)	-2.0 (0.5)**
	CG	11 (0.4)	--	--	11 (0.5)	0.0 (0.5)†
	p-value	NS	NS	NS	NS	0.025
	Polyunsaturated fatty acid, percent					
	IG (AHA)	8 (0.4)	7 (0.4)	8 (0.5)	8 (0.4)	0.0 (0.5)
	IG (HCF)	8 (0.3)	7 (0.4)	7 (0.4)	7 (0.3)	-1.0 (0.4)**
	CG	7 (0.4)	--	--	7 (0.4)	0.0 (0.4)
	p-value	NS	NS	NS	NS	NS

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Anderson, 1992[77] Fair	**Adiposity:** Mean (SD) weight (kg) **BL** / **12 mo** / **Change** **IG (AHA)** 72.04 (8.69) -- -1.06 (2.49) **IG (HCF)** 71.08 (12.7) -- -1.02 (3.54) **CG** 71.44 (9.91) -- -0.44 (2.68) **p-value** NS -- -- **Blood pressure:** NR **Lipids:** Mean (SE) *Total Cholesterol, mmol/L* **IG (AHA)** 6.09 (0.07) 5.50 (0.09) -0.59 (0.09)* **IG (HCF)** 6.09 (0.08) 5.30 (0.10) -0.79 (0.09)** **CG** 5.92 (0.07) 5.50 (0.09) -0.42 (0.08)* **p-value** NS NS 0.009 *LDL cholesterol, mmol/L* **IG (AHA)** 4.13 (0.08) 3.57 (0.09) -0.56 (0.08)* **IG (HCF)** 4.19 (0.08) 3.44 (0.09) -0.75 (0.08)** **CG** 4.00 (0.07) 3.60 (0.08) -0.40 (0.06)* **p-value** NS NS 0.005 *HDL cholesterol, mmol/L* **IG (AHA)** 1.32 (0.04) 1.33 (0.04) 0.01 (0.02) **IG (HCF)** 1.27 (0.05) 1.23 (0.05) -0.04 (0.02) **CG** 1.20 (0.04) 1.21 (0.04) 0.01 (0.02) **p-value** NS NS NS *Log triglyeride* **IG (AHA)** 0.25 (0.1) 0.19 (0.1) -0.05 (0.1) **IG (HCF)** 0.22 (0.1) 0.17 (0.1) -0.06 (0.1) **CG** 0.36 (0.1) 0.30 (0.1) -0.06 (0.1) **p-value** NS NS NS	NR	No other adverse effects reported	**Incentives:** NR **Other:** HTN, DM definitions have changed since 1987 trial recruitment other lipid measures (apolipoprotein A, B)

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Anderson, 1992[77] Fair					

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Anderson, 1992[77] Fair		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes					PA Behavioral Outcomes
Anderson, 1992[77] Fair	*Protein, percent*					
	IG (AHA)	16 (0.5)	18 (0.6)	18 (0.5)	17 (0.5)	1.0 (0.5)
	IG (HCF)	17 (0.5)	18 (0.5)	18 (0.5)	18 (0.5)	0.6 (0.6)
	CG	16 (0.5)	--	--	18 (0.6)	1.2 (0.7)
	p-value	NS	NS	NS	NS	NS
	Dietary cholesterol, mg					
	IG (AHA)	247 (18)	166 (13)	160 (10)	178 (12)	-69 (18)**
	IG (HCF)	261 (18)	169 (10)	188 (13)	194 (14)	-67 (18)**
	CG	267 (21)	--	--	219 (13)	-48 (18)**
	p-value	NS	NS	NS	NS	NS
	Total fiber, g					
	IG (AHA)	17 (1.1)	20 (1.1)	19 (0.9)	20 (1.3)	3.0 (1.3)**
	IG (HCF)	19 (1.6)	27 (2.7)	26 (2.0)	25 (1.6)‡§	5.6 (1.9)** *
	CG	17 (1.4)	--	--	17 (1.3)	0.1 (1.4)
	p-value	NS	0.003	0.002	0.001	0.040
	Soluble fiber, g					
	IG (AHA)	5 (0.3)	6 (0.4)	6 (0.3)	6 (0.5)	1.5 (0.5)**
	IG (HCF)	6 (0.5)	9 (0.8)	9 (0.7)	9 (0.6)‡	3.0 (0.6)**‡§
	CG	5 (0.4)	--	--	5 (0.5)	0.5 (0.5)
	p-value	NS	0.000	0.001	0.001	0.004
	IG (AHA) n analyzed: 47 (BL, 4, 8, 12 mo) **IG (HCF) n analyzed:** 48 (BL, 4, 8, 12 mo) **CG n analyzed:** 51 (BL, 4, 8, 12 mo) *Significantly different from CG, p<0.05 **Significantly different from BL, p<0.05 †Significantly different from both IGs, p<0.05 ‡Significantly different from CG, p<0.01 §Significantly different from AHA, p<0.05					

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Anderson, 1992[77] Fair	*Significantly different from BL, p<0.05 **Significantly different from BL and from CG, p<0.05 **Glucose tolerance:** NR **IG (AHA) n analyzed:** 47 (BL, 4, 8, 12 mo) **IG (HCF) n analyzed:** 48 (BL, 4, 8, 12 mo) **CG n analyzed:** 51 (BL, 4, 8, 12 mo)			

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Baron, 1990[78] Fair	**Design:** RCT **Location:** UK **Setting:** Group general practice **Volunteer**: No	**Inclusion:** Aged 25-60 years **Exclusion:** Severe psychosis; debilitating chronic illness; chronic gastrointestinal disease; being treated for hyperlipidaemia or symptomatic coronary artery disease	**N recruited or assessed for eligibilty:** 507 **N eligible:** 437 **N randomized** Total: 368 IG: 187 (calc) CG: 181 (calc) **Followup (3, 12 mo):** *3 mo* IG: 180 (96.2%) (calc) CG: 178 (98.3%) (calc) *12 mo* IG: 167 (89.3%) (calc) CG: 168 (92.8%) (calc) **Cluster information:** NA	**Age (mean):** 41.7 (calc) **Sex (% men):** 51.4 (calc) **Race/ethnicity:** NR **SES:** % in social class 1 or 2 (professional, managerial and technical): 34.1 **Obesity:** Mean BMI: 24.5 (calc)	**Dietary factors:** Decreased fat and increased fiber **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Baron, 1990[78] Fair	**Intervention description** CG: Were told they were part of a nutrition survey and followed up on same schedule but without dietary advice IG1: Instruction regarding optimal body weight and diet. Decrease in total fat intake from an expected level >40% of calories to 30-35% of calories, with an increase in the ratio of polyunsaturated to saturated fats to approximately 0.4 from an expected level of <0.3. Also stressed the value of increased dietary fiber, including soluble fiber. Booklet given which summarized basics of the diet, provided recipes, and offered advice concerning local restaurants Also received encouragement and advice at followup visits **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individually or small groups, face-to-face **Duration (weeks) and Intensity (total min)** IG1: 12 weeks total, visits at BL, 1, and 3 months. First visit was 30 minutes, intensity of the other two visits NR **Provider type** IG1: Nurse associated with the practice	**Dietary:** Self-administered questionnaire developed by Gear and colleagues with a food frequency format **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Baron, 1990[78] Fair	**Reported efforts at dietary change*** Percent **BL 3 mo 12 mo** *Increased intake of fiber* Men **IG** -- 67 52 **CG** -- 1 3 Women **IG** -- 70 42 **CG** -- 2 3 *Decreased intake of fat* Men **IG** -- 76 55 **CG** -- 1 5 Women **IG** -- 80 38 **CG** -- 1 0 *Increased polyunsaturated fat* Men **IG** -- 29 22 **CG** -- 1 1 Women **IG** -- 53 30 **CG** -- 0 1 * Differences between treatment groups were all statistically significant, p<0.001 **IG n analyzed (Men):** 93 (3 mo); 83 (12 mo) **IG n analyed (Women):** 86 (3 mo); 81 (12 mo) **CG n analyzed (Men):** 91 (3 mo); 86 (12 mo) **CG n analyed (Women):** 87 (3 mo); 79 (12 mo)	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Baron, 1990[78] Fair	**Blood pressure:** NR **Lipids:** Mean (SE) **BL 3 mo 12 mo** *Fasting plasma total cholesterol, mM* Men **IG** 4.92 (0.08) 4.73 (0.08) 4.52 (0.08) **CG** 4.81 (0.08) 4.92 (0.09) 4.50 (0.08) Women **IG** 4.79 (0.09) 4.73 (0.10) 4.80 (0.11) **CG** 4.88 (0.10) 4.75 (0.11) 4.84 (0.11) *Fasting plasma LDL cholesterol, mM* Men **IG** 2.96 (0.08) 2.57 (0.08) 2.36 (0.07) **CG** 2.87 (0.09) 2.83 (0.08)* 2.31 (0.08) Women **IG** 2.70 (0.09) 2.70 (0.09) 2.71 (0.09) **CG** 2.76 (0.10) 2.79 (0.11) 2.73 (0.10) *Fasting plasma HDL cholesterol, mM* Men **IG** 1.33 (0.03) 1.29 (0.03) 1.41 (0.03) **CG** 1.36 (0.03) 1.32 (0.02) 1.48 (0.03) Women **IG** 1.64 (0.04) 1.44 (0.05) 1.49 (0.03) **CG** 1.67 (0.04) 1.51 (0.04) 1.53 (0.03) *p<0.05 versus IG **IG n analyzed (Men):** 97 (BL, Total); 85 (BL, LDL); 88 (BL, HDL); 93 (3 mo, Total); 89 (3 mo, LDL); 92 (3 mo, HDL); 85 (12 mo, Total); 83 (12 mo, LDL); 84 (12 mo, HDL)	NR	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Baron, 1990[78] Fair					

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Baron, 1990[78] Fair		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Baron, 1990[78] Fair	**Reported dietary consumption** Mean (SE) **BL 3 mo 12 mo** *Dietary fiber, g/day* Men **IG** 20.4 (0.8) 27.8 (1.1) 22.8 (1.0) **CG** 19.3 (0.7) 21.1 (0.9) 20.1 (1.0) Women **IG** 18.9 (0.7) 24.8 (1.2) 21.4 (1.0) **CG** 16.4 (0.7) 15.7 (0.7) 15.4 (0.8) Percent **BL 3 mo 12 mo** *Using polyunsaturated fat for spreading* Men **IG** 6 70 58 **CG** 12 8* 15* Women **IG** 9 77 54 **CG** 11 12* 15* *Using polyunsaturated fat for fying* Men **IG** 14 78 66 **CG** 14 8* 14* Women **IG** 10 72 65 **CG** 11 8* 16*	

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Baron, 1990[78] Fair	**IG n analyzed (Women):** 89 (BL, Total); 84 (BL, LDL); 87 (BL, HDL); 87 (3 mo, Total); 77 (3 mo, LDL); 81 (3 mo, HDL); 82 (12 mo, Total); 81 (12 mo, LDL and HDL) **CG n analyzed (Men):** 92 (BL and 3 mo, Total); 80 (BL, LDL); 85 (BL, HDL); 81 (3 mo, LDL); 86 (3 mo, HDL); 86 (12 mo, Total and HDL); 85 (12 mo, LDL) **CG n analyzed (Women):** 89 (BL, Total); 87 (BL, LDL, HDL); 80 (12 mo, Total); 79 (12 mo, LDL and HDL) **Glucose tolerance:** NR **Weight:** NR			

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Baron, 1990[78] Fair					

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Baron, 1990[78] Fair		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Baron, 1990[78] Fair	*Using saturated fat for frying* Men **IG** 26 3 9 **CG** 23 19* 26* Women **IG** 20 5 7 **CG** 19 25* 14* *Using saturated fat for spreading* Men **IG** 41 3 6 **CG** 24 24* 23* Women **IG** 31 0 2 **CG** 36 43* 37* **p<0.05 versus IG* **IG n analyzed (Men):** 97 (BL); 93 (3 mo); 56 (12 mo, Dietary fiber); 83 (12 mo, PUF Spreading, SF Spreading); 77 (12 mo, PUF Frying, SF Frying) **IG n analyzed (Women):** 89 (BL, Dietary fiber); 90 (BL, remaining); 87 (3 mo); 65 (12 mo, Dietary fiber); 83 (12 mo, remaining) **CG n analyzed (Men):** 92 (BL); 91 (3 mo); 69 (12 mo, Dietary fiber); 87 (12 mo, PUF spreading, SF spreading); 85 (12 mo, PUF Frying, SF Frying) **CG n analyzed (Women):** 89 (BL); 85 (3 mo, Dietary fiber); 87 (3 mo, remaining); 68 (12 mo, Dietary fiber); 81 (12 mo, PUF spreading, SF spreading); 79 (12 mo, PUF Frying, SF Frying)	

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Baron, 1990[78] Fair				

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Beresford, 1997[79] Fair	**Design:** RCT **Location:** Washington, US **Setting:** Physician practice units of an HMO **Volunteer**: No	**Inclusion:** Had routine appointments with participating physicians **Exclusion:** Cognitive impairment; critically ill; unable to speak English; pregnant; likely to leave the area within the year	**N recruited or assessed for eligibilty:** 4778 **N eligible:** 3392 (calc) (determined eligibility after randomization) **N randomized** Total: 28 practices, 4778 ppts IG: 2351 CG: 2427 **Completed BL interviews:** Total: 2121 IG: 1010 CG: 1111 **Followup (3, 12mo):** 3 mo IG: 896 (88.7%) (calc) CG: 990 (89.1%) (calc) 12 mo IG: 859 (85.0%) (calc) CG: 959 (86.3%) (calc)	**Age (mean):** NR (24% of IG and 27% of CG were aged ≥65 years) **Sex (% men):** 32.0 (calc) **Race/ethnicity:** % White: 91.0 (calc) **SES:** % Some college education: 72.9 (calc) % Family income <$25,000/year: 28.0 (calc) **Obesity:** NR	**Dietary factors:** Low-fat, high-fiber **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Beresford, 1997[79] Fair	**Intervention description** CG: Usual care, no further detail IG1: Physician introduces self-help booklet, and endorses dietary change. Booklet had self-assessment for current dietary behavior, presented specific behavioral skills in an easy-to-follow format, organized around meals, for each eating pattern displayed small and large changes, included self-assessment questionnaires and sections for recording short- and long-term goals, and sections on eating out, shipping, and social activities. Reminder letter mailed from physician 2 weeks later **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Physician introduced booklet individually, ppts followed self-help booklet individually **Duration (weeks) and Intensity (total min)** IG1: 3 minutes in physician office, followup for 1 year **Provider type** IG1: Physician, self-help	**Dietary:** Modified version of the Food Frequency Questionnaire, modified version of a fat- and fiber-related behavior questionnaire **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Beresford, 1997[79] Fair	Mean (SE) at BL, Mean change/effect (95% CI) at 3, 12 mo **BL** **3 mo** **12 mo** *Fat, percent energy* **IG** 37.6 (0.3) -1.52 (-1.98, -1.06) -1.54 (-1.88, -1.19) **CG** 37.5 (0.3) -0.48 (-0.91, -0.05) -0.34 (-0.66, -0.01) **Intervention Effect** -- -1.04 (-1.67, -0.41)** -1.20 (-1.68, -0.73)** *Fiber, g/1000 kcal* **IG** 10 (0.1) 0.50 (0.14, 0.86) 0.55 (0.27, 0.83) **CG** 10 (0.1) 0.36 (0.02, 0.70) 0.22 (-0.03, 0.49) **Intervention Effect** -- 0.14 (-0.35, 0.64) 0.32 (-0.06, 0.70) *Fat Score* **IG** 1.95 (0.006) -0.085 (-0.105, -0.065) -0.084 (-0.105, -0.063) **CG** 1.95 (0.006) -0.039 (-0.058, -0.020) -0.040 (-0.059, -0.020) **Intervention Effect** -- -0.046 (-0.074, -0.018)** -0.044 (-0.073, -0.016) *Fiber Score* **IG** 1.85 (0.01) 0.062 (0.039, 0.085) 0.046 (0.028, 0.064) **CG** 1.85 (0.01) 0.024 (0.003, 0.046) 0.011 (-0.007, 0.028) **Intervention Effect** -- 0.038 (0.006, 0.069)* 0.036 (0.011, 0.061)* ** *p<0.01* **IG n analyzed:** 859 **CG n analyzed:** 959	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Beresford, 1997[79] Fair	**Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR **Weight:** NR	NR	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Beresford, 1997[79] Fair			**Cluster information:** Number of clusters: 28 Avg cluster size: 75 Inter-cluster correlation: NR Analysis Adjusted for Clustering: Y		
Bernstein, 2002[80] Fair	**Design:** RCT **Location:** Massachusetts, US **Setting:** Home **Volunteer**: Yes	**Inclusion:** Aged ≥70 years; community-dwelling within the greater Boston area; ambulatory (able to stand or walk for 6 minutes with or without assistive devices); sedentary, 2+ deficits on the physical function subscale of the MOS; and score ≤10 on the Short Physical Performance Battery Assessment **Exclusion:** Acute, uncontrolled, or terminal illness; moderate to severe cognitive impairment; limb amputation; joint replacement within 6 months prior to BL; any other feature in the history or physical examination that would have made the proposed nutrition or exercise program inappropriate as determined by the study physician	**N recruited or assessed for eligibilty:** NR **N eligible:** NR **N randomized** Total: 70 IG: 38 CG: 32 **Followup (6 mo):** IG: 100(%) CG: 100(%) **Cluster information:** NA	**Age (mean):** 77.90 (calc) **Sex (% men):** 20 (calc) **Race/ethnicity:** % White: 97.2 (calc) **SES:** NR **Obesity:** Mean BMI: 28.48	**Dietary factors:** Increase fruits and vegetables to ≥5 svgs/day and calcium-rich foods to ≥3 svgs/day **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Beresford, 1997[79] Fair		
Bernstein, 2002[80] Fair	**Intervention description** CG: Home-based exercise program designed to improve strength and balance, duration and intensity to match IG IG1: Home-based in-depth, personalized education program which included home visits, phone calls, letters, and a book. Topics included good nutrition at any age, health benefits of eating more fruits and vegetables, importance of calcium-rich foods and risk factors for osteoporosis, what constitutes a serving, grocery shopping tips, etc. Behavior-modification techniques such as goal setting, rewards, food log recording, role-playing games, and trouble-shooting were included in the home visit sessions **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual home visits, phone calls, letters, and a book **Duration (weeks) and Intensity (total min)** IG1: 8 home visits, bi-weekly calls, and monthly letters over 6 months. **Provider type** IG1: NR	**Dietary:** Food Frequency Questionnaire **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Beresford, 1997[79] Fair		
Bernstein, 2002[80] Fair	Mean (SD) at BL and 6 mo, 6 mo mean (SE) change **BL** **6 mo** **6 mo change** *Energy, kcal* **IG** 1620 (527) 1838 (525) 218 (64.9) **CG** 1708 (476) 1739 (525) 31 (79.0) *Protein, g* **IG** 66 (22) 77 (22) 11 (3.24) **CG** 67 (22) 69 (20) 2 (2.83) *Fat, g* **IG** 56 (24) 61 (26) 5 (2.92) **CG** 61 (23) 60 (25) -0.8 (4.03) *Carbohydrate, g* **IG** 217 (67) 252 (62) 35 (9.25) **CG** 225 (62) 236 (71) 11 (11.3) *Fiber, g* **IG** 17 (6) 21 (5) 4 (0.81) **CG** 18 (7) 20 (7) 2 (0.71) *Fructose* **IG** 22 (8) 29 (9) 7 (1.30) **CG** 23 (11) 25 (10) 2 (1.77)** *Cholesterol, mg* **IG** 203 (98) 220 (94) 17 (14.2) **CG** 200 (89) 198 (86) -2 (15.2) *Breads, servings/day* **IG** 3.0 (1.4) 3.2 (1.4) 0.2 (0.23) **CG** 3.2 (0.9) 3.5 (1.3) 0.3 (0.23)	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Beresford, 1997[79] Fair				
Bernstein, 2002[80] Fair	**Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR **Weight:** N/A (reported but CG is exercise group therefore will only look at behavioral outcomes)	NR	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Bernstein, 2002[80] Fair					

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Bernstein, 2002[80] Fair		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Bernstein, 2002[80] Fair	*Fruit, servings/day* **IG** 2.8 (1.8) 3.9 (1.4) 1.1 (0.21) **CG** 3.0 (1.3) 3.3 (1.5) 0.1 (0.19)** *Vegetables, servings/day* **IG** 2.3 (0.8)* 3.4 (1.2) 1.1 (0.19) **CG** 2.8 (1.2) 2.9 (1.5) 0.1 (0.18)** *Milk/Dairy, servings/day* **IG** 3.0 (1.28) 3.9 (1.69) 0.9 (0.21) **CG** 3.1 (1.8) 3.1 (1.67) 0.0 (0.19)** *Meats, servings/day* **IG** 1.4 (0.7) 1.4 (0.6) 0.0 (0.01) **CG** 1.4 (0.6) 1.4 (0.5) 0.1 (0.09) *Fats/Sweets, servings/day* **IG** 3.1 (2.0) 2.7 (1.7) -0.3 (0.23) **CG** 3.2 (1.9) 2.8 (1.7) -0.4 (0.32) *Significant difference between IG and CG ** p-value < 0.05 for between group change; adjusted for age, sex, and BMI **IG n analyzed:** 38 **CG n analyzed:** 32	

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Bernstein, 2002[80] Fair				

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Brekke, 2005[81] Fair	**Design:** RCT **Location:** Sweden **Setting:** NR **Volunteer**: Yes	**Inclusion:** Aged between 25 and 55 years; 2 first-degree relatives or 1 first-degree and at least 2 second-degree relatives with type 2 diabetes; normal liver function tests, electrolytes, and hemoglobin; no history of endocrine or cardiovascular diseases **Exclusion:** Fasting blood glucose ≥ 6.1mmol/l or 2-h blood glucose ≥ 11.1 mmol/l; BMI > 35 kg/m^2 and presence of any disease or use of medications affecting glucose or lipid metabolism	**N recruited or assessed for eligibilty:** 100 **N eligible:** NR **N randomized** Total: 77 IG1 (Diet): 25 IG2 (Diet+Exer): 30 CG: 22 **Followup (12 mo):** IG1: 24/25 (96%) IG2: 25/30 (83.3%) CG: 19/22 (86.4%) **Cluster information:** NA	**Age (mean):** 42.6 (calc) **Sex (% men):** 63 **Race/ethnicity:** NR **SES:** NR **Obesity:** Mean BMI: 25.7 (calc) *Note: Baseline characteristics from participants that completed 1 year of the study*	**Dietary factors:** Reduce saturated fat intake; increase monounsaturated fat and n-3 fatty acids; increase vegetable, fruit, and fiber intake; decrease high-glycemic index foods **Physical activity:** Exercise 30 minutes, 4-5 times/week

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Brekke, 2005[81] Fair	**Intervention description** CG: Wait-list for 12 months IG1 (Diet): Two dietary education sessions addressing general dietary advice, food examples, meal patterns and meal frequency; phone calls to assess adherence to dietary advice IG2 (Diet + Exercise): Same as diet only group, but also discussed benefits of physical activity particularly on glucose metabolism. Strategies for increasing physical activity were discussed and personal strategies were planned. **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Group, individual; face-to-face, phone IG2: Group, individual; face-to-face, phone **Duration (weeks) and Intensity (total min)** IG1: Education sessions-2 weeks for 4 hours total; Mean of 8 phone interviews during first 4 mo, then every 10 weeks for remaining 8 mo-time NR IG2: Same as IG1 **Provider type** IG1: Dietician IG2: Dietician for diet, NR for physical activity	**Dietary:** FFQ based on the format used in the Northern Sweden Health and Disease Cohort **Physical Activity:** Interview based on the Minnesota leisure time physical activity questionnaire

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Brekke, 2005[81] Fair	Mean (SD) at BL, Mean change (95% CI) at 12 mo **BL 12 mo** *Total energy intake, kcal* **IG1** 2547 (690) -505 (-758, -252) **CG** 2482 (740) -243 (-517, 30) *Protein, percent intake* **IG1** 15.2 (2.5) 1.3 (0.1, 2.4) **CG** 15.7 (2.4) -0.6 (-1.8, 0.6)* *Fat, percent intake* **IG1** 35.8 (5.4) -5.3 (-7.8, -2.7)* **CG** 34.7 (5.3) -0.5 (-3.7, 2.8) *Saturated fatty acids, percent intake* **IG1** 15.0 (3.6) -4.7 (-6.1, -3.3)* **CG** 14.1 (3.9) -0.6 (-2.3, 1.0) *Monounsaturated fatty acids, percent intake* **IG1** 13.0 (1.8) -1.4 (-2.6, -0.3) **CG** 12.6 (1.9) 0.4 (-1.0, 1.8) *Carbohydrate, percent intake* **IG1** 46.4 (4.9) 3.6 (1.0, 6.0) **CG** 47.3 (6.1) 0.3 (-3.1, 3.6) *Fiber, g/1000 kcal* **IG1** 9.3 (3.2) 3.5 (1.7, 5.4)* **CG** 9.7 (2.7) -0.5 (-1.6, 0.7) * p<0.05 **IG1 n analyzed:** 24 **CG n analyzed:** 19	See Brekke in Physical Activity Table

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Brekke, 2005[81] Fair	Mean (SD) at BL, Mean change (95%CI) at 12 mo **Adiposity:** *BMI, kg/m2* **BL** **12mo** **IG1** 25.0 (3.3) -0.15 (-0.5, 0.2) **CG** 26.1 (2.5) 0.22 (-0.39, 0.83) *Weight, kg* **IG1** 78.7 (12.6) -0.45(-1.6, 0.67) **CG** 78.0 (12.0) 0.52(-1.35, 2.39) **Blood pressure:** NR **Lipids:** **BL** **12mo** *Total cholesterol, mmol/L* **IG1** 4.84 (0.72) 0.10 (-0.15, 0.36) **CG** 5.03 (1.15) 0.24 (-0.02, 0.50) *HDL cholesterol, mmol/L* **IG1** 1.26 (0.27) 0.08 (-0.02, 0.19) **CG** 1.31 (0.27) -0.04 (-0.11, 0.03) *LDL cholesterol, mmol/L* **IG1** 3.06 (0.60) 0.01 (-0.24, 0.26) **CG** 3.23 (1.01) 0.28 (0.06, 0.50) *Triglycerides, mmol/L* **IG1** 1.16 (0.50) 0.03 (-0.14, 0.20) **CG** 1.10 (0.51) 0.01 (-0.10, 0.11) **Glucose tolerance:** **BL** **12mo** *Fasting blood glucose, mmol/L* **IG1** 4.69 (1.03) -0.33 (-0.54, 0.11) **CG** 5.04 (1.41) -0.21 (-0.44, 0.02)	NR	No other adverse effects reported	**Incentives:** NR **Other:** Only use 12 mo outcomes since CG offered intervention in 12-24 mo

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Carpenter, 2004[82] Fair	**Design:** RCT **Location:** Texas, US **Setting:** Research institute and at home **Volunteer:** No	**Inclusion:** Planning to stay in the local area for the duration of the study; able to attend weekly meetings; in the precontemplation, contemplation, or preparation stage for at least 2 of the 4 dietary goals of: 1) reducing fat, 2) increasing whole grains, 3) increasing dairy products or calcium-rich foods, and 4) increasing fruits and vegetables **Exclusion:** History of heart attack or stroke within the previous 3 months; diabetes at any time; eating a special diet for medical reasons; family member enrolled in other Cooper Institute studies	**N recruited or assessed for eligibilty:** 292 **N eligible:** 98 **N randomized** Total: 98 IG (Weekly Meeting (WM)): 30 IG (Correspondence (CR)): 33 CG: 35 **Followup (6 mo):** IG(WM): 93.3 (%) IG(CR): 97.0 (%) CG: 94.3 (%) **Cluster information:** NA	**Age (mean):** 49.6 (calc) **Sex (% men):** 35.7 (calc) **Race/ethnicity:** % White: 86.7 (calc) % African American: 8.2 (calc) % Hispanic: 2.0 (calc) % Other: 3.1 (calc) **SES:** Years of education (calc): % ≤12: 11.2 % 12-16: 53.1 % >16: 29.6 **Obesity:** NR	**Dietary factors:** Decrease fats and increase whole grains, dairy products, and other calcium-rich foods, and fruits and vegetables **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Carpenter, 2004[82] Fair	**Intervention description** CG: Usual care, received a copy of The American Dietetic Association's Complete Food & Nutrition Guide IG1 (WM): Received a copy of The American Dietetic Association's Complete Food & Nutrition Guide. Small group meetings which included a round robin check-in, presentation of a session topic and review of materials, interactive learning strategies to personalize the topic to participants' respective lives, review of the homework. Participants were encouraged to turn in weekly food logs for feedback IG2 (CR): Received a copy of The American Dietetic Association's Complete Food & Nutrition Guide. Received weekly curriculum sessions via mail, which focused on teaching the process of behavior change. Also recieved messages via email, voicemail, or regular mail reminding participants to review the week's materials. Also had access to a website through which they could post questions and review responses, read restaurant critiques, obtain recipes, and participate in a weekly live online chat session **Format and Delivery (group, indiv, family, face-to-face, phone, ma** IG1 (WM): Group, face-to-face IG2 (CR): Individual, mail **Duration (weeks) and Intensity (total min)** IG1 (WM): 24 weeks; total 20 75-min sessions: weekly first 16 weeks, biweekly for last 8 weeks IG2 (CR): 24 weeks; 2 weekly curriculum sessions twice a month by r weekly email/voicemail/mail reminder to review curriculum **Provider type** IG1 (WM): 2 staff co-facilitators IG2 (CR): NA	**Dietary:** Modified Healthy Eating Index (uses 9 of the 10 components of the USDA HEI) **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Carpenter, 2004[82] Fair	Mean (SD) at BL, Mean change (95% CI) at 6 mo **BL** **6 mo** *Grain score* **IG1 (WM)** 6.4 (2.3) -0.27 (-1.07, 0.53) **IG2 (CR)** 6.1 (2.4) -0.82 (-1.57, -0.07) **CG** 6.9 (2.3) -0.20 (-0.96, 0.55) *Vegetable score* **IG1 (WM)** 6.8 (2.8) -0.24 (-1.28, 0.80) **IG2 (CR)** 6.8 (2.7) 0.05 (-0.92, 1.02) **CG** 7.8 (2.5) -1.12 (-2.11, -0.14) *Fruit score* **IG1 (WM)** 4.9 (3.5) 2.20 (1.22, 3.18)* **IG2 (CR)** 4.9 (3.4) -0.18 (-1.10, 0.74) **CG** 4.3 (3.5) -0.54 (-1.46, 0.38) *Dairy score* **IG1 (WM)** 5.5 (3.7) 0.46 (-0.61, 1.52) **IG2 (CR)** 5.0 (2.9) 0.38 (-0.62, 1.38) **CG** 5.6 (3.4) -0.25 (-1.25, 0.76) *Meat score* **IG1 (WM)** 8.4 (2.3) 0.07 (-0.78, 0.92) **IG2 (CR)** 8.1 (2.5) 0.12 (-0.66, 0.90) **CG** 7.6 (2.7) 0.06 (-0.74, 0.87) *Total fat score* **IG1 (WM)** 6.3 (3.5) 1.96 (0.68, 3.23) **IG2 (CR)** 6.5 (3.4) 0.81 (-0.39, 2.00) **CG** 5.6 (3.3) 0.39 (-0.81, 1.60) *Saturated fat score* **IG1 (WM)** 7.3 (3.5) 1.24 (-0.01, 2.48)* **IG2 (CR)** 7.3 (3.4) 0.09 (-1.08, 1.25) **CG** 6.8 (3.5) -0.59 (-1.77, 0.58)	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Carpenter, 2004[82] Fair	**Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR **Weight:** NR	NR	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Carpenter, 2004[82] Fair					

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Carpenter, 2004[82] Fair		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Carpenter, 2004[82] Fair	*Cholesterol score* **IG1 (WM)** 8.1 (3.6) 1.11 (0.01, 2.22) **IG2 (CR)** 7.0 (3.9) 0.11 (-0.93, 1.16) **CG** 8.2 (3.4) 0.88 (-0.17, 1.93) *Sodium score* **IG1 (WM)** 7.5 (2.8) 1.18 (0.17, 2.20) **IG2 (CR)** 7.2 (2.9) 1.37 (0.41, 2.32) **CG** 7.0 (3.0) 0.44 (-0.52, 1.40) *MHEI score* **IG1 (WM)** 61.2 (11.5) 7.65 (3.80, 11.50)* **IG2 (CR)** 59.0 (9.4) 2.27 (-1.33, 5.88) **CG** 59.8 (8.9) -1.23 (-4.86, 2.40) Note: Mean change adjusted for baseline measurement, age, gender, education, and baseline caloric intake * p<0.05 for difference between IG1 (WM) and CG **IG (WM) n analyzed:** 28 **IG (CR) n analyzed:** 32 **CG n analyzed:** 33	

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Carpenter, 2004[82] Fair				

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Coates, 1999[83] **Bowen, 1996**[84] **Hall, 2003**[85] Fair	**Design:** RCT **Location:** 3 states, US **Setting:** Clinic **Volunteer**: No	**Inclusion:** Women aged 50-79 years; postmenopausal; consumed ≥36% of energy from fat **Exclusion:** History of any cancer other than nonmelanoma skin cancer or carcinoma in-situ of the cervix, stroke or coronary artery disease, or disease that might make two-year survival questionable; use of physician-prescribed drugs to alter blood lipids, including >1g/day of niacin; history of insulin-dependent diabetes or uncontrolled hyperglycemia; evidence of unstable mental disease, alcoholism, or substance abuse; high likelihood of being unavailable for a significant portion of the 2-year followup period; eating >10 meals a week not prepared at home; >165% of ideal weight; not able to provide reliable dietary information during the prerandomization period	**N recruited or assessed for eligibilty:** NR **N eligible:** NR **N randomized** Total: 2208 (Bowen & Hall), 2207 (Coates) IG: 1325 (text), 1324 (table 2 of Coates) CG: 883 **Followup (6 mo):** IG: 81% CG: 74% **Cluster information:** Number of clusters: 3 Avg cluster size: 736 Inter-cluster correlation: NR Analysis Adjusted for Clustering: N	**Age (mean):** 60 **Sex (% men):** 0 **Race/ethnicity:** % Black: 28 % Hispanic: 16 % White: 55 (remainder=Native American, Asian, "other," refused, or missing) **SES:** Education: % <HS: 11 % HS: 20 % HS+: 35 % College: 33 **Obesity:** Mean BMI: 28.9 (calc)	**Dietary factors:** Reduce fat intake to ≤20% of total energy; increase servings of fruits, grain products, and vegetables; and reduce intake of saturated fat **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Coates, 1999[83] **Bowen, 1996**[84] **Hall, 2003**[85] Fair	**Intervention description** CG: Received a package of standard materials on good dietary practices, including the Dietary Guidelines for Americans IG1: Group in which ppts shared experiences, role play, provide support and reinforcement, low-fat substitutions, and solve problems. Each ppt monitored dietary intake with a goal for grams of fat equivalent to ~20% of total energy, using self-monitoring tools **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Group **Duration (weeks) and Intensity (total min)** IG1: 72 weeks, 20 hours. Met weekly for 6 weeks, biweekly for 6 weeks, monthly for 9 months, then quarterly until end of the study **Provider type** IG1: Research nutritionist	**Dietary:** Food frequency questionnaire, 4-day food records recorded on alternate days **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Coates, 1999[83] **Bowen, 1996**[84] **Hall, 2003**[85] Fair	Daily intakes (FFQ): Mean (SD) at BL, Mean change at 6 months **BL** **6 mo** *Fat (% of energy)* **IG:** 39.7 (7.1) -13.34 **CG:** 39.1 (7.0) -2.33 *Fat (g)* **IG:** 82.4 (47.3) -43.5 **CG:** 78.5 (44.2) -11.6 *Sat Fat (% of energy)* **IG:** 13.26 (2.84) -4.21 **CG:** 12.97 (2.82) -0.71 *Sat Fat (g)* **IG:** 27.83 (17.17) -14.4 **CG:** 26.29 (15.81) -3.7 *Cholesterol (mg)* **IG:** 273.3 (183.5) 107.0 **CG:** 260.2 (170.3) -28.6 *Fruits (servings)* **IG:** 1.53 (1.13) 0.40 **CG:** 1.52 (1.09) 0.03 *Veggies (servings)* **IG:** 1.62 (1.09) 0.26 **CG:** 1.65 (1.08) 0.02 *Grains (servings)* **IG:** 3.91 (2.40) -0.49 **CG:** 3.75 (2.05) -0.15 *Energy (kcal)* **IG:** 1834 (927) -538 **CG:** 1766 (836) -171 **IG n analyzed:** 1324 per Coates **CG n analyzed:** 883	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Coates, 1999[83] **Bowen, 1996**[84] **Hall, 2003**[85] Fair	**Blood pressure:** Mean (SD) at BL, Mean change at 6 mo **BL 6 mo** *SBP (mm Hg)* **IG:** 127.1 (19.1) -3.1 **CG:** 127.3 (18.3) -1.4* *DBP (mm Hg)* **IG:** 76.3 (9.7) -1.1 **CG:** 76.9 (9.5) -0.6 **Lipids:** Mean (SD) at BL, Mean change at 6 mo **BL 6 mo**** *Cholesterol (mg/dl)* **IG:** 219.0 (38.97) -- **CG:** 218.8 (38.01) -- **Glucose tolerance:** Mean (SD) at BL, Mean change at 6 mo **BL 6 mo** *Glucose (mmol/L)* **IG:** 5.3 (1.5) -0.2 **CG:** 5.3 (1.6) -0.1 **Weight:** Mean (SD) at BL, Mean change at 6 mo **BL 6 mo** *Kg* **IG:** 75.1 (12.5) -1.8 **CG:** 75.8 (12.7) -0.3* *BMI* **IG:** 28.7 (4.6) -0.7 **CG:** 29.1 (4.8) -0.1*	NR	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Coates, 1999[83] **Bowen, 1996**[84] **Hall, 2003**[85] Fair					

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Coates, 1999[83] **Bowen, 1996**[84] **Hall, 2003**[85] Fair		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Coates, 1999[83] **Bowen, 1996**[84] **Hall, 2003**[85] Fair		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Coates, 1999[83] **Bowen, 1996**[84] **Hall, 2003**[85] Fair	*P<0.05 for differences between IG and CG **Measured, but will report in future (per Hall 2003) **IG n analyzed:** 1324 per Coates **CG n analyzed:** 883			

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Delichatsios, 2001[159] Fair	**Design:** RCT **Location:** Massachusetts, US **Setting:** Home and phone visits **Volunteer**: No	**Inclusion:** Sedentary and suboptimal diet (suboptimal intake of one of fruits, vegetables, red and processed meats, whole fat dairy foods, or whole grain foods) **Exclusion:** < 25 yrs; medical conditions that would limit ability to participate in the study, such as dementia and severe psychiatric disorders; engaging in moderate PA > 5 days/week for ≥ 30 min/day or vigorous PA > 3 days/week for ≥ 20 min/day	**N recruited or assessed for eligibilty:** 2884 **N eligible:** 363 **N randomized** Total: 298 IG: 148 CG: 150 **Followup (6 mo):** 83% **Cluster information:** NA	**Age (mean):** 45.9 **Sex (% men):** 28 **Race/ethnicity:** % White: 45 % Black: 45 **SES:** % Beyond college education: 24 % Married: 59 **Obesity:** Mean BMI (SD): 28.7 (7.0)	**Dietary factors:** Focused on fruits; vegetables; red and processed meats; whole fat dairy goods; whole grain foods. **Physical activity:** See Pinto in the Physical Activity Table

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Delichatsios, 2001[159] Fair	**Intervention description** CG: Telephone linked communication system providing automated physical activity counseling IG1: Telephone linked communication system that is set up to provide automated healthy eating counseling- functioned as at home monitor, educator, and counselor. The system asked questions and modified the counseling based on responses and kept a cummulative database of responses. **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Phone **Duration (weeks) and Intensity (total min)** IG1: Weekly calls for 6 months; 5-7 min/contact **Provider type** IG1: NR	**Dietary:** PrimeScreen (FFQ was primary outcome measures, but only 50% response rate at 3 and 6 month followup) **Physical Activity:** See Pinto in the Physical Activity table

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Delichatsios, 2001[159] Fair	Mean servings/day at BL and 6 mo with adjusted difference (95%CI) **BL** **6 mo** *Fruit* **IG:** 1.1 1.5 **CG:** 1.2 1.2 Adj Difference: 0.4 (0.2, 0.6) p < 0.05 *Vegetables* **IG:** 1.3 1.5 **CG:** 1.2 1.4 Adj Difference: 0.1 (-0.1, 0.3) *Red/processed meats* **IG:** 0.4 0.4 **CG:** 0.4 0.4 Adj Difference: 0.0 (-0.1, 0.1) *Whole fat dairy foods* **IG:** 0.6 0.4 **CG:** 0.5 0.4 Adj Difference: 0.0 (-0.1, 0.1) *Whole grain foods* **IG:** 0.4 0.5 **CG:** 0.4 0.4 Adj Difference: 0.1 (-0.1, 0.2) *Mean intake Dietary fiber, gm* **IG:** 6.2 7.3 **CG:** 6.0 6.2 1.0 (0.4, 1.6) p<0.05 *% energy intake Saturated fat* **IG:** 12.6 10.7 **CG:** 12.2 11.5 Adj Difference -1.0 (-1.9, -0.2) p<0.05 **IG n analyzed:** 148 **CG n analyzed:** 150	See Pinto in Physical Activity Table

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Delichatsios, 2001[159] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	No other adverse effects reported	**Incentives:** NR **Other:** Very low adherence: 24% never called the system; 36% called 1-10 times; 23% called 11-20 times; 18% called called > 20 times

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Fries, 2005[86] Fair	**Design:** RCT **Location:** Virginia, US **Setting:** Physician practices **Volunteer**: No	**Inclusion:** Age 18 to 72 years; living in targeted geographic region (southern rural Virginia) **Exclusion:** Medically unqualified (serious illness or maintaining a prescribed diet); another study patient was already enrolled; could not comprehend questions being asked on the phone; could not read at all; could not consent to the study	**N recruited or assessed for eligibilty:** 4211 **N eligible:** NR **N randomized** Total: 754 IG: 377 CG: 377 **Followup (12 mo):** IG: 238 (63%) CG: 278 (74%) **Cluster information:** Number of clusters: 3 Avg cluster size: 251 (calc) Inter-cluster correlation: NR Analysis Adjusted for Clustering: Y	**Age (mean):** 47.3 (calc) **Sex (% men):** 35.9 (calc) **Race/ethnicity:** % White: 59.5 (calc) % African American: 37.7 (calc) % Other: 2.8 (calc) **SES:** Education: % 8th Grade: 4.4 % Some HS: 10.7 % HS/GED: 35.1 % Some College: 25.7 % College Degree: 23.7 **Obesity:** NR	**Dietary factors:** Reduce fat itnake and increase fiber intake **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Fries, 2005[86] Fair	**Intervention description** CG: Received intervention materials after final follow-up IG1: Baseline fat and fiber behavior questionnaire provided a basis for the feedback. Received a personalized dietary feedback component, self-help booklets designed to aid in the specific dietary behavior change of reducing fat intake and increasing fiber intake. A phone call supported the mailed materials. **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual; mail, phone **Duration (weeks) and Intensity (total min)** IG1: ~8-10 weeks, mailed feedback immediately after baseline assessment, phone call 2 weeks after mailed feedback (reminder and brief counseling), plus 5 low-literacy self-booklets mailed every week **Provider type** IG1: Trained staff (no further details)	**Dietary:** Fat and fiber behavior-related questionnaire (referenced Kristal and Shannon) **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Fries, 2005[86] Fair	Mean (SD) **BL** **6 mo** **12 mo** *Dietary Fat Behavior* **IG** 2.03 (0.35) 1.87 (0.34) 1.87 (0.35) **CG** 2.05 (0.33) 1.97 (0.34) 1.95 (0.34) *Dietary Fiber Behavior* **IG** 2.24 (0.35) 2.07 (0.37) 2.12 (0.39) **CG** 2.24 (0.36) 2.16 (0.37) 2.16 (0.38) **ANCOVA p-value (6, 12 mo): (fat behavior)** 0.0004, 0.0027, (fiber behavior) 0.0011, 0.0862 **IG n analyzed:** 280 (BL), 221 (6 mo), 238 (12 mo) **CG n analyzed:** 342 (BL), 249 (6 mo), 278 (12 mo)	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Fries, 2005[86] Fair	**Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR **Weight:** NR	NR	No other adverse effects reported	**Incentives:** NR **Other:** Subjects who did not complete follow-up were more likely to be in the intervention group, were more likely to be younger, and have higher fat behavior scores and lower knowledge and fiber intention scores at baseline ($p<0.05$)

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Greene, 2008[42] **Greaney, 2008**[43] **(SENIOR project)** Fair	**Design:** RCT **Location:** Rhode Island, US **Setting:** Home (assessment), mail, phone **Volunteer:** Yes	**Inclusion:** Community dwelling; age 60+; English or Portuguese language **Exclusion:** NR	**N recruited or assessed for eligibilty:** NR **N eligible:** NR **N randomized** Total: 1,280 IG: NR CG: NR **Followup:** PA outcomes (24 mo, but also used this subset to analyze 12 mo data) IG: 470 CG: 496 966/1280=75.5% HD outcomes (both 12 & 24 mo) IG: 410 CG: 424 834/1280=65.2% **Cluster information:** NA	**Age (mean):** 74.7 **Sex (% men):** 27.1 **Race/ethnicity:** % White: 79.5 % Hispanic: 13.2 % Other: 7.3 **SES:** % Annual income <$20,000: 57.0 % No college: 58 **Obesity:** NR *Note: From HD sample (Greene)*	**Dietary factors:** Daily servings of fruits and vegetables **Physical activity:** Moderate-vigorous activity 3-5x/week for at least 20 min per session; flexibility exercises 2x/wk; strengthening 2-3x/wk

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Greene, 2008[42] **Greaney, 2008**[43] **(SENIOR project)** Fair	**Intervention description** CG: Falls prevention manual IG1(F&V): Stage-based fruit and vegetable manual; 9 stage-based fruit and vegetable newsletters; 3 reports from expert system tailored current stage of change variables and baseline information; 3 15-min coaching calls IG2(PA): Stage-based PA manual; 9 stage-based PA newsletters; 3 reports from expert system tailored current stage of change variables and baseline information; 3 15-min coaching calls IG3(Comb): All of IG1 and IG2 **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1-3 individual; phone, mail **Duration (weeks) and Intensity (total min)** IG1&2: 52 weeks, 45 min phone; 9 stage-based fruit and vegetable newsletters; 3 reports from expert system tailored current stage of change variables and baseline information; 3 15-min coaching calls IG3: 52 weeks, assume 90 min; IG1 and IG2 combined **Provider type** IG1: NR, "trained counselors"	**Dietary:** Daily servings of fruits and vegetables (NCI FAV screener frequency without portion size (NCIF), NCI FAV screener respondent-assessed portions (NCIP), Five-a-Day screener (FAD), single-item screener) **Physical Activity:** PA summary score of the Yale Physical Activity Survey

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Greene, 2008[42] **Greaney, 2008**[43] **(SENIOR project)** Fair	Mean (SD) daily servings of fruits and vegetables **n BL 12 mo 24 mo** *NCIP* **IG1&3:** 410 8.0(4.1) 10.1(4.6) 10.2(4.5) **IG2&CG:** 424 7.7(4.0) 8.5(3.8) 9.3(4.5) p<0.001 *NCIF* **IG1&3:** 410 5.7(2.2) 6.6(2.2) 6.7(2.2) **IG2&CG:** 424 5.5(2.2) 5.8(2.0) 6.3(2.3) p<0.001 *FAD screener* **IG1&3:** 365 5.6(2.6) 6.7(2.4) 6.8(2.3) **IG2&CG:** 391 5.3(2.2) 5.7(2.0) 6.2(2.1) p<0.001 *Single-item screener* **IG1&3:** 410 4.8(1.1) 5.2(0.8) 5.2(0.8) **IG2&CG:** 424 4.7(1.2) 4.9(1.0) 5.0(1.0) NS	See Freene/Greaney in Physical Activity and Combined Table

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Greene, 2008[42] **Greaney, 2008**[43] **(SENIOR project)** Fair	**Blood pressure:** NR **Lipids:** NR **Glucose tolerance:**NR **Weight:** NR	None	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Hellenius, 1993[47] **Hellenius, 1995**[48] Fair	**Design:** RCT **Location:** Sweden **Setting:** Primary care health center and hospital **Volunteer**: No	**Inclusion:** No history or cardiovascular disease, diabetes, or other severe illnesses; no regular use of drugs; serum chol 5.2-7.8 mmol/l; fasting triglycerides ≤ 5.6 mmol/l; fasting blood glucose ≤ 6.7 mmol/l; and diastolic blood pressure ≤ 100mmHg. **Exclusion:** NR	**N recruited or assessed for eligibilty:** 187 **N responded:** 160 **N eligible:** 158 **N randomized** Total: 158 IG1 (Diet(D)): 40 IG2 (Exer(E)): 39 IG3 (Diet+Exer(DE)): 39 CG: 40 **Followup (6 mo):** IG1(D): 40 (100%) IG2 (E): 39 (100%) IG3 (DE): 39 (100%) CG: 39 (98%) **Cluster information:** NA	**Age (mean):** 45 **Sex (% men):** 100 **Race/ethnicity:** NR **SES:** NR **Obesity:** Mean BMI (SD): 25.3 (3.2)	**Dietary factors:** NCEP Step 1 diet, of total energy intake: total fat < 30%; sat fat < 10%; polyunsat fat ≤ 10%; monounsat fat 10-15%; Carbs 50-60%; protein 10-20%; cholesterol < 300 mg/day **Physical activity:** Aerobic exercise at 60-80% max for 30-45 minutes, 2-3 times/week

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Hellenius, 1993[47] **Hellenius, 1995**[48] Fair	**Intervention description** CG: Told to maintain normal diet and activity IG1(D): Received written and verbal dietary advice from physician at baseline and advice from dietician after approximately 2 weeks (and advice given to wife/partner) IG2(E): Received verbal and written information regarding physical activity from physician at baseline IG3(DE): Same as IG1(D) and IG2(E) **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1(D): indiv, face-to-face IG2(E): indiv, face-to-face IG3(DE): indiv, face-to-face CG: NA **Duration (weeks) and Intensity (total min)** IG1(D): 2 weeks, intensity NR IG2(E): 1 time, intensity NR IG3(DE): 2 weeks, intensity NR CG: NA **Provider type** IG1(D): Dietician IG2(E): Physician IG3(DE): Dietician, physician CG: NA	**Dietary:** 7-day food record **Physical Activity:** See Hellenius in Physical Activity and Combined tables

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Hellenius, 1993[47] **Hellenius, 1995**[48] Fair	Mean (SD) **BL** **6 mo** *Total energy intake, kJ* **IG1** 8160(1751) 7795(1506) **CG** 9391(2723) 8753(2387) *Fat, % intake* **IG1** 37(4.2) 34(3.6)* **CG** 36(5.8) 36(6.0) *Protein, % intake* **IG1** 14(1.7) 16(1.5)* **CG** 14(2.1) 14(1.9) *Carbohydrate, % intake* **IG1** 43(4.7) 46(3.8)* **CG** 46(5.4) 45(7.2) *p<0.05 **IG n analyzed:** 34 **CG n analyzed:** 33	See Hellenius in Physical Activity and Combined Tables

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Hellenius, 1993[47] **Hellenius, 1995**[48] Fair	Baseline mean (SD); Differences at 6 mo (95% CI) **Blood pressure:** **BL** **6 mo** *SBP, mmHg* **IG1(D):** 130 (16.2) -7(-10, -3) **CG:** 130 (12.2) -1(-3, 4) *DBP, mmHg* **IG1(D):** 82 (7.9) -6(-8, -4)* **CG:** 82 (8.3) -1(-3, 1) **Lipids:** *Total Chol, mmol/l* **IG1(D):** 6.08 (0.80) -0.19(-0.49, 0.11) **CG:** 5.97 (0.90) -0.13(-0.33, 0.07) *LDL, mmol/l* **IG1(D):** 4.29 (0.68) -0.30(-0.54, -0.06) **CG:** 4.14 (0.75) -0.15(-0.33, 0.02) *HDL, mmol/l* **IG1(D):** 1.41 (0.39) 0.01(-0.05, 0.07) **CG:** 1.36 (0.28) -0.02(-0.08, 0.05) *Triglycerides, mmol/l* **IG1(D):** 1.27 (0.47) 0.03(-0.09, 0.15) **CG:** 1.33 (0.53) 0.06(-0.08, 0.20) **Glucose tolerance:** NR **Weight:** *BMI* **IG1(D):** 25.2 (2.9) -0.3(-0.6, 0.03)* **CG:** 24.5 (3.0) 0.3(0.1, 0.5) * p<0.001 **IG n analyzed:** 40 **CG n analyzed:** 39	NR	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
HPT Research Group, 1990[87] **Shah, 1990**[88] **Meinert, 1989**[89] Good	**Design:** RCT **Location:** 4 states, US **Setting:** Clinical centers **Recruitment source:** Community (direct mail, shopping malls, churches, work sites, adult education courses, mass media) **Volunteer**: Yes	**Inclusion:** Age 25-49 years; diastolic blood pressure of 76-99 mm Hg at first baseline visit and 78-89 mm Hg at second baseline visit (7-30 days later) **Exclusion:** Using antihypertensive medication; evidence of cardiovascular disease; BMI≥35; dietary requirements incompatible with counseling regimen; drank 21+ alcoholic beverages a week; perceived as unable to comply with counseling regimen or data collection schedule	**N recruited or assessed for eligibilty:** NR **N enrolled:** 841 **N randomized:** 841 IG1 (Cal): 125 IG2 (Na): 196 (IG2 Na Subset: 126) IG3 (NaCal): 129 IG4 (NaK): 195 CG: 196 (CG subset: 126) **Followup (6, 36 mo):** *6 mo* IG1 (Cal): 112 (89.6%) IG2 (Na): 174 (88.7%) (IG2 Na Subset: 110 (87.2%)) IG3 (NaCal): 113 (87.6%) IG4 (NaK): 181 (92.8%) CG: 191 (97.4) (CG subset: 121 (96.0%))	**Age (mean):** 38.6 **Sex (% men):** 65.3 **Race/ethnicity:** % White: 82.2 **Obesity:** Mean BMI: 27 (calc)	**Dietary factors:** Sodium restriction (≤70 mEq per day); sodium restriction and potassium increase (≥100 mEq per day); energy restriction (reduce energy intake to achieve a normal weight); sodium and energy restriction (High weight participants were assigned to any treatment, normal weight participants were not assigned to calorie restriction treatments) **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
HPT Research Group, 1990[87] **Shah, 1990**[88] **Meinert, 1989**[89] Good	**Intervention description** CG: No dietary treatment or control. IG: The initial phase consisted of 12 group sessions held during a 4 month period. The sessions were conducted by trained nutritionists and behaviorists who provided participants in the 4 treatment groups with dietary counseling specific to their treatment protocol. All treatment participants received counseling related to meal planning and preparation, food purchasing, and lebel reading to assist them in making the required changes. Based on a daily food record, participants were encouraged to make further changes or maintain their current changes. The maintenance phase included group sessions were helf every 2nd month after the initial phase and periodic individual counseling sessions. Participants who did not attend the counseling sessions were contacted by phone. The phone contact included a qualitative assessment of the participant's dietary compliance based on self-report. Participants also received a bimonthly newsletter containing relevant dietary information and recipes. **Format and Delivery (group, indiv, family, face-to-face, phone, ma** IG: Individual and group sessions, mainly face-to-face, some by phon newsletter by mail CG: NR **Duration (weeks) and Intensity (total min)** IG: 4 months (initial groups sessions) and the second part was contin through the remainder of the study (3 years); Intensity NR CG: NR **Provider type** IG: Trained nutritionists and behaviorists CG: NR	**Dietary:** 24-hour excretion rates for sodium and potassium (from timed overnight home urine collections) **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
HPT Research Group, 1990[87] **Shah, 1990**[88] **Meinert, 1989**[89] Good	Mean at BL, Mean change (SE) at 6 and 36 mo **BL** **6 mo** **36 mo** *Potassium excretion, mmol/8 h* Sodium-Calorie **Cal** 13.7 -1.1(0.6) 1.2(0.7) **Na** 13.2 0.9(0.5) 1.0(0.7) **NaCal** 14.1 -0.1(0.5) -0.8(0.7) **CG** 13.8 0.3(0.5) 0.1(0.7) **p, calorie** 0.066 0.328 **p, sodium** 0.708 0.286 **p, interaction** 0.517 0.047 Sodium-Potassium **Na** 13.1 0.2(0.4) 0.9(0.6) **NaK** 13.2 1.2(0.4) 0.9(0.6) **CG** 13.4 -0.1(0.4) -0.4(0.5) **p, potassium** 0.102 0.581 **p, sodium** 0.994 0.044 *Sodium excretion, mmol/8 h* Sodium-Calorie **Cal** 45.8 -4.2(1.9) -0.4(1.9) **Na** 44.9 -7.8(1.8) -2.8(2.0) **NaCal** 45.6 -8.4(1.8) -9.2(1.9) **CG** 45.9 -4.5(1.8) 2.2(1.9) **p, calorie** 0.922 0.114 **p, sodium** 0.124 0.095 **p, interaction** 0.986 0.521 Sodium-Potassium **Na** 42.8 -9.4(1.3) -4.2(1.5) **NaK** 42.1 -11.4(1.3) -5.8(1.5) **CG** 43.4 -3.9(1.3) 0.0(1.5) **p, potassium** 0.452 0.332 **p, sodium** 0.002 0.053	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
HPT Research Group, 1990[87] **Shah, 1990**[88] **Meinert, 1989**[89] Good	Mean at BL, Mean change (SE) at 6 and 36 mo **Blood Pressure:** **BL 6 mo 36 mo** *Diastolic Blood Pressure, mmHg* Sodium-Calorie **Cal** 83.0 -5.3(0.7) -4.2(0.8) **Na** 82.9 -3.4(0.7) -4.0(0.8) **NaCal** 82.6 -4.0(0.7) -3.7(0.8) **CG** 83.3 -2.5(0.7) -2.4(0.8) **p, calorie** 0.010 0.045 **p, sodium** 0.468 0.745 **p, interaction** 0.201 0.514 Sodium-Potassium **Na** 82.6 -3.4(0.5) -2.8(0.5) **NaK** 82.7 -3.7(0.5) -3.7(0.5) **CG** 83.0 -3.0(0.5) -3.0(0.5) **p, potassium** 0.597 0.664 **p, sodium** 0.398 0.787 *Systolic Blood Pressure, mmHg* Sodium-Calorie **Cal** 125.3 -6.9(0.7) -5.0(0.9) **Na** 124.1 -3.6(0.7) -2.3(0.9) **NaCal** 124.4 -5.8(0.7) -3.6(0.9) **CG** 124.7 -1.8(0.7) -2.6(0.9) Sodium-Potassium **Na** 124.0 -3.8(0.6) -2.8(0.7) **NaK** 124.1 -3.4(0.6) -4.1(0.7) **CG** 123.9 -2.1(0.6) -2.9(0.7) **p, potassium** 0.822 0.161 **p, sodium** 0.126 0.885 **Lipids:** NR **Glucose Tolerance:** NR	Mortality (4 total, one death per arm)	No other adverse effects reported	**Incentives:** NR **Other:** 2 different control groups used (1 that was randomized and then a subset of that group) for the sodium-calorie and sodium-potassium components Some participants received drug treatment for hypertension

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
HPT Research Group, 1990[87] **Shah, 1990**[88] **Meinert, 1989**[89] Good			*36 mo* IG1 (Cal): 117 (93.6%) IG2 (Na): 175 (89.2%) (IG2 Na Subset: 114 (90.4%)) IG3 (NaCal): 116 (89.8%) IG4 (NaK): 179 (91.8%) CG: 178 (90.8%) (CG subset: 116 (92.0%))) **Cluster information:** NA		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
HPT Research Group, 1990[87] **Shah, 1990**[88] **Meinert, 1989**[89] Good		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
HPT Research Group, 1990[87] **Shah, 1990**[88] **Meinert, 1989**[89] Good	Sodium-Calorie **Cal n analyzed:** 125 (BL), 102 (6 mo), 101 (36 mo) **Na n analyzed:** 126 (BL), 103 (6 mo), 87 (36 mo) **NaCal n analyzed:** 129 (BL), 104 (6 mo), 96 (36 mo) **CG n analyzed:** 126 (BL), 116 (6 mo), 102 (36 mo) Sodium-Potassium **Na n analyzed:** 196 (BL), 165 (6 mo), 143 (36 mo) **NaK n analyzed:** 195 (BL), 170 (6 mo), 151 (36 mo) **CG n analyzed:** 196 (BL), 185 (6 mo), 155 (36 mo)	

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
HPT Research Group, 1990[87] **Shah, 1990**[88] **Meinert, 1989**[89] Good	Sodium-Calorie **Cal n analyzed:** 125 (BL), 112 (6 mo), 117 (36 mo) **Na n analyzed:** 126 (BL), 109 (6 mo), 113 (36 mo) **NaCal n analyzed:** 129 (BL), 113 (6 mo), 115 (36 mo) **CG n analyzed:** 126 (BL), 121 (6 mo), 115 (36 mo) Sodium-Potassium **Na n analyzed:** 196 (BL), 173 (6 mo), 174 (36 mo) **NaK n analyzed:** 195 (BL), 180 (6 mo), 178 (36 mo) **CG n analyzed:** 196 (BL), 191 (6 mo), 177 (36 mo)			

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
John, 2002[90] Fair	**Design:** RCT **Location:** UK **Setting:** Health center **Volunteer:** no	**Inclusion:** Aged 25-64 years; without serious chronic illness **Exclusion:** Cardiovascular diseases (other than hypertension); gastrointestinal disease; cancer; serious psychiatric disorders; hypercholesterolaemia; undergone a recent traumatic event (such as bereavement); unable to give informed consent; on vitamin supplements	**N recruited or assessed for eligibilty:** NR **N eligible:** 4362 **N randomized** Total: 729 IG: 364 (344 included in analysis) CG: 365 (337 included in analysis) **Followup (6 mo):** IG: 336 (92.3%) CG: 337 (92.3%) **Cluster information:** NA	**Age (mean):** 45.9 (calc) **Sex (% men):** 49.0 (calc) **Race/ethnicity:** NR **SES:** % Social Class: I and II: 48.8 % III non-manual: 16.5 % III manual: 14.3 % IV and V: 10.1 % Housewife: 7.5 % Armed Forces and not known: 2.6 **Obesity:** Mean BMI: 25.9 (calc)	**Dietary factors:** Eating more fruits and vegetables (5 or more portions per day) **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
John, 2002[90] Fair	**Intervention description** CG: explained that they would receive specific advice at 6 months; asked to carry on as usual and not told the trial was a dietary intervention IG1: Benefits of eating more fruit and vegetables and presented a pictorial portion guide; eating pattern assessment questionnaire to elicit meal and snack patterns and a visual representation to show where increases in consumption might be made; brief negotiation method was used to encourage participants to identify specific and practical ways, encouraged to discuss possible barriers to eating more fruit and vegetables, prepared leaflets addressed these difficulties and were given to participants as needed; given a copy of their action plan, a magnet with the 5-a-day logo, a portion guide, and a 2-week self-monitoring record book **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual (face-to-face, phone, mail) **Duration (weeks) and Intensity (total min)** IG1: 3 months, 25 minutes (dietary intervention), at 2 weeks post intervention telephone call, 3 month mailed letter with booklet **Provider type** IG1: Research nurse	**Dietary:** Dietary questionnaire (no further information) **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
John, 2002[90] Fair	**Fruit and Vegetables:** Self-reported daily intake of fruit and vegetables, portions (Mean (SD) at BL, Mean change (SD) at 6 mo) **BL** **6 mo** **IG** 3.4 (1.7) 1.4 (1.7)* **CG** 3.4 (1.5) 0.1 (1.3) adjusted difference in change (95%CI): 1.4 (1.2, 1.6) * p-value for adjusted difference <0.0001 adjusted for baseline value and sex **IG n analyzed:** 329 **CG n analyzed:** 326	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
John, 2002[90] Fair	**Mean (SD) at BL, Mean change (SD) at 6 mo** **Adiposity:** **BL 6 mo** *Weight, kg* **IG** 76.1 (13.8) 0.6 (2.6) **CG** 75.6 (14.9) 0.6 (2.6) **Adjusted difference in change (95%CI):** 0.1 (-0.4, 0.6) **Blood pressure:** *Systolic Blood Pressure, mmHg* **IG** 130.2 (19.7) -2.0 (13.5)* **CG** 129.3 (19.6) 1.4 (14.6) **Adjusted difference in change (95%CI):** 4.0 (2.0, 6.0) *Diastolic Blood Pressure, mmHg* **IG** 79.2 (11.4) -1.6 (8.7)# **CG** 79.9 (11.9) -0.3 (8.7) **Adjusted difference in change (95%CI):** 1.5 (0.2, 2.7) **Lipids:** *Plasma concentration of total cholesterol, mmol/L* **IG** 5.037 (0.96) -0.018 (0.87) **CG** 5.123 (1.02) -0.036 (0.56) **Adjusted difference in change (95%CI):** 0.010 (-0.097, 0.116) **Glucose tolerance:** NR ** p-value for adjusted difference <0.0001* *# p-value for adjusted difference 0.02* **IG n analyzed:** 344 **CG n analyzed:** 346	NR	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
King, 2002[53] Fair	**Design:** RCT **Location:** US **Setting:** home, community recruitment **Volunteer:** Yes	**Inclusion:** Postmenapausal; age 50+ (or 46+ if postmenopausal due to hysterectomy); caregiver to relative with dementia; providing at least 10 hrs of unpaid care/week; not planning of moving out of the area in next year; free from medical conditions contraindicating PA increase; not participating in a regular program of PA; stable on all medications for at least 3 months **Exclusion:** Evidence of ischemia	**N recruited or assessed for eligibilty:** 574 **N eligible:** NR **N randomized** Total: 100 IG: 51 CG: 49 **Followup (12 mo):** IG1: 45/51=88.2% CG: 40/49=81.6% **Cluster information:** NA	**Age (mean):** 62.7 **Sex (% men):** 0 **Race/ethnicity:** % White: 86 % African American: 5 % Hispanic: 4 % Asian/Pacific Islander: 3 **SES:** Mean(SD) years educations: 15.0(2.5) **Obesity:** Mean BMI: 27.4	**Dietary factors:** Reduce % calories from fat, increase fruits and vegetables **Physical activity:** 4+ 30- to 40-minute exercise sessions/wk of primarily brisk walking

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
King, 2002[53] Fair	**Intervention description** IG (HD): Baseline face-to-face counseling session, 14 phone calls with homework assignments, daily food logs mailed back monthly CG (PA): 30-40-min counseling session in home where initial PA plan developed; 14 15-20-min phone calls; daily activity logs **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG (HD): Face-to-face, phone, individual **Duration (weeks) and Intensity (total min)** IG (HD): 52 weeks, 35+17.5*14=280min **Provider type** IG (HD): Health educator	**Dietary:** Block95 FFQ 1995 version **Physical Activity:** PAR VO_{2max}-measured

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
King, 2002[53] Fair	Mean (SD) at BL and 12 mo **BL** **12 mo*** *% cal ories from fat* **IG:** 33.3 (6.9) 29.6 (8.3) **CG:** 31.6 (5.7) 31.8 (6.3) **p-value** <0.01 *% cal foriesrom saturated fat* **IG:** 10.9 (2.7) 9.5 (2.9) **CG:** 10.2 (2.3) 10.3 (2.2) **p-value** <0.01 *Svg/day of fats, oils, sweets, and high-fat snacks* **IG:** 2.2 (1.4) 1.5 (1.2) **CG:** 2.7 (2.0) 2.3 (1.3) **p-value** <0.01 *Kcals/day* **IG:** 1700.2 (656.5) 1432.4 (411.2) **CG:** 1756.5 (520.5) 1699.0 (604.7) **p-value** NS** *Svg/day of vegetables* **IG:** 2.6 (1.1) 2.8 (1.1) **CG:** 2.7 (0.9) 2.7 (1.2) **p-value** NS *Svg/day of fruits* **IG:** 1.6 (0.9) 2.1 (1.0) **CG:** 2.0 (1.1) 2.1 (1.3) **p-value** NS *Adjusted for baseline values ** Within group difference from BL p<0.03 for IG, NS for CG **IG n analyzed:** 45 **CG n analyzed:** 40	See PA table

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
King, 2002[53] Fair	NA	NR	NR	

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Kristal, 2000[91] Fair	**Design:** RCT **Location:** Washington, US **Setting:** Phone **Volunteer:** No	**Inclusion:** Group Health Cooperative enrollment; aged 28-69 years; ability to complete baseline survey in English **Exclusion:** NR	**N recruited or assessed for eligibilty:** 3029 (calc) **N eligible:** 2181 (calc) **N randomized** Total: 1459 IG: 729 CG: 730 **Followup (3, 12 mo):** Total: 91% 3 mo, 87% 12 mo IG: 601 (82.4%, calc) CG: 604 (82.7%, calc) **Cluster information:** NA	**Age (mean):** 44.9 **Sex (% men):** 50.9 **Race/ethnicity:** % White: 85.9 % Black: 4.5 % Asian: 5.8 % Hispanic: 3.0 % Other: 0.8 **SES:** % Household Income ($1000): <25: 12.2 25-34: 16.9 35-49: 25.4 50-69: 23.7 70+: 21.7 **Obesity:** Mean BMI (SD): 26.5 (5.0)	**Dietary factors:** Replacing poor food choices with healthier decisions; reducing fat in diet and increasing fruit/vegetable intake **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Kristal, 2000[91] Fair	**Intervention description** CG: No materials IG1: Package of self-help materials (benefits of decreasing fat and increasing fruits and vegetables; ways to modify specific meals to reduce fat/increase fruits and vegetables; skills for implementing and maintaining dietary changes; messages on basic intervention components; information on recipe modification, portions sizes, fast food); dietary analysis with behavioral feedback, available when participants returned a food frequency questionnaire (analysis of nutrient intake; feedback on current food choices; quanitative goals to reach 30% energy from fat and 5 servings of fruits and vegetables per day; food sources of fat and fruits and vegetables and recommendations for change); motivational phone call (acknowledge participant's motives for dietary change; encourage use of self-help materials; point to most relevant materials in intervention packet); semi-monthly newsletters (maintain salience of intervention messages; additional, seasonal information on food purchasing and preparation; enhance and reinforce motivation through use of "Personal Stories") **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual; Phone and mail **Duration (weeks) and Intensity (total min)** IG1: 1 year, phone call at 1 month, semi-monthly newsletter for 1 year **Provider type** IG1: Trained health educator (motivational phone call), computer program and mailing staff	**Dietary:** Fat-related diet habits questionnaire; 6-item food frequency questionnaire; 24-hour dietary recalls **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Kristal, 2000[91] Fair	(Mean (SD) at BL, Mean Change (SD) at 3, 12 mo) **BL 3 mo 12 mo** *Fat-related score (1.0 low fat to 4.0 high fat)* **IG** 2.29 (0.49) -0.09 (0.37) -0.09 (0.38) **CG** 2.30 (0.49) -0.01 (0.36) -0.00 (0.40) **Intervention effect*:** -0.09 (0.02)** -0.10 (0.2)** *Fuit and Vegetables, servings/day* **IG** 3.62 (1.49) 0.41 (1.88) 0.47 (1.83) **CG** 3.47 (1.41) 0.08 (1.63) 0.14 (1.80) **Intervention effect*** 0.39 (0.10)** 0.46 (0.10)** ** Adjusted for baseline value, age, sex, race, BMI, income* *** p<0.0001* **IG n analyzed:** 601 **CG n analyzed:** 604	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Kristal, 2000[91] Fair	**Adiposity (% body fat, BMI, % overweight):** IG gained 0.18 lb. by 12 mo; CG gained 0.85 lb by 12 mo; Adjusted intervention effect was -0.76 lb. (p=0.088) (adjusted for age, sex, race, and income) **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Lutz, 1999[92] Fair	**Design:** RTC **Location:** North Carolina, US **Setting:** Mail **Volunteer:** No	**Inclusion:** NR **Exclusion:** Younger than 18 years; had other household members participating in the study; followed a special diet; had medical conditions that restricted fruit and vegetable intake; were moving from N. Carolina in the next 6 months.	**N recruited or assessed for eligibilty:** 4469 **N eligible:** 710 **N randomized** Total: 710 IG1 (nontailored newsletter): 177 IG2 (tailored newsletter): 176 IG3 (tailored newsletter and goal-setting): 177 CG: 180 **Followup (6 mo):** Total: 573 (80.8%) IG1: 140 (79.1%, calc) IG2: 136 (77.3%, calc) IG3: 146 (82.5%, calc) CG: 151 (83.9%, calc) **Cluster information:** NA	**Age (mean):** 39.3 **Sex (% men):** 35.6 **Race/ethnicity:** % Black: 19.3 % White: 77.9 % Other: 2.3 % non-response: 0.5 **SES:** Education: % 2-12 grade: 39.4 % >12 grade: 60.0 % Non-response: 0.6 **Obesity:** NR	**Dietary factors:** Fruits and vegetables **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Lutz, 1999[92] Fair	**Intervention description** CG: NR IG1: Traditional newsletters with nontailored nutrition information. Participants were given the vague goal of "eating more fruits and vegetables" IG2: Newsletters with tailored information and no goal-setting component, based on the baseline survey (intake, eating behaviors, nutrition-related activities, psychosocial factors). Tailored messages determined from a computer algorithm were delivered based on baseline response. Given the vague goal of "eating more fruits and vegetables" IG3: Newsletters with tailored nutrition and tailored goal-setting information, based on the baseline survey (intake, eating behaviors, nutrition-related activities, psychosocial factors). Tailored messages determined from a computer algorithm were delivered based on baseline response. The newsletters also provided 3 tailored subgoals to achieve the goal of 5 a day, based on the baseline survey. Participants were given a specific goal of "increasing fruit and vegetable intake to 5 or more servings each day" **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual; Mail **Duration (weeks) and Intensity (total min)** IG1: 4 months, one newsletter 1x a month for 4 months **Provider type** IG1: NR	**Dietary:** Food frequency questionnaire (combination of Campbell 1994, Thompson 1994, and Willett 1990) **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Lutz, 1999[92] Fair	Mean (SE) **BL 6 mo** *Daily fruit and vegetable intake* **IG** 3.4 (0.18) 4.1 (0.19) **IG2** 3.3 (0.19) 4.1 (0.21) **IG3** 3.5 (0.21) 4.4 (0.21) **CG** 3.5 (0.20) 3.6 (0.16)* ** p<0.002 for intake differences based on F tests* **IG n analyzed:** 140 **IG2 n analyzed:** 136 **IG3 n analyzed:** 146 **CG n analyzed:** 151	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Lutz, 1999[92] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	2 participants died	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Prochaska, 2005[93] Fair	**Design:** RCT **Location:** NR (assumed Rhode Island, US) **Setting:** Home **Volunteer:** No	**Inclusion:** Patient in eligible practice in non-hospital based primary care, patient at risk for at least one of the four health risk behaviors (smoking, high-fat diet, sun exposure, relapse from regular mammography screening) **Exclusion:** NR	**N recruited or assessed for eligibilty:** 12384 **N eligible:** 5407 **N randomized** Total: 5407 IG: 2667 CG: 2740 **Followup:** *6 mo* IG: 2118 (79%) CG: No Assessment *12 mo* IG: 2006 (75%) CG: 2252 (82%) *24 mo* IG: 1883 (71%) CG: 2145 (78%) **Cluster information:** Number of clusters: 79 Avg cluster size: NR Inter-cluster correlation: NR Analysis Adjusted for Clustering: Y	**Age (mean):** 44.7 **Sex (% men):** 30.1 **Race/ethnicity:** % White: 96.7 % African American: 1.1 % Asian: 0.4 % Hispanic: 1.3 % Other: 1.8 **SES:** Mean Education (SD): 14.5 (3.2) **Obesity:** NR	**Dietary factors:** Improve diet (substitute lower fat for higher fat foods; avoid high-fat foods; modify food preparation to reduce fat; eat more fruits, vegetables, grains, and high-fiber foods) **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Prochaska, 2005[93] Fair	**Intervention description** CG: NR IG: Subjects were asked "Do you consistently avoid eating high-fat foods?" Those responding "No" were assigned to either Precontemplation ("No--and I do not intend to in the next 6 months"), Contemplation ("No, but I intend to in the next 6 months"), or Preparation ("No, but I intend to in the next 30 days). Those responding "Yes" had to meet a behavioral criterion of estimated fat intake ≤30% calories to be classified into the Action or Maintenance stage. Lastly, subjects who perceived that they consistently avoid high-fat foods, but failed to meet the behavioral criterion, were classified into Precontemplation, Contemplation, or Preparation based on intention to change specific eating habits. 3-5 page reports were sent with the pros and cons of changing and discussed with feedback, when necessary, about under-evaluating the pros of changing and/or over-evaluating the cons. Feedback was given on participants' use of up to 6 change processes relevant to their stage of change. Feedback was given on how to enhance self-efficacy in the most tempting situations and given strategies for taking small steps to the next stage. Participants were a referred to sections of an integrated multiple risk behavior stage-matc self-help manual that were most relevant to their individual process. **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; Mail **Duration (weeks) and Intensity (total min)** IG: Three 3-5 page computer reports at 0, 6, and 12 months **Provider type** IG: "Expert System"	**Dietary:** Dietary Behavior Questionnaire (assessed food consumption over the previous month), 4 subscales **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Prochaska, 2005[93] Fair	**Mean (SD)** **BL 12 mo 24 mo** *Substitution* **IG** 14.3 (5.0) 16.1 (5.1) 16.1 (5.3) **CG** 14.2 (4.3) 15.0 (5.1) 15.1 (5.2) *Modification* **IG** 20.0 (3.5) 20.5 (3.3) 20.6 (3.3) **CG** 19.9 (3.7) 19.9 (3.5) 19.9 (3.6) *Avoidance* **IG** 15.9 (3.4) 16.8 (3.4) 17.0 (3.4) **CG** 15.9 (3.4) 16.0 (3.4) 16.1 (3.3) *Fruit and Vegetable* **IG** 22.5 (5.0) 23.5 (4.9) 23.5 (5.0) **CG** 22.2 (5.0) 22.4 (5.1) 22.4 (5.1) **IG n analyzed:** 1781 **CG n analyzed:** 1920	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Prochaska, 2005[93] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	Died at 12 mo: IG: 7 CG: 7 Died at 24 mo: IG: 7 CG: 8	No other adverse effects reported	**Incentives:** NR **Other:** Cannot combine outcome measures (subscales on dietary behavior questionnaire) in MA

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Roderick, 1997[94] Fair	**Design:** RCT **Location:** UK **Setting:** Practices **Volunteer:** No	**Inclusion:** All patients aged 35-59 years; attending surgery who did not have contra-indications (i.e. known causes of secondary hyperlipidaemia, severe psychiatric illness, pregnancy, terminal illness or those already attending a coronary heart disease health promotion clinic) **Exclusion:** NR	**N recruited or assessed for eligibilty:** NR **N eligible:** NR **N randomized** Total: 956 IG: 473 CG: 483 **Followup (12 mo):** IG: 401 (85% (calc)*) CG: 352 (73% (calc)*) * Percentages calculated were slightly different from reported (86 and 74) **Cluster information:** Number of clusters: 8 Avg cluster size: 120 Inter-cluster correlation: NR Analysis Adjusted for Clustering: Y	**Age (mean):** 47.3 (calc) **Sex (% men):** 50 (calc) **Race/ethnicity:** NR **SES:** % Non-manual: 54.5 (calc) % Car Owners: 84.0 (calc) % Renting: 18.1 (calc) **Obesity:** % BMI > 30 kg/m^2: 16.0 (calc)	**Dietary factors:** fats, complex carbohydrates, fruits/vegetables **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Roderick, 1997[94] Fair	**Intervention description** CG: Standard health education (Guide to Healthy Eating, Giving up Smoking, Look After Your Heart, Heart Disease, and Exercise, Why Bother?) IG: Standard health education (Guide to Healthy Eating, Giving up Smoking, Look After Your Heart, Heart Disease, and Exercise, Why Bother?); Dietary advice aimed at food substitution (nurse and patient negotiated and agreed on up to 5 changes); Dietary sheets were given out according to whether weight loss was required; Special leaflets were given out when appropriate; Overweight patients were given special advice, including a self-monitoring chart and a choice of a calorie-restricted diet. **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual **Duration (weeks) and Intensity (total min)** IG: One appointment at baseline (min NR), further changes at 4-6 weeks, if needed; Intensity NR **Provider type** IG: Nurse	**Dietary:** Dietary food frequency questionnaire (Fehily 1986, 1988) **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Roderick, 1997[94] Fair	Mean (SD) at BL, Mean change at 12 mo **BL 12 mo** *Food Energy from Total Fat, percent* **IG** 34.3 (6.3) -2.4 **CG** 34.2 (6.7) -0.9 **Mean difference* (95%CI):** -1.4 (-2.2, -0.7)** *Food Energy from Saturated Fat, percent* **IG** 13.7 (3.6) -1.5 **CG** 14.0 (3.9) -0.6 **Mean difference (95%CI):** -0.09 (-1.15, -0.2)** *Fiber, g/day* **IG** 23.3 (8.0) 0.86 **CG** 23.2 (9.3) -0.19 **Mean difference (95%CI):** 1.02 (-0.20, 2.23) *Fruit, portions/week* **IG** -- 0.76 **CG** -- 0.28 **Mean difference (95%CI):** 0.44 (-0.24, 1.11) *Vegetables, portions/week* **IG** -- 0.33 **CG** -- -0.25 **Mean difference (95%CI):** 0.50 (-0.9, 1.9) ** Within matched pairs* *** p<0.05* **IG n analyzed:** 473 (BL); 401 (12 mo) **CG n analyzed:** 483 (BL); 352 (12 mo)	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Roderick, 1997[94] Fair	Mean (SD) at BL, Mean change at 12 mo **Adiposity:** **BL 12 mo** *Body Mass Index, kg/m*^{2} **IG** 26.3 (4.4) 0.01 **CG** 25.9 (4.7) 0.14 **Mean difference, matched pairs (95%CI):** -0.12 (-0.30, 0.05) **Blood pressure:** *Systolic Blood Pressure, mmHg* **IG** 124.4 (18.0) -1.14 **CG** 125.2 (15.9) -0.39 **Mean difference, matched pairs (95%CI):** -0.59 (-2.43, 1.24) *Diastolic Blood Pressure, mmHg* **IG** 77.8 (11.8) -0.19 **CG** 77.1 (11.7) -0.09 **Mean difference, matched pairs (95%CI):** 0.09 (-4.9, 5.0) **Lipids:** *Total cholesterol, mmol/L* **IG** NR -0.23 **CG** NR -0.0007 **Mean difference, matched pairs (95%CI):** -0.20 (-0.38, -0.03)** **Glucose tolerance:** NR *** p<0.05* **IG n analyzed:** 473 (BL); 401 (12 mo) **CG n analyzed:** 483 (BL); 352 (12 mo)	4 patients died (not reported by IG and CG)	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Sacerdote, 2005[95] Fair	**Design:** RCT **Location:** Italy **Setting:** GP offices **Volunteer:** No	**Inclusion:** aged 18-65 years; attending the wards of 33 selected GPs; visited their GP for reasons unrelated to gastrointestinal problems and without dietary restrictions **Exclusion:** Obese (BMI>30); affected by chronic or severe diseases	**N recruited or assessed for eligibilty:** NR **N eligible:** 3186 **N randomized** Total: 3179 IG: 1592 CG: 1587 **Followup (12 mo):** IG: 1488 (93.5%) CG: 1489 (93.8%) **Cluster information:** NA	**Age (mean):** 44.5 (calc) **Sex (% men):** 50.0 **Race/ethnicity:** NR **SES:** NR **Obesity:** **%** BMI > 30 kg/m^2: 7.3 *(Exclusion criteria BMI>30 kg/m^2)*	**Dietary factors:** >5 servings a day of fruits and vegetables, >1 serving a week of fish, <3 servings a week of red meat, olive oil in place of other fats **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Sacerdote, 2005[95] Fair	**Intervention description** CG: Received a simpler and non-personalized conversation without the use of a brochure. IG: 15-minutes personalized nutritional intervention, based on a brochure about diet and health and a ahort explanation by the GP. The intervention focused on the importance of higher consumption of fruits, vegetables, fish, and olive oil and lower consumption of red meat, snack, and sweets and was modulated on the basis of sec- and age-specific energy consumption and on unbalanced nutritional habits of each subject. **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual, face-to-face **Duration (weeks) and Intensity (total min)** IG: 1 visit, 15 minutes **Provider type** IG: General practitioner	**Dietary:** Food frequency questionnaire (simplified version of EPIC questionnaire) **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Sacerdote, 2005[95] Fair	Mean (SD) at BL, Mean change (95% CI) at 1 year **BL 12 mo Crude Mean Change** *Fruit and Vegetables, servings/week* **IG** 19.1 (8.4) 22.0 (6.4) 2.89 (1.40, 6.39) **CG** 19.3 (8.5) 20.9 (8.5) 1.58 (-2.12, 2.03) **Adjusted effect of intervention*:** F=2.88, p=0.09 *Fish, servings/week* **IG** 1.3 (1.0) 1.7 (1.3) 0.40 (-0.49, 0.78) **CG** 1.4 (1.1) 1.6 (1.3) 0.16 (-0.27, 0.24) **Adjusted effect of intervention:** F=5.60, p=0.01 *Red Meat, servings/week* **IG** 2.9 (1.9) 2.4 (1.6) -0.47 (-0.38, -0.59) **CG** 2.8 (1.8) 2.6 (1.6) -0.25 (-0.11, -0.35) **Adjusted effect of intervention:** F=1.85, p=0.17 ** Adjusted for sex, BMI, education, and time* **IG n analyzed:** 1592 (BL); 1488 (12 mo) **CG n analyzed:** 1587 (BL); 1489 (12 mo)	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Sacerdote, 2005[95] Fair	Mean (SD) at BL, Mean change (95% CI) at 12 mo **Adiposity:** **BL 12 mo Crude Mean Change** *BMI, kg/m2* **IG** 24.8 (4.2) 24.4 (3.9) -0.41 (-0.07, -0.55) **CG** 24.3 (3.5) 24.3 (3.5) 0 (-0.16, 0.23) **Adjusted effect of intervention*:** F=5.42, p=0.02 **Blood pressure:** *Systolic Blood Pressure, mmHg* **IG** 128.7 (14.5) 128.8 (15.7) 0.15 (-1.40, 0.72) **CG** 128.8 (19.4) 128.6 (14.8) -0.20 (-1.58, 3.44) **Adjusted effect of intervention*:** F=0.01, p=0.93 *Diastolic Blood Pressure, mmHg* **IG** 78.5 (8.6) 78.9 (8.3) 0.44 (-0.75, 0.55) **CG** 78.7 (8.1) 79.3 (20.3) 0.61 (-1.92, 1.16) **Adjusted effect of intervention:** F=0.03, p=0.85 **Lipids:** NR **Glucose tolerance:** NR ** Adjusted for sex, BMI, education, and time* **IG n analyzed:** 1592 (BL); 1488 (12 mo) **CG n analyzed:** 1587 (BL); 1489 (12 mo)	NR	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Stefanick, 1998[96] Fair	**Design:** RCT **Location:** NR (assumed California, US) **Setting:** Face-to-face individual and group sessions, phone, mail **Volunteer:** NR, assumed "mixed"	**Inclusion:** Postmenopausal women 45-64 years, HDL< 60 mg/dL and LDL between 125- 210 mg/dL; men 30-64 years, HDL< 45 mg/dL and LDL between 125 -190 mg/dL; both sexes triglyceride levels ≤500 mg/dL, bp <160/95 mmHg; fasting plasma glucose <140 mg/dL and <200 mg/dL after an oral glucose load; BMI <32 for women, <34 for men; normal results from a maximal treadmill exercise test. **Exclusion:** History of heart disease, stroke, diabetes, recent cancer, other life-threatening illness, or any condition that limited their ability to engage in moderate-intensity exercise; currently using insulin or medications for heart problems, blood pressure, or high serum cholesterol levels; smoked more than 9 cigarettes per day or consumed more than 4 alcoholic drinks per day	**N recruited or assessed for eligibilty:** 1556 **Excluded:** 1076 **Refused:** 65 **N eligible:** 415 **Excluded after eligibility (for treadmill):** 38 **N randomized** Total: 377 Total for diet and CG interventions only: 189 IG: 96 (47 women, 49 men) CG: 93 (46 women, 47 men) **Followup (12 mo):** Women IG: 46 (98%) CG: 45 (98%) Men IG: 49 (100%) CG: 46 (98%) **Cluster information:** NA	**Age (mean):** Women: 56.9 Men: 47.8 (total group) **Sex (% men):** 50.8 (diet component and CG) **Race/ethnicity:** NR **SES:** NR **Obesity:** Mean Body Weight (SD): Women: 69.6 (10.5) (total group) Men: 84.2 (10.8) (total group)	**Dietary factors:** NCEP Step 2 diet (<30% total fat, <7% saturated fat, <200 mg cholesterol) **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Stefanick, 1998[96] Fair	**Intervention description** CG: Asked to maintain usual diet and exercise habits until tests at 1-year were completed. IG1: Dietary recommendations were presented to subjects by dietitians. Participants entered a 12 week adoption phase in which an individualized counseling session was followed by 8 one-hour, mixed-sex group lessons on replacing dietary sources of saturated fat with complex carbohydrates, low-fat dairy foods, and other alternatives, including lean meats. A 6-8 month maintenance phase consisted of monthly contacts with dietitians, by mail, telephone, group, or private meetings. IG2 and 3: Exercise only, exercise plus diet (see PA and combined PA/HD tables) **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: group, individual; face-to-face, phone, mail IG2 and 3: exercise only, exercise plus diet (see PA and combined PA/HD tables) **Duration (weeks) and Intensity (total min)** IG1: 1 individual counseling session (intensity NR), followed by 8 one-hour group sessions for 12 weeks, then monthly contacts by phone, mail, group or individual over 6-8 months, intensity NR IG2 and 3: Exercise only, exercise plus diet (see PA and combined PA tables) **Provider type** IG1: Dietitian IG2 and 3: Exercise only, exercise plus diet (see PA and combined PA tables)	**Dietary:** 24-hour dietary recall questionnaires **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Stefanick, 1998[96] Fair	Mean change (SD) **<u>12 mo</u>** *Caloric intake, kcal/day* Women **IG** -220.2 (355.8) **CG** -19.3 (367.1) Men **IG** -285.2 (540.6) **CG** -24.5 (481.5) *Calories from Carbohydrates, percent* Women **IG** 5.5 (8.0)** **CG** -0.2 (7.3) Men **IG** 8.0 (9.3)*** **CG** 1.1 (6.6) *Calories from Total Fats, percent* Women **IG** -5.7 (7.4)** **CG** -0.2 (6.7) Men **IG** -8.0 (8.1)*** **CG** -0.7 (5.9) *Calories from Saturated Fats, percent* Women **IG** -2.4 (2.8)*** **CG** 0.2 (2.8) Men **IG** -3.4 (3.2)*** **CG** 0.0 (2.4)	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Stefanick, 1998[96] Fair	Mean change (SD) **Adiposity (% body fat, BMI, % overweight):** **<u>12 mo</u>** *Body weight, kg* Women **IG** -2.7 (3.5)*** **CG** 0.8 (4.2) Men **IG** 2.8 (3.5)*** **CG** 0.5 (2.7) *** p<0.001 for comparison with the CG **Blood pressure:** *Resting Systolic Blood Pressure, mmHg* Women **IG** -3.5 (9.2) **CG** -2.4 (7.6) Men **IG** -1.7 (6.4) **CG** 0.3 (7.9) *Resting Diastolic Blood Pressure, mmHg* Women **IG** -1.9 (5.0) **CG** -0.6 (5.9) Men **IG** -0.3 (5.2) **CG** 1.8 (6.1)	NR	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Stefanick, 1998[96] Fair					

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Stefanick, 1998[96] Fair		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Stefanick, 1998[96] Fair	*Calories from Monounsaturated Fats, percent* Women **IG** -2.1 (3.5)* **CG** 0.0 (3.2) Men **IG** -2.8 (3.4)*** **CG** 0.0 (2.9) *Calories from Polyunsaturated Fats, percent* Women **IG** -0.9 (2.3) **CG** -0.3 (2.4) Men **IG** -1.3 (2.2) **CG** -0.7 (1.7) *Cholesterol Intake, mg/day* Women **IG** -67.3 (70.9)*** **CG** 11.8 (85.6) Men **IG** -101.8 (130.5)*** **CG** -3.8 (121.9) *** p<0.001 for comparison with the CG ** p<0.01 for comparison with the CG * p<0.05 for comparison with the CG *Note: Baseline values only presented for the whole group of men and whole group of women, not by IG or CG at baseline* **IG n analyzed: 95** (12 mo) 46(W) + 49(M) **CG n analyzed: 91** (12 mo) 45(W) + 46(M)	

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Stefanick, 1998[96] Fair	**Lipids:** *HDL Cholesterol, mg/dL, mmol/l(calc)* Women **IG** 0.3 (18.9) .008(.489) **CG** 1.0 (6.1) .026(.158) Men **IG** -0.8 (4.4) -.021(.114) **CG** -0.2 (4.3) -.005(.111) *LDL Cholesterol, mg/dL, mmol/l(calc)* Women **IG** -7.3 (18.9) -.189(.489) **CG** -2.5 (16.6) -.026(.504) Men **IG** -10.8 (18.8) -.279(.486) **CG** -4.6 (21.1) -.119(.546) *Total Cholesterol, mg/dL, mmol/l(calc)* Women **IG** -7.9 (20.6) -.204(.533) **CG** -1.0 (19.5) -.026(.504) Men **IG** -13.2 (19.3) -.341(.499) **CG** -3.9 (21.6) -.101(.559) *Triglycerides, mg/dL, mmol/l(calc)* Women **IG** -4.2 (65.1) -.047(.735) **CG** 2.1 (42.4) .024(.479) Men **IG** -6.3 (59.7) -.071(.674) **CG** 8.6 (83.3) .079(.940)			

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Stefanick, 1998[96] Fair					

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Stefanick, 1998[96] Fair		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Stefanick, 1998[96] Fair		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Stefanick, 1998[96] Fair	**Glucose tolerance:** *Fasting Glucose, mg/dL, mmol/l(calc)* Women **IG** -7.7 (6.6) -.428(.367) **CG** -2.6 (15.2) -.144(.844) Men **IG** -7.6 (8.6) -.422(.478) **CG** -3.8 (10.5) -.211(.583) *2-Hour Glucose, mg/dL, mmol/l(calc)* Women **IG** -10.7 (24.6) **CG** -3.3 (28.4) Men **IG** -18.3 (25.2) **CG** -5.8 (28.3) *Note: Baseline values only presented for the whole group of men and whole group of women, not by IG or CG at baseline* *Women* **IG n analyzed:** 46 (12 mo) **CG n analyzed:** 45 (12 mo) *Men* **IG n analyzed:** 49 (12 mo) **CG n analyzed:** 46 (12 mo)			

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Stevens, 2003[97] Fair	**Design:** RCT **Location:** Oregon, US **Setting:** HMO **Volunteer:** No	**Inclusion:** Kaiser health plan member; women aged 40-70; negative results on a recent screening mammogram; cholesterol test within the past 2 years of 200 mg/dL or more, if more than one test was performed the mean had to have been 200 mg/dL or more **Exclusion:** Taking lipid-lowering medications (with the exception of HRT)	**N recruited or assessed for eligibilty:** 5599 **Scheduled for Screening Visit:** 1548 **N eligible:** 755 **Scheduled for secondary screening visit:** 725 **N randomized** Total: 616 IG: 308 CG: 308 **Followup (12 mo):** IG: 274 (calc) (89%) CG: 262 (calc) (85%) **Cluster information:** NA	**Age (mean):** 53.8 (calc) **Sex (% men):** 0 **Race/ethnicity:** % Minority Group Member: 7.1 (calc) **SES:** % College grad or more: 40.3 (calc) **Obesity:** Mean BMI: 30.3 (calc)	**Dietary factors:** Reduction of dietary fat and increased consumption of fruits, vegetables, and whole grains while maintaining or improving nutritional adequacy **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Stevens, 2003[97] Fair	**Intervention description** CG: Breast self-examination, consisting of an individual counseling session plus 2 follow-up calls. Content included a 9-minute video on how to conduct BSE; self-help pamphlets on BSE; barriers-based, problem-solving counseling regarding the participants interest and motivation for BSE. No dietary recommendations. IG: Individual counseling session with an orientation and description of overall goals. Feedback provided on baseline fat, fruit, and vegetable consumption and one or two goals for the first session were selected. If dietary fat was selected, participants completed a computer-assisted assessment and discussed personal goals and plans for change. Personal barriers to dietary change were discussed and tailored strategies to address those barriers were selected. Participants received a personalized printout and nutrition education materials. Those not selecting dietary fat received a counseling session focused on increasing consumption of fruits, vegetables, and grains. The session was tailored along 4 dimensions: barriers, self-efficacy, eating pattern, stage of change. At a second visit, participants received the other intervention section they did not select at baseline. Follow-up calls using motivational interviewing. **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; face-to-face, phone **Duration (weeks) and Intensity (total min)** IG: 2 visits 2-3 weeks apart, 45 minutes each; 2 phone calls 2-3 weeks apart 2-3 weeks after the 2nd visit, 5-10 minutes each **Provider type** IG: Master's degree-level health counselors	**Dietary:** Block Food Frequency Questionnaire, Kristal FFBQ survey **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Stevens, 2003[97] Fair	**Baseline unadjusted mean (SD), 12-mo adjusted Mean (SD)**† **BL** **12 mo** *Energy from fat, percent* **IG** 40.60 (7.25) 34.86 (6.56)* **CG** 39.41 (6.27) 38.61 (6.57) *Fruit and Vegetables, servings/day* **IG** 3.09 (1.76) 4.33 (1.90)* **CG** 3.21 (1.97) 3.40 (1.90) *Kristal Fat Behavior Score* **IG** 1.97 (0.45) 1.70 (0.28)* **CG** 1.87 (0.37) 1.91 (0.28) † Adjusted for baseline values * p-value <0.001 **IG n analyzed:** 274 (Not reported, this is the number present at 12-mo data collection) **CG n analyzed:** 262 (Not reported, this is the number present at 12-mo data collection)	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Stevens, 2003[97] Fair	**Adiposity (% body fat, BMI, % overweight):** NR **Blood pressure:** NR **Lipids:** Mean (SD) **BL** **12 mo** *Serum Cholesterol (mg/dL)* **IG** 230.81 (23.17) 223.42 (26.79)* **CG** 232.08 (25.18) 225.89 (29.24) ** p-value = NS* **IG n analyzed:** 271 **CG n analyzed:** 277 **Glucose tolerance:** NR	NR	No other adverse effects reported	**Incentives:** NR **Other:** Minority enrollement was low, but representative of the demographics of the region.

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
The Trials of Hypertension Research Group, 1992[98] **Kumanyika, 1993**[99] **Satterfield, 1991**[100] **Cook 2007**[109] Fair	**Design:** RCT **Location:** 6 states, US **Setting:** Group and individual counseling sessions **Volunteer:** Yes	**Inclusion:** Healthy men and women; aged 30-54 years; average DBP of all readings throughout each visit: V1-75-97 mmHg, V2-77-94 mmHg, V3-80-89 mmHg); not taking antihypertensive drugs for the previous 2 months **Exclusion:** Average DBP>90 mmHg or current use of antihypertensive medications; average DBP<80 mmHg; BMI>36; history of cardiovascular disease, diabetes mellitus, chronic renal failure, kidney stones, psychiatric disorders, gastointestinal disease; hypercalcemia; unexplained hyperkalemia; malignancy in the past 5 years (except nonmelanoma skin cancer); serious physical handicaps; >21 alcohol drinks/week; other serious or life-threatening illness that requires regular medical treatment; current use of medications that could interfere or interact with study interventions; serum cholesterol ≥260 mg/dL; serum creatine level ≥1.7 mg/dL (men) or ≥1.5 mg/dL (women); casual serum glucose ≥200 mg/dL; unwilling to discontinue use of micronutrient supplements being tested or a dietary regimen incompatible with the intervention; current or intended pregnancy during the study period	**N recruited or assessed for eligibilty:** 16821 **N eligible:** NR **N randomized** Total: 2182 Total in groups pertinent to this review (Na reduction and control): 744 IG: 327 CG: 417 (only 6 of 10 sites were used for Na reduction) **Followup (6, 12, 18 mo):** *6 mo* IG: 228 (69.7% (calc)) CG: 323 (77.5% (calc)) *12 mo* IG: 244 (74.6% (calc)) CG: 342 (82.0% (calc)) *18 mo* IG: 232 (70.9% (calc)) CG: 330 (79.1%) **Cluster information:** NA	**Age (mean):** 43.0 (calc) **Sex (% men):** 71.4 (calc) **Race/ethnicity:** % White: 77.2 (calc) **SES:** % College Graduate: 86.4 (calc) **Obesity:** Mean Weight, kg: 82.8 (calc)	**Dietary factors:** Low sodium **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
The Trials of Hypertension Research Group, 1992[98] **Kumanyika, 1993**[99] **Satterfield, 1991**[100] **Cook 2007**[109] Fair	**Intervention description** CG: Usual care IG1: Group educational sessions, supplemented by individual counseling. Demonstrations and practice were incorporated into each meeting. Focused on shopping, cooking, and food selection behaviors aimed at reducing sodium intake. Participants were provided with additional information, support, and counseling through telephone or mail. IG2-3: Weight loss and stress managment education groups **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Group, individual; face-to-face, telephone, mail **Duration (weeks) and Intensity (total min)** IG1: 8 group sessions and 2 individual sessions of 90 minutes each over 12 weeks. Subsequent meetings semimonthly and then monthly throughout the trial (18 mo), 90 minutes each. **Provider type** IG1: Nutritionists, psychologists, or other experienced counselors (not specified)	**Dietary:** Sodium excretion **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
The Trials of Hypertension Research Group, 1992[98] **Kumanyika, 1993**[99] **Satterfield, 1991**[100] **Cook 2007**[109] Fair	Mean (SD) at BL and 12 mo, Mean change from BL (SD) for 6, 18 mo **BL** **6 mo** **12 mo** **18 mo** *Sodium excretion, mmol/24h* **IG** 154.6 (59.9) -55.68 (76.06)* 100.2 (60.9)† -55.19 (76.93)* **CG** 156.4 (60.5) 2.77 (80.33) 152.1 (73.6) -11.33 (77.68) **Mean difference (95%CI)** -58.45 (-75.80, -45.09) -- -43.86 (-56.88, -30.84) ** p<0.01 for the mean difference between IG and CG* *† p<0.0001 for difference between IG and CG* **IG n analyzed:** 314 (BL); 238 (6 mo); 244 (12 mo); 242 (18 mo) **CG n analyzed:** 401 (BL); 336 (6 mo); 342 (12 mo); 341 (18 mo)	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
The Trials of Hypertension Research Group, 1992[98] **Kumanyika, 1993**[99] **Satterfield, 1991**[100] **Cook 2007**[109] Fair	**Adiposity (% body fat, BMI, % overweight):** NR **Blood pressure:** Mean (SD) at BL, Mean change from BL (SD) at 6, 12, 18 mo and end **BL 6 mo 12mo 18 mo End** *Diastolic Blood Pressure, mmHg* **IG** 83.7 (2.7) -3.88 (6.42) -4.44 (5.38) -4.35 (5.65) -4.12 (5.71) **CG** 83.9 (2.8) -2.88 (6.32) -3.37 (5.74) -3.18 (5.80) -3.27 (5.73) **Mean difference (95%CI)†:** -0.85 (-1.68, -0.02)* *Systolic Blood Pressure, mmHg* **IG** 124.8 (8.5) -5.86 (7.95) -5.83 (7.46) -5.08 (7.94) -4.86 (7.81) **CG** 125.1 (8.1) -3.83 (8.46) -3.93 (7.43) -3.02 (8.31) -3.16 (8.11) **Mean difference (95%CI)†:** -1.69 (-2.85, -0.54)** ** p<0.05* *** p<0.01* *† Mean difference at the end of the study* **IG n analyzed:** 327 (BL); 305 (6 mo); 301 (12 mo); 304 (18 mo); 327 (end) **CG n analyzed:** 417 (BL); 397 (6 mo); 392 (12 mo); 395 (18 mo); 417 (end) **Lipids:** NR **Glucose tolerance:** NR	**TOHP I only** **Long-term mortality** (10 -15 y) IG 10/327 (3.1%) CG 14/417 (3.4%) Adjusted HR 0.76 (0.33, 1.74, P=0.52) **Long-term cardiovascular disease** (MI, stroke, revascularization, or death due to cardiovascular cause) IG 17/231 (7.4%) CG 32/311 (10.3%) Adjusted HR 0.48 (0.25, 0.92, P=0.027) **Overall: TOHP I & II** **Long-term mortality (10 -15 y)** IG 35/1518 (2.3%) CG 42/1608 (2.6%) Adjusted HR 0.80 (0.51, 1.26, P=0.34) **Long-term cardiovascular disease (MI, stroke, revascularization, or death due to cardiovascular cause)** IG 88/1169 (7.5%) CG 112/1246 (9.0%) Adjusted HR 0.70 (0.53, 0.94, P=0.018)	No other adverse effects reported	**Incentives:** NR **Other:** Significant improvements on the Psychological Well-Being scale were observed in the sodium reduction group (p<0.05 at 6 and 18 mo)

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
The Trials of Hypertension Collaborative Research Group, 1997[101] **Hebert, 1995**[102] **Kumanyika, 2005**[103] Good	**Design:** **Location:** 9 states, US **Setting:** Group and individual counseling face-to-face **Volunteer:** Yes	**Inclusion:** Healthy 30-54 year old men and women who were moderately overweight; average DBP 83-89 mmHg and SBP<140 mmHg **Exclusion:** Hypertension (average DBP>90 mmHg and SBP>140) or current use of antihypertensive medication; History of cardiovascular disease, diabetes mellitus, malignancy other than nonmelanoma skin cancer during the past 5 years, or any other serious life-threatening illness that requires regular medical treatment; BMI <26.1 or >37.4 kg/m2 (men) or <24.4 or >37.4 kg/m2 (women); Current use of prescription medications that affect blood pressure or nonprescription diuretics; Serum creatine ≥1.7 mg/dL for men or 1.5 mg/dL for women, or causual serum glucose ≥200 mg/dL; Current alcohol intake >21 drinks/week; Current pregnancy or intent to become pregnant during the study (women)	**N recruited or assessed for eligibilty:** NR **N eligible:** NR **N randomized** Total: 2382 Total in Na reduction and usual care: 1190 IG: 594 CG: 596 **Followup (6, 18, 36 mo)*:** **For Weight:** *6 mo* IG: 539 (90.7%) CG: 561 (94.1%) *18 mo* IG: 532 (89.6%) CG: 551(92.4%) *36 mo* IG: 549 (92.4%) CG: 554 (93.0%) **For Na Excretion:** *18 mo* IG: 450 (77.5%) CG: 470 (79.1%) *36 mo* IG: 467 (78.4%) CG: 482 (80.9%)	**Age (mean):** 43.7 (calc) **Sex (% men):** 66.6 (calc) **Race/ethnicity:** % White: 80.3 (calc) % Black: 17.1 (calc) **SES:** % College Graduate: 52.4 (calc) **Obesity:** Weight: 93.8 kg (calc)	**Dietary factors:** Low sodium **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
The Trials of Hypertension Collaborative Research Group, 1997[101] **Hebert, 1995**[102] **Kumanyika, 2005**[103] Good	**Intervention description** CG: No study-delivered intervention IG: Participants met monthly with a counselor individually until groups could be formed. Groups sessions were conducted weekly for 10 weeks. The goal was to provide participants with core knowledge and behavioral skills necessary to make and maintain reductions in sodium intake. Diet diaries were kept to monitor progress. 4 monthly sessions were then held to prevent relapse. Patients were then contacted on a monthly basis and a series of 3-6 refresher sessions was offered to promote contact and adherence. **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual, group; face-to-face **Duration (weeks) and Intensity (total min)** IG: Initial weekly group sessions 10 weeks (intensity NR); Subsequent monthly group sessions for 4 months (intensity NR); Subsequent one-two time a month contact and offered 3-6 refresher sessions (intensity NR) **Provider type** IG: Centrally trained staff (dietitians, psychologists, or health counselors)	**Dietary:** 24-hour urine collection for sodium excretion **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
The Trials of Hypertension Collaborative Research Group, 1997[101] **Hebert, 1995**[102] **Kumanyika, 2005**[103] Good	Mean (SD) at BL and Mean change (SD) at 18, 36 mo **BL 18 mo 36 mo** *Sodium excretion, mmol/24h* **IG** 186.1 (80.7) -59.5 (91.7) -50.9 (86.3) **CG** 188.0 (80.9) -16.8 (94.8) -10.5 (88.5) **Mean difference (SE)** -42.7 (6.2)** -40.4 (5.7)** *** p<0.001 for comparison with CG* *IG n analyzed: 594 (BL), 450 (18 mo), 470 (36 mo)* *CG n analyzed: 596 (BL), 467 (18 mo), 482 (36 mo)* **Dietary (should not be in MA; use as evidence for no harms):** Mean change (SD) from BL to 18, 36 mo **18 mo 36 mo** *Kcals* † **IG** -284.3 (1002) -414.9 (907.1)* **CG** -113.2 (938) -162.2 (946.1) **Difference (95%CI)** -171.1 (-359.5, 12.2) -252.8 (-429.3, -76.3) *Total fat (g)* † **IG** -18.4 (54.4)* -26.9 (50.7)* **CG** -3.58 (51.1) -9.4 (54.4) **Difference (95%CI)** -14.85 (-25.1, -4.6) -17.7 (-27.7, -7.7) *Saturated fat (g)* † **IG** -7.2 (19.7)* -9.3 (17.2)* **CG** -0.7 (17.9) -2.6 (19.5) **Difference (95%CI)** -6.5 (-10.1, -2.8) -6.7 (-10.2, -3.2) *Fiber (g)* † **IG** 1.1 (10.0) 0.03 (10.1) **CG** -0.5 (10.0) -0.6 (10.4) **Difference (95%CI)** 1.6 (-0.34, 3.54) 0.6 (-1.3, 2.6)	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
The Trials of Hypertension Collaborative Research Group, 1997[101] **Hebert, 1995**[102] **Kumanyika, 2005**[103] Good	**Adiposity (% body fat, BMI, % overweight):** Weight, kg (do not use in MA- can use as evidence for harms) Mean (SD) at BL and Mean change (SD) at 6, 18, 36 mo **BL** / **6 mo** / **18 mo** / **36 mo** **IG** 94.0 (14.3) / -1.1 (3.7)* / 0.4 (4.3) / 1.7 (5.2) **CG** 93.6 (13.5) / 0.1 (3.2) / 0.7 (4.2) / 1.8 (5.3) **Mean difference (SE)** -1.2 (0.2)* / -0.3 (0.3) / 0.0 (0.3) **Blood pressure:** Mean (SD) at BL and Mean change (SD) at 6, 18, 36 mo **BL** / **6 mo** / **18 mo** / **36 mo** *Diastolic* **IG** 86.1 (1.9) / -4.4 (6.7) / -4.4 (6.5) / -3.0 (6.5) **CG** 85.8 (1.9) / -2.8 (6.1) / -3.2 (5.8) / -2.4 (7.0) **Mean difference (SE)** -1.6 (0.4)* / -1.2 (0.4)† / -0.7 (0.4) *Systolic* **IG** 127.7 (6.6) / -5.1 (8.6) / -3.8 (8.2) / -0.7 (9.0) **CG** 127.3 (6.4) / -2.2 (8.1) / -1.8 (7.0) / 0.6 (8.5) **Mean difference (SE)** -2.9 (0.5)* / -2.0 (0.5)* / -1.2 (0.5)# ** p<0.001 for comparison with CG* *† p=0.002 for comparison with CG* *# p=0.02 for comparison with CG* *Note: Subgroups available (White Men, Black Men, White Women, Black Women)* **Lipids:** NR **Glucose tolerance:** NR **IG n analyzed:** 594 (BL), 529 (6 mo), 513 (18 mo), 515 (36 mo) **CG n analyzed:** 596 (BL), 538 (6 mo), 525 (18 mo), 514 (36 mo)	**See TOHP I for overall results** **TOHP II** **Long-term mortality (5 -10 y)** IG 25/1191 (2.1%) CG 28/1191 (4.4%) Adjusted HR 0.83 (0.48, 1.41, P=0.49) **Long-term cardiovascular disease (MI, stroke, revascularization, or death due to cardiovascular cause)** IG 71/938 (7.6%) CG 80/935 (8.6%) Adjusted HR 0.79 (0.57, 1.09, P=0.16)	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
The Trials of Hypertension Collaborative Research Group, 1997[101] **Hebert, 1995**[102] **Kumanyika, 2005**[103] Good			**For BP:** *6 mo* IG: 529 (89.1%) CG: 538 (90.3%) *18 mo* IG: 513 (86.4%) CG: 525 (88.1%) *36 mo* IG: 515 (86.7%) CG: 514 (86.2%) ** All percentages calculated.* **Cluster information:** NA		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
The Trials of Hypertension Collaborative Research Group, 1997[101] **Hebert, 1995**[102] **Kumanyika, 2005**[103] Good		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
The Trials of Hypertension Collaborative Research Group, 1997[101] **Hebert, 1995**[102] **Kumanyika, 2005**[103] Good	*† Conducted on a random subsample of participants:* *IG n at 18, 36 mo: 199, 212* *CG n at 18, 36 mo: 211, 214*	

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
The Trials of Hypertension Collaborative Research Group, 1997[101] **Hebert, 1995**[102] **Kumanyika, 2005**[103] Good				

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Tinker, 2008[104] **Prentice, 2006**[105] **Howard, 2006**[106] **The WHI Study Group, 1998**[107] Good	**Design:** RCT **Location:** 24 states and DC, US **Setting:** Face-to-face **Volunteer:** Yes	**Inclusion:** Women 50-79 years; postmenopausal at time of enrollment; ability to provide informed consent; and agreement to reside in the area for at least 3 years after enrollment **Exclusion:** History of breast or colorectal cancer; any cancer within the past 10 years except nonmelanoma skin cancer; medical conditions with a predicted survival of less than 3 years; adherence or retention concerns; current dietary intake of less than 32% of energy from fat; and type 1 diabetes mellitus	**N recruited or assessed for eligibilty:** 373092 **N excluded:** 316953 **N eligible and provided consent:** 56139 **N further excluded:** 7304 **N randomized** Total: 48835 IG: 19541 (Excluded due to diabetes at BL: 1165) CG: 29294 (Excluded due to diabetes at BL: 1783) **N for analysis:** IG: 18376 CG: 27511	**Age (mean):** 62.2 **Sex (% men):** 0 **Race/ethnicity:** % White: 82.4 % Black: 10.0 % Hispanic: 3.7 % American Indian: 0.4 % Asian/Pacific Islander: 2.2 %Unknown: 1.3 **SES:** NR **Obesity:** % BMI≥30: 36.3	**Dietary factors:** 20% low-fat dietary pattern with increased vegetables, fruits, and grains **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Tinker, 2008[104] **Prentice, 2006**[105] **Howard, 2006**[106] **The WHI Study Group, 1998**[107] Good	**Intervention description** CG: Usual-diet IG: Women were assigned a permanent intervention group of 10-12 members that met with trained nutritionist. Each patient received one individual counseling session with the interventionist to ensure nutritional balance. Optional peer-led meetings were also conducted. Sessions covered the major sources of fat in the American diet and the critical nutrition skills needed for major changes in fat consumption. Later topics emphasized behavioral skills such as problem-solving for low-fat party and holiday foods. Maintenance was discussed in later sessions **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Group, individual; face-to-face **Duration (weeks) and Intensity (total min)** IG: Intervention group met weekly for 6 weeks, every other week for 6 weeks, monthly for the rest of the first year, intensity NR. Individual session 12-16 weeks from beginning of intervention, intensity NR. Dietary maintenance sessions occurred quarterly after the first year, intensity NR. Intensity and Duration of peer-led meetings NR **Provider type** IG: Nutritionist and peer-led	**Dietary:** Food frequency questionnaire (designed for WHI); Electrocardiogram, enzyme levels, and/or hospitalization records (CHD); Rapid onset of a neurologic deficit lasting >24 hours or until death, requiring hospitalization and supported by imaging studies when available (stroke) **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Tinker, 2008[104] **Prentice, 2006**[105] **Howard, 2006**[106] **The WHI Study Group, 1998**[107] Good	Mean (SD) **BL 12 mo* 72 mo*** *Dietary Energy, kcal* **IG** 1790 (709) 1502 (541) 1435 (549) **CG** 1788 (699) 1594 (640) 1548 (635) *Energy from Total Fat, percent* **IG** 37.7 (5.0) 24.2 (7.4) 28.6 (8.3) **CG** 37.7 (5.0) 35.0 (6.9) 36.9 (7.3) *Energy from Saturated Fatty Acids, percent* **IG** 12.7 (2.5) 8.0 (2.8) 9.5 (3.2) **CG** 12.7 (2.5) 11.7 (2.9) 12.4 (3.1) *Energy from Trans-Fatty Acids, percent* **IG** 2.7 (1.1) 1.6 (0.8) 1.8 (0.9) **CG** 2.8 (1.1) 2.5 (1.1) 2.3 (1.1) *Energy from Polyunsaturated fatty acids, percent* **IG** 7.7 (2.0) 5.2 (1.8) 6.0 (2.0) **CG** 7.7 (2.0) 7.2 (2.1) 7.5 (2.1) *Energy from Carbohydrates, percent* **IG** 45.6 (6.3) 58.5 (8.8) 54.1 (9.9) **CG** 45.6 (6.2) 48.0 (8.0) 45.9 (8.8) *Energy from Starch, percent* **IG** 18.3 (4.0) 21.8 (5.3) 19.1 (5.1) **CG** 18.3 (4.0) 18.3 (4.4) 16.9 (4.5) *Energy from Total sugars, percent* **IG** 21.6 (5.7) 28.6 (7.4) 27.3 (7.7) **CG** 21.5 (5.6) 23.4 (6.8) 22.9 (7.1) *Energy from Protein, percent* **IG** 16.4 (2.9) 17.6 (3.1) 17.7 (3.3) **CG** 16.4 (3.0) 16.8 (3.2) 17.1 (3.3)	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Tinker, 2008[104] **Prentice, 2006**[105] **Howard, 2006**[106] **The WHI Study Group, 1998**[107] Good	Mean (SD) **Adiposity (% body fat, BMI, % overweight):** **BL** **12 mo** **72 mo** *Weight, kg* **IG** 76.4 (16.5) 74.0 (16.5)* 75.6 (16.8)* **CG** 76.2 (16.3) 75.9 (16.5) 76.2 (16.6) *BMI, kg/m2* **IG** 28.9 (5.8) 28.0 (5.8)* 28.8 (5.9)* **CG** 28.9 (5.8) 28.7 (5.7) 29.1 (5.8) **IG n analyzed (BL, 12 mo, 72 mo):** 18291, 17026, 14409 **CG n analyzed (BL, 12 mo, 72 mo):** 27386, 24977, 22321 **Blood pressure:** *Systolic, mmHg, Mean (SD)* **IG** 127.1 (17.2) 124.4 (17.1)* 124.5 (16.5) **CG** 127.4 (17.1) 125.4 (16.8) 124.6 (16.3) **IG n analyzed (BL, 12 mo, 72 mo):** 18375, 17126, 14543 **CG n analyzed (BL, 12 mo, 72 mo):** 27510, 25173, 22532 *Diastolic, mmHg, Mean (SD)* **IG** 75.9 (9.1) 73.9 (9.2)* 71.7 (9.2) **CG** 76.0 (9.0) 74.7 (9.1) 71.9 (9.2) **IG n analyzed (BL, 12 mo, 72 mo):** 18370, 17125, 14540 **CG n analyzed (BL, 12 mo, 72 mo):** 27505, 25169, 22532	HR (95% CI)* **36 mo** Major CHD†‡ 0.98 (0.88,1.09) Nonfatal MI 0.98 (0.87, 1.11) CHD death 1.02 (0.84, 1.25) Stroke 1.02 (0.90, 1.15) Fatal§ 0.97 (0.69, 1.36) Nonfatal 1.03 (0.90, 1.17) Ischemic 1.01 (0.86, 1.18) Hemorrhagic 0.90 (0.66, 1.22) *From an unweighted proportional hazards model stratified by prevalent condition, age, and hormone therapy randomization group †MI includes clinical MI and silent MI ‡Nonfatal MI is defined as no definite CHD death within 28 days of MI § Fatal stroke is defined as death within 30 days of stroke, or source of outcome is cause of death only By 36 mo, 950 died in IG and 1454 died in CG **IG n analyzed (36 mo, 8.1 yrs):** 19541 **CG n analyzed (36 mo, 8.1 yrs):** 29294	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Tinker, 2008[104] **Prentice, 2006**[105] **Howard, 2006**[106] **The WHI Study Group, 1998**[107] Good			**Followup (BL, 12, 72 mo):** *BL** IG: 18306 (99.6%) CG: 27435 (99.7%) *12 mo* IG: 17117 (93.1%) CG: 25182 (91.5%) *72 mo* IG: 14117 (76.8%) CG: 21759 (79.1%) ** Dietary data was missing at BL, causing the sample to differ from the number randomized* **Cluster information:** NA		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Tinker, 2008[104] **Prentice, 2006**[105] **Howard, 2006**[106] **The WHI Study Group, 1998**[107] Good		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Tinker, 2008[104] **Prentice, 2006**[105] **Howard, 2006**[106] **The WHI Study Group, 1998**[107] Good	*Vegetable or Fruit, servings/day* **IG** 3.6 (1.8) 5.1 (2.3) 5.0 (2.5) **CG** 3.6 (1.8) 3.9 (2.0) 3.8 (2.0) *Grain, servings/day* **IG** 4.7 (2.5) 5.1 (2.7) 4.1 (2.3) **CG** 4.7 (2.5) 4.2 (2.3) 3.7 (2.1) *Whole Grains, servings/day* **IG** 1.1 (0.8) 1.4 (0.9) 1.2 (0.8) **CG** 1.1 (0.8) 1.1 (0.7) 1.0 (0.7) *Dietary Fiber, g/1000 kcal* **IG** 8.8 (2.4) 12.3 (3.6) 12.0 (3.9) **CG** 8.8 (2.4) 9.7 (3.1) 9.6 (3.2) ** All 12 mo and 72 mo IG results were significantly different from the control at p<0.001* **IG n analyzed:** 18306 (BL); 17117 (12 mo); 14117 (72 mo) **CG n analyzed:** 27435 (BL); 25182 (12 mo); 21759 (72 mo)	

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Tinker, 2008[104] **Prentice, 2006**[105] **Howard, 2006**[106] **The WHI Study Group, 1998**[107] Good	Mean (95% CI) **Lipids:** **BL** **36 mo** *Total Cholesterol, mg/dL* † IG 220.90 (218.38, 223.48) 211.20 (208.51, 213.87) CG 220.90 (218.76, 223.11) 213.60 (211.44-215.78) Relative change (95%CI): 0.98 (0.97, 1.00) *LDL Cholesterol, mg/dL* † IG 128.40 (125.91, 131.04) 118.70 (116.18, 121.33) CG 129.40 (127.32, 131.47) 122.20 (120.13, 124.39) Relative change (95%CI): 0.97 (0.95, 1.00) *HDL Cholesterol, mg/dL* † IG 58.05 (56.95, 59.17) 57.65 (56.47, 58.86) CG 56.44 (55.59, 57.30) 56.20 (55.29, 57.13) Relative change (95%CI): 0.99 (0.98, 1.01) *Triglycerides, mg/dL* † IG 138.60 (133.98, 143.29) 142.30 (137.17, 147.53) CG 141.10 (137.35, 144.95) 144.60 (140.76, 148.50) Relative change (95%CI): 1.00 (0.97, 1.04) Mean (SD) **Glucose tolerance:** *Glucose, mg/dL* †† **IG** 94.4 (14.9) 92.4 (10.9)* 96.6 (15.5) **CG** 94.6 (12.5) 94.3 (13.4) 96.2 (15.6) **IG n analyzed (BL, 12 mo, 72 mo):** 979, 915, 760 (subsample, weighted by ethnicity) **CG n analyzed (BL, 12 mo, 72 mo):** 1525, 1366, 1165 (subsample weighted by ethnicity)			

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Tinker, 2008[104] **Prentice, 2006**[105] **Howard, 2006**[106] **The WHI Study Group, 1998**[107] Good					

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Tinker, 2008[104] **Prentice, 2006**[105] **Howard, 2006**[106] **The WHI Study Group, 1998**[107] Good		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Tinker, 2008[104] **Prentice, 2006**[105] **Howard, 2006**[106] **The WHI Study Group, 1998**[107] Good		

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Tinker, 2008[104] **Prentice, 2006**[105] **Howard, 2006**[106] **The WHI Study Group, 1998**[107] Good	** IG was significantly different from the control at p<0.001* *† Outcomes available for 5.8% subsample, but specific n not reported* *†† Outcomes available for 5.8% of subsample* *Note: Lipid data is from Prentice 2006 and includes diabetics that Tinker 2008 excluded at BL* **Diabetes:** 1303 IG participants and 2039 CG participants reported incident diabetes by 6 years.			

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Watanabe, 2003[108] Fair	**Design:** RCT **Location:** Japan **Setting:** Individual face-to-face and mail **Volunteer:** No	**Inclusion:** Male workers at high risk for type 2 diabetes; aged 35-70 years; living in Tokyo metro **Exclusion:** Taking hypoglycemic agents; cholesterol-lowering drugs; or antihypertensive drugs	**N recruited or assessed for eligibilty:** NR **N eligible:** NR **N randomized** Total: 173 IG: 86 CG: 87 **Followup (12 mo):** IG: 79 (92%) CG: 77 (90%) **Cluster information:** NA	**Age (mean):** 55.1 (calc) **Sex (% men):** 100 **Race/ethnicity:** NR **SES:** NR **Obesity:** Mean BMI: 24.4 (calc)	**Dietary factors:** Reducing total energy intake at dinner, protein energy around 15-20%, fat energy around 20-25%, carbohydrate energy at 55-60% and to optimize the intake of whole-grain products, vegetables, fruits, low-fat milk, beans, fish, meat, and eggs and maintain alcohol intake at an appropriate level. **Physical activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Description of Intervention and Control	Outcome measurement (instrument used)
Watanabe, 2003[108] Fair	**Intervention description** CG: Oral and written information about results of health exam and results of food questionnaire but without a detailed description. Received only conventional group counseling using a leaflet with general information for prevention of lifestyle-related diseases IG: Individualized counseling using a booklet describing the details of dietary education (reduce total energy intake by modifying dietary intake and to adopt habits appropriate for prevention of diabetes). At 1 month, participants received tailored dietary counseling through a booklet illustrating recommendations for meals. For the second part of the program, participants received via mail: checklist of 10 items to assess dietary intake, information related to improving dietary behavior, personalized example menus, information to condirm the necessity of blood glucose control. **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; face-to-face, mail **Duration (weeks) and Intensity (total min)** IG: 1 counseling plus booklet (intensity NR), at 1 month counseling pl booklet, then at 6 months mailed materials **Provider type** IG: NR	**Dietary:** From the FFQW65, a "overintake/underintake fraction" was used to measure dietary intake: (Actual energy intake/RDA - 1)100 **Physical Activity:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	HD Behavioral Outcomes	PA Behavioral Outcomes
Watanabe, 2003[108] Fair	Mean absolute value (SD) at BL, Mean changes at 12 mo (SD) **BL 12 mo** *Daily "overintake/underintake fraction" for total energy intake, percent* **IG** 21.6 (15.0) -1.8 (1.5)* **CG** 19.9 (14.9) 4.0 (1.4) **Adjusted mean difference (95%CI)†:** -6.0 (-9.8, -2.2) *No statistically significant differences at baseline* ** p=0.002 for the adjusted difference between groups at 12 mo* *† Adjusted for baseline value* **IG n analyzed:** 79 **CG n analyzed:** 77	NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Watanabe, 2003[108] Fair	**Adiposity (% body fat, BMI, % overweight):** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** Mean (SD) at BL, mean percent change (SD) at 12 mo *Fasting Plasma Glucose, mmol/L* **BL** **12 mo** **IG** 6.1 (0.55)* -0.5 (0.9) **CG** 5.5 (0.55) 2.2 (0.9) **Adjusted mean difference (95%CI)††:** -1.8 (-4.2, 0.6) *1-h Plasma Glucose, mmol/L* **IG** 10.7 (1.8) -5.2 (2.6) **CG** 10.6 (1.6) -3.3 (2.3) **Adjusted mean difference (95%CI)††:** -3.7 (-9.9, 2.5) *2-h Plasma Glucose, mmol/L* **IG** 8.2 (1.5)** -8.2 (1.9)† **CG** 7.3 (1.7) 11.2 (3.0) **Adjusted mean difference (95%CI)††:** -15.2 (-8.4, -22.0) ***** *p<0.05 for baseline differences between groups* *** p<0.01 for baseline differences between groups* *† p<0.001 for the adjusted difference between groups at 12 mo* *†† Adjusted for baseline values* **IG n analyzed:** 79 **CG n analyzed:** 77	NR	No other adverse effects reported	**Incentives:** NR **Other:** NR

Appendix C Table 2. Healthful Diet Counseling Evidence Table

adj – adjusted; AHA – American Heart Association; BL – baseline; BMI – body mass index; calc – calculated; Cal – calcium; CG – control group; CI – confidence interval; CONSORT – Consolidated Standards of Reporting Trials; COPD – chronic obstructive pulmonary disease; DBP – diastolic blood pressure; DC – District of Columbia; DM – diabetes mellitus; exer – exercise; FFBQ – Food Frequency Block Questionnaire; FFQ – Food Frequency Questionnaire; FPG – fasting plasma glucose; F&V – fruits and vegetables; g – gram; GP – general practitioner; HCF – high-carbohydrate fiber; HD – healthy diet; HDL – high-density lipoprotein; HMO – health maintenance organization; HPT – Hypertension Prevention Trial; HTN – hypertension; IG – intervention group; K – potassium; kcal – kilogram calories; kg – kilograms; kg/m^2 – kilograms per meter squared; lb – pound; LDL – low-density lipoprotein; mEq – milliequivalents; mg – milligrams; mg/dl – milligram per deciliter; MHEI – Modified Healthy Eating Index; min – minutes; mmHg – millimeters of mercury; mmol/L – millimoles per liter; mo – month; MOS – Medical Outcomes Study; N – number; Na – sodium; NA – not applicable; NR – not reported; NS – not significant; PA – physical activity; RCT – randomized controlled trial; SBP – systolic blood pressure; SD – standard deviation; SE – standard error; SES – socioeconomic status; svgs – servings; UK – United Kingdom; US – United States

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Aldana, 2006[110] **Aldana, 2005**[111] Fair	**Design:** RCT **Location:** Illinois **Setting:** NR **Volunteer:** Yes	**Inclusion:** 18 years or older; willing to begin in 1 or 7 months **Exclusion:** Significant systemic or major illnesses including CHF, CAD, cerebrovascular disease, pulmonary disease with hypoxia, renal failure, organ transplantation, serious psychiatric disease, malignancy that would preclude adequate follow-up, or any other condition that would impede regular physical activity	**N recruited or assessed for eligibility:** 403 **N eligible:** 377 **N randomized** Total: 348 IG: 174 CG: 174 **Followup (6 mo):** IG: 153 (88%) CG: 165 (95%) **Cluster information:** NA	**Age (mean):** 50.5 (calc) **Sex (% men):** 28 **Race/ethnicity:** % White: 94 % Black: 4 % Other: 1.4 **SES:** % >$60,000: 50 % Married: 76 % > High school: 72 **% Obese:** Mean BMI: 32.4 (calc)	**Dietary factors:** More plant-based, whole-food diet low in fat (<20%), animal protein, sugar, and salt; high in fiber, antioxidant, and micronutrients; very low in cholesterol **Physical activity:** 30 min/day of walking or general fitness activities

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Aldana, 2006[110] **Aldana, 2005**[111] Fair	**Intervention description** CG: Wait-list IG1: Educational sessions addressing modern medicine and health myths, atherosclerosis, coronary risk factors, obesity, dietary fiber and fat, diabetes, hypertension, cholesterol, exercise, osteoporosis, cancer, lifestyle, behavior change and self-worth. Participants also received a workbook with assignments. They also had access to shopping trips with dietitians and cooking demonstrations **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Group; face-to-face **Duration (weeks) and Intensity (total min)** IG1: 4 times each week for 2 hours over 4 weeks; 2400 minutes **Provider type** IG1: Dietetic and medical professionals	**Dietary:** Block 98 full-length questionnaire **Physical Activity**: 7-day self-recorded pedometer log

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Aldana, 2006[110] **Aldana, 2005**[111] Fair	Mean (SD) at BL and 6 mo, Change in mean between IG and CG (95% CI) at 6 mo **BL** / **6 mo** / **6 mo change** *Kcal intake/day* **IG** 2092 (1030) / 1534 (691) / -412 (-556, -271)* **CG** 1919 (805) / 1773 (777) *Fat, % intake* **IG** 36.7 (6.9) / 28.5 (7.0) / -9.2 (-10.6, -7.6)* **CG** 34.6 (7.4) / 35.6 (8.3) *Protein, % intake* **IG** 15.2 (2.8) / 14.4 (2.2) / -1.5 (-2.1, -0.8)* **CG** 14.7 (2.5) / 15.4 (3.2) *Carbohydrates, % intake* **IG** 48.7 (8.0) / 59.2 (8.5) / 11.9 (10.1, 13.6)* **CG** 50.8 (8.2) / 49.4 (9.6) *Vegetable, servings/day* **IG** 3.3 (2.1) / 4.7 (2.6) / 1.3 (0.9, 1.9)* **CG** 3.4 (2.2) / 3.5 (2.1) *Fruit, servings/day* **IG** 1.3 (1.0) / 2.2 (1.2) / 0.9 (0.6, 1.1)* **CG** 1.6 (1.1) / 1.6 (1.1) *Whole grain, servings/day* **IG** 5.4 (2.9) / 6.1 (3.2) / 1.2 (0.7, 1.7)* **CG** 5.0 (2.4) / 4.5 (2.3) *Fat, g/day* **IG** 88.6 (55.3) / 50.6 (33.5) / -33.1 (-40.6, -25.7)* **CG** 76.8(42.9) / 71.9 (40.3)

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Aldana, 2006[110] **Aldana, 2005**[111] Fair	Mean (SD) at BL and 6 mo, Change in mean between IG and CG (95% CI) at 6 mo **BL** **6 mo** **6 mo change** *Total steps/week* **IG** 40,579 (22,631) 52,951 (24,240) 6711(3026, 10,396)* **CG** 43,869 (23,466) 49,530 (22,544) **p<0.0002* **IG n analyzed:** 174 **CG n analyzed:** 174

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Aldana, 2006[110] **Aldana, 2005**[111] Fair	Mean (SD) at BL and 6 mo, Change in mean between IG and CG (95% CI) at 6 mo **Adiposity:** **BL** / **6 mo** / **6 mo change** *BMI* **IG** 33.3 (8.0) 31.7 (8.1) -1.3 (-1.65, -0.96)* **CG** 31.4 (9.0) 31.1 (9.2) *Body fat, percent* **IG** 40.6 (8.8) 38.2 (9.6) -1.6 (-2.3, -0.9)* **CG** 37.9 (10.3) 37.1 (10.5) *Weight, kg* **IG** 93.3 (24.1) 88.8 (24.0) -3.9 (-5.0, -2.8)* **CG** 87.7 (25.9) 87.1 (26.0) **Blood Pressure:** *Systolic, mmHg* **IG** 129 (16) 124 (18) -1 (-4, 2) **CG** 128 (17) 124 (18) *Diastolic, mmHg* **IG** 78.3 (9.2) 72.8 (9.7) -1.7 (-3.5, -0.0)* **CG** 76.7 (9.6) 72.9 (9.7) **Lipids:** *Cholesterol, mg/dL* **IG** 193 (33) 199 (34) -5 (-11, 1) **CG** 190 (39) 201 (39) *HDL, mg/dL* **IG** 45.0 (12.2) 46.4 (11.8) -1.4 (-2.9, -0.0)* **CG** 45.0 (10.4) 47.8 (10.4)	n (%) **BL** / **6 mo** *Glucose ≥ 126mg/dL* **IG** 21 (12.1) 17 (9.8)* **CG** 7 (4.0) 9 (5.2) *SBP 140-159 mmHg* **IG** 35 (20.1) 28(16.1)* **CG** 40 (23.0) 21(12.1)* *SBP ≥ 160 mmHg* **IG** 8 (4.6) 6(3.4)* **CG** 5 (2.9) 8(4.6) *DBP 90-99 mmHg* **IG** 20 (11.5) 7(4.0)* **CG** 18 (10.3) 5(2.9)* *DBP ≥ 100 mmHg* **IG** 2 (1.2) 1(0.6)* **CG** 2 (1.2) 2(1.2) ** p<0.05, change in proportion* **IG n analyzed:** 174 **CG n analyzed:** 174	NR	Ancillary article states those attending 6 week visit eligible for $50, but nothing stated in primary article.

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Aldana, 2006[110] **Aldana, 2005**[111] Fair					

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Aldana, 2006[110] **Aldana, 2005**[111] Fair		

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes		
Aldana, 2006[110] **Aldana, 2005**[111] Fair	*Cholesterol, mg/day*		
	IG 216 (140)	94 (90)	-132 (-153, -108)*
	CG 182 (112)	192 (140)	
	Polyunsaturated fat, g/day		
	IG 21.2 (14.0)	13.6 (8.3)	-6.0 (-8.1, -4.1)*
	CG 19.3 (12.0)	17.7 (10.4)	
	Monounsat fat, g/day		
	IG 34.3 (21.6)	18.8 (13.1)	-13.7(-16.6, -10.6)*
	CG 29.7 (17.2)	27.9 (16.3)	
	Saturated fat, g/day		
	IG 26.3 (17.3)	13.3 (10.5)	-11.6(-13.9, -9.3)*
	CG 21.8 (12.1)	20.5 (12.0)	
	Sodium, mg/day		
	IG 2941(1530)	2332 (1216)	-383 (-590, -176)*
	CG 2712 (1233)	2486 (1135)	
	**p<0.01*		
	IG n analyzed: 174 **CG n analyzed:** 174		

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Aldana, 2006[110] **Aldana, 2005**[111] Fair	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes			Health Outcomes	Adverse Effects	Comment
Aldana, 2006[110] **Aldana, 2005**[111] Fair	*LDL, mg/dL* **IG** 122 (29) **CG** 121 (33) *Triglycerides, mg/dL* **IG** 133 (102) **CG** 115 (86) **Glucose Tolerance:** *Glucose, mg/dL* **IG** 103 (23) **CG** 100 (19) ** p< 0.05* **IG n analyzed:** 174 **CG n analyzed:** 174	127 (29) 130 (34) 128 (78) 117 (69) 100 (20) 99 (22)	-4 (-9, 2) -7 (-22, 9) -2 (-6, 0.4)			

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Babazono, 2007[112] Fair	**Design:** RCT **Location:** Japan **Setting:** Health Center **Volunteer:** No	**Inclusion:** Systolic blood pressure 130-159 mmHg, diastolic pressure 85-99 mmHg, or $HbA_{1c} \geq 5.6\%$ **Exclusion:** Those judged to be critically in need of medical treatment	**N recruited or assessed for eligibility:** 305 **N eligible:** NR **N attended consent visit:** 113 **N randomized** Total: 99 IG: 50 CG: 49 **Followup (12 mo):** IG: 46 (92%) CG: 41 (84%) **Cluster information:** NA	**Age (mean):** 64.4 **Sex (% men):** 42 **Race/ethnicity:** % Japanese: 100 (assumed) **SES:** NR **% Obese:** Mean BMI: 23.8 (calc)	**Dietary factors:** Improve nutrition (specific goals NR) **Physical activity:** Increase physical activity (specific goals NR)

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Babazono, 2007[112] Fair	**Intervention description** CG: Received results of health examination and written instructions regarding exercise IG1: The support team assisted with goal setting and advice during baseline visit and 2 home visits along with reinforcement at 2 data collection visits **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual; face-to-face **Duration (weeks) and Intensity (total min)** IG1: 6 months of intervention; intensity NR **Provider type** IG1: Support team of dietitians, exercise instructors, public health nurses	**Dietary:** Questionnaire, specific instrument NR **Physical Activity**: Pedometer recording steps/day over the previous 7 days

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Babazono, 2007[112] Fair	Number (percent) **BL 12 mo** *≥ 2 meals/day with vegetable servings* **IG** 34 (73.9) 40 (87.0) **CG** 29 (70.7) 30 (73.2) **OR (95% CI):** 3.8 (1.0, 14.0), p<0.05 Mean (SD) *Energy intake, kcal* **IG** 1931 (482) 1868 (510) **CG** 1859 (417) 1815 (484) NS **IG n analyzed:** 46 **CG n analyzed:** 41

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Babazono, 2007[112] Fair	Mean (SD) **BL** **12 mo** *Number of steps* **IG** 7345(3890) 10373(4089) **CG** 7196(3682) 6815(3421) *p<0.001* **IG n analyzed:** 46 **CG n analyzed:** 41

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Babazono, 2007[112] Fair	Mean(SD) **Adiposity:** **BL 12 mo** *Weight, kg* **IG** 58.5 (9.7) 57.1 (9.5) **CG** 58.6 (9.1) 58.1 (8.8) *BMI* **IG** 23.6 (3.2) 23.1 (3.2) **CG** 24.0 (2.5) 23.9 (2.4) **Blood Pressure:** *Systolic, mmHg(SD)* **IG** 127.6 (15.7) 122.4 (16.3) **CG** 132.0 (17.8) 123.3 (15.2) *Diastolic, mmHg(SD)* **IG** 78.2 (9.0) 74.5 (10.2) **CG** 79.3 (11.8) 75.0 (10.2) **Lipids:** *Total cholesterol, mg/dL(SD)* **IG** 204.3 (31.8) 201.9 (32.2) **CG** 207.0 (30.2) 209.6 (32.4) *HDL, mg/dL(SD)* **IG** 54.5 (13.4) 56.7 (14.2) **CG** 55.7 (12.9) 56.5 (15.6) *LDL, mg/dL(SD)* **IG** 121.0 (29.2) 119.6 (28.0) **CG** 123.8 (28.2) 123.9 (26.6) *Triglycerides, mg/dL(SD)* **IG** 174.8 (103.5) 146.9 (70.9) **CG** 166.0 (7.7) 167.4 (91.1)	n (%) **BL 12 mo** *Hypertensive* **IG** 15 (30.0) 10 (21.7) **CG** 15 (30.6) 6 (14.6) *Diabetic* **IG** 10 (20.0) 11 (23.9) **CG** 7 (14.3) 10 (24.4) **IG n analyzed:** 50 (BL), 46 (12 mo) **CG n analyzed:** 49 (BL), 41 (12 mo)	NR	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Babazono, 2007[112] Fair					

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Babazono, 2007[112] Fair		

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Babazono, 2007[112] Fair	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Babazono, 2007[112] Fair	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Babazono, 2007[112] Fair	**Glucose Tolerance:** *HbA1c, %(SD)* **IG** 5.5 (0.6) 5.5 (0.4) **CG** 5.4 (0.4) 5.4 (0.4) *NS for all measures* **IG n analyzed:** 46 **CG n analyzed:** 41			

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Brekke, 2005[81] **Brekke, 2004**[113] Fair	**Design:** RCT **Location:** Sweden **Setting:** NR **Volunteer:** Yes	**Inclusion:** 2 first-degree relatives or 1 first-degree with at least 2 second-degree relatives with type 2 diabetes; normal liver function tests, electrolytes, and hemoglobin; no history of endocrine or cardiovascular diseases **Exclusion:** Fasting blood glucose ≥ 6.1mmol/l or 2-hour blood glucose ≥ 11.1 mmol/l; BMI > 35 kg/m^2; presence of any disease or use of medications affecting glucose or lipid metabolism	**N recruited or assessed for eligibility:** 100 **N eligible:** NR **N randomized** Total: 77 IG1 (Diet): 25 IG2 (Diet+Exer): 30 CG: 22 **Followup (12 mo):** IG1: 24 (96%) IG2: 25 (83.3%) CG: 19 (86.4%) **Cluster information:** NA	**Age (mean):** 42.6 (calc) **Sex (% men):** 63 **Race/ethnicity:** NR **SES:** NR **% Obese:** Mean BMI: 25.7 (calc) ** All characteristics for 1 year completers*	**Dietary factors:** Reduce saturated fat intake; increase monounsaturated fat and n-3 fatty acids; increase vegetable, fruit, and fiber intake **Physical activity:** Exercise 30 minutes, 4-5 times/week

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Brekke, 2005[81] **Brekke, 2004**[113] Fair	**Intervention description** CG: Wait-list for 12 months IG1 (Diet): Two dietary education sessions addressing general dietary advice, food examples, meal patterns and meal frequency; phone calls to assess adherence to dietary advice IG2 (Diet + Exercise): Same as diet only group, but also discussed benefits of physical activity particularly on glucose metabolism. Strategies for increasing physical activity were discussed and personal strategies were planned **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Group, individual; face-to-face, phone IG2: Group, individual; face-to-face, phone **Duration (weeks) and Intensity (total min)** IG1: Education sessions-2 weeks for 4 hours total; Mean of 8 phone interviews during first 4 mo, then every 10 weeks for remaining 8 mo-time NR IG2: Same as IG1 **Provider type** IG1: Dietician IG2: Dietician for diet, NR for physical activity	**Dietary:** FFQ based on the format used in the Northern Sweden Health and Disease Cohort **Physical Activity**: Interview based on the Minnesota leisure time physical activity questionnaire

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Brekke, 2005[81] **Brekke, 2004**[113] Fair	Mean (SD) at BL, Mean change (95% CI) at 12 mo **BL** **12 mo** *Total energy intake, kcal* **IG2** 2341 (600) -323 (-551, -960) **CG** 2482 (740) -243 (-517, 30) *Protein, % intake* **IG2** 14.7 (2.5) 1.6 (0.8, 2.3)* **CG** 15.7 (2.4) -0.6 (-1.8, 0.6)* *Fat, % intake* **IG2** 34.9 (5.7) -5.1 (-7.6, -2.6)* **CG** 34.7 (5.3) -0.5 (-3.7, 2.8) *Saturated fatty acids, % intake* **IG2** 13.8 (3.5) -3.9 (-5.4, -2.3)* **CG** 14.1 (3.9) -0.6 (-2.3, 1.0) *Monounsaturated fatty acids, % intake* **IG2** 13.3 (2.5) -1.6 (-2.5, -0.7)* **CG** 12.6 (1.9) 0.4 (-1.0, 1.8) *Carbohydrate, % intake* **IG2** 47.5 (4.8) 3.7 (1.4, 6.1) **CG** 47.3 (6.1) 0.3 (-3.1, 3.6) *Fiber, g/1000 kcal* **IG2** 8.6 (3.0) 2.5 (1.0, 4.0)* **CG** 9.7 (2.7) -0.5 (-1.6, 0.7) ** p<0.05* **IG2 n analyzed:** 25 **CG n analyzed:** 19

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Brekke, 2005[81] **Brekke, 2004**[113] Fair	No 12 month outcomes

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Brekke, 2005[81] **Brekke, 2004**[113] Fair	Mean(SD) at BL, Mean (95%CI) changes at 12 mo **Adiposity:** **BL** **12 mo** *BMI, kg/m2* **IG2** 26.1 (3.1) -0.72 (-1.19, -0.25)* **CG** 26.1 (2.5) 0.22 (-0.39, 0.83) *Weight, kg* **IG2** 79.8 (10.3) -2.16 (-3.63, -0.70)* **CG** 78.0 (12.0) 0.52 (-1.35, 2.39) **Blood pressure:** NR **Lipids:** *Total cholesterol, mmol/l* **IG2** 4.74 (0.75) 0.37 (0.09, 0.66) **CG** 5.03 (1.15) 0.24 (-0.02, 0.50) *HDL cholesterol, mmol/l* **IG2** 1.16 (0.27) 0.11 (0.04, 0.17)* **CG** 1.31 (0.27) -0.04 (-0.11, 0.03) *LDL Cholesterol, mmol/L* **IG2** 2.73 (0.88) 0.23 (0.01, 0.44) **CG** 3.23 (1.01) 0.28 (0.06, 0.50) *Triglycerides, mmol/l* **IG2** 1.26 (0.64) 0.08 (-0.11, 0.27) **CG** 1.10 (0.51) 0.01 (-0.10, 0.11) **Glucose tolerance:** *Fasting blood glucose, mmol/l* **IG2** 5.13 (1.02) -0.43 (-0.66, -0.20) **CG** 5.04 (1.41) -0.21 (-0.44, 0.02) **IG2 n analyzed:** 25 **CG n analyzed:** 19	None reported	None reported	Only use 12 mo outcomes since CG offered intervention in 12-24 mo

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Eakin, 2007[114] Fair	**Design:** RCT **Location:** Colorado, US **Setting:** Clinica Campesina Family Health Services North Denver clinic, also could take place in the home **Volunteer:** Yes	**Inclusion:** One or more chronic conditions for which a lifestyle intervention focused on physical activity and diet would be appropriate (i.e. hypertension, chronic pain, hypercholesterolemia, depression, type 2 diabetes, osteoarthritis, obesity, chronic lung disease, heart disease, osteoporosis, hepatitis, history of cancer, previous stroke, multiple sclerosis); aged 30 years or over; having a telephone; not planning to move from the area during the study's time frame **Exclusion:** NR	**N recruited or assessed for eligibility:** 605 **N not able to contact:** 260 **N eligible:** 258 **N Declined:** 58 **N randomized** Total: 200 IG: 101 CG: 99 **Followup (6 weeks, 6 mo):** *6 weeks* IG: 72 (71.3%) CG: 65 (65.7%) *6 mo* IG: 84 (83.2%) CG: 78 (78.8%) **Cluster information:** NA	**Age (mean):** 49.5 (calc) **Sex (% men):** 21.5 (calc) **Race/ethnicity:** % Hispanic/Latino: 75 (calc) % Anglo: 15 (calc) % Other: 10 (calc) **SES:** Yearly Household Income (calc): % <$10,000: 34 % $10-30,000: 47.5 % >$30,000: 13 % NR: 5.5 Education (calc): % Elementary/Some HS: 68 % HS Grad: 15 % Some College/ College Grad: 17 **% Obese:** NR	**Dietary factors:** NR **Physical activity:** NR

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Eakin, 2007[114] Fair	**Intervention description** CG: Mailed a local area community resources guide and 3 newsletters on basic financial management. IG1: Followed the Ask, Assess, Advise, Agree, Arrange approach. Education on PA and dietary recommendations with tailored feedback. Participants chose a PA or dietary goal and identified social-environmental resources and received a 1-page goal sheet with their personal action plan. Followup phone calls were made to reinforce progress and address barriers. At the second call, participants were encouraged to set a second goal. At the third call, goals and barriers were discussed along with strategies for maintenance. Participants received tailored newsletters. **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual; face-to-face, phone, mail **Duration (weeks) and Intensity (total min)** IG1: 2 face-to-face visits 3 months apart, 60-90 minutes; 3 follow-up calls (2, 6, 14 weeks), intensity NR; 3 newsletters **Provider type** IG1: Health educator	**Dietary:** Kristal Fat and Fiber Behavior Questionnaire **Physical Activity:** Behavioral Risk Factor Surveillance Survey Physical Activity items

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Eakin, 2007[114] Fair	Mean (SE) **BL** **6 mo** *Dietary Behavior* † **IG** 2.47 (0.05) 2.24 (0.05)* **CG** 2.48 (0.04) 2.43 (0.05) † Lower scores indicate better dietary behavior change, range 1-4 * p<0.05 **IG n analyzed:** 84 **CG n analyzed:** 78

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Eakin, 2007[114] Fair	Median (IQR) at BL, Mean (SE) at 6 mo and 6 weeks **BL** **6 wks** **6 mo** *Total walking, minutes/week* **IG** 60 (0-840) 11 (20) 16 (20) **CG** 70 (0-840) 47 (23) -11 (23) p=NS **IG n analyzed:** 101 (BL), 72 (6 wk), 84 (6 mo) **CG n analyzed:** 99 (BL), 65 (6 wk), 78 (6 mo)

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Eakin, 2007[114] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	NR

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Edelman, 2005[115] Fair	**Design:** RCT **Location:** NC, US **Setting:** Medical center **Volunteer:** Yes	**Inclusion:** 45 years or older; had a primary care provider; reported 1 or more of the following risk factors for cardiovascular disease: diabetes, hypertension, dyslipidemia, smoking, body mass index > 25 kg/m^2 **Exclusion:** Terminal illness; active cardiovascular disease (history of myocardial infarction, congestive heart failure, or cerebrovascular accident); history of psychosis; no access to a telephone; pregnant	**N recruited or assessed for eligibility:** 294 **N could not be reached:** 34 **N eligible:** 195 **N randomized** Total: 154 IG: 77 CG: 77 **Followup (5, 10 mo):** *5 mo* IG: 61 (79.2%) (calc) CG: 67 (87.0%) (calc) *10 mo* IG: 56 (72.7%) (calc) CG: 66 (85.7%) (calc) **Cluster information:** NA	**Age (mean, range):** 52.8 (calc) **Sex (% men):** 19.5 (calc) **Race/ethnicity:** % White: 76.6 (calc) % African American: 20.2 (calc) % Other: 3.2 (calc) **SES:** Family Income % <$39,999: 15.6 (calc) % $40,000-59,999: 28.6 (calc) % >$60,000: 55.2 (calc) **% Obese** Mean BMI: 33.7 (calc)	**Dietary factors:** NR **Physical activity:** NR

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Edelman, 2005[115] Fair	**Intervention description** CG: Mailed report including their health risk assessment and baseline blood test results. Returned to usual care with not access to the PHP intervention IG1: Personalized Health Planning (PHP) Intervention: Personal risk education; Personalized health plan; Techniques (small group sessions, mind-body approaches, lifestyle approaches); Individual coaching sessions **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual, group; face-to-face, phone **Duration (weeks) and Intensity (total min)** IG1: 3 risk education sessions, intensity NR; 28 groups meetings for health planning, 2 hours; 20 phone sessions for health planning, 20-30 minutes **Provider type** IG1: Health educator, integrative medicine physician or physician's assistant, nutritionist	**Dietary:** NR **Physical Activity:** NR

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Edelman, 2005[115] Fair	NR

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Edelman, 2005[115] Fair	Data primarily reported in a figure. Days of exercise were significantly increased in the IG compared with CG (3.7 v. 2.4 days, p=0.002).

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Edelman, 2005[115] Fair	Mean (SD) at BL, Mean change at 10 mo **Adiposity:** **BL 10 mo** *BMI, kg/m*^{2} **IG** 33.3 (7.8) -1.2 **CG** 34.1 (7.7) -0.6 **IG n analyzed:** 77 (BL), 56 (10 mo) **CG n analyzed:** 77 (BL), 66 (10 mo) **Blood pressure:** Data primarily reported in a figure. IG and CG overall decline in SBP of 8 mmHg. **Lipids:** Data primarily reported in a figure. Overall decline in LDL-cholesterol for IG and CG of 7 mg/dL. Difference in change in LDL-cholesterol between BL and 5 mo was statistically significant between IG and CG (p=0.02), but not at 10 mo (p=0.25). **Glucose tolerance:** NR	NR	NR	NR

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Franko, 2008[116] Fair	**Design:** RCT **Location:** Missouri, Florida, South Carolina, Massachusetts **Setting:** University computer lab **Volunteer:** Yes	**Inclusion:** Enrollment as full-time undergraduate student; aged 18-24 years **Exclusion:** Attending formal diet programs; on a special monitored diet	**N recruited or assessed for eligibility:** 800 **N eligible:** 606 **N randomized** Total: 476 IG: 165 IG2: 164 CG: 147 **Followup (6 mo):** IG: 139 (84.2%) IG: 148 (90.2%) CG: 135 (91.8%) **Cluster information:** NA	**Age (mean):** 20.1 **Sex (% men):** 42.9 **Race/ethnicity:** % Non-White: 40.8 % White: 58.2 % Unknown: 1.1 **SES:** NR **% Obese:** % Underweight: 5.0 % Normal: 58.8 % Overweight: 22.9 % Obese: 12.0 % Unknown: 1.3	**Dietary factors:** Improved nutrition behaviors **Physical activity:** More frequent physical activity

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Franko, 2008[116] Fair	**Intervention description** CG: Interactive anatomy education website for 2 sessions IG1: MSB-N for 2 web sessions IG2: MSB-N for 2 web sessions and a subsequent booster session **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual; internet **Duration (weeks) and Intensity (total min)** IG1: 2 sessions 2 weeks apart, 45 minutes each IG2: 2 sessions 2 weeks apart, 1 session 3 weeks after, 45 minutes each **Provider type** IG1: NR IG2: NR	**Dietary:** Food Frequency Questionnaire **Physical activity:** International Physical Activity Questionnaire

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Franko, 2008[116] Fair	Mean (SE) at BL and Mean change at 6 mo **BL 3 mo 6 mo** *Daily servings of fruit and vegetables* **IG1** 5.4 (0.2) -0.28 -0.35 **IG2** 5.2 (0.2) 0.03 -0.16 **CG** 5.1 (0.2) -0.23 -0.18 *Single-item Fruit and Vegetable Intake* **IG1** 3.2 (0.1) 0.24 0.13 **IG2** 3.0 (0.1) 0.32 0.40 **CG** 2.9 (0.1) 0.21 0.39 *Percent of Energy from Fat* **IG1** 30.7 (0.4) -0.34 0.35 **IG2** 31.4 (0.4) -0.13 -0.37 **CG** 31.9 (0.4) -0.88 -0.46 **IG1 n analyzed:** 165 (BL), 145 (3 mo), 139 (6 mo) **IG2 n analyzed:** 164 (BL), 139 (3 mo), 148 (6 mo) **CG n analyzed:** 147 (BL), 136 (3 mo), 135 (6 mo)

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Franko, 2008[116] Fair	Mean (SE) at BL and change **BL** **3 mo** **6 mo** *Total MET minutes/week* **IG1** 1878 (80) 49.67 112.75 **IG2** 1718 (71) -7.36 133.41 **CG** 1820 (81) 48.61 -68.00 **IG1 n analyzed:** 165 (BL), 145 (3 mo), 139 (6 mo) **IG2 n analyzed:** 164 (BL), 139 (3 mo), 148 (6 mo) **CG n analyzed:** 147 (BL), 136 (3 mo), 135 (6 mo)

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Franko, 2008[116] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	NR

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Hardcastle, 2008[117] Fair	**Design:** RCT **Location:** UK **Setting:** Local health center **Volunteer:** No	**Inclusion:** 18-65 years; at least one of the following CHD risk factors: excess weight (BMI of 28 or more), hypertension (SBP/DBP at least 150/90 mmHg), or hypercholesterolemia (at least 5.2 mmol/L) **Exclusion:** NR	**N recruited or assessed for eligibility:** 1439 **N eligible:** NR **N randomized** Total: 334 IG: 203 CG: 131 **Followup (6 mo):** IG: 125 (61.6%) CG: 93 (71.0%) **Cluster information:** NA	**Age (mean):** 50.2 (calc) **Sex (% men):** NR **Race/ethnicity:** NR **SES:** NR **% Obese:** Mean BMI: 33.9 (calc)	**Dietary factors:** Lifestyle changes determined by the participant **Physical activity:** Lifestyle changes determined by the participant

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Hardcastle, 2008[117] Fair	**Intervention description** CG: Received a standard leaflet that provided information on exercise and nutrition at baseline IG1: Same info as CG plus offered 5 counseling sessions based on models of psychotherapy and behavior change theory. The aim was to integrate motivational interviewing with a stage-matched approach. Open-ended questions and reflective listening were used to elicit expressions of concern from the participants about current health status **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual; face-to-face **Duration (weeks) and Intensity (total min)** IG1: 5 possible counseling sessions over 6 months, 20-30 minutes each. Average attendance: 2 sessions (40-60 minutes total) **Provider type** IG1: Physical Activity Specialist and Registered Dietitian	**Dietary:** Dietary Instrument for Nutrition Education; Five-a-day Community Evaluation Tool **Physical Activity**: International Physical Activity Questionnaire

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Hardcastle, 2008[117] Fair	Mean at BL (SEM), Mean change scores (SEM) **BL** **6 mo** *Fat intake, % fat intake per day* **IG** 23.85 (0.55) -0.92 (0.43)** **CG** 23.72 (0.67) -2.92 (0.60) *Fruit and vegetable intake, portions per day* **IG** 6.41 (0.31) 1.05 (0.30) **CG** 6.88 (0.39) 0.73 (0.44) ** *p<0.01 for t-value between IG and CG* **IG n analyzed:** 203 **CG n analyzed:** 131

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Hardcastle, 2008[117] Fair	Mean at BL (SEM), Mean change scores (SEM) **BL** **6 mo** *Total Physical Activity, Met-min/week* **IG** 2039 (204) 245 (104)* **CG** 2320 (256) -122 (158) *Vigorous Physical Activity, Met-min/week* **IG** 679 (114) 149 (64) **CG** 752 (151) 50 (109) *Moderate Physical Activity, Met-min/week* **IG** 437 (82) 89 (72) **CG** 554 (107) -29 (97) *Walking, Met-min/week* **IG** 1089 (97) 198 (63)** **CG** 1244 (141) -145 (109) ** p<0.05 for t-value between IG and CG* *** p<0.01 for t-value between IG and CG* **IG n analyzed:** 203 (ITT) **CG n analyzed:** 131 (ITT)

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Hardcastle, 2008[117] Fair	Mean at BL (SEM), Mean change scores (SEM) **Adiposity:** **BL** **6 mo** *BMI, kg/m2* **IG** 33.67 (0.38) -0.21 (0.10)** **CG** 34.28 (0.61) 0.15 (0.10) *Bodyweight, kg* **IG** 93.70 (1.20) -0.70 (0.25)* **CG** 91.73 (1.50) 0.12 (0.29) **Blood pressure:** *SBP, mmHg* IG 134.05 (1.36) -2.90 (0.76) CG 133.29 (1.64) -0.60 (0.93) *DBP, mmHg* IG 83.52 (0.72) -1.98 (0.51)*** CG 82.41 (0.91) 0.49 (0.63) **Lipids:** *Triglycerides, mmol/L* **IG** 1.96 (0.09) -0.17 (0.08) **CG** 1.73 (0.09) -0.15 (0.08) *Cholesterol, mmol/L* **IG** 5.48 (0.08) -0.14 (0.05) **CG** 5.42 (0.09) 0.00 (0.06) *HDL, mmol/L* **IG** 1.46 (0.03) -0.05 (0.01) **CG** 1.53 (0.04) -0.07 (0.03) *LDL, mmol/L* **IG** 2.94 (0.09) 0.09 (0.07) **CG** 3.03 (0.10) 0.25 (0.08)	NR	NR	Differences in mean scores also available by high and low attendees at 6 months

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Hardcastle, 2008[117] Fair					

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Hardcastle, 2008[117] Fair		

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Hardcastle, 2008[117] Fair	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Hardcastle, 2008[117] Fair	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Hardcastle, 2008[117] Fair	**Glucose tolerance:** NR *** p<0.01 for t-value between IG and CG* **** p<0.001 for t-value between IG and CG* **IG n analyzed:** 203 (ITT) **CG n analyzed:** 131 (ITT)			

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Hellenius, 1993[47] **Hellenius, 1995**[48] **Naslund, 1996**[49] Fair	**Design:** RCT **Location:** Sweden **Setting:** Primary care health center and hospital **Volunteer:** No	**Inclusion:** No history or cardiovascular disease, diabetes, or other severe illnesses; no regular use of drugs; serum cholesterol 5.2-7.8 mmol/l; fasting triglycerides ≤ 5.6 mmol/l; fasting blood glucose ≤ 6.7 mmol/l; diastolic blood pressure ≤ 100 mmHg **Exclusion:** NR	**N recruited or assessed for eligibility:** 187 **N responded:** 160 **N eligible:** 158 **N randomized** Total: 158 IG1 (Diet (D)): 40 IG2 (Exercise (E)): 39 IG3 (Diet+Exercise (DE)): 39 CG: 40 **Followup (6 mo):** IG1(D): 40 (100%) IG2 (E): 39 (100%) IG3 (DE): 39 (100%) CG: 39 (98%) **Cluster information:** NA	**Age (mean):** 45 **Sex (% men):** 100 **Race/ethnicity:** NR **SES:** NR **Obesity:** Mean (SD) BMI: 25.3 (3.2)	**Dietary factors:** Of total energy intake: Total fat < 30%; saturated fat < 10%; polyunsaturated fat ≤ 10%; monounsaturated fat 10-15%; carbohydrates 50-60%; protein 10-20%; cholesterol < 300 mg/day **Physical activity:** Aerobic exercise at 60-80% maximum for 30-45 minutes, 2-3 times/week

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Hellenius, 1993[47] **Hellenius, 1995**[48] **Naslund, 1996**[49] Fair	**Intervention description** CG: Told to maintain normal diet and activity IG1(D): Received written and verbal dietary advice from physician at baseline and advice from dietician after approximately 2 weeks IG2(E): Received verbal and written information regarding physical activity from physician at baseline IG3(DE): Same as IG1(D) and IG2(E) **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1(D): Individual; face-to-face IG2(E): Individual; face-to-face IG3(DE): Individual; face-to-face CG: NA **Duration (weeks) and Intensity (total min)** IG1(D): 2 weeks, intensity NR IG2(E): 1 time, intensity NR IG3(DE): 2 weeks, intensity NR CG: NA **Provider type** IG1(D): Dietician IG2(E): Physician IG3(DE): Dietician, physician CG: NA	**Dietary:** 7-day food record **Physical Activity**: Exercise minutes obtained in structured interview

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Hellenius, 1993[47] **Hellenius, 1995**[48] **Naslund, 1996**[49] Fair	Mean (SD) **BL** **6 mo** *Total energy intake, kJ* **IG3(DE)** 8635 (2055) 7705 (1674)* **CG** 9391 (2723) 8753 (2387) *Fat, % intake* **IG3(DE)** 36 (5.3) 33 (4.9)* **CG** 36 (5.8) 36 (6.0) *Protein, % intake* **IG3(DE)** 15 (1.8) 16 (2.4)* **CG** 14 (2.1) 14 (1.9) *Carbohydrate, % intake* **IG3(DE):** 44 (6.1) 46 (6.4) **CG** 46 (5.4) 45 (7.2) **p<0.05* **IG n analyzed:** 39 **CG n analyzed:** 39

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Hellenius, 1993[47] **Hellenius, 1995**[48] **Naslund, 1996**[49] Fair	Mean (SD) **BL** **6 mo** *# exercise sessions/month* **IG3(DE)** 5.1 (7.3) 9.9 (6.8)* **CG** 5.3 (7.1) 5.4 (7.4) *Duration of sessions, minutes* **IG3(DE)** 30 (35) 56 (36)* **CG** 30 (32) 29 (30) **p<0.01* **IG n analyzed:** 39 **CG n analyzed:** 39

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Hellenius, 1993[47] **Hellenius, 1995**[48] **Naslund, 1996**[49] Fair	Mean (SD) at BL, Differences at 6 mo (95% CI) **Adiposity:** **BL** **6 mo** *BMI, kg/m²* **IG3(DE)** 26.1 (3.7) -0.6 (-0.9, -0.03)* **CG** 24.5 (3.0) 0.3 (0.1, 0.5) **p<0.05* **Blood pressure:** *SBP, mmHg* **IG3(DE)** 129 (12.6) -4 (-7, -1) **CG** 130 (12.2) -1 (-3, 4) *DBP, mmHg* **IG3(DE)** 81 (7.7) -2 (-4, 1) **CG** 82 (8.3) -1 (-3, 1) **Lipids:** *Total Chol, mmol/L* **IG3(DE)** 6.53 (0.93) -0.45 (-0.77, -0.13) **CG** 5.97 (0.90) -0.13 (-0.33, 0.07) *LDL, mmol/L* **IG3(DE)** 4.66 (0.86) -0.35 (-0.64, -0.05) **CG** 4.14 (0.75) -0.15 (-0.33, 0.02) *HDL, mmol/L* **IG3(DE)** 1.33 (0.35) -0.03 (-0.09, 0.04) **CG** 1.36 (0.28) -0.02 (-0.08, 0.05) *Triglycerides, mmol/L* **IG3(DE)** 1.57 (0.70) -0.12 (-0.31, 0.08) **CG** 1.33 (0.53) 0.06 (-0.08, 0.20) **Glucose tolerance:** NR **IG n analyzed:** 39 **CG n analyzed:** 39	NR	NR	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Hivert, 2007[119] Fair	**Design:** RCT **Location:** Quebec, Canada **Setting:** University hospital **Volunteer:** Yes	**Inclusion:** Full time, first- or second-year student at the Faculte de Medecine et des Sciences de la santa de l'University de Sherbrooke; having left parental home for less than 2 years; body mass index between 18 and 30 kg/m^2 **Exclusion:** Any medical condition; regular use of any medication except oral contraceptives; pregnant or planning a pregnancy during the 2 years of the study	**N recruited or assessed for eligibility:** 117 **N eligible:** 115 **N randomized** Total: 115 IG: 58 CG: 57 **Followup (24 mo):** IG: 48 (82.8%) CG: 48 (84.2%) **Cluster information:** NA	**Age (mean):** 19.7 (calc) **Sex (% men):** 18.3 (calc) **Race/ethnicity:** % Caucasian: 93 (calc) **SES:** NR **% Obese:** Mean BMI: 22.4 (calc) % BMI 25-30 kg/m^2: 13.0 (calc)	**Dietary factors:** Maintain a healthy lifestyle **Physical activity:** Maintain an active lifestyle

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Hivert, 2007[119] Fair	**Intervention description** CG: NR IG1: 23 seminars over 2 years. The first 3 were to increase knowledge on weight gain and its complications, national dietary recommendations and exercise categories, expected benefits and recommendations for the maintenance of health. The remaining seminars were designed to introduce behavioral modification methods using discussion on problem-solving, goal-setting, and monitoring strategies. Some seminars focused on behavioral strategies to maintain a healthy lifestyle during specific periods, such as final exams. Monitors and older students were offered as role models to promote a positive image of a healthy lifestyle **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Group; face-to-face **Duration (weeks) and Intensity (total min)** IG1: 23 seminars over 2 years, intensity NR **Provider type** IG1: Endocrinology resident and physical education graduate student	**Dietary:** 3-day food diaries **Physical Activity:** Step test from the Canadian Home Fitness Test

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Hivert, 2007[119] Fair	Mean (SEM) at BL, Mean change (SEM) at 12, 24 mo **BL** **12 mo** **24 mo** *Total caloric intake, kcal/day* **IG** 2051 (77) -194 (66) -224 (73) **CG** 2016 (77) -112 (67) -229 (80) *% of carbohydrates* **IG** 52.6 (1.0) 1.2 (1.2) -1.6 (1.1) **CG** 52.4 (0.9) 0.7 (1.0) -1.7 (1.2) *% of proteins* **IG** 16.5 (0.4) 0.4 (0.6) 1.5 (0.6) **CG** 16.6 (0.4) 0.4 (0.4) 1.5 (0.6) *% of lipids* **IG** 29.5 (0.8) -0.9 (1.0) 0.6 (1.2) **CG** 30.1 (0.8) -1.4 (1.0) 0.0 (1.0) *All NS* **IG n analyzed**: 58 **CG n analyzed:** 57

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Hivert, 2007[119] Fair	Mean (SEM) at BL, Mean change (SEM) at 12, 24 mo **BL** **12 mo** **24 mo** *Physical Activity, kcal/kg/year* **IG** 1216 (112) -81 (92) -89 (127) **CG** 1378 (145) -260 (111) -292 (110) *VO2 Max* **IG** 39.0 (0.6) -0.31 (0.34) 0.28 (0.34) **CG** 38.8 (0.6) -0.96 (0.46) 0.31 (0.42) *All NS* **IG n analyzed:** 58 (ITT) **CG n analyzed:** 57 (ITT)

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Hivert, 2007[119] Fair	Mean (SEM) at BL, Mean change (SEM) at 12, 24 mo **Adiposity:** **BL** **12 mo** **24 mo** *Weight, kg* IG 62.9 (1.4) -0.2 (0.4) -0.6 (0.5)* CG 63.5 (1.3) 1.2 (0.5) 0.7 (0.6) *BMI, kg/m²* IG 22.4 (0.4) -0.1 (0.1) -0.3 (0.2)* CG 22.4 (0.3) 0.4 (0.2) 0.2 (0.2) *Lean Mass, kg* IG 48.0 (1.1) -0.4 (0.2) -0.2 (0.4) CG 48.5 (1.0) 0.0 (0.2) 0.2 (0.2) *Non-Lean Mass, kg* IG 15.0 (0.5) 0.2 (0.2) -0.3 (0.2) CG 15.0 (0.6) 1.3 (0.2) 0.4 (0.2) **Blood pressure:** *Systolic Blood Pressure, mmHg* **IG** 111 (1) -- 5 (2) **CG** 110 (2) -- 7 (2) *Diastolic Blood Pressure, mmHg* **IG** 70 (1) -- 2 (1) **CG** 71 (1) -- 0 (1) **Lipids:** *Total cholesterol, mmol/L* **IG** 4.55 (0.12) -- 0.02 (0.10) **CG** 4.33 (0.10) -- 0.26 (0.08) *Triglycerides, mmol/L* **IG** 1.24 (0.08) -- -0.10 (0.08)* **CG** 1.11 (0.05) -- 0.10 (0.06)	NR	NR	NR

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Hivert, 2007[119] Fair					

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Hivert, 2007[119] Fair		

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Hivert, 2007[119] Fair	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Hivert, 2007[119] Fair	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Hivert, 2007[119] Fair	*HDL, mmol/L* **IG** 1.30 (0.03) -- 0.20 (0.03) **CG** 1.31 (0.04) -- 0.27 (0.03) *LDL, mmol/L* **IG** 2.68 (0.10) -- -0.14 (0.07) **CG** 2.52 (0.08) -- -0.06 (0.07) **Glucose tolerance**: NR ** ANOVA p<0.05 for group effect* **IG n analyzed:** 58 (ITT) **CG n analyzed:** 57 (ITT)			

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Jeffery, 1999[120] Fair	**Design:** RCT **Location:** Minnesota, US **Setting:** NR, Primarily recruited through mail **Volunteer:** Yes	**Inclusion:** 20-45 years; not currently pregnant and not pregnant in the previous 12 months; free of serious medical or psychological conditions requiring treatment; willing to participate in the project for 3 years **Exclusion:** NR	**N recruited or assessed for eligibility:** NR **N eligible:** 1226 **N randomized** Total: 1226 IG1(Edu): NR IG2(Edu + Incentive): NR CG: NR Excluded after for pregnancy: 106 Completed all visits: 809 Total presented that were randomized: 809 **Followup (36 mo):** Total: 809 (66%) IG1(Edu): 197 (NR) IG2 (Edu + Incentive): 198 (NR) CG: 414 (NR) **Cluster information:** NA	**Age (mean):** 38.3 (calc) **Sex (% men):** 19.8 (calc) **Race/ethnicity:** % White: 89.6 (calc) **SES:** % HS or less: 11.1 (calc) % Some College: 34.9 (calc) % College or more: 54.0 (calc) **% Obese** Mean BMI: 26.6 (calc)	**Dietary factors:** Weighing oneself regularly (at least once per week); eating more fruit (2 servings per day); eating more vegetables (3 servings per day); reducing consumption of high-fat foods **Physical activity:** Increasing exercise, with a particular emphasis on walking

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Jeffery, 1999[120] Fair	**Intervention description** CG: NR IG1 (Edu): Encouraged to pay attention to weight and make small changes in diet and exercise habits (not energy reduction). Education messages were delivered with a monthly newsletter that focused on one of the program messages and included practical guides for behavior. Once every 6 months, participants were asked to participate in low-cost intervention activities, such as weight control classes, educational seminars on physical activity, aerobics dance, free 1-mo membership to exercise facility, walking group, mailbased weight-loss course, home-based walking competition IG2 (Edu + Incentive): Same as IG1and participants were asked to return monthly postcards monitoring behavior and these were used for a $100 lottery drawing each month **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1&2: Primarily individual and some group; primarily mail, some face-to-face **Duration (weeks) and Intensity (total min)** IG1&2: Monthly newsletter over 36 mo, intensity NR; additional activites offered once every 6 months over 36 mo, ir **Provider type** IG1&2: NR	**Dietary:** Block Food Frequency Questionnaire **Physical Activity:** Instrument adapted from Jacobs et al. that reported frequency of 13 selected activities

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Jeffery, 1999[120] Fair	Mean at BL, Mean change (SEM) at 12, 24, 36 mo **BL** **12 mo** **24 mo** **36 mo** *Energy Intake, kcal/d* **IG1** 1753 -198 (76) -142 (74) -213 (78) **IG2** 1682 -88 (76) -158 (74) -183 (78) **CG** 1702 -122 (52) -172 (51) -130 (54) *Fat Intake, % of energy* **IG1** 33.9 -1.8 (0.5) -1.5 (0.6) -1.3 (0.6) **IG2** 34.0 -1.7 (0.5) -1.1 (0.6) -1.4 (0.6) **CG** 34.0 -0.6 (0.4) -0.7 (0.4) -1.1 (0.4) *p-values all not significant* **IG1 n analyzed:** 197 **IG2 n analyzed:** 198 **CG n analyzed:** 414

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Jeffery, 1999[120] Fair	Mean at BL, Mean change (SEM) at 12, 24, 36 mo **BL 12 mo 24 mo 36 mo** *Exercise, metabolic equivalent units* **IG1** 42.9 1.4 (2.2) 0.4 (2.0) 0.9 (2.1) **IG2** 48.0 -0.3 (2.2) -1.6 (2.0) -2.3 (2.1) **CG** 46.6 -1.2 (1.5) -1.9 (1.4) -4.5 (1.5) *p-values all not significant* **IG1 n analyzed:** 197 **IG2 n analyzed:** 198 **CG n analyzed:** 414

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Jeffery, 1999[120] Fair	Mean change (SEM) at 12, 24, 36 mo **Adiposity:** **12 mo 24 mo 36 mo** *Weight, kg* **IG1** 0.5 (0.3) 1.3 (0.4) 1.6 (0.5) **IG2** 0.4 (0.3) 1.2 (0.4) 1.5 (0.5) **CG** 0.6 (0.2) 1.4 (0.3) 1.8 (0.3) *No BL values reported, and p-values all not significant* **IG1 n analyzed:** 197 **IG2 n analyzed:** 198 **CG n analyzed:** 414 **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	NR

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Keyserling, 2008[121] **WISE WOMAN NC** Fair	**Design:** RCT **Location:** Wilmington, NC **Setting:** Community health center **Volunteer:** Yes	**Inclusion:** Female; aged 40-64 years; income at or below 200% of the federal poverty line; little or no health insurance; accessible by phone **Exclusion:** Medical condition for which the intervention was inappropriate; pregnant or lactating; acute medical problems that would alter baseline measures	**N recruited or assessed for eligibility:** 258 **N eligible:** 245 **N randomized** Total: 236 IG: 118 CG: 118 **Followup (12 mo):** IG: 106 (89.8%) CG: 106 (89.8%) **Cluster information:** NA	**Age (mean):** 53 (calc) **Sex (% men):** 0 **Race/ethnicity:** % White: 58 (calc) % African American: 40.5 (calc) **SES:** Household income: % <$0/year: 38 (calc) % $0-30,000/year: 56.5 (calc) % >$30,000/year: 5.5 (calc) **% Obese:** Mean BMI: 33.1 (calc)	**Dietary factors:** Increase participants' use of community resources that promote positive lifestyle change **Physical activity:** Increase participants' use of community resources that promote positive lifestyle change

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Keyserling, 2008[121] **WISE WOMAN NC** Fair	**Intervention description** CG: One-time mailing of two American Heart Association pamphlets on healthy dietary and physical activity practices IG1: 2 individual sessions addressing goals and action plan; motivational videotape to view at home; 3 group sessions to teach behavioral strategies, healthy eating education and PA segment doing chair exercises (15 minutes); 10 phone contacts to offer support; also 5 mailings for reinforcement **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual, group; face-to-face, phone **Duration (weeks) and Intensity (total min)** IG1: 2 counseling sessions, intensity NR; 3 group sessions, 90 minutes; 10 monthly phone calls, intensity NR **Provider type** IG1: Health counselor, community health advisor	**Dietary:** New Leaf Dietary Risk Assessment; Serum carotenoids **Physical Activity:** New Leaf Physical Activity Assessment; Actigraph

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Keyserling, 2008[121] **WISE WOMAN** **NC** Fair	Mean (SE) **BL** **6 mo** **12 mo** *Dietary Risk Assessment, Total score* **IG** 34.2 (1.0) 29.2 (0.6)* 29.2 (0.7)* **CG** 34.2 (1.0) 33.2 (0.6) 32.8 (0.7) ** p<0.05* **IG n analyzed:** 102 (BL, 6 mo), 85 (12 mo) **CG n analyzed:** 108 (BL, 6 mo), 89 (12 mo)

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Keyserling, 2008[121] **WISE WOMAN NC** Fair	Mean (SE) **BL 6 mo 12 mo** *Physical activity (accelerometer), moderate minutes per day* **IG** 11.6 (1.3) 12.2 (1.1) 12.5 (1.1) **CG** 13.0 (1.2) 11.7 (1.1) 11.0 (1.1) **IG n analyzed:** 94 (BL, 6 mo), 91 (12 mo) **CG n analyzed:** 84 (BL, 6 mo), 82 (12 mo) *Physical activity assessment (self-reported), moderate* **IG** 13.3 (0.4) 14.4 (0.3)* 14.0 (0.4) **CG** 13.4 (0.4) 13.4 (0.3) 13.0 (0.3) *Physical activity assessment (self-reported), vigorous* **IG** 8.8 (0.4) 9.3 (0.3)* 9.0 (0.3) **CG** 9.1 (0.4) 8.7 (0.3) 8.6 (0.3) *Physical activity assessment (self-reported), all activity* **IG** 29.4 (0.8) 30.8 (0.7) 29.8 (0.7) **CG** 29.2 (0.8) 29.4 (0.6) 28.6 (0.6) *Moderate, Vigorous Activity* **IG n analyzed:** 107 (BL, 6 mo), 86 (12 mo) **CG n analyzed:** 110 (BL, 6 mo), 89 (12 mo) *All Activity* **IG n analyzed:** 107 (BL, 6 mo), 86 (12 mo) **CG n analyzed:** 111 (BL, 6 mo), 90 (12 mo) ** p<0.05*

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Keyserling, 2008[121] **WISE WOMAN NC** Fair	Mean (SE) **Adiposity (adjusted for baseline at fup):** **BL 6 mo 12 mo** *Weight, pounds* **IG** 181 (4.8) 179 (0.9) 180 (0.9) **CG** 180 (4.7) 179 (0.8) 180 (0.8) Adiposity (unadjusted, provided by author): BL 6 mo 12 mo Weight, pounds IG 181 (4.8) 179 (4.9) 181(5.1) CG 180 (4.7) 179 (4.6) 178 (4.9) (used unadjusted for MA) **IG n analyzed:** 108 (BL, 6 mo), 106 (12 mo) **CG n analyzed:** 110 (BL, 6 mo), 106 (12 mo) **Blood pressure:** *Systolic Blood Pressure, mmHg* **IG** 126 (1.8) 125 (1.5) 126 (1.5) **CG** 129 (2.0) 125 (1.5) 125 (1.5) *Diastolic Blood Pressure, mmHg* **IG** 77 (1.0) 81 (0.8) 79 (0.8) **CG** 80 (1.2) 80 (0.9) 79 (0.9) *SBP* **IG n analyzed:** 107 (BL, 6 mo), 105 (12 mo) **CG n analyzed:** 110 (BL, 6 mo), 105 (12 mo) *DBP* **IG n analyzed:** 107 (BL, 6 mo), 105 (12 mo) **CG n analyzed:** 110 (BL, 6 mo), 106 (12 mo)	NR	NR	IG and CG differed at BL Incentive: $10 accelerometer; $5 phlebotomy $5 phone surveys

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Keyserling, 2008[121] **WISE WOMAN NC** Fair					

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Keyserling, 2008[121] **WISE WOMAN NC** Fair		

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Keyserling, 2008[121] **WISE WOMAN NC** Fair	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Keyserling, 2008[121] **WISE WOMAN NC** Fair	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Keyserling, 2008[121] **WISE WOMAN NC** Fair	**Lipids:** *Total cholesterol, mg/dL* **IG** 205 (4.0) 203 (3.0) 199 (2.9) **CG** 215 (3.5) 205 (3.0) 199 (3.0) *HDL, mg/dL* **IG** 57 (1.4) 59 (0.8) 57 (0.8) **CG** 56 (1.4) 58 (0.8) 58 (0.8) *LDL, mg/dL* **IG** 121 (3.3) 119 (2.5) 114 (2.5) **CG** 130 (3.3) 121 (2.7) 115 (2.7) *Total, HDL* **IG n analyzed:** 106 **CG n analyzed:** 110 (BL, 6 mo), 106 (12 mo) *LDL* **IG n analyzed:** 102 (BL, 6 mo), 103 (12 mo) **CG n analyzed:** 103 (BL, 6 mo), 101 (12 mo) **Glucose tolerance:** NR *All NS*			

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Mosca, 2008[122] **FIT Heart** Good	**Design:** RCT **Location:** New York, US **Setting:** University medical center **Volunteer:** No	**Inclusion:** English or Spanish speaking; 20-79 years; lived within 3 hours of the medical center; a family member with acute atherosclerotic CVD (family member defined as a blood relative, spouse, or other individual that currently lived with the index case or had been a cohabitant for a minimum of 1 year within the previous 5 years, or for 10 years in the past) **Exclusion:** Current or planned pregnancy; established CVD, diabetes, active liver disease, chronic kidney disease; life expectancy < 5 years; prescription of a special diet non compatible with study diet; participation in a clinical drug study within 3 months of randomization	**N recruited or assessed for eligibility:** 3649 **N eligible:** 2740 **N randomized** Total: 501 IG: 250 CG: 251 **Followup (12 mo):** IG: 232 (92.8%) CG:232 (92.4%) **Cluster information:** NA	**Age (mean):** 48 **Sex (% men):** 34 (calc) **Race/ethnicity:** % NonWhite: 36 **SES:** % High school or less education: 22 (calc) % Unemployed: 26 (calc) **% Obese:** 34% (calc)	**Dietary factors:** Avoiding foods that contain saturated fat, cholesterol, partially hydrogenated fats, trans fats, refined sugars; eating ≥ 2 servings of fruits, ≥ 3 servings of vegetables, and ≥ 20 g of fiber per day **Physical activity:** 30 minutes of moderate activity daily

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Mosca, 2008[122] **FIT Heart** Good	**Intervention description** CG: Received a 1-pg handout recommending to avoid tobacco, choose good nutrition, and increase activity. A report was sent to the PCP if results from assessment passed a critical threshold for a CVD risk factor (BP X>140/90 mmHg, LDL-C X>190 mg/dL, HDL-C < 25 mg/dL, triglycerides X500 mg/dL, total cholesterol >300 mg/dL) IG: Personalized CVD risk factor screening with immediate feedback. Contact was made in person or over the phone at 2 wk, 6 wk, 3 mo, 6 mo, and 9 mo to discuss goals and barriers. Those with abnormal lipid levels were given opportunity for re-assessment at 3, 6, and 9 mo with immediate feedback. Progress reports were faxed to PCP **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; face-to-face, phone **Duration (weeks) and Intensity (total min)** IG: 5 contacts over 39 weeks; 150-300 minutes **Provider type** IG1: Health educator, dietician, physician	**Dietary:** MEDFICTS Questionnaire; 1998 Gladys Block Food Frequency Questionnaire **Physical Activity:** Questions adapted from the Behavioral Risk Factor Surveillance System questionnaire

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Mosca, 2008[122] **FIT Heart** Good	Mean (95% CI) **BL** **12 mo** **% Change** *MEDFICTS score* **IG** 46.3 (42.9, 49.7) 31.3 (28.9, 33.7) -18.4 (-26.8, -9.9) **CG** 50.3 (46.5, 54.0) 40.2 (36.7, 43.6) -5.0 (-14.3, 4.2)* *Total fat, % total intake* **IG** 37.7 (36.8, 38.5) 36.8 (35.8, 37.7) -1.5 (-4.2, 1.1) **CG** 37.8 (37.0, 38.7) 36.5 (35.5, 37.4) -1.9 (-4.3, 0.5) *Saturated Fat, % total intake* **IG** 10.7 (10.4, 11.0) 9.9 (9.6, 10.2) -4.7 (-7.5, -2.0) **CG** 10.7 (10.4, 11.1) 10.3 (9.9, 10.7) -1.3 (-4.4, 1.7) *Monounsaturated Fat, % total intake* **IG** 14.8 (14.4, 15.2) 14.9 (14.4, 15.4) 1.6 (-2.0, 5.3) **CG** 15.0 (14.6, 15.5) 14.6 (14.1, 15.1) -0.6 (-3.9, 2.6) *Polyunsaturated Fat, % total intake* **IG** 9.2 (8.9, 9.5) 9.0 (8.6, 9.4) 1.9 (-3.1, 6.8) **CG** 9.1 (8.7, 9.4) 8.6 (8.3, 9.0) 0.4 (-3.8, 4.6) *Trans Fat, % total intake* **IG** 2.6 (2.4, 2.7) 2.3 (2.2, 2.5) 1.3 (-7.9, 10.6) **CG** 2.5 (2.3, 2.6) 2.3 (2.2, 2.5) 1.0 (-4.4, 6.4) *Dietary cholesterol, mg/day* **IG** 238.4 (222.9, 253.9) 193.3 (179.7, 206.8) -5.8 (-13.5, 1.9) **CG** 241.5 (224.5, 258.6) 211.3 (195.9, 226.7) -1.4 (-8.0, 5.2) *Fruit/Vegetables, servings/day* **IG** 4.8 (4.5, 5.1) 4.7 (4.4, 5.0) 8.7 (1.9, 15.5) **CG** 4.9 (4.6, 5.3) 4.9 (4.5, 5.2) 11.1 (3.4, 18.7) *Fiber, g/day* **IG** 18.3 (17.2, 19.5) 18.2 (17.0, 19.4) 6.0 (-0.1, 12.1) **CG** 18.8 (17.7, 19.9) 17.7 (16.6, 18.8) 1.4 (-3.9, 6.7) **p=0.04* **IG n analyzed:** 232 (BL, 12 mo) **CG n analyzed:** 232 (BL, 12 mo)

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Mosca, 2008[122] **FIT Heart** Good	Mean (95% CI) **BL** **12 mo** **% Change** *Activity days/week* **IG** 1.9 (1.6, 2.1) 2.5 (2.2, 2.8) 11.0 (-4.7, 26.7) **CG** 1.6 (1.4, 1.9) 2.0 (1.8, 2.3) -2.8 (-17.4, 11.7) *p=NS* **IG n analyzed:** 232 (BL, 12 mo) **CG n analyzed:** 232 (BL, 12 mo)

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Mosca, 2008[122] **FIT Heart** Good	Mean (95% CI) **Adiposity:** **BL** / **12 mo** / **% Change** *BMI, kg/m²* **IG** 27.8 (27.1, 28.5) 27.7 (26.9, 28.5) 0.5 (-0.2, 1.2) **CG** 28.4 (27.6, 29.2) 28.4 (27.5, 29.2) 0.6 (-0.4, 1.5) *Waist Circumference, inches* **IG** 35.6 (34.9, 36.3) 36.2 (35.5, 37.0) 2.4 (1.6, 3.3) **CG** 35.9 (35.2, 36.7) 36.6 (35.8, 37.4) 3.0 (1.9, 4.0) **Blood pressure:** *SBP, mmHg* **IG** 126.7 (124.8 128.6) 129.7 (127.3, 132.0) 3.1 (1.6, 4.7) **CG** 126.4 (124.4, 128.4) 129.8 (127.5, 132.0) 3.3 (1.8, 4.8) *DBP, mmHg* **IG** 77.9 (76.5, 79.3) 79.0 (77.5, 80.6) 2.8 (1.2, 4.5) **CG** 77.0 (75.6, 78.5) 78.9 (77.3, 80.4) 3.5 (1.6, 5.5) **Lipids:** *Total cholesterol, mg/dL* **IG** 202.7 (197.9, 207.4) 202.2 (196.8, 207.6) 0.84 (-1.4, 3.0) **CG** 205.9 (200.9, 210.9) 203.1 (197.7, 208.5) 0.6 (-1.2, 2.4) *LDL, mg/dL* **IG** 128.5 (124.1, 132.9) 123.7 (118.9, 128.4) -1.0 (-4.3, 2.3) **CG** 130.6 (126.1, 135.1) 124.2 (119.6, 128.9) -2.0 (-4.4, 0.4) *HDL, mg/dL* **IG** 58.5 (56.2, 60.7) 58.7 (56.1, 61.3) 0.3 (-1.7, 2.4)* **CG** 59.9 (57.5, 62.3) 57.6 (55.0, 60.2) -3.2 (-5.1, -1.3) *Triglycerides, mg/dL* **IG** 115.0 (106.7, 123.3) 113.5 (102.6, 124.4) 4.0 (-1.5, 9.4) **CG** 118.0 (109.6, 126.4) 119.2 (109.2, 129.2) 6.4 (1.0, 11.8)	NR	NR	**Incentive:** $100 at 1 year followup

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Mosca, 2008[122] **FIT Heart** Good					

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Mosca, 2008[122] **FIT Heart** Good		

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Mosca, 2008[122] **FIT Heart** Good	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Mosca, 2008[122] **FIT Heart** Good	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Mosca, 2008[122] **FIT Heart** Good	**Glucose tolerance:** *Glucose mg/dL* **IG** 97.9 (96.0 99.8) 98.1 (96.1, 100.1) 1.2 (-1.0, 3.4) **CG** 99.3 (96.9, 101.7) 9 8.6 (96.4, 100.8) -0.4 (-1.8, 1.0) **p<0.05* **IG n analyzed:** 232 (BL, 12 mo) **CG n analyzed:** 232 (BL, 12 mo)			

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Oldroyd, 2001[123] **Oldroyd, 2006**[118] **(High risk)** Fair	**Design:** RCT **Location:** UK **Setting:** Hospital **Volunteer:** No	**Inclusion:** Men and women of European origin; aged 24-75 years; IGT identified on two consecutive oral glucose tolerance tests (the second within 2-12 weeks of the first) **Exclusion:** Pregnant; on therapeutic diets; medical condition prevented moderate physical activity	**N recruited or assessed for eligibility:** 498 **N eligible:** 82 **N randomized** Total: 78 IG: 39 CG: 39 **Followup (6, 12, 24 mo):** *6 mo* IG: 35 (89.7%*) CG: 32 (82.1%*) *12 mo* IG: 32 (82.1%*) CG: 30 (76.9%*) *24 mo* IG: 30 (76.9%*) CG: 24 (61.5%*) * *Calculated* **Cluster information:** NA	**Age (mean):** 57.9 **Sex (% men):** 57 **Race/ethnicity:** NR **SES:** NR **% Obese:** NR * *All characterisitics for participants that were present at follow-up*	**Dietary factors:** Eat more fruits and vegetables; reduce the fat content of their food; reduce BMI to <25 kg/m^2 for participants overweight **Physical activity:** 20-30 minutes of aerobic activity 2-3 times per week

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Oldroyd, 2001[123] **Oldroyd, 2006**[118] **(High risk)** Fair	**Intervention description** CG: Asked to live their normal, day to day life for the duration of the study IG: Regular counseling from a dietician and physiotherapist using the stages of change. The dietician performed a dietary assessment in a one to one interview using the baseline food diary and assessed the position of the participant on the stages of change. The dietician used stage-specific motivational interviewing to develop with the participant individual targets for behavior change. The physiotherapist assessed participants' level of physical activity and provided a graded physical activity at baseline, tailored to the participant's lifestyle, designed to enable them to achieve 20-30 minutes of aerobic activity 2-3 times per week. Information about exercise facilities was provided as appropriate. A discount card for public leisure facilities in the city was offered to all participants **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG: Individual; face-to-face **Duration (weeks) and Intensity (total min)** IG: Over the first 6 months there were 6 reviews with the dietician and physiotherapist, 3 at two weekly intervals and 3 at monthly intervals; One after 9 months and five at two monthly intervals between 12 and 24 months; 15-20 minutes each **Provider type** IG: Dietician and physiotherapist	**Dietary:** 4 day food diary over 2 weekend days and 2 weekdays **Physical Activity:** Self-completion questionnaire on health related behaviors including physical activity and the Shuttle test

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Oldroyd, 2001[123] **Oldroyd, 2006**[118] **(High risk)** Fair	Mean (SD) for BL and 6 mo, Mean (SD) change at 12 and 24 mo **BL** **6 mo** **12 mo** **24 mo** *Energy, kJ/day* **IG** 8317 (2464) 7485 (2390) -- -- **CG** 8942 (2298) 8972 (2977) -- -- *Total Fat, g/day* **IG** 85.4 (29.0) 68.7 (30.0)* -16.7 (26.5)* -24.4 (24.5)* **CG** 84.7 (23.4) 89.8 (34.3) -0.43 (33.5) -6.5 (30.9) *Monosaturated Fat, g/day* **IG** 26.4 (10.1) 21.2 (10.1)* -- -- **CG** 27.1 (8.5) 28.8 (11.6) -- -- *Polyunsaturated Fat, g/day* **IG** 15.6 (6.8) 12.7 (7.2)* -- -- **CG** 13.5 (6.1) 15.6 (9.3) -- -- *Saturated Fat, g/day* **IG** 27.9 (10.3) 23.9 (13.1) -- -- **CG** 32.2 (11.8) 31.1 (15.1) -- -- *Fiber, g/day* **IG** 20.0 (6.6) 20.2 (7.5) 1.9 (8.6) 1.2 (7.6) **CG** 19.8 (8.2) 19.0 (7.3) -0.02 (6.6) 0.60 (7.4) ** p<0.05* **IG n analyzed:** 33 **CG n analyzed:** 32

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Oldroyd, 2001[123] **Oldroyd, 2006**[118] **(High risk)** Fair	Mean (SD) **BL** **6 mo** **12 mo** **24 mo** *Distance walked, m* **IG** 405 (219) 463 (220) -- -- **CG** 389 (206) 436 (230) -- -- **IG n analyzed:** 35 **CG n analyzed:** 31 Percent (n) *Vigorous activity* **IG** 14.3 (5) 41.2 (14)* -- -- **CG** 18.8 (6) 15.6 (5) -- -- *Regular activity at least once per week* **IG** 25.0 (7) -- -- 57.1 (16)* **CG** 50.0 (12) -- -- 45.8 (11) **IG n analyzed:** 34 (vigorous), 30 (regular) **CG n analyzed:** 32 (vigorous), 24 (regular) Percent Change from BL (95% CI) *Engaging in regular activity sufficient to get their heart thumping at least once per week* **IG** 24.2(8) 33.3 (13, 50)* 34.3 (16, 49)* 32.1 (12, 48)* **CG** 53.1(17) -3.1 (-14, 8.5) 7.1 (-8, 21) -4.2 (-23, 14) **IG n analyzed:** 33 **CG n analyzed:** 32 ** p<0.05*

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Oldroyd, 2001[123] **Oldroyd, 2006**[118] **(High risk)** Fair	Mean (SD) for BL and 6 mo, Mean (SD) change at 12 and 24 mo **Adiposity:** **BL** **6 mo** **12 mo** **24 mo** *Weight, kg* **IG** 83.3 (16.1) 81.9 (16.6)* -1.1 (3.4)* -1.8 (5.9)* **CG** 85.5 (14.2) 86.1 (13.8) 1.5 (2.6) 1.5 (2.6) *BMI, kg/m2* **IG** 30.4 (5.6) 29.9 (5.8) -- -- **CG** 29.9 (4.9) 30.3 (5.1) -- -- **IG n analyzed:** 35 **CG n analyzed:** 32 **Blood pressure:** *Systolic Blood Pressure, mmHg* **IG** 137.2 (19.9) 129.3 (19.5)* -- -- **CG** 132.8 (16.4) 132.6 (14.4) -- -- *Diastolic Blood Pressure, mmHg* **IG** 77.0 (12.6) 74.1 (10.0) -- -- **CG** 75.5 (9.8) 77.4 (9.2) -- -- (p=.052) **IG n analyzed:** 35 **CG n analyzed:** 32 **Lipids:** *Total Cholesterol, mmol/L* **IG** 5.7 (1.2) 5.5 (1.2) -0.12 (0.62) 0.04 (0.79) **CG** 5.7 (1.0) 5.5 (1.0) -0.12 (0.63) -0.06 (0.59) **IG n analyzed:** 34 (BL), 35 (6 mo), 31 (12 mo) **CG n analyzed:** 31 (BL), 32 (6 mo), 29 (12 mo) ** p<0.05*	NR	NR	NR

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Oldroyd, 2001[123] **Oldroyd, 2006[118]** **(High risk)** Fair					

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Oldroyd, 2001[123] **Oldroyd, 2006[118]** **(High risk)** Fair		

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Oldroyd, 2001[123] **Oldroyd, 2006[118]** **(High risk)** Fair	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Oldroyd, 2001[123] **Oldroyd, 2006[118]** **(High risk)** Fair	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Oldroyd, 2001[123] **Oldroyd, 2006**[118] **(High risk)** Fair	*HDL Cholesterol, mmol/L* **IG** 1.2 (0.42) 1.2 (0.43) -- -- **CG** 1.1 (0.36) 1.2 (0.34) -- -- **IG n analyzed:** 32 (BL), 34 (6 mo) **CG n analyzed:** 31 (BL), 31 (6 mo) *LDL Cholesterol, mmol/L* **IG** 3.6 (1.1) 3.5 (1.1) -0.11 (0.58) -0.09 (0.71) **CG** 3.5 (1.0) 3.3 (1.0) -0.13 (0.69) -0.14 (0.56) **IG n analyzed:** 33 (BL), 34 (6 mo), 30 (12 mo) **CG n analyzed:** 31 (BL), 31 (6 mo), 30 (12 mo) Mean (95% CI) *Triglycerides, mmol/L* **IG** 1.9 (1.6, 2.2) 1.7 (1.4, 2.0) -- -- **CG** 2.2 (1.9, 2.5) 2.1 (1.8, 2.5) -- -- **IG n analyzed:** 34 (BL), 35 (6 mo) **CG n analyzed:** 31 (BL), 32 (6 mo) **Glucose tolerance:** Mean (SD) for BL and 6 mo, Mean (SD) change at 12 and 24 mo *Fasting Plasma Glucose, mmol/L* **IG** 6.0 (0.9) 6.1 (0.9) 0.03 (0.60) 0.25 (0.77) **CG** 6.2 (0.9) 6.3 (0.9) 0.08 (0.97) 0.12 (1.0) *2-hour Plasma Glucose, mmol/L* **IG** 9.1 (0.9) 8.5 (2.0) -0.63 (1.6) 0.23 (1.6) **CG** 9.2 (0.9) 8.8 (2.1) 0.22 (1.9) -0.52 (1.9) **IG n analyzed:** 35 (BL, 6 mo), 35 (6 mo), 32 (12 mo), 30 (24 mo) **CG n analyzed:** 32 (BL, 6 mo), 32 (6 mo), 30 (12 mo), 24 (24 mo)			

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Simkin-Silverman, 1998[124] **Simkin-Silverman, 1995**[125] **Simkin-Silverman, 2003**[126] **Kuller, 2001**[132] **WHLP** Good	**Design:** RCT **Location:** Pennsylvania, US **Setting:** NR **Volunteer:** No	**Inclusion:** Women 44-50 years of age; less than 3 months amenorrhea last 6 months; not taking hormone replacement therapy; no surgically induced menopause; diastolic blood pressure <95 mmHg; BMI between 20 and 34; fasting glucose <140 mg/dL; LDL between 80 and 160 mg/dL; total cholesterol between 140 and 260 mg/dL; not taking any lipid-lowering agents, insulin, thyroid, anti-hypertensive, or psychotropic medications; not treated for cancer in the past 5 years; not having participated in a commercial weight reduction program within the past 4 months **Exclusion:** NR	**N recruited or assessed for eligibility:** 18,233 (calc) **N responded:** 2115 **N attended screening visit:** 1021 **N eligible:** 637 **N randomized** Total: 535 IG: 260 CG: 275 **Followup (6, 18, 54 mo):** *6 mo* IG: 253 (97.3%) CG: 267 (97.1%) *18 mo* IG: 236 (90.8%) CG: 253 (92.0%) *54 mo* IG: 246 (94.6%) CG: 263 (95.6%) **Cluster information:** NA	**Age (mean):** 47.1 **Sex (% men):** 0 **Race/ethnicity:** % White: 91.9* (calc) **SES:** % HS Graduate: 15.0 (calc) % College (>0-4 years): 48.7* (calc) % Graduate School: 36.0* (calc) % Employed for wages: 86.1* (calc) **% Obese:** Mean (SD) BMI: 25.1 (3.3) Mean (SD) Weight: 148.3 (21.6) ** All characteristics for participants present at BL and 6 months*	**Dietary factors:** Lower intake of fat to 25% of daily calories, saturated fat to 7% of daily calories, and total cholesterol to 100 mg/day **Physical activity:** Increase physical activity levels, primarily in the form of moderate-intensity activities such as walking

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Simkin-Silverman, 1998[124] **Simkin-Silverman, 1995**[125] **Simkin-Silverman, 2003**[126] **Kuller, 2001**[132] **WHLP** Good	**Intervention description** CG: NR IG1: Groups sessions teaching behavioral strategies that advised participants to follow a 1300-1500 kcal meal plan for 4 weeks to achieve modest weight loss. Intake and physical activity were self-monitored. Were given information to gradually increase physical activity in a step-wise fashion to 1,000-1,500 kcal/week. Maintenance phase consisted of 6 group sessions over 9 months plus newsletters or phone contact. **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Group, individual; face-to-face, mail, phone **Duration (weeks) and Intensity (total min)** IG1: 15 group over 20 weeks; intensity NR; Group, mail or phone contact on average every 2-3 months after initial 20 weeks; intensity NR **Provider type** IG1: Trained nutritional and behavioral interventionists	**Dietary:** Block Food Frequency Questionnaire **Physical Activity:** Paffenbarger Activity Questionnaire; 3-day Caltrac monitor

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Simkin-Silverman, 1998[124] **Simkin-Silverman, 1995**[125] **Simkin-Silverman, 2003**[126] **Kuller, 2001**[132] **WHLP** Good	Mean (SD) at BL, 6 mo, and 18 mo, Mean change at (SD) at 54 mo **BL** **6 mo** **18 mo** **54 mo** *Total energy intake, kcal* **IG** 1491.3 (562.6) 1296.0 (458.0)* 1302.6 (446.2)* -159.6 (465.0)* **CG** 1427.2 (544.3) 1405.1 (479.1) 1348.4 (461.2) -24.8 (559.9) *% Fat* **IG** 32.5 (7.0) 22.8(5.9)* 23.3 (6.1)* -- **CG** 32.4 (7.4) 31.8 (7.9) 30.6 (7.8) -- *% Saturated Fat* **IG** 11.8 (3.0) 7.8 (2.4)* 8.0 (2.6)* -- **CG** 11.4 (3.0) 11.2 (3.3) 10.9 (3.2) -- *Cholesterol, mg/day* **IG** 197.4 (90.5) 131.9 (60.9)* 136.2 (72.8)* -- **CG** 199.5 (106.3) 191.4 (95.4) 181.9 (121.8) -- ** p<0.05* **IG n analyzed:** 236 (BL, 6, 18 mo), 246 (54 mo) **CG n analyzed:** 253 (BL, 6, 18 mo), 263 (54 mo)

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Simkin-Silverman, 1998[124] **Simkin-Silverman, 1995**[125] **Simkin-Silverman, 2003**[126] **Kuller, 2001**[132] **WHLP** Good	Mean (SD) at BL, 6 mo, and 18 mo, Mean change (SD) at 54 mo **BL** **6 mo** **18 mo** **54 mo** *Total physical activity, kcal* **IG** 1216.6 (1026.0) 1618.7 (1055.9)* 1648.3 (1395)* 274.9 (1172.9)* **CG** 1389.1 (1352.2) 1341.0 (1382.2) 1432.5 (1385.3) -113.3 (1261.0) Mean (95% CI) at BL, Mean change (95% CI) at 6 mo, and Mean (SD) 54 mo *Caltrac (motion counts/hr)* **IG** 18.3 (17.5, 19.2) 3.2 (2.1, 4.3)* -- 2.3 (9.1)* **CG** 19.9 (18.9, 21.1) 0.08 (-0.93, 1.1) -- -0.26 (7.8) ** p<0.05* **IG n analyzed:** 236 (BL, 6, 18 mo), 246(54 mo)† **CG n analyzed:** 253 (BL, 6, 18 mo), 263(54 mo)† † *Total n analyzed for Caltrac at 54 mo: 313 (due to missing or incomplete data)*

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Simkin-Silverman, 1998[124] **Simkin-Silverman, 1995**[125] **Simkin-Silverman, 2003**[126] **Kuller, 2001**[132] **WHLP** Good	Mean (SD) at BL, 6 mo, and 18 mo, Mean change (SD) at 54 mo **Adiposity:** **BL** / **6 mo** / **18 mo** / **54 mo** *Body weight, lb* **IG** 148.0 (21.3) 137.1 (20.5)* 141.3 (20.7)* -0.18 (--)* **CG** 147.6 (21.9) 146.8 (21.8) 148.2 (22.2) 5.2 (--) *BMI, kg/m2* **IG** 24.9 (3.2) 23.1 (3.1)* 23.8 (3.2)* 0.05 (2.0)* **CG** 25.1 (3.3) 25.0 (3.3) 25.2 (3.4) 0.96 (1.8) Mean (95% CI) at BL, Mean change (95% CI) at 6 mo, and Mean change (SD) at 54 mo *Body fat, percent* **IG** 33.2 (32.7, 33.8) -4.9 (-5.4, -4.4)* -- -0.5 (4.1)* **CG** 33.0 (32.4, 33.5) -0.95 (-1.4, -0.55) -- 1.1 (3.9) Mean (SD) at BL, 6 mo, and 18 mo, Mean change (SD) at 54 mo **Blood pressure:** *SBP, mmHg* **IG** 110.0 (12.5) 106.6 (10.7)* 107.3 (13.2)* -0.12 (--) **CG** 110.1 (13.0) 108.7 (11.9) 109.6 (12.3) 0.20 (--) *DBP, mmHg* **IG** 68.5 (7.6) 66.0 (7.0)* 69.9 (8.1) 1.5 (--)* **CG** 67.9 (8.5) 67.6 (8.0) 69.8 (8.1) 2.2 (--) **Lipids:** *Cholesterol, mg/dL* **IG** 189.7 (24.5) 175.9 (28.0)* 188.1 (28.3)* -- **CG** 189.6 (24.3) 190.5 (26.4) 197.4 (28.0) -- *LDL, mg/dL* **IG** 114.7 (21.8) 103.4 (24.3)* 110.5 (24.2)* 3.5 (--)* **CG** 116.3 (21.8) 116.2 (23.9) 119.0 (25.7) 8.9 (--)	NR	Higher levels of bone loss in IG compared with CG, related to weight loss.	30 and 42 mo outcomes sometimes available

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Simkin-Silverman, 1998[124] **Simkin-Silverman, 1995**[125] **Simkin-Silverman, 2003**[126] **Kuller, 2001**[132] **WHLP** Good					

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Simkin-Silverman, 1998[124] **Simkin-Silverman, 1995**[125] **Simkin-Silverman, 2003**[126] **Kuller, 2001**[132] **WHLP** Good		

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Simkin-Silverman, 1998[124] **Simkin-Silverman, 1995**[125] **Simkin-Silverman, 2003**[126] **Kuller, 2001**[132] **WHLP** Good	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Simkin-Silverman, 1998[124] **Simkin-Silverman, 1995**[125] **Simkin-Silverman, 2003**[126] **Kuller, 2001**[132] **WHLP** Good	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Simkin-Silverman, 1998[124] **Simkin-Silverman, 1995**[125] **Simkin-Silverman, 2003**[126] **Kuller, 2001**[132] **WHLP** Good	*HDL, mg/dL* **IG** 59.7 (13.0) 57.3 (12.0)* 60.7 (11.8)* 2.3 (--) **CG** 58.4 (12.1) 58.2 (11.9) 61.3 (13.2) 3.1 (--) *Triglycerides, mg/dL* **IG** 82.2 (38.2) 77.7 (35.5)* 84.6 (41.3)* 18.2 (--)* **CG** 78.2 (42.4) 83.7 (56.3) 85.6 (51.3) 29.9 (--) **Glucose tolerance:** *Fasting glucose, mg/dL* **IG** 98.1 (8.0) 97.1 (7.8)* 99.4 (9.1)* 1.6 (--) **CG** 97.8 (8.3) 98.7 (8.0) 100.6 (9.6) 3.3 (--) ** p<0.05 for group*time effect* **IG n analyzed:** 236 (BL, 6, 18 mo), 246 (54 mo)† **CG n analyzed:** 253 (BL, 6, 18 mo), 263 (54 mo)† *† n analyzed not reported by IG and CG for SBP, DBP, Total Cholesterol, HDL, LDL, Glucose at 54 mo, however total n analyzed is 459*	NR	NR	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Thompson, 2008[127] **Herman, 2006**[128] **Allen, 2008**[129] Fair	**Design:** RCT **Location:** New Mexico, US **Setting:** Research Center **Volunteer:** Yes	**Inclusion:** Women 18-40 years; self-reported identity as American Indian; not pregnant and verified with a pregnancy test at baseline and not planning a pregnancy over the subsequent 2 years; willingness to stay in the urban area for 2 years; not having type 2 diabetes; fasting blood glucose ≤ 6.94 mmol/L **Exclusion:** NR	**N recruited or assessed for eligibility:** 473 **N eligible:** 333 **N completed consent process:** 228 **N eligible via phone and consented:** 211 **N randomized** Total: 200 IG: 100 CG: 100 **Followup (6, 12, 18 mo):** *6 mo* IG: 82 (82%) CG: 82 (82%) *12 mo* IG: 80 (80%) CG: 74 (74%) *18 mo* IG: 64 (64%) CG: 71 (71%) **Cluster information:** NA	**Age (mean):** 29.3 (calc) **Sex (% men):** 0 **Race/ethnicity:** % American Indian: 100 **SES:** % College Graduate: 24.7 % 1-3 Years of College: 59.9 % Graduated HS: 11.9 % Not HS Graduate: 3.6 **% Obese:** **%** BMI ≥ 30 kg/m^2: 40	**Dietary factors:** Increase fruits and vegetable intake; lower saturated fat **Physical activity:** Increase physical activity to 150 minutes/week of moderate or vigorous physical activity

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Thompson, 2008[127] **Herman, 2006**[128] **Allen, 2008**[129] Fair	**Intervention description** CG: Delayed intervention IG1: 5 discussion group sessions using social cognitive theory strategies. Sessions also included learning to read food labels, strategies for healthy eating, recipes to support study goals. 15-minute outdoor walk was conducted at the beginning of each session. Goal-setting, action steps, addressing barriers, and enhancing behavior change through nonfood rewards. For missed sessions, participants received didactic materials and a brief review of content prior to the subsequent session **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Group; face-to-face **Duration (weeks) and Intensity (total min)** IG1: 1 meeting each month for 5 months; 2-2.5 hours each **Provider type** IG1: Trained American Indian health educators	**Dietary:** Block 98 food frequency questionnaire **Physical Activity:** Modifiable Activity Questionnaire; VO_2 peak estimated on bicycle ergometer

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Thompson, 2008[127] **Herman, 2006**[128] **Allen, 2008**[129] Fair	Mean (SD) **BL** **6 mo** **12 mo** **18 mo** *Total energy intake, kcal/day* **IG** 2201.3 (971.8) 1921.5 (763.9) 1846.2 (710.7) 1883.3 (652.9)* **CG** 2191.8 (978.2) 1953.8 (795.5) 1976.2 (855.9) 1694.8 (876.4) *Total fat intake, g/day* **IG** 94.9 (44.5) 82.4 (36.5) 80.2 (35.4) 81.0 (33.2)* **CG** 96.6 (49.6) 85.4 (41.9) 87.8 (44.2) 86.3 (44.6) *Saturated Fat Intake, g/day* **IG** 29.7 (14.2) 25.7 (11.5) 25.0 (10.9) 24.9 (10.0)* **CG** 30.0 (15.2) 26.2 (12.6) 26.4 (12.5) 26.4 (13.5) *Vegetable Intake, servings/day* **IG** 2.90 (1.71) 3.21 (2.41) 2.81 (1.67) 3.17 (2.05) **CG** 2.73 (1.69) 2.86 (1.96) 2.68 (1.68) 2.83 (1.96) *Fruit intake, servings/day* **IG** 1.03 (0.73) 1.27 (0.86) 1.23 (0.88) 1.31 (0.92) **CG** 1.12 (0.85) 1.17 (0.96) 1.08 (0.85) 1.12 (0.95) **IG n analyzed:** 96 **CG n analyzed:** 95 ** RM ANOVA effect of visit p<0.001*

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Thompson, 2008[127] **Herman, 2006**[128] **Allen, 2008**[129] Fair	Mean (SD) **BL** **6 mo** **12 mo** **18 mo** *Total leisure-time activity, hrs/wk* **IG** 5.06 (4.83) 5.22 (4.56) 5.08 (5.14) 4.94 (4.89) **CG** 6.13 (6.40) 5.67 (6.58) 5.29 (4.93) 5.22 (4.93) *Peak VO2, L/min* **IG** 2.08(0.45) 2.05(0.43) 2.06(0.41) 2.05(0.40) **CG** 1.20(0.41) 1.94(0.36) 1.98(0.39) 1.94(0.38) *Both NS* *Leisure-time* **IG n analyzed:** 100 **CG n analyzed:** 100 *Peak VO2* **IG n analyzed:** 98 (BL, 6 mo), 99 (12, 18 mo) **CG n analyzed:** 99

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Thompson, 2008[127] **Herman, 2006**[128] **Allen, 2008**[129] Fair	Mean (SD) **Adiposity:** **BL** / **6 mo** / **12 mo** / **18 mo** *BMI, kg/m²* **IG** 29.5 (5.9) 29.4 (5.8) 29.4 (6.0) 29.4 (6.0) **CG** 29.2 (6.7) 29.3 (6.3) 29.5 (6.4) 29.6 (6.5) *Body fat, percent* **IG** 41.6 (6.3) 41.8 (6.4) 42.1 (6.3) 42.3 (6.4)* **CG** 40.8 (6.6) 41.2 (6.3) 41.5 (6.2) 41.6 (6.2) **Blood pressure:** *Systolic Blood Pressure, mmHg* **IG** 115.8 (13.2) 115.3 (13.7) 114.4 (13.1) 114.9 (12.2) **CG** 116.6 (11.2) 116.9 (14.3) 116.7 (14.1) 117.0 (14.0) *Diastolic Blood Pressure, mmHg* **IG** 67.6 (10.8) 66.1 (10.0) 68.0 (10.4) 67.9 (9.3) **CG** 68.7 (9.4) 69.9 (10.6) 69.1 (10.4) 68.8 (9.7) **Lipids:** *Total cholesterol, mmol/L* **IG** 4.34 (0.81) 4.20 (0.78) 4.20 (0.79) 4.18 (0.78)* **CG** 4.36 (0.65) 4.28 (0.62) 4.22 (0.69) 4.27 (0.64) *LDL, mmol/L* **IG** 2.42 (0.65) 2.28 (0.66) 2.26 (0.63) 2.28 (0.61)* **CG** 2.38 (0.52) 2.28 (0.51) 2.23 (0.56) 2.27 (0.57) *HDL, mmol/L* **IG** 1.26 (0.31) 1.26 (0.30) 1.29 (0.33) 1.26 (0.29)* **CG** 1.31 (0.31) 1.30 (0.27) 1.34 (0.32) 1.30 (0.29) *Triglycerides, mmol* **IG** 1.46 (0.64) 1.44 (0.68) 1.41 (0.60) 1.40 (0.68) **CG** 1.46 (3.15**) 1.52 (0.68) 1.40 (0.57) 1.52 (0.72) ***assume 3.15 is an error, use 0.64 for MA*	NR	NR	Incentive: $50 per clinic visit

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Thompson, 2008[127] **Herman, 2006**[128] **Allen, 2008**[129] Fair					

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Thompson, 2008[127] **Herman, 2006**[128] **Allen, 2008**[129] Fair		

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Thompson, 2008[127] **Herman, 2006**[128] **Allen, 2008**[129] Fair	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Thompson, 2008[127] **Herman, 2006**[128] **Allen, 2008**[129] Fair	

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Thompson, 2008[127] **Herman, 2006**[128] **Allen, 2008**[129] Fair	**Glucose tolerance**: *Fasting blood glucose, mmol/L* **IG** 5.20 (0.46) 5.14 (0.43) 5.17 (0.49) 5.12 (0.54) **CG** 5.16 (0.50) 5.21 (0.53) 5.15 (0.51) 5.16 (0.49) ** RM ANOVA effect of visit p<0.05* **IG n analyzed:** 100 **CG n analyzed:** 100			

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Vandelanotte, 2005[130] Fair	**Design:** RCT **Location:** Belgium **Setting:** Computer-based **Volunteer:** Yes	**Inclusion:** Between 20-60 years; without medical complaints related to physical activity or fat intake (such as cardiovascular disease, diabetes, anorexia, problems with stomach , liver, gallbladder, or intestine) **Exclusion:** NR	**N recruited or assessed for eligibility:** 1164 **N eligible:** 1023 **N randomized** Total: 1023 Completed all study requirements: 771 IG1: NR IG2: NR IG3: NR CG: NR **Followup (6 mo):** Total: 771 (75.4%) *PA Outcomes* IG1: 189 (NR%) IG2: 180 (NR%) CG: 204 (NR%) *HD Outcomes* IG1: 176 (NR%) IG3: 194 (NR%) CG: 195 (NR%) **Cluster information:** NA	**Age (mean):** 39.1 **Sex (% men):** 35.5 (calc) **Race/ethnicity:** NR **SES:** % College or university degree: 69.6 % Employed: 86.3 **% Obese** Mean (SD) BMI: 24.5 (4.1)	**Dietary factors:** Consume less than 30% of energy from fat **Physical activity:** Public health recommendations for physical activity (at least 30 minutes of moderate-intensity physical activity on all days of the week)

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Vandelanotte, 2005[130] Fair	**Intervention description** Both fat and physical activity interventions were entirely computerized. Participants filled out a questionnaire consisting of demographics, health behavior, and psychosocial variables. Tailored feedback was displayed immediately on the screen. Feedback was based on theory of planned behavior and the stages of change concept from the transtheoretical model. Feedback consisted of normative feedback, which related participants' physical activity or fat intake to current recommendations and tips and suggestions on how to increase physical activity or decrease fat intake CG: Received both tailored interventions after posttest measurement at 6 months IG1: Tailored physical activity and tailored fat intake at baseline IG2: Tailored physical activity intervention at baseline and tailored fat intake intervention 3 months later IG3: Tailored fat intake at baseline and tailored physical activity 3 months later **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1, 2, 3 and CG: Individual; computer **Duration (weeks) and Intensity (total min)** IG1, 2, 3 and CG: 1 session, 50 minutes **Provider type** IG1, 2, 3 and CG: NR	**Dietary factors:** Food frequency questionnaire **Physical activity:** International Physical Activity Questionnaire

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Vandelanotte, 2005[130] Fair	Mean (SD) **BL** **6 mo** *Total Fat Intake, g/day* **IG1** 118 (43) 85 (28) **IG3** 110 (39) 85 (30) **CG** 101 (39) 94 (33) Energy from fat, percent **IG1** 40.8 (13.2) 29.3 (9.1) **IG3** 38.0 (12.7) 29.4 (10.8) **CG** 35.3 (12.2) 33.2 (12.0) *p<0.001 for time x group for both* **IG1 n analyzed:** 176 **IG3 n analyzed:** 194 **CG n analyzed:** 195

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Vandelanotte, 2005[130] Fair	Mean (SD) **BL 6 mo** *Total PA, minutes/week* **IG1** 532 (519) 705 (519) **IG2** 514 (367) 727 (492) **CG** 720 (485) 734 (516) p<0.001 for time x group *Moderate+High PA, minutes/week* **IG1** 325 (312) 386 (329) **IG2** 295 (249) 388 (306) **CG** 392 (340) 437 (348) *NS* **IG1 n analyzed:** 189 **IG2 n analyzed:** 180 **CG n analyzed:** 204

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Vandelanotte, 2005[130] Fair	**Adiposity:** NR **Blood pressure:** NR **Lipids:** NR **Glucose tolerance:** NR	NR	NR	NR

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Study characteristics	Inclusion/Exclusion	CONSORT numbers	Participant characteristics	Intervention aim/theory
Wister, 2007[131] Good	**Design:** RCT **Location:** British Columbia, Canada **Setting:** NR **Volunteer:** Mixed	**Inclusion:** 45-64 years; residence in the Fraser Health region; cardiovascular risk profile according to the literature for primary and secondary prevention (participants in the primary prevention group had a Framingham risk score of 10% of higher over 10 year period) **Exclusion:** NR	**N recruited or assessed for eligibility:** 2326 **N eligible:** 613 **N randomized** Total: 611 IG1: 157 CG1: 158 IG2: 153* CG2: 143* **Followup (12 mo):** IG1: 137 (87.3%) CG1: 141 (89.2%) **Cluster information:** NA * Participants in the secondary prevention group had a diagnosis of coronary artery disease and are out of scope of this review	**Age (mean):** 55.4 **Sex (% men):** 41.6 **Race/ethnicity:** NR **SES:** NR **% Obese:** Mean BMI: 32.5	**Dietary factors:** Decrease risk (The ideal: choices from all 4 food groups) **Physical activity:** Decrease risk (The ideal: 4-6 times per week for 41+ minutes)

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Description of Intervention and Control	Outcome measurement (instrument used)
Wister, 2007[131] Good	**Intervention description** CG1: Received usual care from their physicians, based on their own determination of the need for visits IG1: A letter grading system (A, B, C, D, F) was developed for the risk scores, based on recommeded risk guidelines for cardiovascular disease. Staged target levels were developed for each patient. Smoking was considered the top priority for lifestyle counseling, followed by physical activity, dietary habits, weight management and stress. A counselor addressed the areas where the grade was lowest first. Comparisons with previous report card grades were dicussed with the participant to set new goals. Summaries of each counseling sessions and supporting evidence were mailed to the participants **Format and Delivery (group, indiv, family, face-to-face, phone, mail, internet, etc.)** IG1: Individual; face-to-face, phone **Duration (weeks) and Intensity (total min)** IG1: Report card annually; 2 sessions of approximately 30 minutes each over 1 year **Provider type** IG1: Clinical lifestyle counselors (were also kinesiologists)	**Dietary:** 5-point ordinal scale based on the number of recommended food groups met per day **Physical Activity:** 5-point ordinal scale based on the American College of Sports Medicine's guidelines for physical activity in the prevention and rehabilitation of cardiovascular disease

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	HD Behavioral Outcomes
Wister, 2007[131] Good	Adjusted Change (95% CI) **BL** **12 mo** *Nutrition Level (an ordinal measure treated continuously)* **IG1** NR 0.30 (0.13, 0.47) **CG1** NR -0.05 (-0.22, 0.12)* ** p<0.01* **IG n analyzed:** 157 **CG n analyzed:** 158

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	PA Outcomes
Wister, 2007[131] Good	Adjusted Change (95% CI) **BL** **12 mo** *Physical Activity (an ordinal measure treated continuously)* **IG1** NR 0.17 (-0.06, 0.40) **CG1** NR 0.16 (-0.08, 0.40) **IG n analyzed:** 157 **CG n analyzed:** 158

Appendix C Table 3. Healthy Lifestyle Counseling Evidence Table

Study reference Quality Rating	Intermediate Outcomes	Health Outcomes	Adverse Effects	Comment
Wister, 2007[131] Good	Mean (SD) at BL, Adjusted Change (95% CI) at 12 mo **Adiposity:** (Self-reported, not included) **Blood pressure:** **BL** **12 mo** *Systolic Blood Pressure, mmHg* **IG1** 139.0 (15.2) -7.49 (-9.97, -5.01) **CG1** 136.1 (14.3) -3.58 (-6.08, -1.08)* **Lipids:** *Total cholesterol, mmol/L* **IG1** 5.8 (1.3) -0.41 (-0.59, -0.23) **CG1** 5.6 (1.2) -0.14 (-0.32, 0.04)* *High-density lipoprotein cholesterol, mmol/L* **IG1** 1.3 (0.3) 0.04 (0.01, 0.07) **CG1** 1.3 (0.3) 0.03 (0.00, 0.06) **Glucose tolerance:** *Glucose, mmol/L* **IG1** 8.3 (2.6) -0.37 (-0.85, 0.11) **CG1** 8.1 (2.3) 0.01 (-0.41, 0.43) **Framingham risk score** IG 12.5 (5.9) -3.10 (-3.98, -2.22) CG 11.0 (6.0) -1.30 (-2.18, -0.42)* ** p<0.05* **IG n analyzed:** 157 **CG n analyzed:** 158	NR	NR	Participants in IG and CG and their doctors received reminders to provide annual results of blood work, which might have affected their outcomes through increased monitoring of their risk factors.

Appendix C Table 4. Evidence of Serious Harms Associated With Physical Activity Counseling: Case-Crossover Analyses of Exertion-Related Acute Cardiac Events

Author, year Country Quality	Subject Characteristics	Event N, Ascertainment	Results
Albert, 2000[133] Finland Fair	Participants of Physicians' Health Study (n=21,481) 100% men Mean age 60.5 10.7% diabetes 8.2% hyperlipidemia 32.5% hypertension 0% previous MI	N=122 sudden deaths from cardiac causes, 23 (18.8%) related to vigorous exertion Outcome from medical records with independent review and next of kin PA determined by self-report questionnaire, followup time NR	**Incidence of sudden death associated with vigorous exertion:** 1/1.42 million person-hours of exertion (n=12,481) **RR of sudden death associated with vigorous exertion, by frequency of habitual exercise:** **Habitual Exercise** — **RR (95% CI)** <1 times/week — 74.1 (22.0, 249) 1-4 times/week — 18.9 (10.2, 35.1) ≥5 times/week — 10.6 (4.5, 26.2) All — 16.9 (10.5, 27.0)
Giri 1999[134] US Fair	Patients with MI treated with primary angioplasty in study hospital 57% men Mean age 60.8 18.1% diabetes 42.2% hyperlipidemia 44.8% hypertension 25.0% coronary artery disease	N=640 MIs, 64 (10%) related to vigorous exertion Outcome from medication records during hospitalization with independent review PA determined through structured interview in hospital	**RR of MI associated with vigorous exertion, by habitual activity level:** **Habitual Activity** — **RR (95% CI)** Very low — 30.5 (4.4, 209.9) Low — 20.9 (3.1, 142.1) Moderate — 2.9 (0.5, 15.9) High — 1.2 (0.3, 5.2) All — 10.1 (1.56, 65.6)
Hallqvist, 2000[135] Sweden Fair	Survivors of an incident MI in a single county in Sweden 76.8% men Mean age 49 26.2% diabetes 35.4% hypertension 0% previous MI	N=660 MIs, 42 (6.4%) related to vigorous exertion Outcome from medical records and/or death certificates, plus structured interview in hospital or soon after discharge PA determined through structured interview in hospital or soon after discharge	**RR of MI associated with vigorous exertion:** 3.3 (2.4, 4.5) **RR of MI associated with vigorous exertion, by habitual activity level, among those without premonitory symptoms (n=399, 27 with vigorous exertion):** **Habitual Activity** — **RR (95% CI)** Very little — 54.7 (13.7, 218.4) Sporadic Walks — 4.6 (1.7, 12.5) Occasional — 2.3 (0.9, 6.0) Regular — 12.1 (6.8, 21.4)

Appendix C Table 4. Evidence of Serious Harms Associated With Physical Activity Counseling: Case-Crossover Analyses of Exertion-Related Acute Cardiac Events

Author, year Country Quality	Subject Characteristics	Event N, Ascertainment	Results
Mittleman, 1993[136] US Fair	Patients from coronary care units 68% men Mean age 62 19% diabetes 44% hypertension 29% previous MI	N=1228 MIs, 54 (4.4%) related to vigorous exertion Outcome from medical records with independent review, plus structured interview in hospital or soon after discharge PA determined through structured interview in hospital or soon after discharge	**RR of MI associated with vigorous exertion, by frequency of habitual exercise:** **Habitual Exercise** — **RR (95% CI)** <1 times/week — 107 (67, 171) 1-2 times/week — 19.4 (9.9, 38.1) 3-4 times/week — 8.6 (3.6, 20.5) ≥5 times/week — 2.4 (1.5, 3.7) All — 5.9 (4.6, 7.7)
Siscovick, 1984[137] US Fair	Married men with out-of-hospital incident cardiac arrest requiring EMS 100% men Mean age NR Risk factors NR 0% heart disease	N=133 MIs, 9 (6.8%) related to vigorous exertion Outcome from paramedics reports PA determined through structured interview with wives	**RR of MI associated with vigorous exertion, by habitual minutes/week of activity:** **Habitual Activity** — **RR (95% CI)** 0 — (no events during exertion) 1-19 — 56 (23, 131) 20-139 — 13 (5, 32) ≥140 — 5 (2, 14)
von Klot, 2008[138] Germany Fair	Patients hospitalized by MI in any area hospital, 77% men Median age 61 26% diabetes 72% hypertension 15% previous MI	N=1301 MIs, 90(6.9%) related to vigorous exertion Outcome from medical records with independent review, plus structured interview in hospital or soon after discharge PA determined through structured interview in hospital or soon after discharge	**RR of MI associated with vigorous exertion, by habitual minutes/week of activity of at least moderate-intensity):** **Habitual Activity** — **RR (95% CI)** 0-59 — 26 (6.2, 113) 60-180 — 10 (4.3, 25) >180 — 1.2 (0.6, 2.4) All — 5.7 (3.6, 9.0)
Willich, 1993[139] Germany Fair	Patients hospitalized by MI in any area hospital, 74.5% men Mean age 60.6 18.8% diabetes 49.4% hypertension 61.3% hyperlipidemia 18.3% previous MI	N=270 MIs, 44 (16.3%) related to vigorous exertion Outcome from medical records with independent review, plus structured interview in hospital or soon after discharge PA determined through structured interview in hospital or soon after discharge	**RR of MI associated with vigorous exertion, by frequency of habitual exercise:** **Habitual Exercise** — **RR (95% CI)** <4 times/week — 6.9 (4.1, 12.2) ≥4 times/week — 1.3 (0.8, 2.2) All — 2.1 (1.6, 3.1)

CI – confidence interval; MI – myocardial infarction; NR – not reported; RR – relative risk; US – United States

Appendix D Table 1. Healthful Diet Studies Excluded From the Review for Key Questions 1–3

Reference	Reason for exclusion
Aberegg, Scott K. and Majure, David T. "Low-Fat Dietary Pattern and Risk of Cardiovascular Disease: The Women's Health Initiative Randomized Controlled Dietary Modification Trial": Comment. JAMA: Journal of the American Medical Association 296[3], 280. 2006.	No relevant outcomes
Alli C, Avanzini F, Bettelli G et al. Feasibility of a long-term low-sodium diet in mild hypertension. *J Hum Hypertens.* 1992;6:281-286.	Population > 50% hypertension or dyslipidemia
Ammerman AS, Keyserling TC, Atwood JR, Hosking JD, Zayed H, Krasny C. A randomized controlled trial of a public health nurse directed treatment program for rural patients with high blood cholesterol. *Prev Med.* 2003;36:340-351.	Population > 50% hypertension or dyslipidemia
Anderson, Cheryl A. M. and Appell, Lawrence J. Dietary Modification and CVD Prevention: A Matter of Fat. [References]. JAMA: Journal of the American Medical Association 295[6], 693-695. 2006.	No relevant outcomes
Anderson JV, Bybee DI, Brown RM et al. 5 a day fruit and vegetable intervention improves consumption in a low income population. *Journal of the American Dietetic Association.* 2001;101:195-202.	Less than 6 months of followup
Anderssen S, Holme I, Urdal P, Hjermann I. Diet and exercise intervention have favourable effects on blood pressure in mild hypertensives: the Oslo Diet and Exercise Study (ODES). *Blood Press.* 1995;4:343-349.	Population > 50% hypertension or dyslipidemia
Anderssen SA, Hjermann I, Urdal P, Torjesen PA, Holme I. Improved carbohydrate metabolism after physical training and dietary intervention in individuals with the "atherothrombogenic syndrome'. Oslo Diet and Exercise Study (ODES). A randomized trial. *J Intern Med.* 1996;240:203-209.	Population > 50% hypertension or dyslipidemia
Anderssen SA, Carroll S, Urdal P, Holme I. Combined diet and exercise intervention reverses the metabolic syndrome in middle-aged males: results from the Oslo Diet and Exercise Study. *Scandinavian Journal of Medicine & Science in Sports.* 2007;17:687-695.	Population > 50% hypertension or dyslipidemia
Anderssen SA, Haaland A Hjerman I Urdal P Gjesdal K Holme I. Oslo diet and exercise study: a one year randomized intervention trial. Efect on Haemostatic variables and other coronary risk factors. *Nutrition, Metabolism & Cardiovascular Diseases*. 1995;5:189-200.	Population > 50% hypertension or dyslipidemia
Appel LJ, Hebert PR, Cohen JD et al. Baseline characteristics of participants in phase II of the Trials of Hypertension Prevention (TOHP II). Trials of Hypertension Prevention (TOHP) Collaborative Research Group. *Ann Epidemiol.* 1995;5:149-155.	No relevant outcomes
Appel LJ, Champagne CM, Harsha DW et al. Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial. *JAMA.* 2003;289:2083-2093.	Comparative-effectiveness
Appel LJ, Espeland M, Whelton PK et al. Trial of Nonpharmacologic Intervention in the Elderly (TONE). Design and rationale of a blood pressure control trial. *Ann Epidemiol.* 1995;5:119-129.	Population > 50% hypertension or dyslipidemia
Appel LJ, Espeland MA, Easter L, Wilson AC, Folmar S, Lacy CR. Effects of reduced sodium intake on hypertension control in older individuals: results from the Trial of Nonpharmacologic Interventions in the Elderly (TONE). *Arch Intern Med.* 2001;161:685-693.	Population > 50% hypertension or dyslipidemia
Applegate WB, Miller ST, Elam JT et al. Nonpharmacologic intervention to reduce blood pressure in older patients with mild hypertension. *Arch Intern Med.* 1992;152:1162-1166.	Population > 50% hypertension or dyslipidemia
Armitage CJ, Conner M. Efficacy of a minimal intervention to reduce fat intake. *Social Science & Medicine.* 2001;52:1517-1524.	Less than 6 months of followup
Armitage, Christopher J. Effects of an implementation intention-based intervention on fruit consumption. *Psychology & Health*. 2007;22(8):917-928. 2007.	Less than 6 months of followup
Arroll B, Beaglehole R. Salt restriction and physical activity in treated hypertensives. *N Z Med J.* 1995;108:266-268.	Population > 50% hypertension or dyslipidemia

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Reference	Reason for exclusion
Bahnson JL, Whelton PK, Appel LJ et al. Baseline characteristics of randomized participants in the Trial of Nonpharmacologic Intervention in the Elderly (TONE). *Disease Management and Clinical Outcomes.* 1997;1:61-68.	Population > 50% hypertension or dyslipidemia
Bakx JC, Stafleu A, Van Staveren WA, Van den Hoogen HJ, van WC. Long-term effect of nutritional counseling: a study in family medicine. *Am J Clin Nutr.* 1997;65:1946S-1950S.	Population > 50% hypertension or dyslipidemia
Barclay C, Procter KL, Glendenning R, Marsh P, Freeman J, Mathers N. Can type 2 diabetes be prevented in UK general practice? A lifestyle-change feasibility study (ISAIAH). *Br J Gen Pract.* 2008;58:541-547.	Intervention involves supervised physical activity or medications
Beckmann SL, Os I, Kjeldsen SE, Eide IK, Westheim AS, Hjermann I. Effect of dietary counselling on blood pressure and arterial plasma catecholamines in primary hypertension. *Am J Hypertens.* 1995;8:704-711.	Population > 50% hypertension or dyslipidemia
Beresford SA, Farmer EM, Feingold L, Graves KL, Sumner SK, Baker RM. Evaluation of a self-help dietary intervention in a primary care setting. *Am J Public Health.* 1992;82:79-84.	Less than 6 months of followup
Blaufox MD, Lee HB, Davis B, Oberman A, Wassertheil-Smoller S, Langford H. Renin predicts diastolic blood pressure response to nonpharmacologic and pharmacologic therapy. *JAMA.* 1992;267:1221-1225.	Population > 50% hypertension or dyslipidemia
Block G, Wakimoto P, Metz D et al. A randomized trial of the Little by Little CD-ROM: demonstrated effectiveness in increasing fruit and vegetable intake in a low-income population. *Preventing Chronic Disease.* 2004;1:A08.	Less than 6 months of followup
Bloemberg BP, Kromhout D, Goddijn HE, Jansen A, Obermann-de Boer GL. The impact of the Guidelines for a Healthy Diet of The Netherlands Nutrition Council on total and high density lipoprotein cholesterol in hypercholesterolemic free-living men. *Am J Epidemiol.* 1991;134:39-48.	Population > 50% hypertension or dyslipidemia
Blumenthal JA, Sherwood A, Gullette EC et al. Exercise and weight loss reduce blood pressure in men and women with mild hypertension: effects on cardiovascular, metabolic, and hemodynamic functioning. *Arch Intern Med.* 2000;160:1947-1958.	Population > 50% hypertension or dyslipidemia
Bo S, Ciccone G, Baldi C et al. Effectiveness of a lifestyle intervention on metabolic syndrome. A randomized controlled trial. *J Gen Intern Med.* 2007;22:1695-1703.	Population > 50% hypertension or dyslipidemia
Bowen D, Ehret C, Pedersen M et al. Results of an adjunct dietary intervention program in the Women's Health Initiative. *Journal of the American Dietetic Association.* 2002;102:1631-1637.	No relevant outcomes
Bowen DJ, Beresford SAA, Christensen CL, Kuniyuk AA, McLerran D, Feng Z, Hart A Jr, Tinker L, Campbell M, Satia J. Effects of a multilevel dietary intervention in religious organizations. *Am.J.Health Promot.* 24(1):15-22, 2009.	Setting not primary care or generalizable to primary care
Boyd NF, Cousins M, Beaton M et al. Clinical trial of low-fat, high-carbohydrate diet in subjects with mammographic dysplasia: report of early outcomes. *J Natl Cancer Inst.* 1988;80:1244-1248.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Boyd NF, Cousins M, Beaton M, Kriukov V, Lockwood G, Tritchler D. Quantitative changes in dietary fat intake and serum cholesterol in women: results from a randomized, controlled trial. *Am J Clin Nutr.* 1990;52:470-476.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Boyd NF, Martin LJ, Beaton M, Cousins M, Kriukov V. Long-term effects of participation in a randomized trial of a low-fat, high-carbohydrate diet. *Cancer Epidemiol Biomarkers Prev.* 1996;5:217-222.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Brekke HK, Sunesson A, Axelsen M, Lenner RA. Attitudes and barriers to dietary advice aimed at reducing risk of type 2 diabetes in first-degree relatives of patients with type 2 diabetes. *Journal of Human Nutrition & Dietetics.* 2004;17:513-521.	No relevant outcomes
British family heart study: its design and method, and prevalence of cardiovascular risk factors. Family heart study group. *Br J Gen Pract.* 1994;44:62-67.	Other quality issues

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Reference	Reason for exclusion
Bruckert E, Giral P, Paillard F et al. Effect of an educational program (PEGASE) on cardiovascular risk in hypercholesterolaemic patients. *Cardiovascular Drugs & Therapy.* 2008;22:495-505.	Population > 50% hypertension or dyslipidemia
Brug J, Glanz K, Van AP, Kok G, van Breukelen GJ. The impact of computer-tailored feedback and iterative feedback on fat, fruit, and vegetable intake. *Health Educ Behav.* 1998;25:517-531.	Less than 6 months of followup
Burke LE, Dunbar-Jacob J, Orchard TJ, Sereika SM. Improving adherence to a cholesterol-lowering diet: a behavioral intervention study. *Patient Education & Counseling.* 2005;57:134-142.	Population > 50% hypertension or dyslipidemia
Burke V, Beilin LJ, Cutt HE, Mansour J, Mori TA. Moderators and mediators of behaviour change in a lifestyle program for treated hypertensives: a randomized controlled trial (ADAPT). *Health Education Research.* 2008;23:583-591.	Population > 50% hypertension or dyslipidemia
Burke V, Giangiulio N, Gillam HF, Beilin LJ, Houghton S, Milligan RA. Health promotion in couples adapting to a shared lifestyle. *Health Educ Res.* 1999;14:269-288.	Less than 6 months of followup
Burke V, Giangiulio N, Gillam HF, Beilin LJ, Houghton S. Physical activity and nutrition programs for couples: a randomized controlled trial. *Journal of Clinical Epidemiology.* 2003;56:421-432.	High or differential attrition
Burke V, Mori TA, Giangiulio N et al. An innovative program for changing health behaviours. *Asia Pac J Clin Nutr.* 2002;11 Suppl 3:S586-S597.	High or differential attrition
Burr ML, Fehily AM. Fatty fish and heart disease: a randomized controlled trial. *World Rev Nutr Diet.* 1991;66:306-312.	Limited to children and adolescents, parents (if change intended for children), persons with any acute disease or symptomatic disease, persons with known coronary heart disease (or angina) or peripheral vascular disease or diabetes, pregnant women, institutionalized persons, or persons with SPMI or cognitive impairment
Caggiula AW, Christakis G, Farrand M et al. The multiple risk intervention trial (MRFIT). IV. Intervention on blood lipids. *Prev Med.* 1981;10:443-475.	Population > 50% hypertension or dyslipidemia
Caggiula AW, Watson JE, Kuller LH et al. Cholesterol-lowering intervention program. Effect of the step I diet in community office practices. *Arch Intern Med.* 1996;156:1205-1213.	Comparative-effectiveness
Chapman J, Armitage CJ, Norman P. Comparing implementation intention interventions in relation to young adults' intake of fruit and vegetables. *Psychology & Health* 24(3):317-332, 2009.	Less than 6 months of followup
Clark M, Ghandour G, Miller NH, Taylor CB, Bandura A, DeBusk RF. Development and evaluation of a computer-based system for dietary management of hyperlipidemia. *J Am Diet Assoc.* 1997;97:146-150.	Not an allowable study design
Cook NR, Kumanyika SK, Cutler JA. Effect of change in sodium excretion on change in blood pressure corrected for measurement error. The Trials of Hypertension Prevention, Phase I. *Am J Epidemiol.* 1998;148:431-444.	No relevant outcomes
Cook NR, Obarzanek E, Cutler JA et al. Joint effects of sodium and potassium intake on subsequent cardiovascular disease: the Trials of Hypertension Prevention follow-up study. *Arch Intern Med.* 2009;169:32-40	No relevant outcomes
Coulter A, Fowler G, Fuller A et al. Effectiveness of health checks conducted by nurses in primary care: final results of the OXCHECK study. *British Medical Journal.* 1995;310:1099-1104.	Other quality issues
Crandall J, Schade D, Ma Y et al. The influence of age on the effects of lifestyle modification and metformin in prevention of diabetes. *J Gerontol A Biol Sci Med Sci.* 2006;61:1075-1081.	Comparative-effectiveness
Cutler JA, Neaton JD, Hulley SB, Kuller L, Paul O, Stamler J. Coronary heart disease and all-causes mortality in the Multiple Risk Factor Intervention Trial: subgroup findings and comparisons with other trials. *Prev Med.* 1985;14:293-311.	Intervention involves supervised physical activity or medications

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Reference	Reason for exclusion
Davey SG, Bracha Y, Svendsen KH et al. Incidence of type 2 diabetes in the randomized multiple risk factor intervention trial. *Ann Intern Med.* 2005;142:313-322.	Population > 50% hypertension or dyslipidemia
Davis BR, Oberman A, Blaufox MD et al. Lack of effectiveness of a low-sodium/high-potassium diet in reducing antihypertensive medication requirements in overweight persons with mild hypertension. TAIM Research Group. Trial of Antihypertensive Interventions and Management. *Am J Hypertens.* 1994;7:926-932.	Population > 50% hypertension or dyslipidemia
de Vries, H., Kremers, S. P. J., Smeets, T., Brug, J., and Eijmael, K. The effectiveness of tailored feedback and action plans in an intervention addressing multiple health behaviors. *Am J of Health Promot*. 2008;22(6):417-425.	Comparative-effectiveness
Delahanty LM, Sonnenberg LM, Hayden D, Nathan DM. Clinical and cost outcomes of medical nutrition therapy for hypercholesterolemia: a controlled trial. *Journal of the American Dietetic Association.* 2001;101:1012-1023.	Population > 50% hypertension or dyslipidemia
Djuric Z, Vanloon G, Radakovich K, Dilaura NM, Heilbrun LK, Sen A. Design of a Mediterranean exchange list diet implemented by telephone counseling. *Journal of the American Dietetic Association.* 2008;108:2059-2065.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Dolecek TA, Milas NC, Van Horn LV et al. A long-term nutrition intervention experience: lipid responses and dietary adherence patterns in the Multiple Risk Factor Intervention Trial. *J Am Diet Assoc.* 1986;86:752-758.	Intervention involves supervised physical activity or medications
Dubbert PM, Cushman WC, Meydrech EF, Rowland AK, Maury P. Effects of dietary instruction and sodium excretion feedback in hypertension clinic patients. *Behav Ther.* 1995;26:721-732.	Population > 50% hypertension or dyslipidemia
Dutton GR, Napolitano MA, Whiteley JA, Marcus BH. Is physical activity a gateway behavior for diet? Findings from a physical activity trial. *Prev Med.* 2008;46:216-221.	Not one of specified interventions
Dzator JA, Hendrie D, Burke V et al. A randomized trial of interactive group sessions achieved greater improvements in nutrition and physical activity at a tiny increase in cost. *Journal of Clinical Epidemiology.* 2004;57:610-619.	High or differential attrition
Eakin E, Reeves M, Lawler S et al. Telephone counseling for physical activity and diet in primary care patients. *Am J Prev Med.* 2009;36:142-149.	Population > 50% hypertension or dyslipidemia
Effectiveness of health checks conducted by nurses in primary care: results of the OXCHECK study after one year. Imperial Cancer Research Fund OXCHECK Study Group. *BMJ.* 1994;308:308-312.	Other quality issues
Elder JP, Williams SJ, Drew JA, Wright BL, Boulan TE. Longitudinal effects of preventive services on health behaviors among an elderly cohort. *Am J Prev Med.* 1995;11:354-359.	High or differential attrition
Ellingsen I, Hjerkinn EM, Arnesen H, Seljeflot I, Hjermann I, Tonstad S. Follow-up of diet and cardiovascular risk factors 20 years after cessation of intervention in the Oslo Diet and Antismoking Study. *European Journal of Clinical Nutrition.* 2006;60:378-385.	Population > 50% hypertension or dyslipidemia
Ellingsen I, Hjermann I, Abdelnoor M, Hjerkinn EM, Tonstad S. Dietary and antismoking advice and ischemic heart disease mortality in men with normal or high fasting triacylglycerol concentrations: a 23-y follow-up study. *The American journal of clinical nutrition.* 2003;78:935-940.	Population > 50% hypertension or dyslipidemia
Ellsworth DL, O'Dowd SC, Salami B et al. Intensive lifestyle modification: impact on cardiovascular disease risk factors in subjects with and without clinical cardiovascular disease. *Preventive Cardiology.* 2004;7:168-175.	Not an allowable study design

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Reference	Reason for exclusion
Elmer PJ, Obarzanek E, Vollmer WM et al. Effects of comprehensive lifestyle modification on diet, weight, physical fitness, and blood pressure control: 18-month results of a randomized trial (summary for patients in Ann Intern Med. 2006 Apr 4;144(7):I27); *Ann Intern Med.* 2006;144:485-495.	Comparative-effectiveness
Emmons, Karen M., Stoddard, Ann M., Fletcher, Robert, Gutheil, Caitlin, Suarez, Elizabeth Gonzalez, Lobb, Rebecca, Weeks, Jane, and Bigby, Judy Anne. Cancer Prevention Among Working Class, Multiethnic Adults: Results of the Healthy Directions--Health Centers Study. *Am J Pub Health.* 2005; 95(7):1200-1205.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Eriksson J, Lindstrom J, Valle T et al. Prevention of Type II diabetes in subjects with impaired glucose tolerance: the Diabetes Prevention Study (DPS) in Finland. Study design and 1-year interim report on the feasibility of the lifestyle intervention programme. *Diabetologia.* 1999;42:793-801.	Intervention involves supervised physical activity or medications
Espeland MA, Whelton PK, Kostis JB et al. Predictors and mediators of successful long-term withdrawal from antihypertensive medications. TONE Cooperative Research Group. Trial of Nonpharmacologic Interventions in the Elderly. *Arch Fam Med.* 1999;8:228-236.	Population > 50% hypertension or dyslipidemia
Evans AT, Rogers LQ, Peden JG, Jr. et al. Teaching dietary counseling skills to residents: patient and physician outcomes. The CADRE Study Group. *Am J Prev Med.* 1996;12:259-265.	Population > 50% hypertension or dyslipidemia
Fagerberg B, Wikstrand J, Berglund G, Samuelsson O, Agewall S. Mortality rates in treated hypertensive men with additional risk factors are high but can be reduced: a randomized intervention study. *Am J Hypertens.* 1998;11:14-22.	Intervention involves supervised physical activity or medications
Ferrer RL, Mody-Bailey P, Jaen CR, Gott S, Araujo S. A medical assistant-based program to promote healthy behaviors in primary care. *Ann Fam Med.* 2009;7:504-512.	High or differential attrition
Gaston MH, Porter GK, Thomas VG. Prime Time Sister Circles: evaluating a gender-specific, culturally relevant health intervention to decrease major risk factors in mid-life African-American women. *J Natl Med Assoc.* 2007;99:428-438.	Setting not primary care or generalizable to primary care
Gorbach SL, Morrill-LaBrode A, Woods MN et al. Changes in food patterns during a low-fat dietary intervention in women. *J Am Diet Assoc.* 1990;90:802-809.	Population > 50% hypertension or dyslipidemia
Halbert JA, Silagy CA, Finucane PM, Withers RT, Hamdorf PA. Physical activity and cardiovascular risk factors: effect of advice from an exercise specialist in Australian general practice. *Med J Aust.* 2000;173:84-87.	No relevant outcomes
Harari D, Iliffe S, Kharicha K et al. Promotion of health in older people: a randomised controlled trial of health risk appraisal in British general practice. *Age Ageing.* 2008;37:565-571.	Does not focus on counseling interventions
Harting J, Van AP, van LP et al. Effects of health counseling on behavioural risk factors in a high-risk cardiology outpatient population: a randomized clinical trial. *European Journal of Cardiovascular Prevention & Rehabilitation.* 2006;13:214-221.	Limited to children and adolescents, parents (if change intended for children), persons with any acute disease or symptomatic disease, persons with known coronary heart disease (or angina) or peripheral vascular disease or diabetes, pregnant women, institutionalized persons, or persons with SPMI or cognitive impairment
Havas S, Anliker J, Damron D, Langenberg P, Ballesteros M, Feldman R. Final results of the Maryland WIC 5-A-Day Promotion Program. *Am J Public Health.* 1998;88:1161-1167.	Not one of specified interventions
He J, Whelton PK, Appel LJ, Charleston J, Klag MJ. Long-term effects of weight loss and dietary sodium reduction on incidence of hypertension. *Hypertension.* 2000;35:544-549.	No relevant outcomes
Heller RF, Walker RJ, Boyle CA, O'Connell DL, Rusakaniko S, Dobson AJ. A randomised controlled trial of a dietary advice program for relatives of heart attack victims. *Med J Aust.* 1994;161:529-531.	High or differential attrition

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Reference	Reason for exclusion
Henderson MM, Kushi LH, Thompson DJ et al. Feasibility of a randomized trial of a low-fat diet for the prevention of breast cancer: dietary compliance in the Women's Health Trial Vanguard Study. *Prev Med.* 1990;19:115-133.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Henkin Y, Shai I, Zuk R et al. Dietary treatment of hypercholesterolemia: do dietitians do it better? A randomized, controlled trial. *Am J Med.* 2000;109:549-555.	Comparative-effectiveness
Hernan WH, Brandle M, Zhang P et al. Costs associated with the primary prevention of type 2 diabetes mellitus in the diabetes prevention program. *Diabetes Care.* 2003;26:36-47.	Comparative-effectiveness
Hoffmeister H, Mensink GB, Stolzenberg H et al. Reduction of coronary heart disease risk factors in the German cardiovascular prevention study. *Prev Med.* 1996;25:135-145.	Not an allowable study design
Holme I, Hostmark AT, Anderssen SA. ApoB but not LDL-cholesterol is reduced by exercise training in overweight healthy men. Results from the 1-year randomized Oslo Diet and Exercise Study. *Journal of Internal Medicine.* 2007;262:235-243.	Population > 50% hypertension or dyslipidemia
Holtrop JS, Dosh SA, Torres T, Thum YM. The community health educator referral liaison (CHERL): a primary care practice role for promoting healthy behaviors. *Am J Prev Med.* 2008;35:Suppl-72.	Comparative-effectiveness
Hsieh YC, Hung CT, Lien LM, Bai CH, Chen WH, Yeh CY, Chen YH, Hsieh FI, Chiu HC, Chiou HY, Hsu CY. A significant decrease in blood pressure through a family-based nutrition health education programme among community residents in Taiwan. *Public Health Nutrition* 12 (4):570-577, 2009.	Quality- poor reporting
Huxley RR, Lean M, Crozier A, John JH, Neil HA, Oxford Fruit and Vegetable Study Group. Effect of dietary advice to increase fruit and vegetable consumption on plasma flavonol concentrations: results from a randomised controlled intervention trial. *Journal of Epidemiology & Community Health.* 2004;58:288-289.	No relevant outcomes
Hyman DJ, Herd JA, Ho KS, Dunn JK, Gregory KA. Maintenance of cholesterol reduction using automated telephone calls. *Am J Prev Med.* 1996;12:129-133.	Population > 50% hypertension or dyslipidemia
Hyman DJ, Ho KS, Dunn JK, Simons-Morton D. Dietary intervention for cholesterol reduction in public clinic patients. *Am J Prev Med.* 1998;15:139-145.	Population > 50% hypertension or dyslipidemia
Hyman DJ, Pavlik VN, Taylor WC, Goodrick GK, Moye L. Simultaneous vs sequential counseling for multiple behavior change. *Arch Intern Med.* 2007;167:1152-1158.	Population > 50% hypertension or dyslipidemia
Inoue S, Odagiri Y, Wakui S et al. Randomized controlled trial to evaluate the effect of a physical activity intervention program based on behavioral medicine. *Zasshi/Tokyo Ika Daigaku.* 2003;61:154-165.	Population > 50% hypertension or dyslipidemia
Insull W, Jr., Henderson MM, Prentice RL et al. Results of a randomized feasibility study of a low-fat diet. *Arch Intern Med.* 1990;150:421-427.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Ives DG, Kuller LH, Traven ND. Use and outcomes of a cholesterol-lowering intervention for rural elderly subjects. *Am J Prev Med.* 1993;9:274-281.	Population > 50% hypertension or dyslipidemia
Jacobs AD, Ammerman AS, Ennett ST et al. Effects of a tailored follow-up intervention on health behaviors, beliefs, and attitudes. *Journal of Women's Health.* 2004;13:557-568.	Population > 50% hypertension or dyslipidemia
Jacobs DR, Jr., Sluik D, Rokling-Andersen MH, Anderssen SA, Drevon CA. Association of 1-y changes in diet pattern with cardiovascular disease risk factors and adipokines: results from the 1-y randomized Oslo Diet and Exercise Study. *Am J Clin Nutr.* 2009;89:509-517.	Population > 50% hypertension or dyslipidemia
Jalkanen L. The effect of a weight reduction program on cardiovascular risk factors among overweight hypertensives in primary health care. *Scand J Soc Med.* 1991;19:66-71.	Primary aim is weight loss
John JH, Yudkin PL, Neil HAW, Ziebland S. Does Stage of Change predict outcome in a primary care intervention to encourage an increase in fruit and vegetable consumption? *Health Education Research.* 2003;18:429-438.	No relevant outcomes

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Reference	Reason for exclusion
Johnston HJ, Jones M, Ridler-Dutton G, Spechler F, Stokes GS, Wyndham LE. Diet modification in lowering plasma cholesterol levels. A randomised trial of three types of intervention. *Med J Aust.* 1995;162:524-526.	Population > 50% hypertension or dyslipidemia
Jorgensen T, Borch-Johnsen K, Thomsen TF, Ibsen H, Glumer C, Pisinger C. A randomized non-pharmacological intervention study for prevention of ischaemic heart disease: baseline results Inter99. *European Journal of Cardiovascular Prevention & Rehabilitation.* 2003;10:377-386.	Population > 50% hypertension or dyslipidemia
Jula A, Ronnemaa T, Rastas M, Karvetti RL, Maki J. Long-term nopharmacological treatment for mild to moderate hypertension. *J Intern Med.* 1990;227:413-421.	Population > 50% hypertension or dyslipidemia
Jula AM, Karanko HM. Effects on left ventricular hypertrophy of long-term nonpharmacological treatment with sodium restriction in mild-to-moderate essential hypertension. *Circulation.* 1994;89:1023-1031.	Population > 50% hypertension or dyslipidemia
Kastarinen MJ, Puska PM, Korhonen MH et al. Non-pharmacological treatment of hypertension in primary health care: a 2-year open randomized controlled trial of lifestyle intervention against hypertension in eastern Finland. *J Hypertens.* 2002;20:2505-2512.	Population > 50% hypertension or dyslipidemia
Kawano M, Shono N, Yoshimura T, Yamaguchi M, Hirano T, Hisatomi A. Improved cardio-respiratory fitness correlates with changes in the number and size of small dense LDL: randomized controlled trial with exercise training and dietary instruction. *Internal Medicine.* 2009;48:25-32.	Intervention involves supervised physical activity or medications
Keller S, Donner-Banzhoff N, Kaluza G, Baum E, Basler HD. Improving physician-delivered counseling in a primary care setting: lessons from a failed attempt. *Educ Health (Abingdon).* 2000;13:387-397.	High or differential attrition
Ketola E, Makela M, Klockars M. Individualised multifactorial lifestyle intervention trial for high-risk cardiovascular patients in primary care. *Br J Gen Pract.* 2001;51:291-294.	Population > 50% hypertension or dyslipidemia
Keyserling TC, Ammerman AS, Davis CE, Mok MC, Garrett J, Simpson R, Jr. A randomized controlled trial of a physician-directed treatment program for low-income patients with high blood cholesterol: the Southeast Cholesterol Project. *Arch Fam Med.* 1997;6:135-145.	Population > 50% hypertension or dyslipidemia
Kinzel LS, Averbach FM, Clark KS et al. A high carbohydrate, low fat, hypocaloric eating pattern using functional foods along with increased physical activity in postmenopausal women decreases cardiovascular risk factors. *Journal of the American Dietetic Association.* 2004;104:31.	Comparative-effectiveness
Kjelsberg MO, Cutler JA, Dolecek TA. Brief description of the Multiple Risk Factor Intervention Trial. *Am J Clin Nutr.* 1997;65:191S-195S.	Intervention involves supervised physical activity or medications
Klem ML, Viteri JE, Wing RR. Primary prevention of weight gain for women aged 25-34: the acceptability of treatment formats. *Int J Obes Relat Metab Disord.* 2000;24:219-225.	High or differential attrition
Knowler WC, Barrett-Connor E, Fowler SE et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *New England Journal of Medicine.* 2002;346:393-403.	Comparative-effectiveness
Knutsen SF, Knutsen R. The Tromso Survey: the Family Intervention study--the effect of intervention on some coronary risk factors and dietary habits, a 6-year follow-up. *Prev Med.* 1991;20:197-212.	Population > 50% hypertension or dyslipidemia
Koopman H, Spreeuwenberg C, Westerman RF, Donker AJ. Dietary treatment of patients with mild to moderate hypertension in a general practice: a pilot intervention study (2). Beyond three months. *J Hum Hypertens.* 1990;4:372-374.	Population > 50% hypertension or dyslipidemia
Korhonen MH, Litmanen H, Rauramaa R, Vaisanen SB, Niskanen L, Uusitupa M. Adherence to the salt restriction diet among people with mildly elevated blood pressure. *Eur J Clin Nutr.* 1999;53:880-885.	Population > 50% hypertension or dyslipidemia
Kosaka K, Noda M, Kuzuya T. Prevention of type 2 diabetes by lifestyle intervention: a Japanese trial in IGT males. *Diabetes Research & Clinical Practice.* 2005;67:152-162.	Comparative-effectiveness

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Reference	Reason for exclusion
Kreuter MW, Strecher VJ. Do tailored behavior change messages enhance the effectiveness of health risk appraisal? Results from a randomized trial. *Health Educ Res.* 1996;11:97-105.	Does not focus on counseling interventions
Kreuter MW, Sugg-Skinner C, Holt CL et al. Cultural tailoring for mammography and fruit and vegetable intake among low-income African-American women in urban public health centers. *Prev Med.* 2005;41:53-62.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Kristal AR, Shattuck AL, Patterson RE. Differences in fat-related dietary patterns between black, Hispanic and White women: results from the Women's Health Trial Feasibility Study in Minority Populations. *Public Health Nutr.* 1999;2:253-262.	No relevant outcomes
Kristal AR, White E, Shattuck AL et al. Long-term maintenance of a low-fat diet: durability of fat-related dietary habits in the Women's Health Trial. *J Am Diet Assoc.* 1992;92:553-559.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Kuller LH, Kinzel LS, Pettee KK et al. Lifestyle intervention and coronary heart disease risk factor changes over 18 months in postmenopausal women: the Women On the Move through Activity and Nutrition (WOMAN study) clinical trial. *Journal of Women's Health.* 2006;15:962-974.	Comparative-effectiveness
Kulzer B, Hermanns N, Gorges D, Schwarz P, Haak T. Prevention of diabetes self-management program (PREDIAS): effects on weight, metabolic risk factors, and behavioral outcomes. *Diabetes Care.* 2009;32:1143-1146.	Primary aim is weight loss
Langford HG, Davis BR, Blaufox D et al. Effect of drug and diet treatment of mild hypertension on diastolic blood pressure. The TAIM Research Group. *Hypertension.* 1991;17:210-217.	Population > 50% hypertension or dyslipidemia
Leduc, C. P., Cherniak, D., and Faucher, J. Effectiveness of a group dietary intervention on hypercholesterolemia: a randomized, controlled clinical trial. *Atherosclerosis* 1994;109(1-2):149.	Poor reporting
Liao D, Asberry PJ, Shofer JB et al. Improvement of BMI, body composition, and body fat distribution with lifestyle modification in Japanese Americans with impaired glucose tolerance. *Diabetes Care.* 2002;25:1504-1510.	Comparative-effectiveness
Lichtenstein AH, Ausman LM, Jalbert SM et al. Efficacy of a Therapeutic Lifestyle Change/Step 2 diet in moderately hypercholesterolemic middle-aged and elderly female and male subjects. *Journal of Lipid Research.* 2002;43:264-273.	Not one of specified interventions
Lin, P. H., Appel, L. J., Funk, K., Craddick, S., Chen, C., Elmer, P., McBurnie, M. A., and Champagne, C. The PREMIER intervention helps participants follow the Dietary Approaches to Stop Hypertension dietary pattern and the current Dietary Reference Intakes recommendations. *Journal of the American Dietetic Association*. 2007;107(9):1541-1551.	Comparative-effectiveness
Lindholm LH, Ekbom T, Dash C, Eriksson M, Tibblin G, Schersten B. The impact of health care advice given in primary care on cardiovascular risk. CELL Study Group. *BMJ.* 1995;310:1105-1109.	Population > 50% hypertension or dyslipidemia
Lindholm LH, Ekbom T, Dash C, Isacsson A, Schersten B. Changes in cardiovascular risk factors by combined pharmacological and nonpharmacological strategies: the main results of the CELL Study. *J Intern Med.* 1996;240:13-22.	Population > 50% hypertension or dyslipidemia
Lindsey, Lisa L. M. The influence of persuasive messages on attitude and subjective norm: A test of the theory of reasoned action. *Dissertation Abstracts International Section A: Humanities and Social Sciences*. 2004;64(8-A):2705.	Does not focus on counseling interventions
Lindström J, Eriksson JG, Valle TT et al. Prevention of diabetes mellitus in subjects with impaired glucose tolerance in the Finnish Diabetes Prevention Study: results from a randomized clinical trial. *Journal of the American Society of Nephrology.* 2003;14:S108-S113.	Intervention involves supervised physical activity or medications

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Reference	Reason for exclusion
Lindstrom J, Louheranta A, Mannelin M et al. The Finnish Diabetes Prevention Study (DPS): Lifestyle intervention and 3-year results on diet and physical activity. *Diabetes Care.* 2003;26:3230-3236.	Intervention involves supervised physical activity or medications
Lyons GK, Woodruff SI, Candelaria JI, Rupp JW, Elder JP. Effect of a nutrition intervention on macronutrient intake in a low English-proficient Hispanic sample. *Am J Health Promot.* 1997;11:371-374.	Less than 6 months of followup
Marcus AC, Heimendinger J, Wolfe P et al. A randomized trial of a brief intervention to increase fruit and vegetable intake: a replication study among callers to the CIS. *Prev Med.* 2001;33:204-216.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Marcus AC, Heimendinger J, Wolfe P et al. Increasing fruit and vegetable consumption among callers to the CIS: results from a randomized trial. *Prev Med.* 1998;27:S16-S28.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Marcus AC, Morra M, Rimer BK et al. A feasibility test of a brief educational intervention to increase fruit and vegetable consumption among callers to the Cancer Information Service. *Prev Med.* 1998;27:250-261.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Maruthur NM, Wang NY, Appel LJ. Lifestyle interventions reduce coronary heart disease risk: results from the PREMIER Trial. *Circulation.* 2009;119:2026-2031.	Comparative-effectiveness
Maskarinec G, Chan CL, Meng L, Franke AA, Cooney RV. Exploring the feasibility and effects of a high-fruit and -vegetable diet in healthy women. *Cancer Epidemiol Biomarkers Prev.* 1999;8:919-924.	Comparative-effectiveness
Mayer JA, Jermanovich A, Wright BL, Elder JP, Drew JA, Williams SJ. Changes in health behaviors of older adults: the San Diego Medicare Preventive Health Project. *Prev Med.* 1994;23:127-133.	Does not focus on counseling interventions
Mayer-Davis EJ, Sparks KC, Hirst K et al. Dietary intake in the diabetes prevention program cohort: baseline and 1-year post randomization. *Annals of Epidemiology.* 2004;14:763-772.	Comparative-effectiveness
McGowan MP, Joffe A, Duggan AK, McCay PS. Intervention in hypercholesterolemic college students: a pilot study. *J Adolesc Health.* 1994;15:155-162.	Comparative-effectiveness
McKeown-Eyssen G.E., Bright-See E, Bruce WR et al. A randomized trial of a low fat high fibre diet in the recurrence of colorectal polyps. Toronto Polyp Prevention Group. *J Clin Epidemiol.* 1994;47:525-536.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Meland E, Laerum E, Ulvik RJ. Effectiveness of two preventive interventions for coronary heart disease in primary care. *Scand J Prim Health Care.* 1997;15:57-64.	Population > 50% hypertension or dyslipidemia
Melanson KJ, Dell'Olio J, Carpenter MR, Angelopoulos TJ. Changes in multiple health outcomes at 12 and 24 weeks resulting from 12 weeks of exercise counseling with or without dietary counseling in obese adults. *Nutrition.* 2004;20:849-856.	Primary aim is weight loss
Mensink M, Blaak EE, Corpeleijn E, Saris WH, de Bruin TW, Feskens EJ. Lifestyle intervention according to general recommendations improves glucose tolerance. *Obesity Research.* 2003;11:1588-1596.	Intervention involves supervised physical activity or medications
Mensink, M., Feskens, E. J. M., Saris, W. H. M., de Bruin, T. W. A., and Blaak, E. E. Study on Lifestyle Intervention and Impaired Glucose Tolerance Maastricht (SLIM): Preliminary results after one year. International Journal of Obesity. 2003; 27(3):377-384.	Intervention involves supervised physical activity or medications
Milkereit J, Graves JS. Follow-up dietary counseling benefits attainment of intake goals for total fat, saturated fat, and fiber. *J Am Diet Assoc.* 1992;92:603-605.	Population > 50% hypertension or dyslipidemia
Molitch ME, Fujimoto W, Hamman RF, Knowler WC, Diabetes-Prevention-Program-Research-Group. The diabetes prevention program and its global implications. *Journal of the American Society of Nephrology.* 2003;14:S103-S107.	Comparative-effectiveness
Moy TF, Yanek LR, Raquen~o-JV et al. Dietary counseling for high blood cholesterol in families at risk of coronary disease. *Preventive Cardiology.* 2001;4:158-164.	Population > 50% hypertension or dyslipidemia
Muhlhauser I, Sawicki PT, Didjurgeit U, Jorgens V, Trampisch HJ, Berger M. Evaluation of a structured treatment and teaching programme on hypertension in general practice. *Clin Exp Hypertens.* 1993;15:125-142.	Population > 50% hypertension or dyslipidemia

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Reference	Reason for exclusion
Multiple risk factor intervention trial. Risk factor changes and mortality results. Multiple Risk Factor Intervention Trial Research Group. *JAMA.* 1982;248:1465-1477.	Population > 50% hypertension or dyslipidemia
Naslund GK, Fredrikson M, Hellenius ML, de FU. Effect of diet and physical exercise intervention programmes on coronary heart disease risk in smoking and non-smoking men in Sweden. *J Epidemiol Community Health.* 1996;50:131-136.	No relevant outcomes
Neaton JD, Broste S, Cohen L, Fishman EL, Kjelsberg MO, Schoenberger J. The multiple risk factor intervention trial (MRFIT). VII. A comparison of risk factor changes between the two study groups. *Prev Med.* 1981;10:519-543.	Population > 50% hypertension or dyslipidemia
Neil HA, Roe L, Godlee RJ et al. Randomised trial of lipid lowering dietary advice in general practice: the effects on serum lipids, lipoproteins, and antioxidants. *BMJ.* 1995;310:569-573.	Population > 50% hypertension or dyslipidemia
Neville, Leonie M., O'Hara, Blythe, and Milat, Andrew J. Computer-tailored dietary behaviour change interventions: A systematic review. Health Education Research 24[4], 699-720. 2009.	Not one of the allowable study designs
Nichols, G. Testing a culturally consistent behavioral outcomes strategy for cardiovascular disease risk reduction and prevention in low income African American women. Unpublished doctoral dissertation, Univ of Maryland. 1995.	Less than 6 months of followup
Nilsson PM, Lindholm LH, Schersten BF. Life style changes improve insulin resistance in hyperinsulinaemic subjects: a one-year intervention study of hypertensives and normotensives in Dalby. *J Hypertens.* 1992;10:1071-1078.	Population > 50% hypertension or dyslipidemia
Nitzke S, Kritsch K, Boeckner L et al. A stage-tailored multi-modal intervention increases fruit and vegetable intakes of low-income young adults. *Am J Health Promot.* 2007;22:6-14.	High or differential attrition
Norris SL, Zhang X, Avenell A et al. Long-term effectiveness of weight-loss interventions in adults with pre-diabetes: a review. *Am J Prev Med.* 2005;28:126-139.	Not an allowable study design
O'Halloran, Peggy, Lazovich, DeAnn, Patterson, Ruth E., Harnack, Lisa, French, Simone, Curry, Sue J., and Beresford, Shirley A. A. Effect of health lifestyle pattern on dietary change. American Journal of Health Promotion 16[1], 27-33. 2001.	No relevant outcomes
Oberman A, Wassertheil-Smoller S, Langford HG et al. Pharmacologic and nutritional treatment of mild hypertension: changes in cardiovascular risk status. *Ann Intern Med.* 1990;112:89-95.	Population > 50% hypertension or dyslipidemia
Ockene IS, Hebert JR, Ockene JK et al. Effect of physician-delivered nutrition counseling training and an office-support program on saturated fat intake, weight, and serum lipid measurements in a hyperlipidemic population: Worcester Area Trial for Counseling in Hyperlipidemia (WATCH). *Arch Intern Med.* 1999;159:725-731.	Population > 50% hypertension or dyslipidemia
Ockene IS, Hebert JR, Ockene JK, Merriam PA, Hurley TG, Saperia GM. Effect of training and a structured office practice on physician-delivered nutrition counseling: the Worcester-Area Trial for Counseling in Hyperlipidemia (WATCH). *Am J Prev Med.* 1996;12:252-258.	Population > 50% hypertension or dyslipidemia
ODES Investigators. The Oslo Diet and Exercise Study (ODES): design and objectives. *Control Clin Trials.* 1993;14:229-243.	Population > 50% hypertension or dyslipidemia
Oenema A, Brug J, Lechner L. Web-based tailored nutrition education: results of a randomized controlled trial. *Health Education Research.* 2001;16:647-660.	Less than 6 months of followup
Papadaki A, Scott JA. Follow-up of a web-based tailored intervention promoting the Mediterranean diet in Scotland. *Patient Education & Counseling.* 2008;73:256-263.	Comparative-effectiveness

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Reference	Reason for exclusion
Park A, Nitzke S, Kritsch K, Kattelmann K, White A, Boeckner L, Lohse B, Hoerr S, Greene G, and Zhang Z. Internet-based interventions have potential to affect short-term mediators and indicators of dietary behavior of young adults. Journal of Nutrition Education and Behavior 40[5], 288-297. 2008.	Comparative-effectiveness
Pereira, R. F. Franz M. J. Prevention and Treatment of Cardiovascular Disease in People With Diabetes Through Lifestyle Modification: Current Evidence-Based Recommendations. *Diabetes Spectr*. 2008;21:189-193.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Perkins-Porras L, Cappuccio FP, Rink E, Hilton S, McKay C, Steptoe A. Does the effect of behavioral counseling on fruit and vegetable intake vary with stage of readiness to change? *Prev Med.* 2005;40:314-320.	Comparative-effectiveness
Pierce JP, Faerber S, Wright FA et al. Feasibility of a randomized trial of a high-vegetable diet to prevent breast cancer recurrence. *Nutr Cancer.* 1997;28:282-288.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Pinto BM, Friedman R, Marcus BH, Kelley H, Tennstedt S, Gillman MW. Effects of a computer-based, telephone-counseling system on physical activity. *Am J Prev Med.* 2002;23:113-120.	No relevant outcomes
Ramachandran A, Snehalatha C, Mary S, Mukesh B, Bhaskar AD, Vijay V. The Indian Diabetes Prevention Programme shows that lifestyle modification and metformin prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1). *Diabetologia.* 2006;49:289-297.	Not on list of countries with HDI > 0.90
Randomised controlled trial evaluating cardiovascular screening and intervention in general practice: principal results of British family heart study. Family Heart Study Group. *BMJ.* 1994;308:313-320.	Other quality issues
Rankinen T, Rauramaa R, Vaisanen SB, Halonen JP, Penttila IM. Blood coagulation and fibrinolytic factors are unchanged by aerobic exercise or fat modified diet. Randomized clinical trial in middle-aged men. *Fibrinolysis.* 1994;8:48-53.	Not one of specified interventions
Ratner R, Goldberg R, Haffner S et al. Impact of intensive lifestyle and metformin therapy on cardiovascular disease risk factors in the diabetes prevention program. *Diabetes Care.* 2005;28:888-894.	Comparative-effectiveness
Ratner RE, Christophi CA, Metzger BE et al. Prevention of diabetes in women with a history of gestational diabetes: effects of metformin and lifestyle interventions. *Journal of Clinical Endocrinology & Metabolism.* 2008;93:4774-4779.	Comparative-effectiveness
Reseland JE, Anderssen SA, Solvoll K et al. Effect of long-term changes in diet and exercise on plasma leptin concentrations. *Am J Clin Nutr.* 2001;73:240-245.	Population > 50% hypertension or dyslipidemia
Ritenbaugh C, Patterson RE, Chlebowski RT et al. The Women's Health Initiative Dietary Modification trial: overview and baseline characteristics of participants. *Ann Epidemiol.* 2003;13:Suppl-97.	No relevant outcomes
Roca-Cusachs A, Sort D, Altimira J et al. The impact of a patient education programme in the control of hypertension. *J Hum Hypertens.* 1991;5:437-441.	Population > 50% hypertension or dyslipidemia
Roumen C, Corpeleijn E, Feskens EJ, Mensink M, Saris WH, Blaak EE. Impact of 3-year lifestyle intervention on postprandial glucose metabolism: the SLIM study. *Diabetic Medicine.* 2008;25:597-605.	Intervention involves supervised physical activity or medications
Rydwik E, Lammes E, Frandin K, Akner G. Effects of a physical and nutritional intervention program for frail elderly people over age 75. A randomized controlled pilot treatment trial. *Aging-Clinical & Experimental Research.* 2008;20:159-170.	Does not focus on counseling interventions
Salkeld G, Phongsavan P, Oldenburg B et al. The cost-effectiveness of a cardiovascular risk reduction program in general practice. *Health Policy.* 1997;41:105-119.	Population > 50% hypertension or dyslipidemia
Sallinen J, Fogelholm M, Pakarinen A et al. Effects of strength training and nutritional counseling on metabolic health indicators in aging women. *Canadian Journal of Applied Physiology.* 2005;30:690-707.	Less than 6 months of followup

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Reference	Reason for exclusion
Sallis JF, Patrick K, Calfas KJ et al. A multi-media behavior change program for nutrition and physical activity in primary care: PACE+ for adults. *Homeostasis.* 1999;39:196-202.	Less than 6 months of followup
Shike M, Latkany L, Riedel E et al. Lack of effect of a low-fat, high-fruit, -vegetable, and -fiber diet on serum prostate-specific antigen of men without prostate cancer: results from a randomized trial. *Journal of Clinical Oncology.* 2002;20:3592-3598.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Stamler J, Briefel RR, Milas C, Grandits GA, Caggiula AW. Relation of changes in dietary lipids and weight, trial years 1-6, to changes in blood lipids in the special intervention and usual care groups in the Multiple Risk Factor Intervention Trial. *Am J Clin Nutr.* 1997;65:272S-288S.	Intervention involves supervised physical activity or medications
Staten, Lisa K., Gregory-Mercado, Karen Y., Ranger-Moore, James, Will, Julie C., Giuliano, Anna R., Ford, Earl S., and Marshall, James. Provider Counseling, Health Education, and Community Health Workers: The Arizona WISEWOMAN Project. *Journal of Women's Health* 2004;13(5):547-556.	Comparative-effectiveness
Steptoe A, Perkins-Porras L, Hilton S, Rink E, Cappuccio FP. Quality of life and self-rated health in relation to changes in fruit and vegetable intake and in plasma vitamins C and E in a randomised trial of behavioural and nutritional education counselling. *British Journal of Nutrition.* 2004;92:177-184.	Comparative-effectiveness
Steptoe A, Perkins-Porras L, McKay C, Rink E, Hilton S, Cappuccio FP. Behavioural counselling to increase consumption of fruit and vegetables in low income adults: randomised trial. *BMJ.* 2003;326:855.	Comparative-effectiveness
Stevens VJ, Glasgow RE, Toobert DJ, Karanja N, Smith KS. Randomized trial of a brief dietary intervention to decrease consumption of fat and increase consumption of fruits and vegetables. *Am J Health Promot.* 2002;16:129-134.	Less than 6 months of followup
Stoddard AM, Palombo R, Troped PJ, Sorensen G, Will JC. Cardiovascular disease risk reduction: the Massachusetts WISEWOMAN project. *Journal of women's health.* 2004;13:539-546.	Comparative-effectiveness
Strandberg TE, Salomaa VV, Naukkarinen VA, Vanhanen HT, Sarna SJ, Miettinen TA. Long-term mortality after 5-year multifactorial primary prevention of cardiovascular diseases in middle-aged men. *JAMA.* 1991;266:1225-1229.	Intervention involves supervised physical activity or medications
Strandberg TE, Salomaa VV, Vanhanen HT, Naukkarinen VA, Sarna SJ, Miettinen TA. Mortality in participants and non-participants of a multifactorial prevention study of cardiovascular diseases: a 28 year follow up of the Helsinki Businessmen Study. *Br Heart J.* 1995;74:449-454.	Intervention involves supervised physical activity or medications
Swinburn BA, Metcalf PA, Ley SJ. Long-term (5-year) effects of a reduced-fat diet intervention in individuals with glucose intolerance. *Diabetes Care.* 2001;24:619-624.	Limited to children and adolescents, parents (if change intended for children), persons with any acute disease or symptomatic disease, persons with known coronary heart disease (or angina) or peripheral vascular disease or diabetes, pregnant women, institutionalized persons, or persons with SPMI or cognitive impairment
Takahashi Y, Sasaki S, Okubo S, Hayashi M, Tsugane S. Blood pressure change in a free-living population-based dietary modification study in Japan. *J Hypertens.* 2006;24:451-458.	Other quality issues
The Diabetes Prevention Program. Design and methods for a clinical trial in the prevention of type 2 diabetes. *Diabetes Care.* 1999;22:623-634.	Comparative-effectiveness
The Diabetes Prevention Program: baseline characteristics of the randomized cohort. The Diabetes Prevention Program Research Group. *Diabetes Care.* 2000;23:1619-1629.	Comparative-effectiveness
The WISEWOMAN Workgroup. Cardiovascular disease prevention for women attending breast and cervical cancer screening programs: the WISEWOMAN projects. *Prev Med.* 1999;28:496-502.	Comparative-effectiveness

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Reference	Reason for exclusion
Toft U, Kristoffersen L, Ladelund S et al. The effect of adding group-based counselling to individual lifestyle counselling on changes in dietary intake. The Inter99 study - a randomized controlled trial. *International Journal of Behavioral Nutrition & Physical Activity.* 2008;5:59.	Population > 50% hypertension or dyslipidemia
Toft U, Kristoffersen L, Ladelund S et al. The impact of a population-based multi-factorial lifestyle intervention on changes in long-term dietary habits The Inter99 study. *Prev Med.* 2008.	Population > 50% hypertension or dyslipidemia
Tomson Y, Johannesson M, Aberg H. The costs and effects of two different lipid intervention programmes in primary health care. *J Intern Med.* 1995;237:13-17.	Population > 50% hypertension or dyslipidemia
Tuomilehto J, Lindstrom J, Eriksson JG et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *New England Journal of Medicine.* 2001;344:1343-1350.	Intervention involves supervised physical activity or medications
Uusitupa M, Lindi V, Louheranta A, Salopuro T, Lindstrom J, Tuomilehto J. Long-term improvement in insulin sensitivity by changing lifestyles of people with impaired glucose tolerance: 4-year results from the Finnish Diabetes Prevention Study. *Diabetes.* 2003;52:2532-2538.	Intervention involves supervised physical activity or medications
Uusitupa M, Louheranta A, Lindstrom J et al. The Finnish Diabetes Prevention Study. *Br J Nutr.* 2000;83 Suppl 1:S137-42.:S137-S142.	Intervention involves supervised physical activity or medications
van der Veen J, Bakx C, van den Hoogen H et al. Stage-matched nutrition guidance for patients at elevated risk for cardiovascular disease: a randomized intervention study in family practice. *J Fam Pract.* 2002;51:751-758.	Population > 50% hypertension or dyslipidemia
van Steenkiste B, van-der Weijden T, Stoffers HE, Kester AD, Timmermans DR, Grol R. Improving cardiovascular risk management: a randomized, controlled trial on the effect of a decision support tool for patients and physicians. *European journal of cardiovascular prevention and rehabilitation : official journal of the European Society of Cardiology, Working Groups on Epidemiology & Prevention and Cardiac Rehabilitation and Exercise Physiology.* 2007;14:44-50.	No relevant outcomes
Verheijden M, Bakx JC, Akkermans R et al. Web-based targeted nutrition counselling and social support for patients at increased cardiovascular risk in general practice: randomized controlled trial. *J Med Internet Res.* 2004;6:e44.	Population > 50% hypertension or dyslipidemia
Verheijden MW, van d, V, Bakx JC et al. Stage-matched nutrition guidance: stages of change and fat consumption in Dutch patients at elevated cardiovascular risk. *J Nutr Educ Behav.* 2004;36:228-237.	Population > 50% hypertension or dyslipidemia
Villareal DT, Miller BV, III, Banks M, Fontana L, Sinacore DR, Klein S. Effect of lifestyle intervention on metabolic coronary heart disease risk factors in obese older adults. *Am J Clin Nutr.* 2006;84:1317-1323.	Primary aim is weight loss
Walden CE, Retzlaff BM, Buck BL, McCann BS, Knopp RH. Lipoprotein lipid response to the National Cholesterol Education Program step II diet by hypercholesterolemic and combined hyperlipidemic women and men. *Arterioscler Thromb Vasc Biol.* 1997;17:375-382.	Population > 50% hypertension or dyslipidemia
Wassertheil-Smoller S, Oberman A, Blaufox MD, Davis B, Langford H. The Trial of Antihypertensive Interventions and Management (TAIM) Study. Final results with regard to blood pressure, cardiovascular risk, and quality of life. *Am J Hypertens.* 1992;5:37-44.	Population > 50% hypertension or dyslipidemia
Whelton PK, Kumanyika SK, Cook NR et al. Efficacy of nonpharmacologic interventions in adults with high-normal blood pressure: results from phase 1 of the Trials of Hypertension Prevention. Trials of Hypertension Prevention Collaborative Research Group. *Am J Clin Nutr.* 1997;65:652S-660S.	No relevant outcomes
Whelton PK, Appel LJ, Espeland MA et al. Sodium reduction and weight loss in the treatment of hypertension in older persons: a randomized controlled trial of nonpharmacologic interventions in the elderly (TONE). TONE Collaborative Research Group. *JAMA.* 1998;279:839-846.	Population > 50% hypertension or dyslipidemia

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Reference	Reason for exclusion
White E, Shattuck AL, Kristal AR et al. Maintenance of a low-fat diet: follow-up of the Women's Health Trial. *Cancer Epidemiol Biomarkers Prev.* 1992;1:315-323.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Wildman RP, Schott LL, Brockwell S, Kuller LH, Sutton-Tyrrell K. A dietary and exercise intervention slows menopause-associated progression of subclinical atherosclerosis as measured by intima-media thickness of the carotid arteries. *Journal of the American College of Cardiology.* 2004;44:579-585.	No relevant outcomes
Will JC, Massoudi B, Mokdad A et al. Reducing risk for cardiovascular disease in uninsured women: combined results from two WISEWOMAN projects. *Journal of the American Medical Women's Association.* 2001;56:161-165.	Comparative-effectiveness
Wing RR, Venditti E, Jakicic JM, Polley BA, Lang W. Lifestyle intervention in overweight individuals with a family history of diabetes. *Diabetes Care.* 1998;21:350-359.	Primary aim is weight loss
Wolf RL, Lepore SJ, Vandergrift JL, Basch CE, Yaroch AL. Tailored telephone education to promote awareness and adoption of fruit and vegetable recommendations among urban and mostly immigrant black men: a randomized controlled trial. *Prev Med.* 2009;48:32-38.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Wylie-Rosett J, Wassertheil-Smoller S, Blaufox MD et al. Trial of antihypertensive intervention and management: greater efficacy with weight reduction than with a sodium-potassium intervention. *J Am Diet Assoc.* 1993;93:408-415.	Population > 50% hypertension or dyslipidemia
Young DR, King AC, Sheehan M, Stefanick ML. Stage of motivational readiness: predictive ability for exercise behavior. *American Journal of Health Behavior.* 2002;26:331-341.	Population > 50% hypertension or dyslipidemia
Young DR, Vollmer WM, King AC et al. Can individuals meet multiple physical activity and dietary behavior goals? *American Journal of Health Behavior.* 2009;33:277-286.	Comparative-effectiveness

Appendix D Table 2. Healthful Diet Studies Excluded From the Review for Key Question 4

Reference	Reason for exclusion
Ferrer RL, Mody-Bailey P, Jaen CR, Gott S, Araujo S. A medical assistant-based program to promote healthy behaviors in primary care. *Ann Fam Med.* 2009;7:504-512.	High or differential attrition
Geleijnse JM, Witteman JC, Bak AA, den Breeijen JH, Grobbee DE. Long-term moderate sodium restriction does not adversely affect the serum HDL/total cholesterol ratio. *J Hum Hypertens.* 1995;9:975-979.	Population > 50% hypertension or dyslipidemia
Boyd NF, Greenberg C, Lockwood G et al. Effects at two years of a low-fat, high-carbohydrate diet on radiologic features of the breast: results from a randomized trial. Canadian Diet and Breast Cancer Prevention Study Group. *J Natl Cancer Inst.* 1997;89:488-496.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Hislop TG, Bajdik CD, Balneaves LG et al. Physical and emotional health effects and social consequences after participation in a low-fat, high-carbohydrate dietary trial for more than 5 years. *Journal of Clinical Oncology.* 2006;24:2311-2317.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition

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Reference	Reason for exclusion
Albright, Cheryl, Pruitt, Leslie, Castro, Cynthia, Gonzalez, Alma, Woo, Sandi, and King, Abby C. Modifying physical activity in a multiethnic sample of low-income women: One-year results from the IMPACT (increasing motivation for physical ACTivity) project. *Annals of Behavioral Medicine*. 2005;30(3):191-200.	Comparative-effectiveness
Allison MJ, Keller C. Self-efficacy intervention effect on physical activity in older adults. *Western Journal of Nursing Research.* 2004;26:31-46.	Limited to children and adolescents, parents (if change intended for children), persons with any acute disease or symptomatic disease, persons with known coronary heart disease (or angina) or peripheral vascular disease or diabetes, pregnant women, institutionalized persons, or persons with SPMI or cognitive impairment
Amati, Francesca, Barthassat, Vincent, Miganne, Guy, Hausman, Isabelle, Monnin, Dominique, Constanza, Michael C., and Golay, Alain. Enhancing regular physical activity and relapse prevention through a 1-day therapeutic patient education workshop: A pilot study. *Patient Educ Couns*. 2007;68(1):70-78.	Not an allowable study design
Anderson RT, King A, Stewart AL, Camacho F, Rejeski WJ. Physical activity counseling in primary care and patient well-being: Do patients benefit? *Ann Behav Med.* 2005;30:146-154.	Comparative-effectiveness
Anderssen S, Holme I, Urdal P, Hjermann I. Diet and exercise intervention have favourable effects on blood pressure in mild hypertensives: the Oslo Diet and Exercise Study (ODES). *Blood Press.* 1995;4:343-349.	Population > 50% hypertension or dyslipidemia
Anderssen SA, Carroll S, Urdal P, Holme I. Combined diet and exercise intervention reverses the metabolic syndrome in middle-aged males: results from the Oslo Diet and Exercise Study. *Scandinavian Journal of Medicine & Science in Sports.* 2007;17:687-695.	Intervention involves supervised physical activity or medications
Anderssen SA, Haaland A Hjerman I Urdal P Gjesdal K Holme I. Oslo diet and exercise study: a one year randomized intervention trial. Efect on Haemostatic variables and other coronary risk factors. *Nutrition, Metabolism & Cardiovascular Diseases*. 1995;5:189-200.	Intervention involves supervised physical activity or medications
Anderssen SA, Hjermann I, Urdal P, Torjesen PA, Holme I. Improved carbohydrate metabolism after physical training and dietary intervention in individuals with the "atherothrombogenic syndrome'. Oslo Diet and Exercise Study (ODES). A randomized trial. *J Intern Med.* 1996;240:203-209.	Population > 50% hypertension or dyslipidemia
Appel LJ, Champagne CM, Harsha DW et al. Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial. *JAMA.* 2003;289:2083-2093.	Comparative-effectiveness
Applegate WB, Miller ST, Elam JT et al. Nonpharmacologic intervention to reduce blood pressure in older patients with mild hypertension. *Arch Intern Med.* 1992;152:1162-1166.	Population > 50% hypertension or dyslipidemia
Armit CM, Brown WJ, Marshall AL et al. Randomized trial of three strategies to promote physical activity in general practice. *Prev Med.* 2009;48:156-163.	Comparative-effectiveness
Armit CM, Brown WJ, Ritchie CB, Trost SG. Promoting physical activity to older adults: a preliminary evaluation of three general practice-based strategies. *Journal of Science & Medicine in Sport.* 2005;8:446-450.	Comparative-effectiveness
Asikainen TM, Miilunpalo S, Kukkonen-Harjula K et al. Walking trials in postmenopausal women: effect of low doses of exercise and exercise fractionization on coronary risk factors. *Scandinavian Journal of Medicine & Science in Sports.* 2003;13:284-292.	Intervention involves supervised physical activity or medications
Baker MK, Atlantis E, Fiatarone Singh MA. Multi-modal exercise programs for older adults. *Age Ageing.* 2007;36:375-381.	Not an allowable study design
Barclay C, Procter KL, Glendenning R, Marsh P, Freeman J, Mathers N. Can type 2 diabetes be prevented	Intervention involves supervised physical activity

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Reference	Reason for exclusion
in UK general practice? A lifestyle-change feasibility study (ISAIAH). *Br J Gen Pract.* 2008;58:541-547.	or medications
Bennett JA, Young HM, Nail LM, Winters-Stone K, Hanson G. A telephone-only motivational intervention to increase physical activity in rural adults: a randomized controlled trial. *Nursing Research.* 2008;57:24-32.	Comparative-effectiveness
Bergstrom I, Lombardo C, Brinck J. Physical training decreases waist circumference in postmenopausal borderline overweight women. *Acta Obstetricia et Gynecologica Scandinavica.* 2009;88:308-313.	Biased recruitment strategy or selection of patients not generalizable to primary care
Blue CL, Black DR. Synthesis of intervention research to modify physical activity and dietary behaviors. *Res Theory Nurs Pract.* 2005;19(1):25-61.	Not an allowable study design
Blumenthal JA, Sherwood A, Gullette EC et al. Exercise and weight loss reduce blood pressure in men and women with mild hypertension: effects on cardiovascular, metabolic, and hemodynamic functioning. *Arch Intern Med.* 2000;160:1947-1958.	Intervention involves supervised physical activity or medications
Bo S, Ciccone G, Baldi C et al. Effectiveness of a lifestyle intervention on metabolic syndrome. A randomized controlled trial. *J Gen Intern Med.* 2007;22:1695-1703.	Population > 50% hypertension or dyslipidemia
Bock BC, Marcus BH, Pinto BM, Forsyth LH. Maintenance of physical activity following an individualized motivationally tailored intervention. *Ann Behav Med.* 2001;23:79-87.	Comparative-effectiveness
Brawley LR, Rejeski W, Lutes LA. A group-mediated cognitive-behavioral intervention for increasing adherence to physical activity in older adults. *Journal of Applied Biobehavioral Research.* 2000;5:47-65.	Intervention involves supervised physical activity or medications
British family heart study: its design and method, and prevalence of cardiovascular risk factors. Family heart study group. *Br J Gen Pract.* 1994;44:62-67.	Other quality issues
Bull FC, Jamrozik K. Advice on exercise from a family physician can help sedentary patients to become active. *Am J Prev Med.* 1998;15:85-94.	High or differential attrition
Burke V, Beilin LJ, Cutt HE, Mansour J, Mori TA. Moderators and mediators of behaviour change in a lifestyle program for treated hypertensives: a randomized controlled trial (ADAPT). *Health Education Research.* 2008;23:583-591.	Population > 50% hypertension or dyslipidemia
Burke V, Giangiulio N, Gillam HF, Beilin LJ, Houghton S, Milligan RA. Health promotion in couples adapting to a shared lifestyle. *Health Educ Res.* 1999;14:269-288.	Less than 6 months of followup
Burke V, Giangiulio N, Gillam HF, Beilin LJ, Houghton S. Physical activity and nutrition programs for couples: a randomized controlled trial. *Journal of Clinical Epidemiology.* 2003;56:421-432.	High or differential attrition
Burke V, Mori TA, Giangiulio N et al. An innovative program for changing health behaviours. *Asia Pac J Clin Nutr.* 2002;11 Suppl 3:S586-S597.	High or differential attrition
Burton LC, Paglia MJ, German PS, Shapiro S, Damiano AM. The effect among older persons of a general preventive visit on three health behaviors: smoking, excessive alcohol drinking, and sedentary lifestyle. The Medicare Preventive Services Research Team. *Prev Med.* 1995;24:492-497.	Other quality issues
Byfield, Cynthia Louise. Development and evaluation of a lifestyle physical activity intervention for obese sedentary women. Dissertation Abstracts International: *Section B:The Sciences and Engineering.* 2001;62(5-B):2280.	Comparative-effectiveness
Cardinal BJ, Sachs ML. Prospective analysis of stage-of-exercise movement following mail-delivered, self-instructional exercise packets. *Am J Health Promot.* 1995;9:430-432.	No relevant outcomes
Carlfjord S, Nilsen P, Leijon M, Andersson A, Johansson K, Bendtsen P. Computerized lifestyle intervention in routine primary health care: evaluation of usage on provider and responder levels. *Patient Education & Counseling* 75 (2):238-243, 2009.	No relevant outcomes

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Reference	Reason for exclusion
Carr LJ, Bartee RT, Dorozynski CM, Broomfield JF, Smith ML, Smith DT. Eight-month follow-up of physical activity and central adiposity: results from an Internet-delivered randomized control trial intervention. *Journal of Physical Activity & Health* 6 (4):444-455, 2009.	Less than 6 months of followup
Carroll R, Ali N, Azam N. Promoting physical activity in South Asian Muslim women through "exercise on prescription". *Health Technol Assess.* 2002;6:1-101.	Not an allowable study design
Castro CM, King AC, Brassington GS. Telephone versus mail interventions for maintenance of physical activity in older adults. *Health Psychology.* 2001;20:438-444.	Comparative-effectiveness
Chen AH, Sallis JF, Castro CM et al. A home-based behavioral intervention to promote walking in sedentary ethnic minority women: project WALK. *Womens Health.* 1998;4:19-39.	High or differential attrition
Chen, AH-W. The effectiveness of a home-based intervention to promote walking in ethnic minority women. 1996. U California San Diego and San Diego State U.	High or differential attrition
Conn VS, Burks KJ, Minor MA, Mehr DR. Randomized trial of 2 interventions to increase older women's exercise. *Am J Health Behav.* 2003;27:380-388.	Less than 6 months of followup
Corace, Kimberly M. Does reducing negative affect facilitate readiness to exercise? A stage-based, cognitive-behavioural intervention for individuals at risk for primary and secondary Coronary Heart Disease. *Dissertation Abstracts International: Section B: The Sciences and Engineering*. 2008;69(6-B):3841.	Population > 50% hypertension or dyslipidemia
Costanzo C, Walker SN, Yates BC, McCabe B, Berg K. Physical activity counseling for older women. *West J Nurs Res.* 2006;28:786-801.	Less than 6 months of followup
Coulter A, Fowler G, Fuller A et al. Effectiveness of health checks conducted by nurses in primary care: final results of the OXCHECK study. *British Medical Journal.* 1995;310:1099-1104.	Other quality issues
Crandall J, Schade D, Ma Y et al. The influence of age on the effects of lifestyle modification and metformin in prevention of diabetes. *J Gerontol A Biol Sci Med Sci.* 2006;61:1075-1081.	Comparative-effectiveness
Cutler JA, Neaton JD, Hulley SB, Kuller L, Paul O, Stamler J. Coronary heart disease and all-causes mortality in the Multiple Risk Factor Intervention Trial: subgroup findings and comparisons with other trials. *Prev Med.* 1985;14:293-311.	Population > 50% hypertension or dyslipidemia
Davey SG, Bracha Y, Svendsen KH et al. Incidence of type 2 diabetes in the randomized multiple risk factor intervention trial. *Ann Intern Med.* 2005;142:313-322.	Population > 50% hypertension or dyslipidemia
Davidson LE, Hudson R, Kilpatrick K et al. Effects of exercise modality on insulin resistance and functional limitation in older adults: a randomized controlled trial. *Arch Intern Med.* 2009;169:122-131.	Intervention involves supervised physical activity or medications
de Vries, H., Kremers, S. P. J., Smeets, T., Brug, J., and Eijmael, K. The effectiveness of tailored feedback and action plans in an intervention addressing multiple health behaviors. *American Journal of Health Promotion.* 2008;22(6):417-425.	Comparative-effectiveness
Delahanty LM, Sonnenberg LM, Hayden D, Nathan DM. Clinical and cost outcomes of medical nutrition therapy for hypercholesterolemia: a controlled trial. *Journal of the American Dietetic Association.* 2001;101:1012-1023.	Not one of specified interventions
Deley G, Kervio G, Van HJ, Verges B, Grassi B, Casillas JM. Effects of a one-year exercise training program in adults over 70 years old: a study with a control group. *Aging-Clinical & Experimental Research.* 2007;19:310-315.	Intervention involves supervised physical activity or medications
Dolecek TA, Milas NC, Van Horn LV et al. A long-term nutrition intervention experience: lipid responses and dietary adherence patterns in the Multiple Risk Factor Intervention Trial. *J Am Diet Assoc.* 1986;86:752-758.	Population > 50% hypertension or dyslipidemia
Dubbert PM, Cooper KM, Kirchner KA, Meydrech EF, Bilbrew D. Effects of nurse counseling on walking for	Comparative-effectiveness

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Reference	Reason for exclusion
exercise in elderly primary care patients. *Journals of Gerontology Series A-Biological Sciences & Medical Sciences.* 2002;57:M733-M740.	
Dubbert PM, Morey MC, Kirchner KA, Meydrech EF, Grothe K. Counseling for home-based walking and strength exercise in older primary care patients. *Arch Intern Med.* 2008;168:979-986.	Limited to children and adolescents, parents (if change intended for children), persons with any acute disease or symptomatic disease, persons with known coronary heart disease (or angina) or peripheral vascular disease or diabetes, pregnant women, institutionalized persons, or persons with SPMI or cognitive impairment
Dutton GR, Davis MP, Welsch MA, Brantley PJ. Promoting physical activity for low-income minority women in primary care. *American Journal of Health Behavior.* 2007;31:622-631.	Primary aim is weight loss
Dzator JA, Hendrie D, Burke V et al. A randomized trial of interactive group sessions achieved greater improvements in nutrition and physical activity at a tiny increase in cost. *Journal of Clinical Epidemiology.* 2004;57:610-619.	High or differential attrition
Eakin E, Reeves M, Lawler S et al. Telephone counseling for physical activity and diet in primary care patients. *Am J Prev Med.* 2009;36:142-149.	Population > 50% hypertension or dyslipidemia
Eakin EG, Brown WJ, Marshall AL, Mummery K, Larsen E. Physical activity promotion in primary care: bridging the gap between research and practice. *Am J Prev Med.* 2004;27:297-303.	No relevant outcomes
Eckstrom E, Hickam DH, Lessler DS, Buchner DM. Changing physician practice of physical activity counseling. *J Gen Intern Med.* 1999;14:376-378.	High or differential attrition
Effectiveness of health checks conducted by nurses in primary care: results of the OXCHECK study after one year. Imperial Cancer Research Fund OXCHECK Study Group. *BMJ.* 1994;308:308-312.	Other quality issues
Elder JP, Williams SJ, Drew JA, Wright BL, Boulan TE. Longitudinal effects of preventive services on health behaviors among an elderly cohort. *Am J Prev Med.* 1995;11:354-359.	High or differential attrition
Elley R, Kerse N, Arroll B, Swinburn B, Ashton T, Robinson E. Cost-effectiveness of physical activity counselling in general practice. *New Zealand Medical Journal.* 2004;117:U1216.	No relevant outcomes
Ellingsen I, Hjerkinn EM, Arnesen H, Seljeflot I, Hjermann I, Tonstad S. Follow-up of diet and cardiovascular risk factors 20 years after cessation of intervention in the Oslo Diet and Antismoking Study. *European Journal of Clinical Nutrition.* 2006;60:378-385.	No relevant outcomes
Ellingsen I, Hjermann I, Abdelnoor M, Hjerkinn EM, Tonstad S. Dietary and antismoking advice and ischemic heart disease mortality in men with normal or high fasting triacylglycerol concentrations: a 23-y follow-up study. *The American journal of clinical nutrition.* 2003;78:935-940.	Not one of specified interventions
Ellsworth DL, O'Dowd SC, Salami B et al. Intensive lifestyle modification: impact on cardiovascular disease risk factors in subjects with and without clinical cardiovascular disease. *Preventive Cardiology.* 2004;7:168-175.	Not an allowable study design
Elmer PJ, Obarzanek E, Vollmer WM et al. Effects of comprehensive lifestyle modification on diet, weight, physical fitness, and blood pressure control: 18-month results of a randomized trial. *Ann Intern Med.* 2006;144:485-495.	Comparative-effectiveness
Emmons, Karen M., Stoddard, Ann M., Fletcher, Robert, Gutheil, Caitlin, Suarez, Elizabeth Gonzalez, Lobb, Rebecca, Weeks, Jane, and Bigby, Judy Anne. Cancer Prevention Among Working Class, Multiethnic Adults: Results of the Healthy Directions--Health Centers Study. *American Journal of Public Health*. 2005;95(7):1200-1205.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Engels HJ, Drouin J, Zhu W, Kazmierski JF. Effects of low-impact, moderate-intensity exercise training with	Intervention involves supervised physical activity

Appendix D Table 3. Physical Activity Studies Excluded From the Review for Key Questions 1–3

Reference	Reason for exclusion
and without wrist weights on functional capacities and mood states in older adults. *Gerontology.* 1998;44:239-244.	or medications
Eriksson J, Lindstrom J, Valle T et al. Prevention of Type II diabetes in subjects with impaired glucose tolerance: the Diabetes Prevention Study (DPS) in Finland. Study design and 1-year interim report on the feasibility of the lifestyle intervention programme. *Diabetologia.* 1999;42:793-801.	Intervention involves supervised physical activity or medications
Espeland MA, Whelton PK, Kostis JB et al. Predictors and mediators of successful long-term withdrawal from antihypertensive medications. TONE Cooperative Research Group. Trial of Nonpharmacologic Interventions in the Elderly. *Arch Fam Med.* 1999;8:228-236.	Population > 50% hypertension or dyslipidemia
Evans EM, Van Pelt RE, Binder EF, Williams DB, Ehsani AA, Kohrt WM. Effects of HRT and exercise training on insulin action, glucose tolerance, and body composition in older women. *Journal of Applied Physiology.* 2001;90:2033-2040.	Intervention involves supervised physical activity or medications
Fagerberg B, Wikstrand J, Berglund G, Samuelsson O, Agewall S. Mortality rates in treated hypertensive men with additional risk factors are high but can be reduced: a randomized intervention study. *Am J Hypertens.* 1998;11:14-22.	Population > 50% hypertension or dyslipidemia
Ferrer RL, Mody-Bailey P, Jaen CR, Gott S, Araujo S. A medical assistant-based program to promote healthy behaviors in primary care. *Ann Fam Med.* 2009;7:504-512.	High or differential attrition
Figueroa A, Going SB, Milliken LA et al. Effects of exercise training and hormone replacement therapy on lean and fat mass in postmenopausal women. *Journals of Gerontology Series A-Biological Sciences & Medical Sciences.* 2003;58:266-270.	Intervention involves supervised physical activity or medications
Findorff MJ, Stock HH, Gross CR, Wyman JF. Does the Transtheoretical Model (TTM) explain exercise behavior in a community-based sample of older women? *Journal of Aging & Health.* 2007;19:985-1003	Does not focus on counseling interventions
Frierson GM, Williams DM, Dunsiger S et al. Recruitment of a racially and ethnically diverse sample into a physical activity efficacy trial. *Clinical Trials.* 2008;5:504-516.	Comparative-effectiveness
Garcia A, King A. Predicting long-term adherence to aerobic exercise: a comparison of two models. *J Sport Exerc Psychol.* 1991;13:394-410.	Comparative-effectiveness
Gaston MH, Porter GK, Thomas VG. Prime Time Sister Circles: evaluating a gender-specific, culturally relevant health intervention to decrease major risk factors in mid-life African-American women. *J Natl Med Assoc.* 2007;99:428-438.	Setting not primary care or generalizable to primary care
Goodpaster BH, Chomentowski P, Ward BK et al. Effects of physical activity on strength and skeletal muscle fat infiltration in older adults: a randomized controlled trial. *Journal of applied physiology (Bethesda, Md : 1985).* 2008;105:1498-1503.	Intervention involves supervised physical activity or medications
Graham-Clarke P, Oldenburg B. The effectiveness of a general-practice-based physical activity intervention on patient physical activity status. *Behavioral Change.* 1994;11:132-144.	High or differential attrition
Greaves CJ, Middlebrooke A, O'Loughlin L et al. Motivational interviewing for modifying diabetes risk: a randomised controlled trial. *Br J Gen Pract.* 2008;58:535-540.	Primary aim is weight loss
Hamdorf PA, Penhall RK. Walking with its training effects on the fitness and activity patterns of 79-91 year old females. *Aust N Z J Med.* 1999;29:22-28.	Intervention involves supervised physical activity or medications
Hamdorf PA, Withers RT, Penhall RK, Haslam MV. Physical training effects on the fitness and habitual activity patterns of elderly women. *Arch Phys Med Rehabil.* 1992;73:603-608.	Intervention involves supervised physical activity or medications
Hamdorf PA, Withers RT, Penhall RK, Plummer JL. A follow-up study on the effects of training on the fitness and habitual activity patterns of 60- to 70-year-old women. *Arch Phys Med Rehabil.* 1993;74:473-477.	Intervention involves supervised physical activity or medications
Harari D, Iliffe S, Kharicha K et al. Promotion of health in older people: a randomised controlled trial of	Does not focus on counseling interventions

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Reference	Reason for exclusion
health risk appraisal in British general practice. *Age Ageing.* 2008;37:565-571.	
Hardman AE, Jones PR, Norgan NG, Hudson A. Brisk walking improves endurance fitness without changing body fatness in previously sedentary women. *Eur J Appl Physiol Occup Physiol.* 1992;65:354-359.	Outcome assessment unblinded
Harralson, TL, Emig JC, Polansky M, WalkerRE, Otero Cruz J, Garcia-Leeds C. Un corazon saludable: Factors influencing outcomes of an exercise program designed to impact cardiac and metabolic risks among urban Latinas. Journal of Community Health: The Publication for Health Promotion and Disease Prevention 32[6], 401-412. 2007.	Intervention involves supervised physical activity
Harrison RA, Roberts C, Elton PJ. Does primary care referral to an exercise programme increase physical activity one year later? A randomized controlled trial. *Journal of Public Health.* 2005;27:25-32.	Population > 50% hypertension or dyslipidemia
Harting J, Van AP, van LP et al. Effects of health counseling on behavioural risk factors in a high-risk cardiology outpatient population: a randomized clinical trial. *European Journal of Cardiovascular Prevention & Rehabilitation.* 2006;13:214-221.	Limited to children and adolescents, parents (if change intended for children), persons with any acute disease or symptomatic disease, persons with known coronary heart disease (or angina) or peripheral vascular disease or diabetes, pregnant women, institutionalized persons, or persons with SPMI or cognitive impairment
Havenar, Jacob. Adapted motivational interviewing for increasing physical activity: A 12 month clinical trial. *Dissertation Abstracts International: Section B: The Sciences and Engineering*. 2007;68(4-B):2291.	Outcome assessment unblinded
He J, Whelton PK, Appel LJ, Charleston J, Klag MJ. Long-term effects of weight loss and dietary sodium reduction on incidence of hypertension. *Hypertension.* 2000;35:544-549.	No relevant outcomes
Hebert PR, Bolt RJ, Borhani NO et al. Design of a multicenter trial to evaluate long-term life-style intervention in adults with high-normal blood pressure levels. Trials of Hypertension Prevention (phase II). Trials of Hypertension Prevention (TOHP) Collaborative Research Group. *Ann Epidemiol.* 1995;5:130-139.	Not one of specified interventions
Hernan WH, Brandle M, Zhang P et al. Costs associated with the primary prevention of type 2 diabetes mellitus in the diabetes prevention program. *Diabetes Care.* 2003;26:36-47.	Comparative-effectiveness
Hillsdon M, Thorogood M, White I, Foster C. Advising people to take more exercise is ineffective: a randomized controlled trial of physical activity promotion in primary care. *Int J Epidemiol.* 2002;31:808-815.	High or differential attrition
Hoffmeister H, Mensink GB, Stolzenberg H et al. Reduction of coronary heart disease risk factors in the German cardiovascular prevention study. *Prev Med.* 1996;25:135-145.	Not an allowable study design
Holland SK, Greenberg J, Tidwell L, Malone J, Mullan J, Newcomer R. Community-based health coaching, exercise, and health service utilization. *Journal of Aging & Health.* 2005;17:697-716.	Limited to children and adolescents, parents (if change intended for children), persons with any acute disease or symptomatic disease, persons with known coronary heart disease (or angina) or peripheral vascular disease or diabetes, pregnant women, institutionalized persons, or persons with SPMI or cognitive impairment
Holme I, Hostmark AT, Anderssen SA. ApoB but not LDL-cholesterol is reduced by exercise training in overweight healthy men. Results from the 1-year randomized Oslo Diet and Exercise Study. *Journal of Internal Medicine.* 2007;262:235-243.	Population > 50% hypertension or dyslipidemia
Holtrop JS, Dosh SA, Torres T, Thum YM. The community health educator referral liaison (CHERL): a primary care practice role for promoting healthy behaviors. *Am J Prev Med.* 2008;35:Suppl-72.	Comparative-effectiveness
Hughes SL, Seymour RB, Campbell RT, Whitelaw N, Bazzarre T. Best-practice physical activity programs	Intervention involves supervised physical activity

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Reference	Reason for exclusion
for older adults: findings from the national impact study. *American Journal of Public Health.* 2009;99:362-368.	or medications
Hyman DJ, Herd JA, Ho KS, Dunn JK, Gregory KA. Maintenance of cholesterol reduction using automated telephone calls. *Am J Prev Med.* 1996;12:129-133.	Not one of specified interventions
Hyman DJ, Ho KS, Dunn JK, Simons-Morton D. Dietary intervention for cholesterol reduction in public clinic patients. *Am J Prev Med.* 1998;15:139-145.	Not one of specified interventions
Hyman DJ, Pavlik VN, Taylor WC, Goodrick GK, Moye L. Simultaneous vs sequential counseling for multiple behavior change. *Arch Intern Med.* 2007;167:1152-1158.	Population > 50% hypertension or dyslipidemia
Inoue S, Odagiri Y, Wakui S et al. Randomized controlled trial to evaluate the effect of a physical activity intervention program based on behavioral medicine. *Zasshi/Tokyo Ika Daigaku.* 2003;61:154-165.	Intervention involves supervised physical activity or medications
Irwin ML, Yasui Y, Ulrich CM et al. Effect of exercise on total and intra-abdominal body fat in postmenopausal women: a randomized controlled trial. *JAMA.* 2003;289:323-330.	Intervention involves supervised physical activity or medications
Isaacs AJ, Critchley JA, Tai SS et al. Exercise Evaluation Randomised Trial (EXERT): a randomised trial comparing GP referral for leisure centre-based exercise, community-based walking and advice only. *Health Technol Assess.* 2007;11:1-iv.	Intervention involves supervised physical activity or medications
Ives DG, Kuller LH, Traven ND. Use and outcomes of a cholesterol-lowering intervention for rural elderly subjects. *Am J Prev Med.* 1993;9:274-281.	Population > 50% hypertension or dyslipidemia
Jacobs AD, Ammerman AS, Ennett ST et al. Effects of a tailored follow-up intervention on health behaviors, beliefs, and attitudes. *Journal of Women's Health.* 2004;13:557-568.	Population > 50% hypertension or dyslipidemia
Jacobs DR, Jr., Sluik D, Rokling-Andersen MH, Anderssen SA, Drevon CA. Association of 1-y changes in diet pattern with cardiovascular disease risk factors and adipokines: results from the 1-y randomized Oslo Diet and Exercise Study. *Am J Clin Nutr.* 2009;89:509-517.	Intervention involves supervised physical activity or medications
Jalkanen L. The effect of a weight reduction program on cardiovascular risk factors among overweight hypertensives in primary health care. *Scand J Soc Med.* 1991;19:66-71.	Primary aim is weight loss
Jarvis KL, Friedman RH, Heeren T, Cullinane PM. Older women and physical activity: using the telephone to walk. *Womens Health Issues.* 1997;7:24-29.	Less than 6 months of followup
Jenum AK, Lorentzen C, Anderssen SA et al. Promoting physical activity in a multi-ethnic district - methods and baseline results of a pseudo-experimental intervention study. *European Journal of Cardiovascular Prevention & Rehabilitation.* 2003;10:387-396.	No relevant outcomes
Jimmy G, Martin BW. Implementation and effectiveness of a primary care based physical activity counselling scheme. *Patient Education & Counseling.* 2005;56:323-331.	Comparative-effectiveness
Jorgensen T, Borch-Johnsen K, Thomsen TF, Ibsen H, Glumer C, Pisinger C. A randomized non-pharmacological intervention study for prevention of ischaemic heart disease: baseline results Inter99. *European Journal of Cardiovascular Prevention & Rehabilitation.* 2003;10:377-386.	Population > 50% hypertension or dyslipidemia
Jula A, Ronnemaa T, Rastas M, Karvetti RL, Maki J. Long-term nopharmacological treatment for mild to moderate hypertension. *J Intern Med.* 1990;227:413-421.	Population > 50% hypertension or dyslipidemia
Jula AM, Karanko HM. Effects on left ventricular hypertrophy of long-term nonpharmacological treatment with sodium restriction in mild-to-moderate essential hypertension. *Circulation.* 1994;89:1023-1031.	Population > 50% hypertension or dyslipidemia
Kastarinen MJ, Puska PM, Korhonen MH et al. Non-pharmacological treatment of hypertension in primary health care: a 2-year open randomized controlled trial of lifestyle intervention against hypertension in eastern Finland. *J Hypertens.* 2002;20:2505-2512.	Population > 50% hypertension or dyslipidemia
Katzel LI, Bleecker ER, Colman EG, Rogus EM, Sorkin JD, Goldberg AP. Effects of weight loss vs aerobic exercise training on risk factors for coronary disease in healthy, obese, middle-aged and older men. A	Intervention involves supervised physical activity or medications

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Reference	Reason for exclusion
randomized controlled trial. *JAMA.* 1995;274:1915-1921.	
Kawano M, Shono N, Yoshimura T, Yamaguchi M, Hirano T, Hisatomi A. Improved cardio-respiratory fitness correlates with changes in the number and size of small dense LDL: randomized controlled trial with exercise training and dietary instruction. *Internal Medicine.* 2009;48:25-32.	Intervention involves supervised physical activity or medications
Keller S, Donner-Banzhoff N, Kaluza G, Baum E, Basler HD. Improving physician-delivered counseling in a primary care setting: lessons from a failed attempt. *Educ Health (Abingdon).* 2000;13:387-397.	High or differential attrition
Kerse NM, Flicker L, Jolley D, Arroll B, Young D. Improving the health behaviours of elderly people: randomised controlled trial of a general practice education programme. *BMJ.* 1999;319:683-687.	Does not focus on counseling interventions
Ketola E, Makela M, Klockars M. Individualised multifactorial lifestyle intervention trial for high-risk cardiovascular patients in primary care. *Br J Gen Pract.* 2001;51:291-294.	Population > 50% hypertension or dyslipidemia
King AC, Sallis JF, Dunn AL et al. Overview of the Activity Counseling Trial (ACT) intervention for promoting physical activity in primary health care settings. Activity Counseling Trial Research Group. *Med Sci Sports Exerc.* 1998;30:1086-1096.	Comparative-effectiveness
King AC, Friedman R, Marcus B et al. Harnessing motivational forces in the promotion of physical activity: the Community Health Advice by Telephone (CHAT) project. *Health Education Research.* 2002;17:627-636.	No relevant outcomes
Kinzel LS, Averbach FM, Clark KS et al. A high carbohydrate, low fat, hypocaloric eating pattern using functional foods along with increased physical activity in postmenopausal women decreases cardiovascular risk factors. *Journal of the American Dietetic Association.* 2004;104:31.	Comparative-effectiveness
Kjelsberg MO, Cutler JA, Dolecek TA. Brief description of the Multiple Risk Factor Intervention Trial. *Am J Clin Nutr.* 1997;65:191S-195S.	Population > 50% hypertension or dyslipidemia
Klem ML, Viteri JE, Wing RR. Primary prevention of weight gain for women aged 25-34: the acceptability of treatment formats. *Int J Obes Relat Metab Disord.* 2000;24:219-225.	High or differential attrition
Knowler WC, Barrett-Connor E, Fowler SE et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *New England Journal of Medicine.* 2002;346:393-403.	Comparative-effectiveness
Knutsen SF, Knutsen R. The Tromso Survey: the Family Intervention study--the effect of intervention on some coronary risk factors and dietary habits, a 6-year follow-up. *Prev Med.* 1991;20:197-212.	Not one of specified interventions
Korhonen MH, Litmanen H, Rauramaa R, Vaisanen SB, Niskanen L, Uusitupa M. Adherence to the salt restriction diet among people with mildly elevated blood pressure. *Eur J Clin Nutr.* 1999;53:880-885.	Not one of specified interventions
Kosaka K, Noda M, Kuzuya T. Prevention of type 2 diabetes by lifestyle intervention: a Japanese trial in IGT males. *Diabetes Research & Clinical Practice.* 2005;67:152-162.	Comparative-effectiveness
Kreuter MW, Strecher VJ. Do tailored behavior change messages enhance the effectiveness of health risk appraisal? Results from a randomized trial. *Health Educ Res.* 1996;11:97-105.	Does not focus on counseling interventions
Kukkonen-Harjula KT, Borg PT, Nenonen AM, Fogelholm MG. Effects of a weight maintenance program with or without exercise on the metabolic syndrome: a randomized trial in obese men. *Prev Med.* 2005;41:784-790.	Primary aim is weight loss
Kuller LH, Kinzel LS, Pettee KK et al. Lifestyle intervention and coronary heart disease risk factor changes over 18 months in postmenopausal women: the Women On the Move through Activity and Nutrition (WOMAN study) clinical trial. *Journal of Women's Health.* 2006;15:962-974.	Comparative-effectiveness
Kulzer B, Hermanns N, Gorges D, Schwarz P, Haak T. Prevention of diabetes self-management program (PREDIAS): effects on weight, metabolic risk factors, and behavioral outcomes. *Diabetes Care.* 2009;32:1143-1146.	Primary aim is weight loss
Lamb SE, Bartlett HP, Ashley A, Bird W. Can lay-led walking programmes increase physical activity in	Comparative-effectiveness

Appendix D Table 3. Physical Activity Studies Excluded From the Review for Key Questions 1–3

Reference	Reason for exclusion
middle aged adults? A randomised controlled trial. *Journal of Epidemiology & Community Health.* 2002;56:246-252.	
Langford HG, Davis BR, Blaufox D et al. Effect of drug and diet treatment of mild hypertension on diastolic blood pressure. The TAIM Research Group. *Hypertension.* 1991;17:210-217.	Intervention involves supervised physical activity or medications
Lee C, White SW. Controlled trial of a minimal-intervention exercise program for middle-aged working women. *Psychology & Health.* 1997;12:361-374.	Intervention involves supervised physical activity or medications
Leinonen R, Heikkinen E, Hirvensalo M et al. Customer-oriented counseling for physical activity in older people: study protocol and selected baseline results of a randomized-controlled trial (ISRCTN 07330512). *Scandinavian Journal of Medicine & Science in Sports.* 2007;17:156-164.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Leveille SG, Wagner EH, Davis C et al. Preventing disability and managing chronic illness in frail older adults: a randomized trial of a community-based partnership with primary care. *J Am Geriatr Soc.* 1998;46:1191-1198.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Liao D, Asberry PJ, Shofer JB et al. Improvement of BMI, body composition, and body fat distribution with lifestyle modification in Japanese Americans with impaired glucose tolerance. *Diabetes Care.* 2002;25:1504-1510.	Intervention involves supervised physical activity or medications
Life S, I, Pahor M, Blair SN et al. Effects of a physical activity intervention on measures of physical performance: Results of the lifestyle interventions and independence for Elders Pilot (LIFE-P) study. *Journals of Gerontology Series A-Biological Sciences & Medical Sciences.* 2006;61:1157-1165.	Intervention involves supervised physical activity or medications
Lin, P. H., Appel, L. J., Funk, K., Craddick, S., Chen, C., Elmer, P., McBurnie, M. A., and Champagne, C. The PREMIER intervention helps participants follow the Dietary Approaches to Stop Hypertension dietary pattern and the current Dietary Reference Intakes recommendations. *Journal of the American Dietetic Association*. 2007;107(9):1541-1551.	Comparative-effectiveness
Lindholm LH, Ekbom T, Dash C, Eriksson M, Tibblin G, Schersten B. The impact of health care advice given in primary care on cardiovascular risk. CELL Study Group. *BMJ.* 1995;310:1105-1109.	Population > 50% hypertension or dyslipidemia
Lindholm LH, Ekbom T, Dash C, Isacsson A, Schersten B. Changes in cardiovascular risk factors by combined pharmacological and nonpharmacological strategies: the main results of the CELL Study. *J Intern Med.* 1996;240:13-22.	Population > 50% hypertension or dyslipidemia
Lindström J, Eriksson JG, Valle TT et al. Prevention of diabetes mellitus in subjects with impaired glucose tolerance in the Finnish Diabetes Prevention Study: results from a randomized clinical trial. *Journal of the American Society of Nephrology.* 2003;14:S108-S113.	Intervention involves supervised physical activity or medications
Lindstrom J, Louheranta A, Mannelin M et al. The Finnish Diabetes Prevention Study (DPS): Lifestyle intervention and 3-year results on diet and physical activity. *Diabetes Care.* 2003;26:3230-3236.	Intervention involves supervised physical activity or medications
Little P, Dorward M, Gralton S et al. A randomised controlled trial of three pragmatic approaches to initiate increased physical activity in sedentary patients with risk factors for cardiovascular disease. *Br J Gen Pract.* 2004;54:189-195.	Population > 50% hypertension or dyslipidemia
Lombard DN, Lombard TN, Winett RA. Walking to meet health guidelines: the effect of prompting frequency and prompt structure. *Health Psychol.* 1995;14:164-170.	Comparative-effectiveness
Lowther M, Mutrie N, Scott EM. Promoting physical activity in a socially and economically deprived community: a 12 month randomized control trial of fitness assessment and exercise consultation. *J Sports Sci.* 2002;20:577-588.	High or differential attrition
Manty M, Heinonen A, Leinonen R et al. Long-term effect of physical activity counseling on mobility limitation among older people: a randomized controlled study. *Journals of Gerontology Series A-Biological Sciences & Medical Sciences.* 2009;64:83-89.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition

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Reference	Reason for exclusion
Marcus BH, Bock BC, Pinto BM, Forsyth LH, Roberts MB, Traficante RM. Efficacy of an individualized, motivationally-tailored physical activity intervention. *Ann Behav Med.* 1998;20:174-180.	Comparative-effectiveness
Marcus BH, Lewis BA, Williams DM et al. A comparison of Internet and print-based physical activity interventions. *Arch Intern Med.* 2007;167:944-949.	Comparative-effectiveness
Maruthur NM, Wang NY, Appel LJ. Lifestyle interventions reduce coronary heart disease risk: results from the PREMIER Trial. *Circulation.* 2009;119:2026-2031.	Comparative-effectiveness
Mayer JA, Jermanovich A, Wright BL, Elder JP, Drew JA, Williams SJ. Changes in health behaviors of older adults: the San Diego Medicare Preventive Health Project. *Prev Med.* 1994;23:127-133.	Does not focus on counseling interventions
Mayer-Davis EJ, Sparks KC, Hirst K et al. Dietary intake in the diabetes prevention program cohort: baseline and 1-year post randomization. *Annals of Epidemiology.* 2004;14:763-772.	Comparative-effectiveness
McAuley E, Jerome GJ, Elavsky S, Marquez DX, Ramsey SN. Predicting long-term maintenance of physical activity in older adults. *Prev Med.* 2003;37:110-118.	Comparative-effectiveness
McAuley E, Morris KS, Motl RW, Hu L, Konopack JF, Elavsky S. Long-term follow-up of physical activity behavior in older adults. *Health Psychology.* 2007;26:375-380.	Intervention involves supervised physical activity or medications
McGowan MP, Joffe A, Duggan AK, McCay PS. Intervention in hypercholesterolemic college students: a pilot study. *J Adolesc Health.* 1994;15:155-162.	Comparative-effectiveness
Meland E, Laerum E, Ulvik RJ. Effectiveness of two preventive interventions for coronary heart disease in primary care. *Scand J Prim Health Care.* 1997;15:57-64.	Population > 50% hypertension or dyslipidemia
Mensink M, Blaak EE, Corpeleijn E, Saris WH, de Bruin TW, Feskens EJ. Lifestyle intervention according to general recommendations improves glucose tolerance. *Obesity Research.* 2003;11:1588-1596.	Intervention involves supervised physical activity or medications
Mensink, M., Feskens, E. J. M., Saris, W. H. M., de Bruin, T. W. A., and Blaak, E. E. Study on Lifestyle Intervention and Impaired Glucose Tolerance Maastricht (SLIM): Preliminary results after one year. *International Journal of Obesity.* 2003;27(3):377-384.	Intervention involves supervised physical activity or medications
Michalowski J. *The effects of a stage-matched intervention on physical activity and coronary heart disease risk factors in women* West Lafayette, Indiana: Purdue University, 1999.	Less than 6 months of followup
Molitch ME, Fujimoto W, Hamman RF, Knowler WC, Diabetes-Prevention-Program-Research-Group. The diabetes prevention program and its global implications. *Journal of the American Society of Nephrology.* 2003;14:S103-S107.	Comparative-effectiveness
Morey MC, Sloane R, Pieper CF et al. Effect of physical activity guidelines on physical function in older adults. *J Am Geriatr Soc.* 2008;56:1873-1878.	Not an allowable study design
Morey, Miriam C., Dubbert, Patricia M., Doyle, Martha E., MacAller, Helga, Crowley, Gail M., Kuchibhatla, Maggie, Schenkman, Margaret, and Horner, Ronnie D. From Supervised to Unsupervised Exercise: Factors Associated With Exercise Adherence. *Journal of Aging and Physical Activity.* 2003;11(3):351-368.	Comparative-effectiveness
Muda SH, Kadir AA. The effectiveness of physical activity counseling in Primary Care Clinic University Science Malaysia Hospital. *International Medical Journal.* 2006;13:249-253.	Not on list of countries with HDI > 0.90
Munro JF, Nicholl JP, Brazier JE, Davey R, Cochrane T. Cost effectiveness of a community based exercise programme in over 65 year olds: cluster randomised trial. *Journal of Epidemiology & Community Health.* 2004;58:1004-1010.	Intervention involves supervised physical activity or medications
Napolitano MA, Papandonatos GD, Lewis BA et al. Mediators of physical activity behavior change: a multivariate approach. *Health Psychology.* 2008;27:409-418.	No relevant outcomes
Naylor PJ, Simmonds G, Riddoch C, Velleman G, Turton P. Comparison of stage-matched and unmatched interventions to promote exercise behaviour in the primary care setting. *Health Educ Res.* 1999;14:653-666.	High or differential attrition

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Reference	Reason for exclusion
Neville LM, O'Hara B, Milat A. Computer-tailored physical activity behavior change interventions targeting adults: a systematic review. *International Journal of Behavioral Nutrition & Physical Activity.* 2009;6:30.	Not an allowable study design
Newton RL, Jr., Perri MG. A randomized pilot trial of exercise promotion in sedentary African-American adults. *Ethnicity & Disease.* 2004;14:548-557.	High or differential attrition
Nichols, G. Testing a culturally consistent behavioral outcomes strategy for cardiovascular disease risk reduction and prevention in low income African American women. Unpublished doctoral dissertation, Univ of Maryland. 1995.	Less than 6 months of followup
Nies MA, Chruscial HL, Hepworth JT. An intervention to promote walking in sedentary women in the community. *American Journal of Health Behavior.* 2003;27:524-535.	Comparative-effectiveness
Nilsson PM, Lindholm LH, Schersten BF. Life style changes improve insulin resistance in hyperinsulinaemic subjects: a one-year intervention study of hypertensives and normotensives in Dalby. *J Hypertens.* 1992;10:1071-1078.	Population > 50% hypertension or dyslipidemia
No, authorship indicated. Promoting physical activity in an at-risk population. *J Sport Exerc Psychol.* 2008;30(3):434.	Not an allowable study design
Norris SL, Zhang X, Avenell A et al. Long-term effectiveness of weight-loss interventions in adults with pre-diabetes: a review. *Am J Prev Med.* 2005;28:126-139.	Not an allowable study design
ODES Investigators. The Oslo Diet and Exercise Study (ODES): design and objectives. *Control Clin Trials.* 1993;14:229-243.	Population > 50% hypertension or dyslipidemia
O'Halloran, Peggy, Lazovich, DeAnn, Patterson, Ruth E., Harnack, Lisa, French, Simone, Curry, Sue J., and Beresford, Shirley A. A. Effect of health lifestyle pattern on dietary change. *Am J Health Promot.* 2001;16(1):27-33.	Not one of specified interventions
Ohkubo T, Hozawa A, Nagatomi R et al. Effects of exercise training on home blood pressure values in older adults: a randomized controlled trial. *J Hypertens.* 2001;19:1045-1052.	Intervention involves supervised physical activity or medications
Oida Y, Kitabatake Y, Nishijima Y et al. Effects of a 5-year exercise-centered health-promoting programme on mortality and ADL impairment in the elderly. *Age & Ageing.* 2003;32:585-592.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Opdenacker J, Boen F, Coorevits N, Delecluse C. Effectiveness of a lifestyle intervention and a structured exercise intervention in older adults. *Prev Med.* 2008;46:518-524.	Intervention involves supervised physical activity or medications
Opdenacker J, Boen F, Vanden AY, De B, I. Effectiveness of a lifestyle physical activity intervention in a women's organization. *Journal of Women's Health.* 2008;17:413-421.	High or differential attrition
Pakkala I, Read S, Leinonen R, Hirvensalo M, Lintunen T, Rantanen T. The effects of physical activity counseling on mood among 75- to 81-year-old people: a randomized controlled trial. *Prev Med.* 2008;46:412-418.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Park SK, Park JH, Kwon YC, Kim HS, Yoon MS, Park HT. The effect of combined aerobic and resistance exercise training on abdominal fat in obese middle-aged women. *Journal of Physiological Anthropology & Applied Human Science.* 2003;22:129-135.	Intervention involves supervised physical activity or medications
Pekmezi D, Barbera B, Bodenlos JS, Jones GN, Brantley PJ. Promoting physical activity in low income African Americans: Six month results from Project LAPS. *Ann Behav Med.* 2008;35:S117.	High or differential attrition
Pereira MA, Kriska AM, Day RD, Cauley JA, LaPorte RE, Kuller LH. A randomized walking trial in postmenopausal women: effects on physical activity and health 10 years later. *Arch Intern Med.* 1998;158:1695-1701.	Intervention involves supervised physical activity or medications
Pereira, R. F. Franz M. J. Prevention and Treatment of Cardiovascular Disease in People With Diabetes Through Lifestyle Modification: Current Evidence-Based Recommendations. *Diabetes Spectr*. 2008;21:189-193.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition

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Reference	Reason for exclusion
Perkio-Makela M. Influence of exercise-focused group activities on the physical activity, functional capacity, and work ability of female farmers--a three-year follow-Up. *Int J Occup Saf Ergon.* 1999;5:381-394.	Intervention involves supervised physical activity or medications
Petrella RJ, Koval JJ, Cunningham DA, Paterson DH. Can primary care doctors prescribe exercise to improve fitness? The Step Test Exercise Prescription (STEP) project. *Am J Prev Med.* 2003;24:316-322.	Comparative-effectiveness
Pfeffer, Ines and Alfermann, Dorothee. Initiation of physical exercise: An intervention study based on the transtheoretical model. *International Journal of Sport Psychology*. 2008;39(1):41-58.	Comparative-effectiveness
Pinto BM, Lynn H, Marcus BH, DePue J, Goldstein MG. Physician-based activity counseling: intervention effects on mediators of motivational readiness for physical activity. *Ann Behav Med.* 2001;23:2-10.	No relevant outcomes
Pollock ML, Carroll JF, Graves JE et al. Injuries and adherence to walk/jog and resistance training programs in the elderly. *Med Sci Sports Exerc.* 1991;23:1194-1200.	Intervention involves supervised physical activity or medications
Potteiger JA, Jacobsen DJ, Donnelly JE, Hill JO, Midwest ET. Glucose and insulin responses following 16 months of exercise training in overweight adults: the Midwest Exercise Trial. *Metabolism: Clinical & Experimental.* 2003;52:1175-1181.	Intervention involves supervised physical activity or medications
Ramachandran A, Snehalatha C, Mary S, Mukesh B, Bhaskar AD, Vijay V. The Indian Diabetes Prevention Programme shows that lifestyle modification and metformin prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1). *Diabetologia.* 2006;49:289-297.	Not on list of countries with HDI > 0.90
Randomised controlled trial evaluating cardiovascular screening and intervention in general practice: principal results of British family heart study. Family Heart Study Group. *BMJ.* 1994;308:313-320.	Other quality issues
Rankinen T, Rauramaa R, Vaisanen SB, Halonen JP, Penttila IM. Blood coagulation and fibrinolytic factors are unchanged by aerobic exercise or fat modified diet. Randomized clinical trial in middle-aged men. *Fibrinolysis.* 1994;8:48-53.	Comparative-effectiveness
Ratner R, Goldberg R, Haffner S et al. Impact of intensive lifestyle and metformin therapy on cardiovascular disease risk factors in the diabetes prevention program. *Diabetes Care.* 2005;28:888-894.	Comparative-effectiveness
Ratner RE, Christophi CA, Metzger BE et al. Prevention of diabetes in women with a history of gestational diabetes: effects of metformin and lifestyle interventions. *Journal of Clinical Endocrinology & Metabolism.* 2008;93:4774-4779.	Comparative-effectiveness
Reed J, Malvern L, Muthukrishnan S, Hardy R, King L. An ecological approach with primary-care counseling to promote physical activity. *Journal of Physical Activity & Health.* 2008;5:169-183.	Less than 6 months of followup
Rejeski W, Brawley L. Shaping active lifestyles in older adults: a group-facilitated behavior change intervention. *Ann Behav Med.* 1997;19:s106.	Poor reporting
Reseland JE, Anderssen SA, Solvoll K et al. Effect of long-term changes in diet and exercise on plasma leptin concentrations. *Am J Clin Nutr.* 2001;73:240-245.	Intervention involves supervised physical activity or medications
Resnick B. Testing the effect of the WALC intervention on exercise adherence in older adults. *Journal of Gerontological Nursing.* 2002;28:40-49.	Setting not primary care or generalizable to primary care
Richardson, Amanda Hope. A comparison of physician based exercise counseling protocols: A pilot study. Does physical activity counseling provided by a physician in the form of verbal, written or combination delivery increase physical activity in a sedentary geriatric population? Dissertation Abstracts International: Section B: The Sciences and Engineering 68(8-B), 5180. 2008.	Less than 6 months of followup
Rose SB, Lawton BA, Elley CR, Dowell AC, Fenton AJ. The 'Women's Lifestyle Study', 2-year randomized controlled trial of physical activity counselling in primary health care: rationale and study design. *BMC Public Health.* 2007;7:166.	No relevant outcomes
Roumen C, Corpeleijn E, Feskens EJ, Mensink M, Saris WH, Blaak EE. Impact of 3-year lifestyle intervention on postprandial glucose metabolism: the SLIM study. *Diabetic Medicine.* 2008;25:597-605.	Intervention involves supervised physical activity or medications

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Reference	Reason for exclusion
Roussel M, Garnier S, Lemoine S et al. Influence of a walking program on the metabolic risk profile of obese postmenopausal women. *Menopause.* 2009;16:566-575.	Intervention involves supervised physical activity or medications
Rydwik E, Lammes E, Frandin K, Akner G. Effects of a physical and nutritional intervention program for frail elderly people over age 75. A randomized controlled pilot treatment trial. *Aging-Clinical & Experimental Research.* 2008;20:159-170.	Biased recruitment strategy or selection of patients not generalizable to primary care
Salkeld G, Phongsavan P, Oldenburg B et al. The cost-effectiveness of a cardiovascular risk reduction program in general practice. *Health Policy.* 1997;41:105-119.	Population > 50% hypertension or dyslipidemia
Sallinen J, Fogelholm M, Pakarinen A et al. Effects of strength training and nutritional counseling on metabolic health indicators in aging women. *Canadian Journal of Applied Physiology.* 2005;30:690-707.	Less than 6 months of followup
Sallis JF, Patrick K, Calfas KJ et al. A multi-media behavior change program for nutrition and physical activity in primary care: PACE+ for adults. *Homeostasis.* 1999;39:196-202.	Less than 6 months of followup
Sevick MA, Napolitano MA, Papandonatos GD, Gordon AJ, Reiser LM, Marcus BH. Cost-effectiveness of alternative approaches for motivating activity in sedentary adults: results of Project STRIDE. *Prev Med.* 2007;45:54-61.	No relevant outcomes
Slootmaker SM, Chinapaw MJ, Schuit AJ, Seidell JC, van MW. Feasibility and effectiveness of online physical activity advice based on a personal activity monitor: randomized controlled trial. *Journal of Medical Internet Research.* 2009;11:e27.	Setting not primary care or generalizable to primary care
Smith BJ, Bauman AE, Bull FC, Booth ML, Harris MF. Promoting physical activity in general practice: a controlled trial of written advice and information materials. *Br J Sports Med.* 2000;34:262-267.	Other quality issues
Staffileno BA, Minnick A, Coke LA, Hollenberg SM. Blood pressure responses to lifestyle physical activity among young, hypertension-prone African-American women. *Journal of Cardiovascular Nursing.* 2007;22:107-117.	Less than 6 months of followup
Stamler J, Briefel RR, Milas C, Grandits GA, Caggiula AW. Relation of changes in dietary lipids and weight, trial years 1-6, to changes in blood lipids in the special intervention and usual care groups in the Multiple Risk Factor Intervention Trial. *Am J Clin Nutr.* 1997;65:272S-288S.	Population > 50% hypertension or dyslipidemia
Staten, Lisa K., Gregory-Mercado, Karen Y., Ranger-Moore, James, Will, Julie C., Giuliano, Anna R., Ford, Earl S., and Marshall, James. Provider Counseling, Health Education, and Community Health Workers: The Arizona WISEWOMAN Project*. Journal of Women's Health*. 2004;13(5):547-556.	Comparative-effectiveness
Stefanick ML, Mackey S, Sheehan M, Ellsworth N, Haskell WL, Wood PD. Effects of diet and exercise in men and postmenopausal women with low levels of HDL cholesterol and high levels of LDL cholesterol. *N Engl J Med.* 1998;339:12-20.	Intervention involves supervised physical activity or medications
Stevens W, Hillsdon M, Thorogood M, McArdle D. Cost-effectiveness of a primary care based physical activity intervention in 45-74 year old men and women: a randomised controlled trial. *Br J Sports Med.* 1998;32:236-241.	Poor reporting
Stoddard AM, Palombo R, Troped PJ, Sorensen G, Will JC. Cardiovascular disease risk reduction: the Massachusetts WISEWOMAN project. *Journal of women's health.* 2004;13:539-546.	Comparative-effectiveness
Strandberg TE, Salomaa VV, Naukkarinen VA, Vanhanen HT, Sarna SJ, Miettinen TA. Long-term mortality after 5-year multifactorial primary prevention of cardiovascular diseases in middle-aged men. *JAMA.* 1991;266:1225-1229.	Population > 50% hypertension or dyslipidemia
Strandberg TE, Salomaa VV, Vanhanen HT, Naukkarinen VA, Sarna SJ, Miettinen TA. Mortality in participants and non-participants of a multifactorial prevention study of cardiovascular diseases: a 28 year follow up of the Helsinki Businessmen Study. *Br Heart J.* 1995;74:449-454.	Population > 50% hypertension or dyslipidemia
Sugiura H, Sugiura H, Kajima K, Mirbod SM, Iwata H, Matsuoka T. Effects of long-term moderate exercise	Intervention involves supervised physical activity

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Reference	Reason for exclusion
and increase in number of daily steps on serum lipids in women: Randomised controlled trial. *BMC Women's Health.* 2002;2:3.	or medications
Taylor AH, Doust J, Webborn N. Randomised controlled trial to examine the effects of a GP exercise referral programme in Hailsham, East Sussex, on modifiable coronary heart disease risk factors. *J Epidemiol Community Health.* 1998;52:595-601.	High or differential attrition
Taylor AH, Fox KR. Effectiveness of a primary care exercise referral intervention for changing physical self-perceptions over 9 months. *Health Psychology.* 2005;24:11-21.	High or differential attrition
The Diabetes Prevention Program. Design and methods for a clinical trial in the prevention of type 2 diabetes. *Diabetes Care.* 1999;22:623-634.	Comparative-effectiveness
The Diabetes Prevention Program: baseline characteristics of the randomized cohort. The Diabetes Prevention Program Research Group. *Diabetes Care.* 2000;23:1619-1629.	Comparative-effectiveness
The WISEWOMAN Workgroup. Cardiovascular disease prevention for women attending breast and cervical cancer screening programs: the WISEWOMAN projects. *Prev Med.* 1999;28:496-502.	Comparative-effectiveness
Toft U, Kristoffersen L, Ladelund S et al. The effect of adding group-based counselling to individual lifestyle counselling on changes in dietary intake. The Inter99 study - a randomized controlled trial. *International Journal of Behavioral Nutrition & Physical Activity.* 2008;5:59.	Population > 50% hypertension or dyslipidemia
Toft U, Kristoffersen L, Ladelund S et al. The impact of a population-based multi-factorial lifestyle intervention on changes in long-term dietary habits The Inter99 study. *Prev Med.* 2008.	Population > 50% hypertension or dyslipidemia
Tulloch H, Fortier M, Hogg W. Physical activity counseling in primary care: who has and who should be counseling? *Patient Educ Couns.* 2006;64(1-3):6-20.	Not an allowable study design
Tully MA, Cupples ME, Chan WS, McGlade K, Young IS. Brisk walking, fitness, and cardiovascular risk: a randomized controlled trial in primary care. *Prev Med.* 2005;41:622-628.	Less than 6 months of followup
Tuomilehto J, Lindstrom J, Eriksson JG et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *New England Journal of Medicine.* 2001;344:1343-1350.	Intervention involves supervised physical activity or medications
van Steenkiste B, van-der Weijden T, Stoffers HE, Kester AD, Timmermans DR, Grol R. Improving cardiovascular risk management: a randomized, controlled trial on the effect of a decision support tool for patients and physicians. *European journal of cardiovascular prevention and rehabilitation : official journal of the European Society of Cardiology, Working Groups on Epidemiology & Prevention and Cardiac Rehabilitation and Exercise Physiology.* 2007;14:44-50.	Other quality issues
Vandelanotte C, Spathonis KM, Eakin EG, Owen N. Website-delivered physical activity interventions a review of the literature. *Am J Prev Med.* 2007;33:54-64.	Not an allowable study design
Veverka DV, Anderson J, Auld GW, Coulter GR, Kennedy C, Chapman PL. Use of the stages of change model in improving nutrition and exercise habits in enlisted Air Force men. *Military Medicine.* 2003;168:373-379.	Biased recruitment strategy or selection of patients not generalizable to primary care
Villareal DT, Miller BV, III, Banks M, Fontana L, Sinacore DR, Klein S. Effect of lifestyle intervention on metabolic coronary heart disease risk factors in obese older adults. *Am J Clin Nutr.* 2006;84:1317-1323.	Primary aim is weight loss
Wassertheil-Smoller S, Oberman A, Blaufox MD, Davis B, Langford H. The Trial of Antihypertensive Interventions and Management (TAIM) Study. Final results with regard to blood pressure, cardiovascular risk, and quality of life. *Am J Hypertens.* 1992;5:37-44.	Population > 50% hypertension or dyslipidemia
Whelton PK, Appel LJ, Espeland MA et al. Sodium reduction and weight loss in the treatment of hypertension in older persons: a randomized controlled trial of nonpharmacologic interventions in the elderly (TONE). TONE Collaborative Research Group. *JAMA.* 1998;279:839-846.	Not one of specified interventions
Whitehead D, Bodenlos JS, Cowles ML, Jones GN, Brantley PJ. A stage-targeted physical activity	High or differential attrition

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Reference	Reason for exclusion
intervention among a predominantly African-American low-income primary care population. *Am J Health Promot.* 2007;21:160-163.	
Whiteley, Jessica Ann. An internet-based walking program for women. Dissertation Abstracts International: Section B: The Sciences and Engineering 64(6-B), 2946. 2003.	Less than 6 months of followup
Wilbur J, McDevitt JH, Wang E et al. Outcomes of a home-based walking program for African-American women. *Am J Health Promot.* 2008;22:307-317.	Comparative-effectiveness
Wilbur J, Miller AM, McDevitt J, Wang E, Miller J. Menopausal status, moderate-intensity walking, and symptoms in midlife women. *Research & Theory for Nursing Practice.* 2005;19:163-180.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Wildman RP, Schott LL, Brockwell S, Kuller LH, Sutton-Tyrrell K. A dietary and exercise intervention slows menopause-associated progression of subclinical atherosclerosis as measured by intima-media thickness of the carotid arteries. *Journal of the American College of Cardiology.* 2004;44:579-585.	No relevant outcomes
Will JC, Massoudi B, Mokdad A et al. Reducing risk for cardiovascular disease in uninsured women: combined results from two WISEWOMAN projects. *Journal of the American Medical Women's Association.* 2001;56:161-165.	Comparative-effectiveness
Williams NH, Hendry M, France B, Lewis R, Wilkinson C. Effectiveness of exercise-referral schemes to promote physical activity in adults: systematic review. *Br J Gen Pract.* 2007;57:979-986.	Not an allowable study design
Williamson JD, Espeland M, Kritchevsky SB et al. Changes in cognitive function in a randomized trial of physical activity: results of the lifestyle interventions and independence for elders pilot study. *Journals of Gerontology Series A-Biological Sciences & Medical Sciences.* 2009;64:688-694.	Not one of specified interventions
Wing RR, Venditti E, Jakicic JM, Polley BA, Lang W. Lifestyle intervention in overweight individuals with a family history of diabetes. *Diabetes Care.* 1998;21:350-359.	Primary aim is weight loss
Woods C, Mutrie N, Scott M. Physical activity intervention: a transtheoretical model-based intervention designed to help sedentary young adults become active. *Health Education Research.* 2002;17:451-460.	No relevant outcomes
Writing Group for the Activity Counseling Trial Research Group. Effects of physical activity counseling in primary care: the Activity Counseling Trial: a randomized controlled trial. *JAMA.* 2001;286:677-687.	Comparative-effectiveness
Wylie-Rosett J, Wassertheil-Smoller S, Blaufox MD et al. Trial of antihypertensive intervention and management: greater efficacy with weight reduction than with a sodium-potassium intervention. *J Am Diet Assoc.* 1993;93:408-415.	Not one of specified interventions
Yates T, Davies M, Gorely T et al. Twelve-month follow-up from the PREPARE (Prediabetes Risk Education and Physical Activity Recommendation and Encouragement) programme study: a randomized controlled trial: A47 (P427). *Diabetic Medicine.* 2009;26:17.	No relevant outcomes
Young DR, King AC, Sheehan M, Stefanick ML. Stage of motivational readiness: predictive ability for exercise behavior. *American Journal of Health Behavior.* 2002;26:331-341.	Population > 50% hypertension or dyslipidemia

Appendix D Table 4. Physical Activity Studies Excluded From the Review for Key Question 4

Reference	Reason for exclusion
Boyd NF, Greenberg C, Lockwood G et al. Effects at two years of a low-fat, high-carbohydrate diet on radiologic features of the breast: results from a randomized trial. Canadian Diet and Breast Cancer Prevention Study Group. *J Natl Cancer Inst.* 1997;89:488-496.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Durakovic Z, Misigoj-Durakovic M, Medved R, Skavic J, Torovic N. Sudden death due to physical exercise in the elderly. *Collegium Antropologicum.* 2002;26:239-243.	Poor reporting
Durakovic Z, Misigoj-Durakovic M, Skavic J. Sudden death due to recreational exercise in physicians. *Collegium Antropologicum.* 2002;26:509-513.	Poor reporting
Ferrer RL, Mody-Bailey P, Jaen CR, Gott S, Araujo S. A medical assistant-based program to promote healthy behaviors in primary care. *Ann Fam Med.* 2009;7:504-512.	High or differential attrition
Geleijnse JM, Witteman JC, Bak AA, den Breeijen JH, Grobbee DE. Long-term moderate sodium restriction does not adversely affect the serum HDL/total cholesterol ratio. *J Hum Hypertens.* 1995;9:975-979.	Population > 50% hypertension or dyslipidemia
Goodrich DE, Larkin AR, Lowery JC, Holleman RG, Richardson CR. Adverse events among high-risk participants in a home-based walking study: a descriptive study. *International Journal of Behavioral Nutrition & Physical Activity.* 2007;4:20.	Intervention involves supervised physical activity or medications
Hislop TG, Bajdik CD, Balneaves LG et al. Physical and emotional health effects and social consequences after participation in a low-fat, high-carbohydrate dietary trial for more than 5 years. *Journal of Clinical Oncology.* 2006;24:2311-2317.	Intervention meets criteria but specifically targets a non-cardiovascular-related condition
Manninen P, Riihimaki H, Heliovaara M, Suomalainen O. Physical exercise and risk of severe knee osteoarthritis requiring arthroplasty. *Rheumatology.* 2001;40:432-437.	Not an allowable study design
Mozaffarian D, Furberg CD, Psaty BM, Siscovick D. Physical activity and incidence of atrial fibrillation in older adults: the cardiovascular health study. *Circulation.* 2008;118:800-807.	Does not focus on counseling interventions
Pollock ML, Carroll JF, Graves JE et al. Injuries and adherence to walk/jog and resistance training programs in the elderly. *Med Sci Sports Exerc.* 1991;23:1194-1200.	Intervention involves supervised physical activity or medications
Pons-Villanueva J, Segui-Gomez M, Martinez-Gonzalez MA. Risk of injury according to participation in specific physical activities: a 6-year follow-up of 14 356 participants of the SUN cohort. *Int J Epidemiol.* 2009; 1-8.	Not an allowable study design
Reddy PR, Reinier K, Singh T et al. Physical activity as a trigger of sudden cardiac arrest: the Oregon Sudden Unexpected Death Study. *International Journal of Cardiology.* 2009;131:345-349.	Does not focus on counseling interventions
Thompson PD, Funk EJ, Carleton RA, Sturner WQ. Incidence of death during jogging in Rhode Island from 1975 through 1980. *JAMA.* 1982;247:2535-2538.	Not an allowable study design
van Teeffelen WM, de Beus MF, Mosterd A et al. Risk factors for exercise-related acute cardiac events. A case-control study. *Br J Sports Med.* 2009;43:722-725.	Does not focus on counseling interventions

Appendix D Table 5. Combination Lifestyle Studies Excluded From the Review for Key Questions 1–3

Reference	Reason for exclusion
Block G, Sternfeld B, Block CH et al. Development of Alive! (A Lifestyle Intervention Via Email), and its effect on health-related quality of life, presenteeism, and other behavioral outcomes: randomized controlled trial. *Journal of Medical Internet Research.* 2008;10:e43.	High or differential attrition
Greene GW, Fey-Yensan N, Padula C, Rossi SR, Rossi JS, Clark PG. Change in fruit and vegetable intake over 24 months in older adults: results of the SENIOR project intervention. *Gerontologist.* 2008;48:378-387.	No relevant outcomes
Hilton S, Doherty S, Kendrick T, Kerry S, Rink E, Steptoe A. Promotion of healthy behaviour among adults at increased risk of coronary heart disease in general practice: methodology and baseline data from the Change of Heart study. *Health Education Journal*. 1999;58:3-16.	High or differential attrition
Jilcott SB, Keyserling TC, Samuel-Hodge CD et al. Linking clinical care to community resources for cardiovascular disease prevention: the North Carolina Enhanced WISEWOMAN project. *Journal of Women's Health.* 2006;15:569-583.	No relevant outcomes
Lombard CB, Deeks AA, Ball K, Jolley D, Teede HJ. Weight, physical activity and dietary behavior in young mothers: short term results of the HeLP-her cluster randomized controlled trial. *Nutrition Journal.* 2009;8:17.	Less than 6 months of followup
Merrill RM, Aldana SG, Ellrodt G, Orsi R, Grelle-Laramee J. Efficacy of the Berkshire Health System Cardiovascular Health Risk Reduction Program. *Journal of Occupational & Environmental Medicine.* 2009;51:1024-1031.	Not an allowable study design
Narayan KM, Hoskin M, Kozak D et al. Randomized clinical trial of lifestyle interventions in Pima Indians: a pilot study. *Diabet Med.* 1998;15:66-72.	Comparative-effectiveness
Pritchard DA, Hyndman J, Taba F. Nutritional counselling in general practice: a cost effective analysis. *J Epidemiol Community Health.* 1999;53:311-316.	High or differential attrition
Rosamond WD, Ammerman AS, Holliday JL et al. Cardiovascular disease risk factor intervention in low-income women: the North Carolina WISEWOMAN project. *Prev Med.* 2000;2000:370-379.	Population > 50% hypertension or dyslipidemia
Steptoe A, Doherty S, Rink E, Kerry S, Kendrick T, Hilton S. Behavioural counselling in general practice for the promotion of healthy behaviour among adults at increased risk of coronary heart disease: randomised trial. *BMJ.* 1999;319:943-947.	High or differential attrition
Steptoe A, Kerry S, Rink E, Hilton S. The impact of behavioral counseling on stage of change in fat intake, physical activity, and cigarette smoking in adults at increased risk of coronary heart disease. *Am J Public Health.* 2001;91:265-269.	High or differential attrition
Sternfeld B, Block C, Quesenberry CP, Jr. et al. Improving diet and physical activity with ALIVE: a worksite randomized trial. *Am J Prev Med.* 2009;36:475-483.	High or differential attrition
Svetkey LP, Pollak KI, Yancy WS, Jr. et al. Hypertension improvement project: randomized trial of quality improvement for physicians and lifestyle modification for patients. *Hypertension.* 2009;54:1226-1233.	Population > 50% hypertension or dyslipidemia
Tuomilehto J. Nonpharmacologic therapy and exercise in the prevention of type 2 diabetes. *Diabetes Care.* 2009;32:Suppl-93.	Not an allowable study design
Voils CI, Yancy WS, Jr., Kovac S et al. Study protocol: Couples Partnering for Lipid Enhancing Strategies (CouPLES) - a randomized, controlled trial. *Trials [Electronic Resource].* 2009;10:10.	No relevant outcomes

Appendix E. Meta-Analysis Details

For trials with multiple intervention arms, we combined intervention arms when the interventions were in the same intensity category, and analyzed the arms separately if they fell into different intensity categories. We used the following formulae to calculate combined means and standard deviations:[154]

$$Mean_{combined} = N_1M_1 + N_2M_2 / N_1 + N_2$$

$$SD_{combined} = \sqrt{\frac{(N_1 - 1)SD_1^2 + (N_2 - 1)SD_2^2 + \frac{N_1N_2}{N_1 + N_2}(M_1^2 + M_2^2 - 2M_1M_2)}{N_1 + N_2 - 1}}$$

All but one of the outcomes we examined were continuous, and we analyzed the change from baseline in all of these cases, using random effects models. If both adjusted and unadjusted change from baseline were reported in a trial, we selected the adjusted estimate. We used standard calculations to convert standard errors and 95% confidence intervals to standard deviations:

$SD_{mean} = SE_{mean} * sqrt(n)$ or

$SD_{mean} = (CI_{upper} - CI_{Lower}) * sqrt(n) / 3.29$

If only baseline and followup values were reported, we calculated the crude mean change by subtracting the baseline mean from the follow-up mean for each group, and estimated the standard deviation using the following formula:

$$SD_{change} = Sqrt(SD^2_{base} + SD^2_{post} – 2 * SD_{base} * SD_{post} * r_{base,post})$$

In order to use this formula, we estimated the correlation between baseline and followup for each outcome. To do this, we examined studies that reported mean change as well as baseline and followup means and used the formula above to determine the correlations in their samples. These studies were quite variable in the resulting correlations, the time of followup, the quality of the study, and the number of estimates we were able to find. Because of this variability both in quality of the estimate and the absolute value of the correlations, we grouped like outcomes and used what we believed to be reasonable, somewhat conservative (lower) values for that set of outcomes. We assigned larger discrepancies between intervention and control group estimates for behavioral variables than the intermediate health outcomes, since we reasoned that behavior would be more likely to be affected by the interventions. See Appendix E Table 1 for the final values we chose.

One test of the accuracy of our estimates is whether the statistical significance of the difference in our calculated change scores was generally consistent with the statistical tests run by the authors on the unadjusted baseline and follow-up means. Differences may suggest a mismatch between our estimated correlations and the study sample. We found this to have occurred only rarely, and when we tested higher (less conservative) correlations that were still in the range of our studies, these differences persisted. We therefore, concluded that our estimates were adequate.

We converted to common metrics for ease of interpretation of the meta-analysis. See Table 1 for the conversion factors we used.

Table 1. Conversion Factors

Measure	Original Metric	Final Metric	Conversion Factor
Total Cholesterol	mg/dl	mmol/l	38.67
High-Density Lipoproteins	mg/dl	mmol/l	38.67
Low-Density Lipoproteins	mg/dl	mmol/l	38.67
Triglycerides	mg/dl	mmol/l	88.57
Glucose	mg/dl	mmol/l	18.0
Energy	kJ	kcal	4.184
Weight	pounds	kg	2.2

Data Substitutions. In one case,[59] we used the median to estimate the mean, and 1.35 times the interquartile range to estimate the standard deviation.[154] We only did this in the one case where the interquartile range was relatively symmetrical around the median and did not appear to have marked ceiling or floor effect. In one case,[127] the standard deviation of the triglycerides in the control group at baseline was approximately five times larger than all other standard deviations, so we assume that was a typo and substituted baseline intervention group standard deviation instead.

Studies missing standard deviations at followup were examined to see if a standard deviation from another time point could be substituted. Acknowledging that this was likely a conservative substitution (since baseline standard deviations tend to be large than standard deviation of change), substitution of standard deviations was allowed in three cases.[68,83,94]

Appendix E. Meta-Analysis Details

The only non-continuous outcome was the proportion of people meeting recommended level physical activity. We calculated a relative risk and its standard error using the raw numbers reported from each study and combined using a random effects model.[155,156] One study reported an odds ratio rather than raw data or a relative risk,[60] so we also ran a meta-analysis model that calculated and analyzed odds ratios in order to see if this study was consistent with those providing raw data. We also ran a meta-analysis model that calculated and analyzed absolute risk difference. We then used the estimated absolute risk difference to calculate the number needed to treat to get one more person to meet recommended levels of physical activity using the formula 1/absolute risk difference.

For studies with clustered randomization, we used the reported estimate if the study reported an estimate adjusted for clustering effect. Three studies used clustered randomization, but did not report outcomes that adjusted for clustering.[32,36,52] We adjusted for clustering effect by multiplying the standard deviation by the square root of the design effect. Here, design effect = $1+(m-1)\rho$, where m is the average cluster size and ρ is the intracluster correlation coefficient. We assumed ρ to be 0.05 for all three studies, which clustered at the level of the physician or clinic.

We ran a series of meta-regression to examine the effects of measurement, population, setting, and other study characteristics on effect size. To do this, we included a single factor of interest in each meta-regression model, controlling for intervention intensity, intervention target, risk status of the sample, and volunteer status of sample (whether participants were recruited through screening or other outreach, vs. participants proactively volunteering for the study). We selected these four control variables a priori on the basis of clinical judgment.

In this way we explored sample characteristics (percent male, percent non-white, baseline BMI), design characteristics (months of followup, whether the trial was conducted in the U.S., whether the sample was selected from a primary care setting or among health plan enrollees, whether the study targeted older adults, overall methodological quality of the study), and other characteristics (year published, degree of calculation and/or estimation needed to use a study's data in the meta-analysis (0=none, 1=direct calculation (e.g. confidence interval to standard deviation), 2=some estimate required (e.g., calculating standard deviation of change from baseline and followup scores, or calculating combined effects from two groups reported separately), 3=some judgment involved (e.g., using baseline standard deviation to estimate followup standard deviation))). To explore the effects of using different measures on self-reported physical activity, fat intake, and fruit-and-vegetable intake, we grouped like measures and then ran adjusted meta-regressions using measure type to predict the effect size. Two-level variables were entered as 1/0 dummy variables and 3-level variables were converted to two 1/0 dummy variables with reference groups selected on the basis of interpretability of results.

Appendix E Table 1. Meta-Analysis Correlations

Outcome (treatment group)	Range of correlations in identified publications (number of estimates found)*	Correlation used in data calculations for meta-analysis
Adiposity (CG)	0.98-0.99 (2)	0.90
Adiposity (IG)	0.97-0.98 (2)	0.90
Systolic BP (CG)	0.57-0.82 (2)	0.65
Systolic BP (IG)	0.64-0.77 (2)	0.60
Diastolic BP (CG)	0.48-0.68 (2)	0.65
Diastolic BP (IG)	0.58-0.64 (2)	0.60
Total Cholesterol (CG)	0.44-0.83 (3)	0.65
Total Cholesterol (IG)	0.39-0.89 (4)	0.60
High-Density Lipoproteins (CG)	0.50-0.91 (3)	0.75
High-Density Lipoproteins (IG)	0.50-0.90 (4)	0.70
Low-Density Lipoproteins (CG)	0.67-0.88 (3)	0.65
Low-Density Lipoproteins (IG)	0.68-0.92 (4)	0.60
Triglycerides (CG)	(none found)	0.65
Triglycerides (IG)	(none found)	0.60
Glucose (CG)	(none found)	0.65
Glucose (IG)	(none found)	0.60
Total Energy (CG)	0.49-0.60 (2)	0.60
Total Energy (IG)	0.48-0.71 (2)	0.50
Percent Fat/Saturated Fat (CG)	0.27-0.55 (3)	0.50
Percent Fat/Saturated Fat (IG)	0.11-0.74 (5)	0.40
Fiber (CG)	0.46-0.84 (2)	0.50
Fiber (IG)	0.29-0.60 (3)	0.40
Fruits and Vegetables (CG)	0.73-0.75 (2)	0.70
Fruits and Vegetables (IG)	0.56-0.68 (3)	0.55
Urinary Sodium (CG)	(none found)	0.50
Urinary Sodium (IG)	(none found)	0.40
Self-reported physical activity (CG)	0.28-0.96 (4) 0.28-0.33 (3)	0.25
Self-reported physical activity (IG)	0.03-0.92 (10) 0.03-0.27 (9)	0.10
Fitness (CG)	(none found)	0.25
Fitness (IG)	(none found)	0.10

* Estimates reported in trials included in the review

Appendix F Table 1. Studies Included in the Previous Reviews

Studies included in the previous healthy diet counseling review

Study ID	Current review
Baron 1990[78]	Included
Beresford 1992[157]	Excluded for <6 months of followup
Beresford 1997[79]	Included
Campbell 1994[158]	Excluded for <6 months of followup
Coates 1999[83]	Included
Delichatsios, Friedman et al 2001[34]	Included
Delichatsios, Hunt et al 2001[159]	Excluded for <6 months of followup
Henderson 1990[160]	Excluded for targeting a noncardiovascular-related condition
Keyserling 1997[161]	Excluded for population >50% with hypertension or dyslipidemia
Knutsen 1991[162]	Excluded for population >50% with hypertension or dyslipidemia
Kristal 2000[91]	Included
Lindholm 1995[163]	Excluded for population >50% with hypertension or dyslipidemia
Lutz 1999[92]	Included
Maskarinec 1999[164]	Excluded for comparative-effectiveness study design
Mojonnier 1980[165]	Excluded at abstract phase (coversheet says I4 – hyperchol)
Neaton 1981[166]	Excluded for population >50% with hypertension or dyslipidemia
Ockene 1996[167]	Excluded for population >50% with hypertension or dyslipidemia
Roderick 1997[94]	Included
Siero 2000[168]	Excluded for <6 months of followup
Simkin-Silverman 1995[124]	Included for lifestyle counseling review
Steptoe 1999[169]	Excluded for high or differential attrition

Studies included in the previous physical activity counseling review

Study ID	Current review
Activity Counseling Trial 2001[25]	Excluded for comparative-effectiveness study design
Burton 1995[170]	Excluded for other quality issues
Goldstein 1999[38]	Included
Kerse 1999[171]	Excluded for not focusing on counseling interventions to improve physical activity to reduce cardiovascular risk
Norris 2000[68]	Included
Smith 2000[172]	Excluded for other quality issues
Steptoe 1999[169]	Excluded for high or differential attrition
Swinburn 1998[173]	Excluded for <6 months of followup

Appendix F Table 2. Trials Pending Assessment

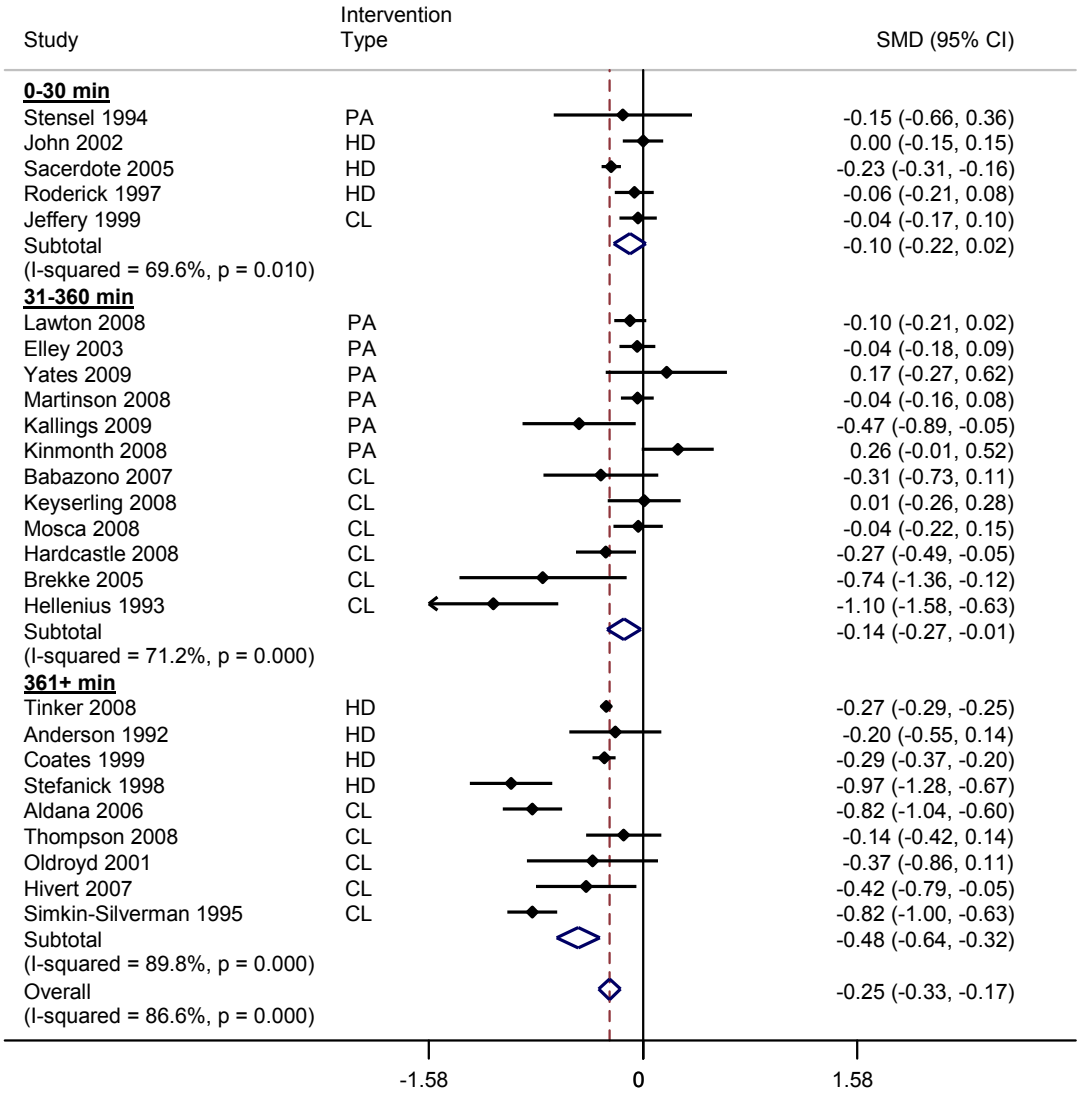
Investigator, study name	Location	Number of participants	Intervention	Outcomes	2010 Status
Dr. Nabila El Bassel[174] Project Eban Health Promotion Intervention	Columbia University, Emory University, University of California at Los Angeles, and the University of Pennsylvania	--	Counseling African American couples on healthful behaviors including physical activity, healthful dietary practices, ceasing cigarette smoking and alcohol abuse, and practicing early detection and screening behaviors	--	Outcomes of interest not yet published
Dr. Masanori Munakata[175] Japanese study to organize proper lifestyle modifications for metabolic syndrome (J-STOP-MetS 2)	Japan	2000	Individualized guidance for life style modification	Body weight, waist circumference, body composition, blood pressure, arterial stiffness, fasting blood	Outcomes of interest not yet published
Dr. Iris Groeneveld[176] The Health Under Construction Study	The Netherlands	692	Counseling to increase physical activity and improve dietary behavior and/or smoking cessation	Behavior change, body mass index, systolic and diastolic blood pressure, total and HDL blood cholesterol, Hba 1 c and cardio-respiratory fitness	Outcomes of interest not yet published
Dr. Hilde van Keulen[177] Vitalum study	The Netherlands	2881	Print and telephone counseling for physical activity and nutrition behavior	Behavior change, saturated fat intake, health-related quality of life, body mass index, and cognitive behavioral determinants	Outcomes of interest not yet published
Dr. Karen Hosper[178] Exercise on Prescription	The Netherlands	360	Weekly supervised exercise sessions during 20 weeks	Minutes of self-reported physical activity per week, wellbeing, perceived health, fitness, body size, use of primary health care	Planned closing date December 2010
Dr. Maria Gine-Garriga[179]	Spain	424	Two, 60-minute physical activity sessions per week for 12 weeks	Health-related quality of life, physical activity stage of change, level of physical activity, change in perception of health, level of social support for the physical activity practice, control based on analysis	Not yet recruiting, estimated completion December 2010

Appendix F Table 2. Trials Pending Assessment

Investigator, study name	Location	Number of participants	Intervention	Outcomes	2010 Status
Dr. Claire F. Fitzsimons[180] Walking for Wellbeing in the West	Scotland	79	Pedometer-based walking program in combination with a physical activity consultation	Pedometer step counts, physical activity recall, stage of change, mood, quality of life, body composition, blood pressure, heart rate, total cholesterol, HDL cholesterol, insulin and glucose, circulating measures of inflammatory markers, perceived environmental barriers or facilitators to activity, social context, cost-effectiveness	Trial completed, 12-week outcomes published, awaiting full length of followup
Dr. Corinne Voils [181]	Durham, NC	250 couples	Monthly telephone-based intervention administered to couples to lower above-goal LDL through medication adherence, diet, exercise, and patient-physician communication.	LDL, dietary and physical activity behavior.	Trial completion expected August 2010

Appendix G Figures 1–16. Forest Plots of All Trials

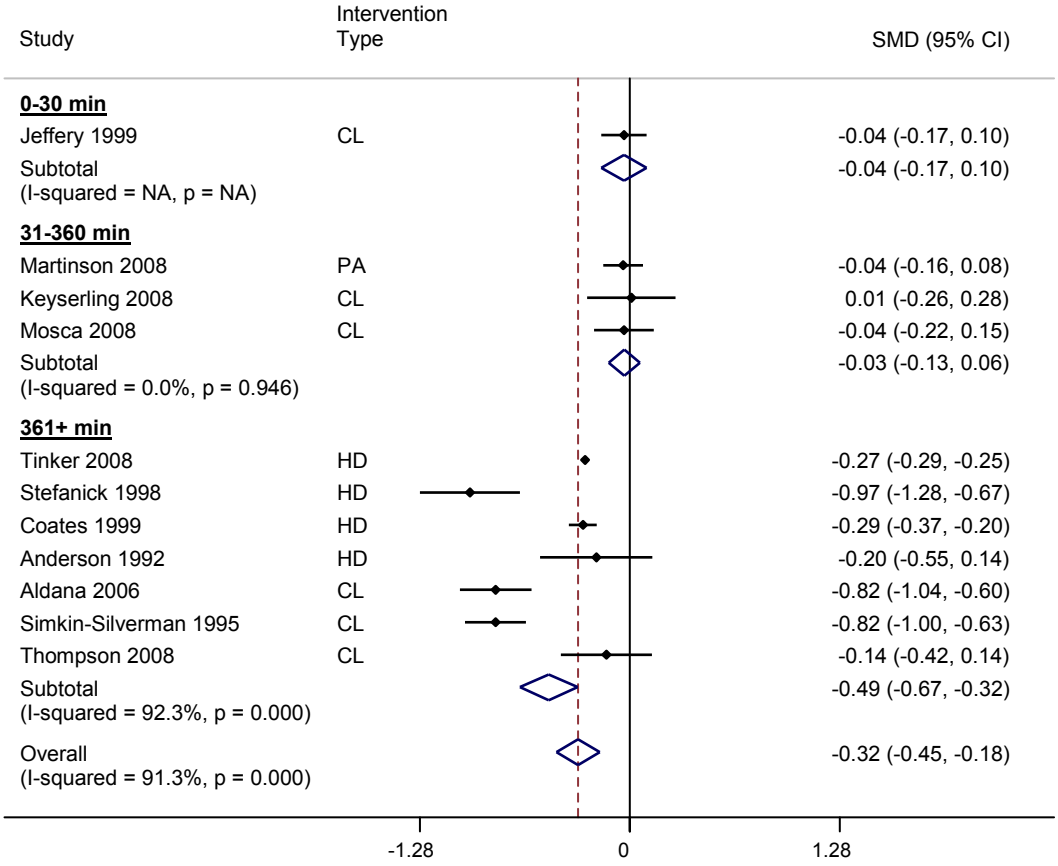
Appendix G Figure 1. Meta-Analysis of All Trials Combined, By Intervention Intensity (KQ2): Adiposity



SMD - standardized mean difference; 95% CI - 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

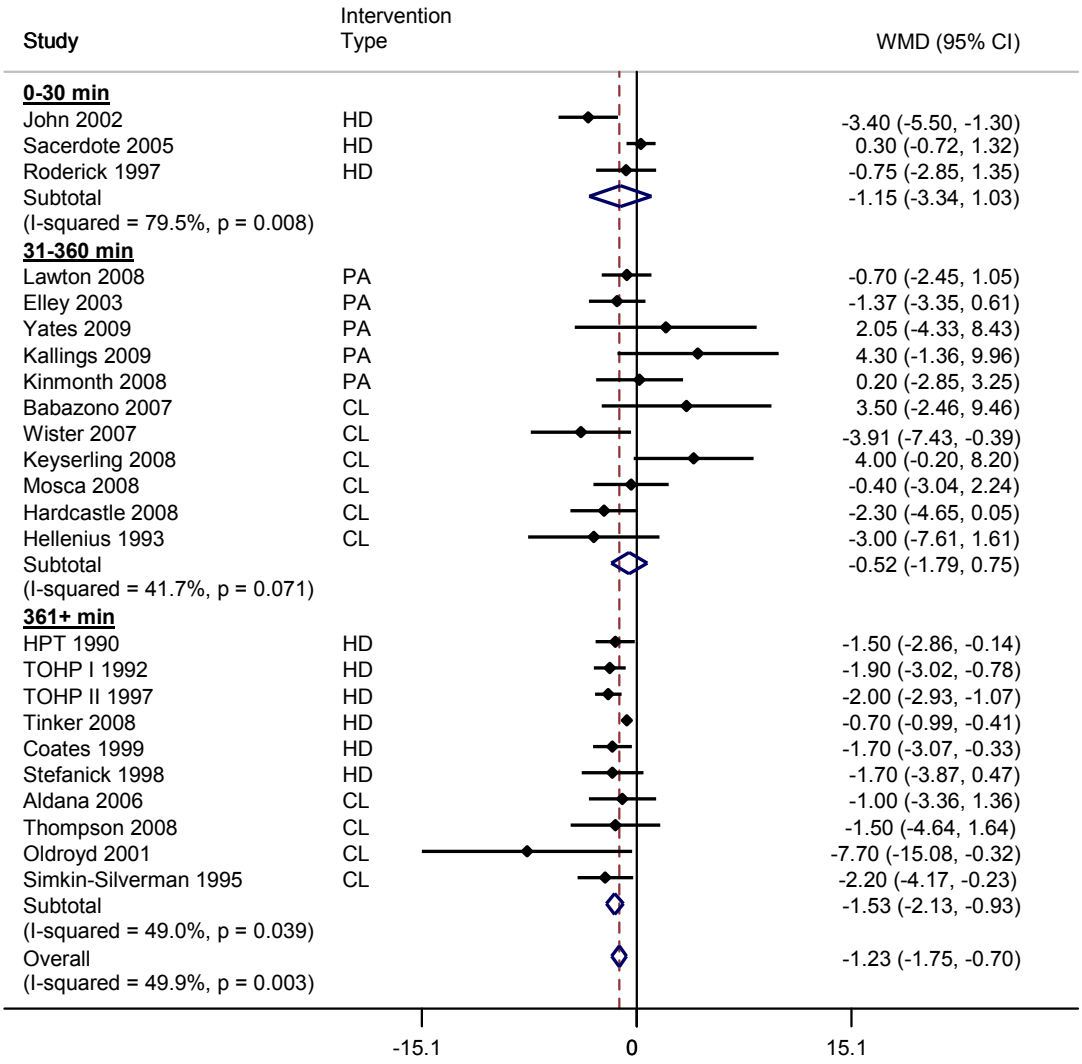
Appendix G Figure 2. Meta-Analysis of All Trials Combined, US Trials Only (KQ2): Adiposity



SMD - standardized mean difference; 95% CI - 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

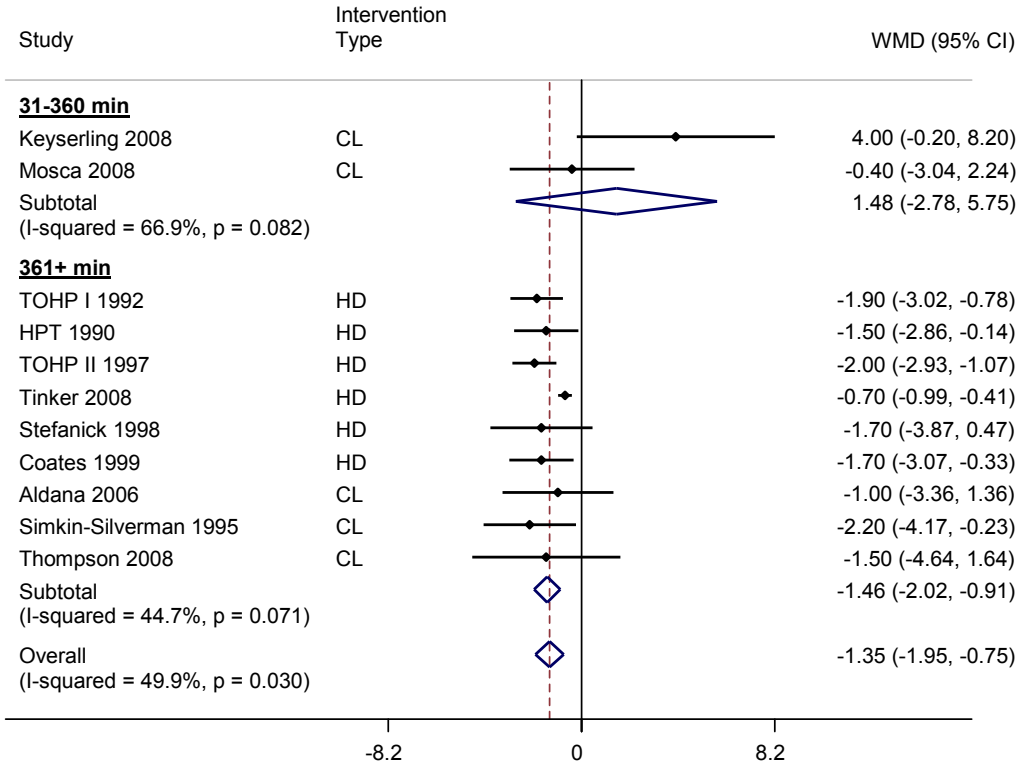
Appendix G Figure 3. Meta-Analysis of All Trials Combined, By Intervention Intensity (KQ2): Systolic Blood Pressure



WMD - unstandardized mean difference; 95% CI - 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

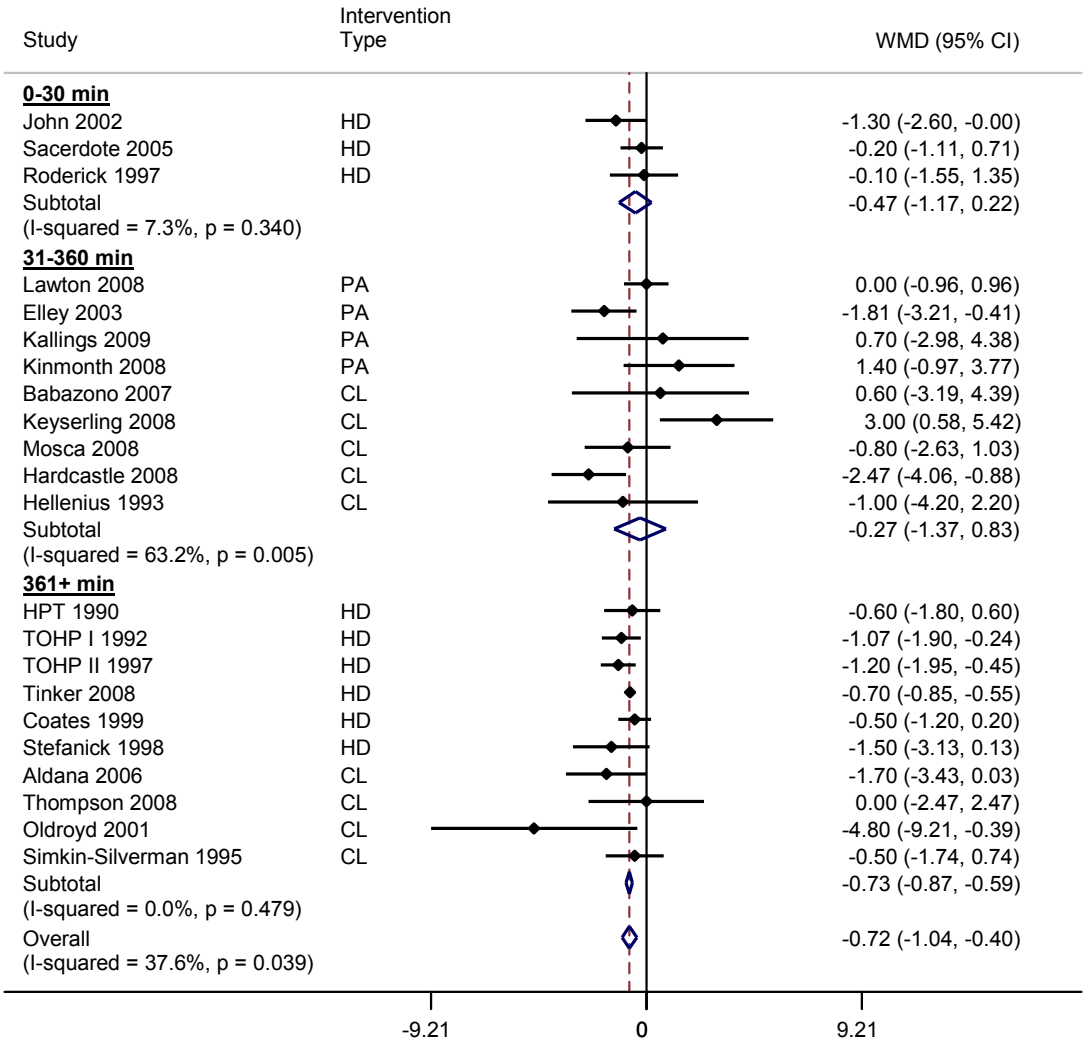
Appendix G Figure 4. Meta-Analysis of All Trials Combined, US Trials Only (KQ2): Systolic Blood Pressure



WMD - unstandardized mean difference; 95% CI - 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

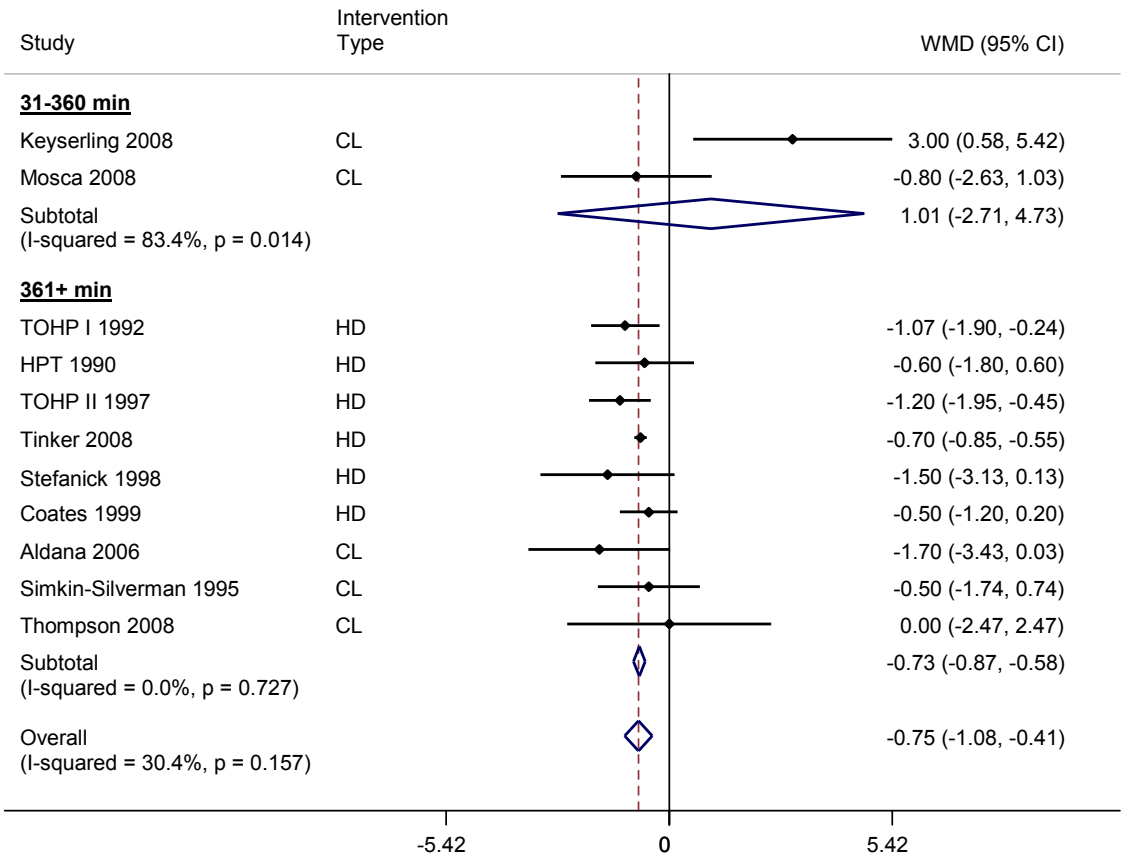
Appendix G Figure 5. Meta-Analysis of All Trials Combined (KQ2): Diastolic Blood Pressure



WMD - unstandardized mean difference; 95% CI - 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

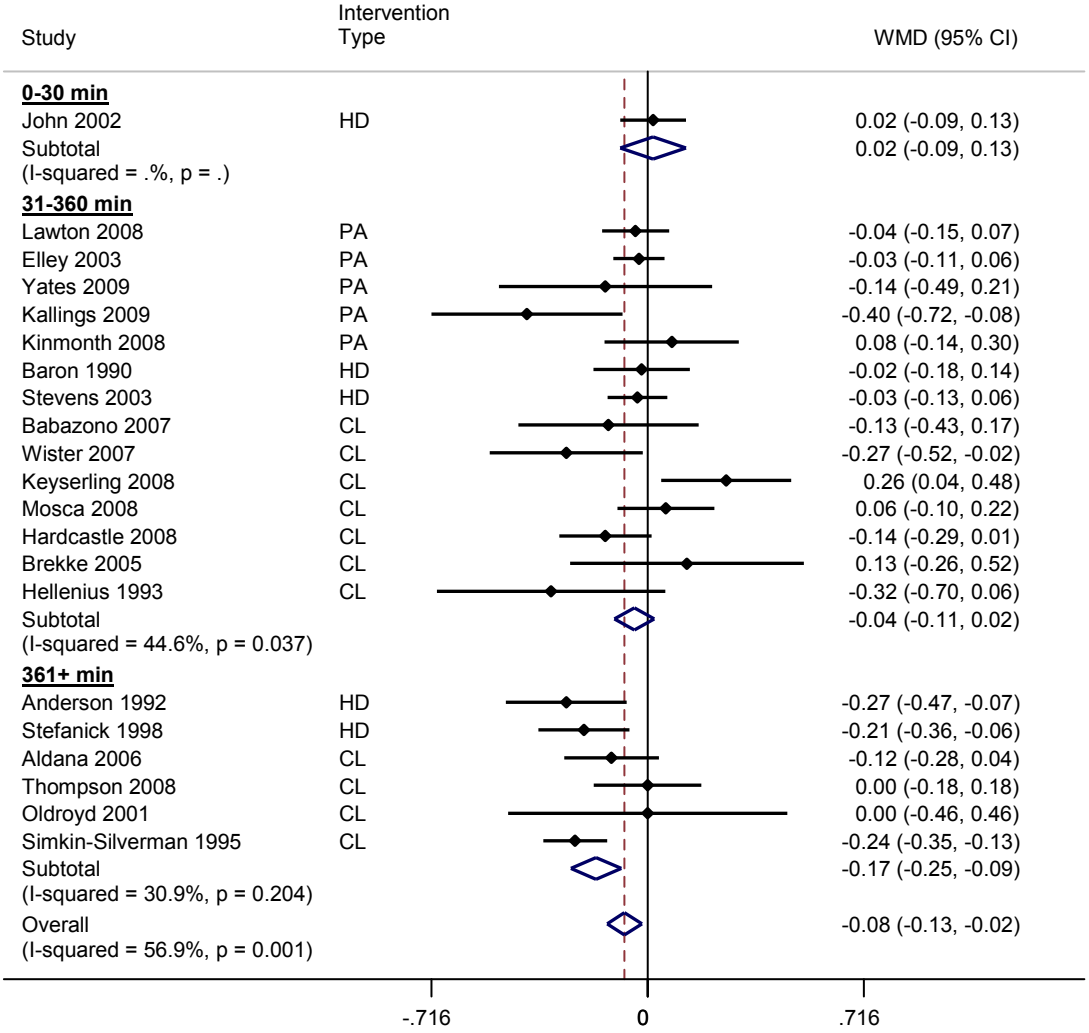
Appendix G Figure 6. Meta-Analysis of All Trials Combined, US Trials Only (KQ2): Diastolic Blood Pressure



WMD - unstandardized mean difference; 95% CI - 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

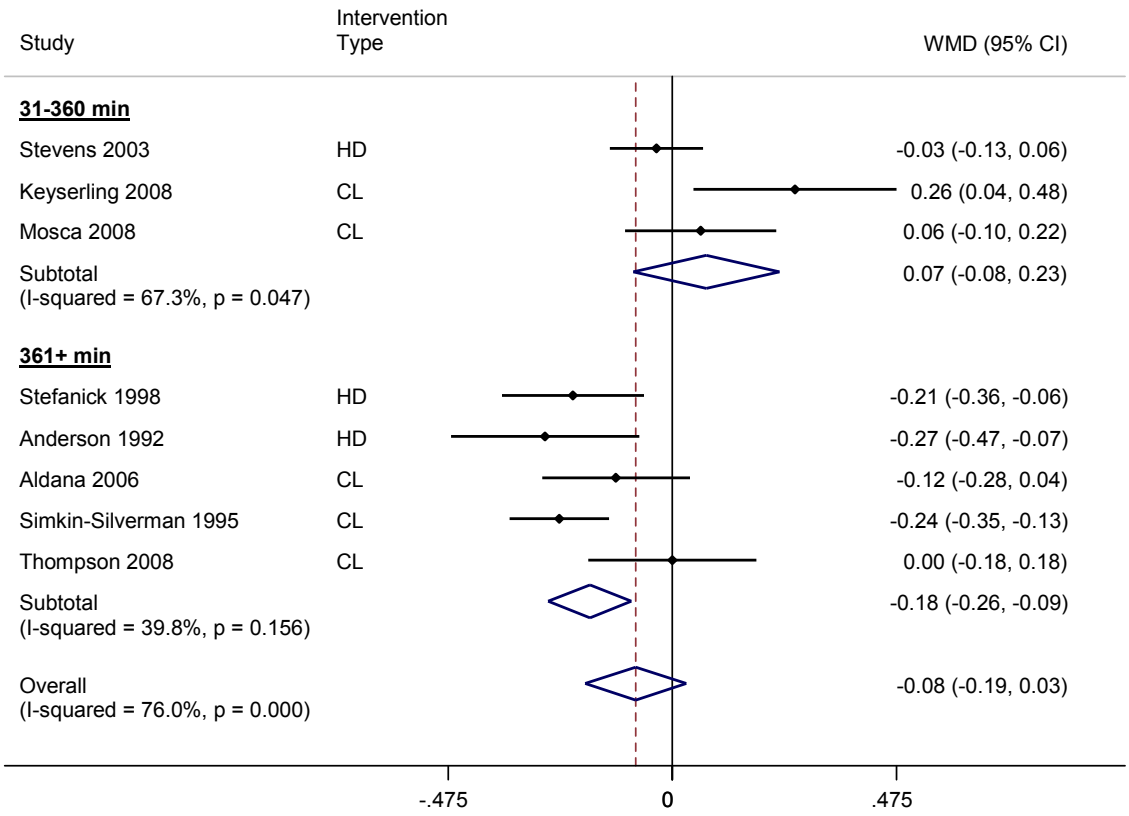
Appendix G Figure 7. Meta-Analysis of All Trials Combined (KQ2): Total Cholesterol



WMD - unstandardized mean difference; 95% CI - 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

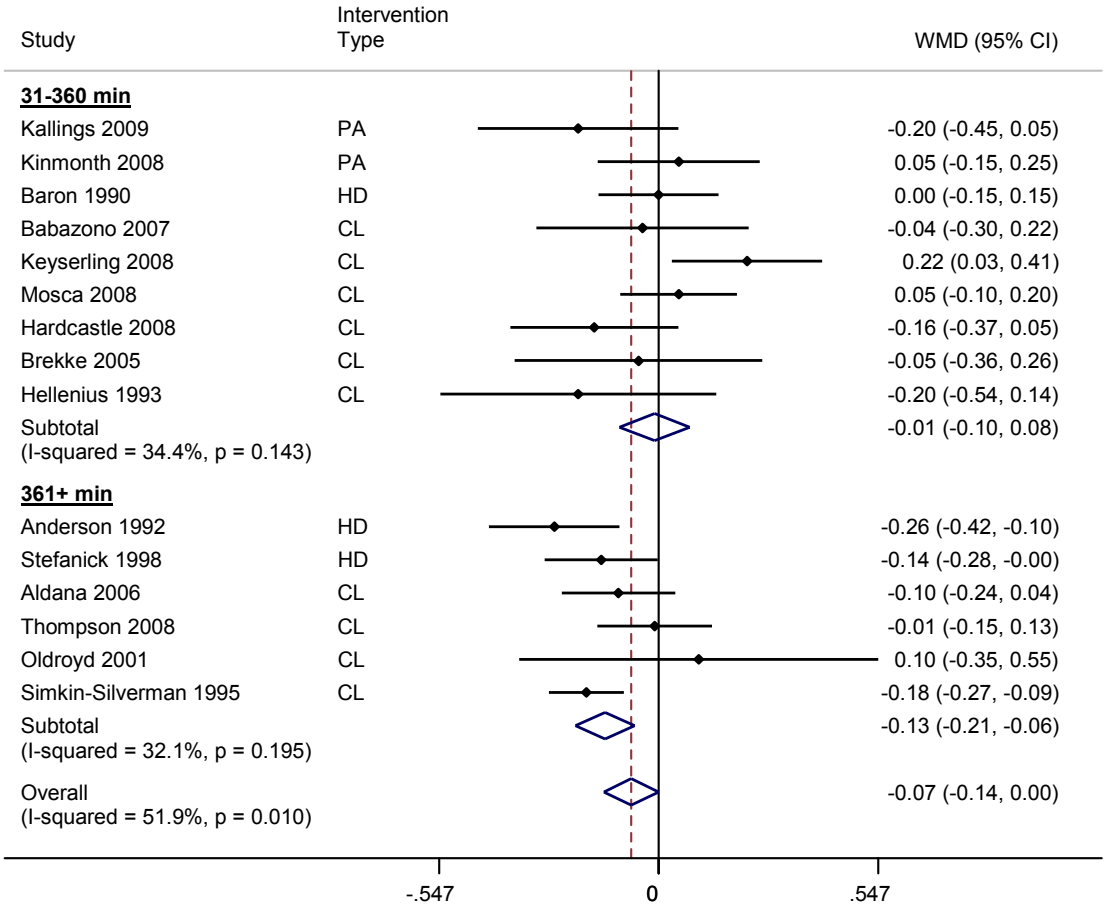
Appendix G Figure 8. Meta-Analysis of All Trials Combined, US Trials Only (KQ2): Total Cholesterol



WMD - unstandardized mean difference; 95% CI - 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

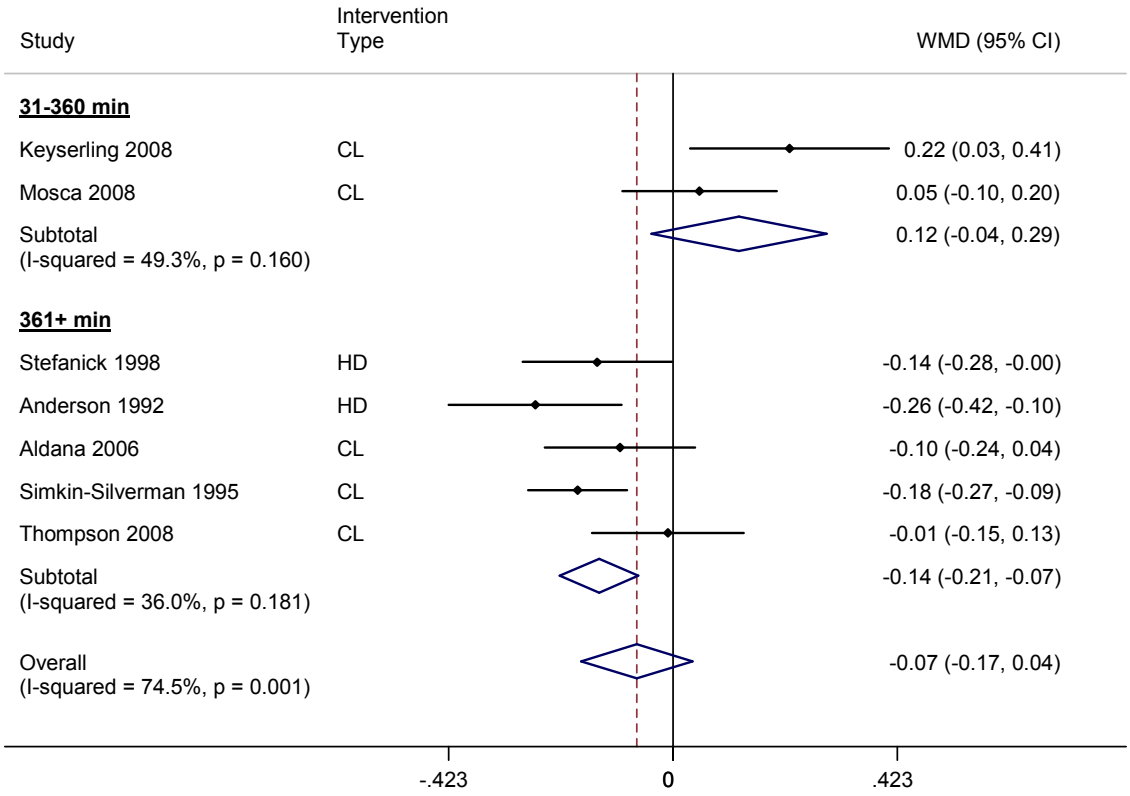
Appendix G Figure 9. Meta-Analysis of All Trials Combined, By Intervention Intensity (KQ2): Low-Density Lipoproteins



WMD – unstandardized mean difference; 95% CI – 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

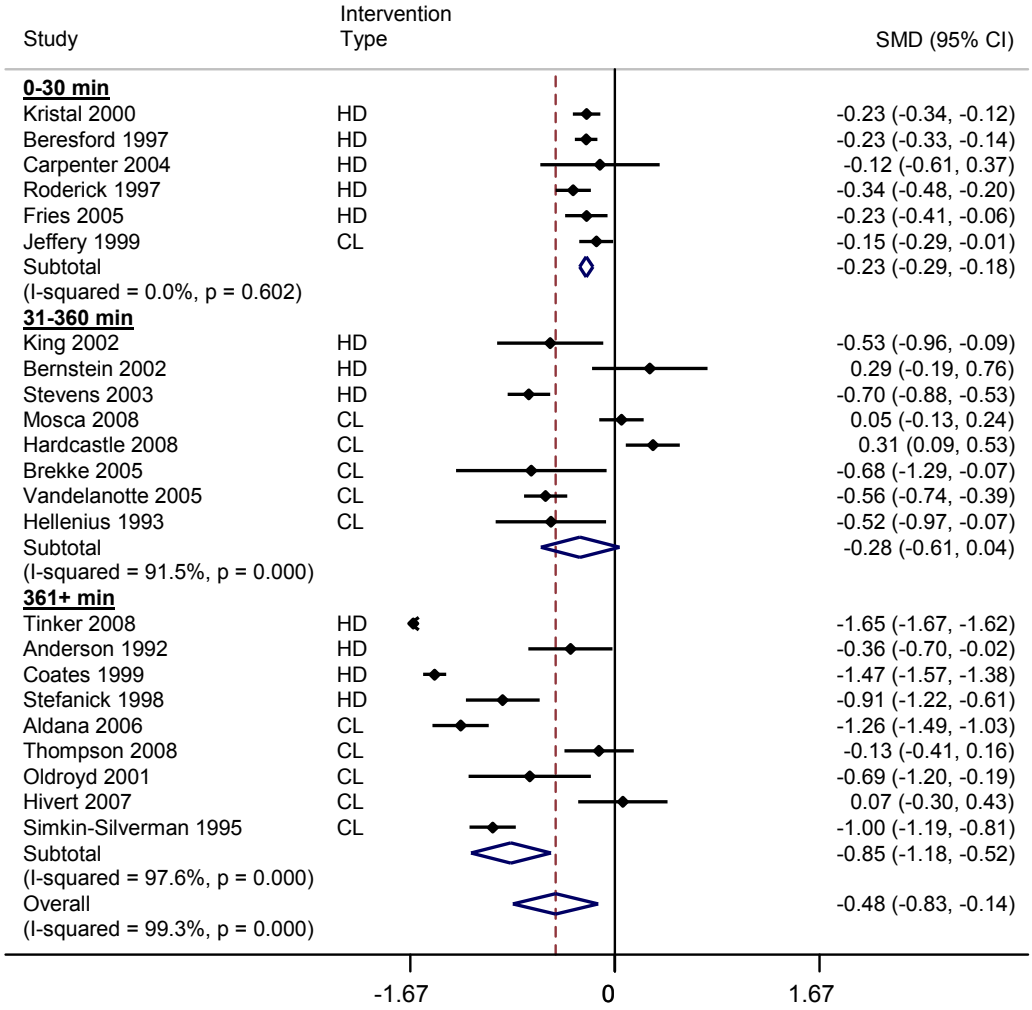
Appendix G Figure 10. Meta-Analysis of All Trials Combined, US Trials Only (KQ2): Low-Density Lipoproteins



WMD – unstandardized mean difference; 95% CI – 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

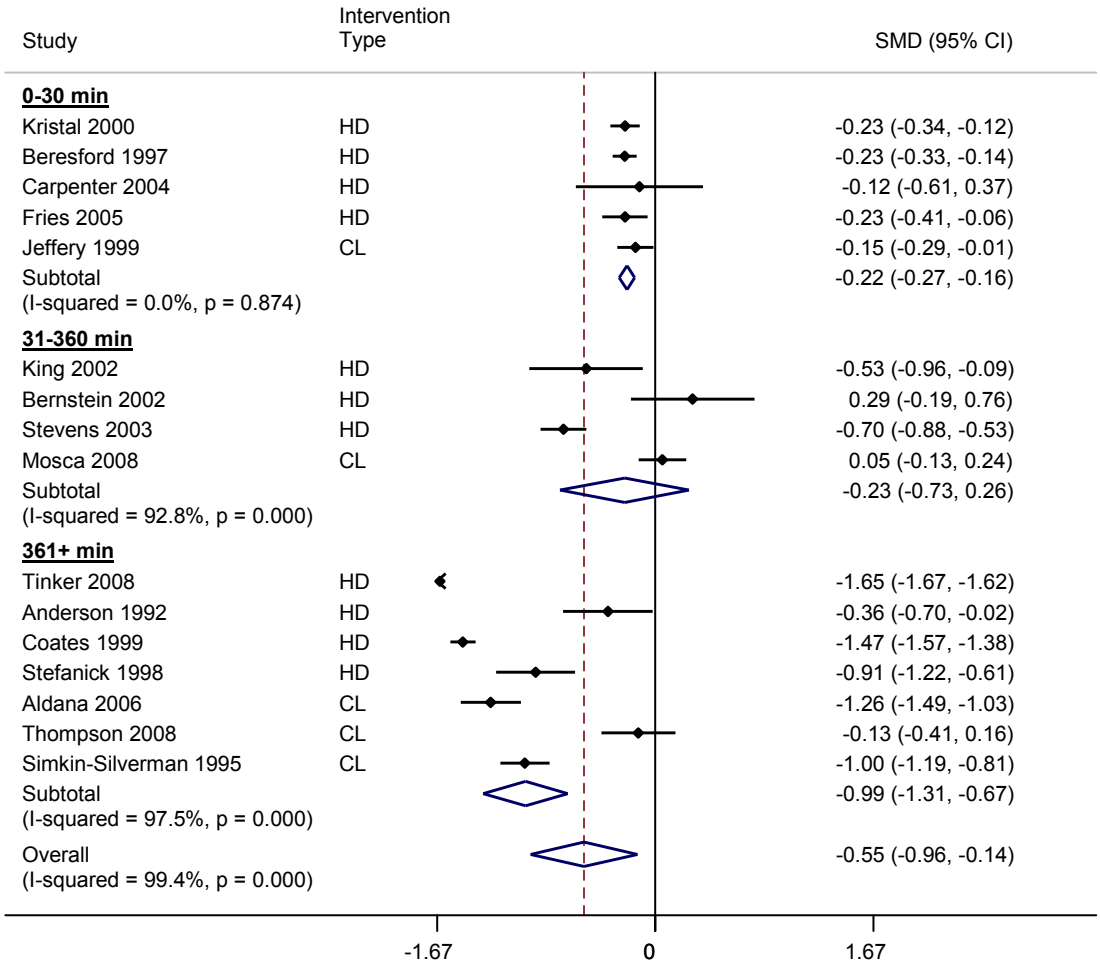
Appendix G Figure 11. Meta-Analysis of All Trials Combined, By Intervention Intensity (KQ3): Self-Reported Fat Intake



SMD – standardized mean difference; 95% CI – 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

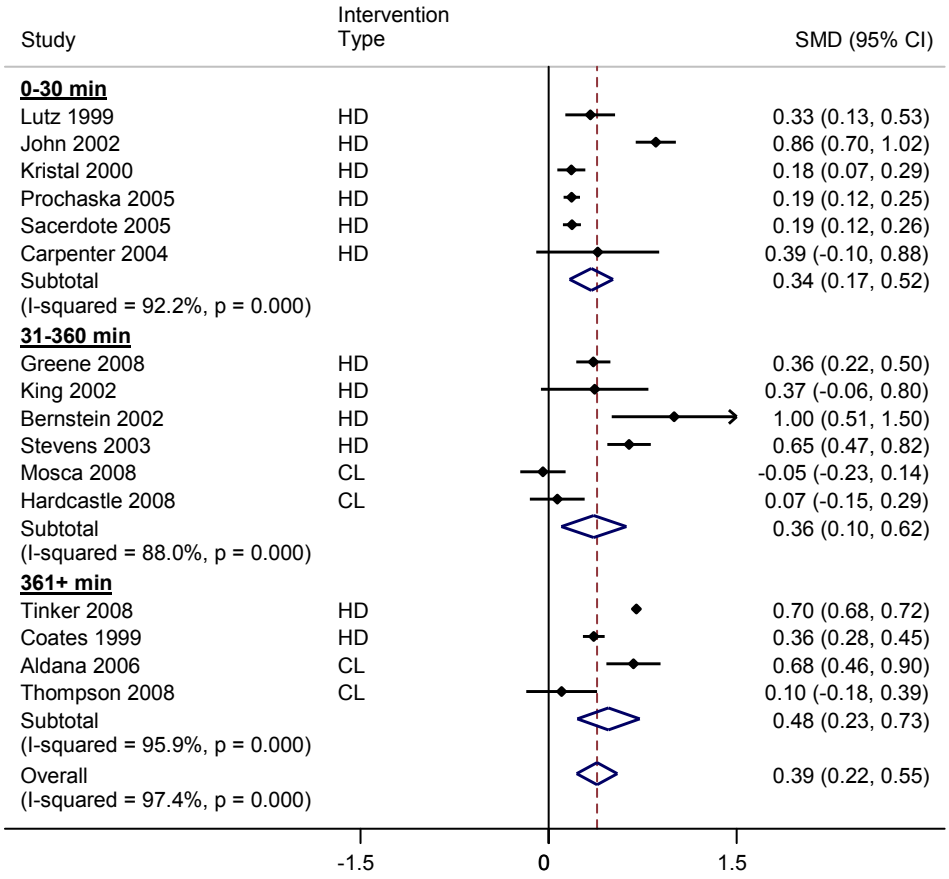
Appendix G Figure 12. Meta-Analysis of All Trials Combined, US Trials Only (KQ3): Self-Reported Fat Intake



SMD – standardized mean difference; 95% CI – 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

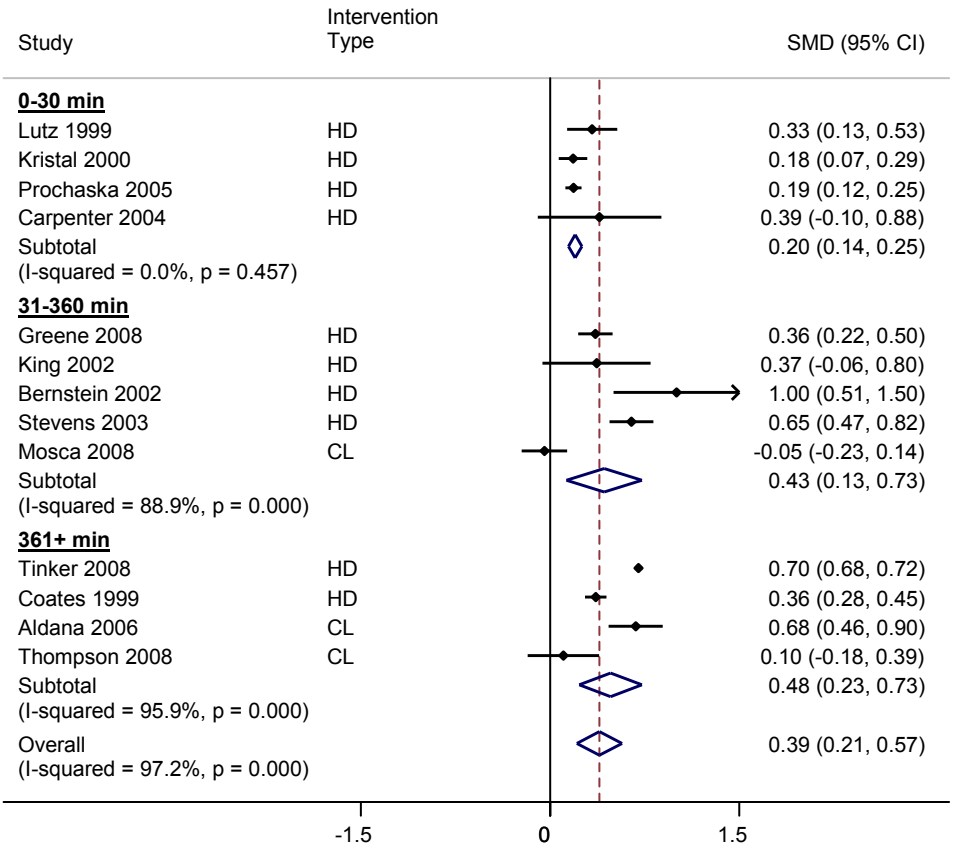
Appendix G Figure 13. Meta-Analysis of All Trials Combined, By Intervention Intensity (KQ3): Self-Reported Fruits and Vegetables Intake



SMD – standardized mean difference; 95% CI – 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

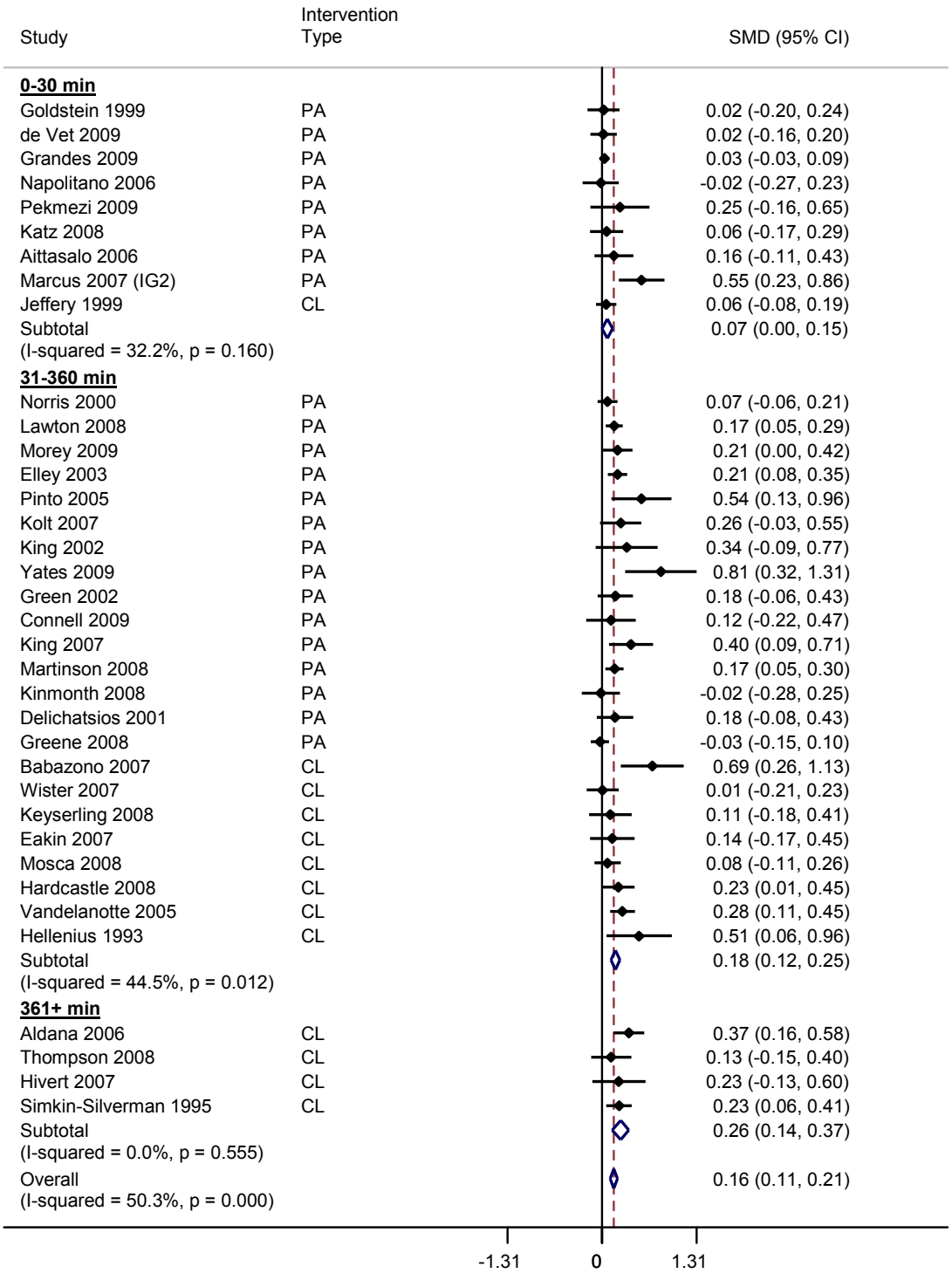
Appendix G Figure 14. Meta-Analysis of All Trials Combined, US Trials Only (KQ3): Self-Reported Fruits and Vegetables Intake



SMD – standardized mean difference; 95% CI – 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

Appendix G Figure 15. Meta-Analysis of All Trials Combined, By Intervention Intensity (KQ3): Self-Reported Physical Activity



SMD – standardized mean difference; 95% CI – 95% confidence interval

Appendix G Figures 1–16. Forest Plots of All Trials

Appendix G Figure 16. Meta-Analysis of All Trials Combined, US Trials Only (KQ3): Self-Reported Physical Activity