

Review protocol for review question: B.1b What physical rehabilitation interventions are effective and acceptable for children and young people with complex rehabilitation needs after traumatic injury?

Table 8: Review protocol for physical rehabilitation interventions in children and young people

ID	Field	Content
0.	PROSPERO registration number	CRD42019130144
1.	Review title	Rehabilitation packages and programmes for children and young people
2.	Review question	2.1b: What physical rehabilitation interventions are effective and acceptable for children and young people with complex rehabilitation needs after traumatic injury?
3.	Objective	To evaluate the effectiveness of physical rehabilitation interventions among children and young people with complex rehabilitation needs after traumatic injury
4.	Searches	The following databases will be searched:

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		<ul style="list-style-type: none"> • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE <p>Searches will be restricted by:</p> <ul style="list-style-type: none"> • Date: 1995 onwards as there has been significant change in practice since then • English language • Human studies <p>The full search strategies for MEDLINE database will be published in the final review.</p>
5.	Condition or domain being studied	<p>Complex rehabilitation needs resulting from traumatic injury</p> <p>‘Complex rehab needs’ refers to ‘multiple needs, and will always involve coordinated multidisciplinary input from 2 or more allied health professional disciplines, and also include the following:</p> <ul style="list-style-type: none"> • Vocational or educational social support for the person to return to their previous functional level, including return to work, school or college • Emotional, psychological and psychosocial support • Equipment or adaptations • Ongoing recovery from injury that may change the person’s rehabilitation needs (for example, restrictions of weight bearing, cast immobilisation in feature clinic) • Further surgery and readmissions to hospital <p>Traumatic injury is defined as ‘traumatic injury as injury that requires admission to hospital at the time of injury.’</p>
6	Population	<p>Inclusion:</p> <p>Children and young people (aged below 18 years) with complex rehabilitation needs resulting from traumatic injury that required admission to hospital</p> <p>Exclusion:</p> <ul style="list-style-type: none"> • Children and young people with complex rehabilitation needs resulting from traumatic brain injury (including anoxic brain injury, for example, drowning and strangulation) • Children and young people with traumatic injuries who do not have complex rehabilitation needs

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		<p>and/or do not require admission to hospital</p> <ul style="list-style-type: none"> • Children and young people with complex rehabilitation needs resulting from traumatic injury who are admitted to the PICU
7	Intervention	<p>Standard rehabilitation care consisting of: physiotherapy [range of movement exercises, exercises to maintain muscle function, mobilisation and training with mobilisation aids such as crutches or frame], occupational therapy assessment, and identification and support of basic activities of daily living through training or aids (e.g. toileting equipment, perching stools, long-handled aids, adapted eating utensils) in addition to at least one of the following:</p> <ul style="list-style-type: none"> • Exercise class /Reconditioning/Cardiovascular/Fitness training • Strengthening, balance, proprioception, vestibular rehabilitation/training • Splinting/orthotic • Gait re-education • Early weight bearing to mobilize (i.e., sitting or standing) • Manual therapy (soft tissue massage/release, joint mobilization) • Hydrotherapy • Scar, swelling and oedema management (i.e. elevation, compression, soft tissue massage, creams, hydrated, desensitization, laser therapy, hand therapy) • Anti-gravity treadmill training • Nutrition support (eg supplements, dietetics, optimising calorie intake, gastrostomy, PEG RIG, NG feeding, swallowing therapy, early feeding plans, patient education, dysphagia) • Play therapy <p>Exclusion:</p> <ul style="list-style-type: none"> • Rehabilitation packages and programmes relating to traumatic brain injury, sight loss and hearing loss • Social care interventions (for example, home care or personal assistance) • Long-term care and rehabilitation packages for people with long-term care needs • Specific pain management interventions
8	Comparator/Reference standard/Confounding factors	<p>1) Standard rehabilitation care consisting of: physiotherapy [range of movement exercises, exercises to maintain muscle function, mobilisation and training with mobilisation aids such as crutches or frame], occupational therapy assessment, and identification and support of basic activities of daily living through training or aids (e.g. toileting equipment, perching stools, long-handled aids, adapted eating utensils).</p>

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		<p>2) Studies that employ the same intervention program as listed under 'interventions' but vary it in terms of any of the following:</p> <ul style="list-style-type: none"> • Frequency • Intensity • Timing
9	Types of study to be included	<ul style="list-style-type: none"> • Systematic review of RCTs • Randomised controlled trial <p>If no RCT data are available for an intervention, evidence from the followings will be considered in order</p> <ul style="list-style-type: none"> • Cluster-randomised trial • Systematic review of non-randomised studies • Comparative prospective cohort studies with N≥100 per treatment arm • Comparative retrospective cohort studies with N≥100 per treatment arm
10	Other exclusion criteria	<p>Study design:</p> <ul style="list-style-type: none"> • Cross-over design • Case-controls • Cross-sectional • Case series and case reports • Audits <p>Language:</p> <ul style="list-style-type: none"> • Non-English <p>Publication status:</p> <ul style="list-style-type: none"> • Abstract only
11	Context	<p>Settings - Inclusion:</p> <ul style="list-style-type: none"> • All inpatient, outpatient and community settings in which rehabilitation services following traumatic injury are provided

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		<p>Exclusion:</p> <ul style="list-style-type: none"> • Accident and emergency departments • Critical care units • Prisons
12	Primary outcomes (critical outcomes)	<p>Critical:</p> <ul style="list-style-type: none"> • Patient and families and carers' acceptability (any direct measure; if not reported, but patient satisfaction is, this will be reported instead) • Changes in mobility (WeeFIM, any measure) • Upper limb function (e.g., DASH, ARMA) <p>Babies only:</p> <ul style="list-style-type: none"> • Alberta Infant Motor Scale (AIMS; pre-term to 19 months. • Bayley Assessment (1 to 42 months) <p>Timeframe for the follow-up will be 0 to 5 years. This will be grouped into short-term (0 to 6 months) and long-term (> 6 months to 5 years).</p>
13	Secondary outcomes (important outcomes)	<p>Important:</p> <ul style="list-style-type: none"> • Return to nursery, education, training or work • Pain [VAS, any measure] • Overall quality of life including quality of sleep [e.g., CHQ-CF80, CHQ-PF-50, PEDS-QL, EURO-QoL 5D 3L Y, SF-36, SF-12, SF-6D, Tarn, SCIM]] • Changes in activity of daily living (e.g., COPM, Barthel ADL index, Katz, PSMS, OARS, PAT, EADL-Test, GAS, FIMFAM) <p>Timeframe for the follow-up will be 0 to 5 years. This will be grouped into short-term (0 to 6 months) and long-term (> 6 months to 5 years).</p>
14	Data extraction (selection and coding)	<p>All references identified by the searches and from other sources will be uploaded into STAR and de-duplicated. 5% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. A standardised form will be used to extract data from studies (see Developing NICE guidelines: the manual section 6.4.</p>

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15	Risk of bias (quality) assessment	Risk of bias will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual.
16	Strategy for data synthesis	<p>NGA STAR software will be used for generating bibliographies/citations, study sifting and data extraction.</p> <p>If pairwise meta-analyses are undertaken, they will be performed using Cochrane Review Manager (RevMan).</p> <p>'GRADEpro' will be used to assess the quality of evidence for each outcome.</p>
17	Analysis of sub-groups	<p>The following subgroups were specified for this question for stratification of the data:</p> <ul style="list-style-type: none"> • Children and young people who are suspected of sustaining non-accidental injuries versus accidental injuries • Children and young people with parents known to social services versus not known • Children and young people with young (< 20 years at birth of child) parents versus not young (\geq 20 years at birth of child) • Children and young people with parents from deprived backgrounds versus not deprived backgrounds • Children and young people with parents who have mental health issues versus none <p>If there is any further unexplained heterogeneity, we will look at the following subgroups to try to identify the source of it:</p> <ul style="list-style-type: none"> • Upper limb / lower limb • Children and young people with pre-existing physical and/or mental health conditions (including substance misuse), physical and learning disability versus no pre-existing conditions • Children and young people whose parents are very involved in their rehabilitation/recovery (e.g., by staying overnight in hospital) versus not involved • Age (0-3 versus 4-7 versus 8-12 versus 13-17)
18	Type and method of review	Intervention
19	Language	English
20	Country	England
21	Anticipated or actual start date	01/11/2019
22	Anticipated completion date	14/02/2020

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23	Stage of review at time of this submission	<table border="1"> <thead> <tr> <th>Review stage</th> <th>Started</th> <th>Completed</th> </tr> </thead> <tbody> <tr> <td>Preliminary searches</td> <td><input checked="" type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Piloting of the study selection process</td> <td><input checked="" type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Formal screening of search results against eligibility criteria</td> <td><input checked="" type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Data extraction</td> <td><input checked="" type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Risk of bias (quality) assessment</td> <td><input checked="" type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Data analysis</td> <td><input checked="" type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> </tr> </tbody> </table>	Review stage	Started	Completed	Preliminary searches	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Piloting of the study selection process	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Formal screening of search results against eligibility criteria	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Data extraction	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Risk of bias (quality) assessment	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Data analysis	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
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24	Named contact	National Guideline Alliance																					
25	Review team members	National Guideline Alliance																					
26	Funding sources/sponsor	This systematic review is being completed by the National Guideline Alliance which receives funding from NICE.																					
27	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.																					
28	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10105																					
29	Other registration details	-																					
30	Reference/URL for published	https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=130144																					

ID	Field	Content
	protocol	
31	Dissemination plans	
32	Keywords	
33	Details of existing review of same topic by same authors	
34	Current review status	
35	Additional information	
36	Details of final publication	www.nice.org.uk

ADL: Activities of daily living; ARMA: Arm activity measure; CCTR: Cochrane Controlled Trials Register; CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; CHQ-CF-80: 80 item child health questionnaire; CHQ PF-50: 50 item child health questionnaire, parent completed; COPM: Canadian occupational performance measure; DARE: Database of Abstracts of Reviews of Effects; DAS: Disability assessment schedule; DASH: Disabilities of the Arm, Shoulder and Hand; EADL: Extended activities of daily living; EURO-QoL 5D 3L: EuroQol 5 dimensions and 3 levels; FIMFAM: Functional independence measure and functional assessment measure; GAS: Goal attainment scaling; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HTA: Health Technology Assessment; ICU: intensive care unit; NG: Nasogastric; NGA: National Guideline Alliance; NICE: National Institute for Health and Care Excellence; NIHR: National Institute for Health Research; OARS: Older Americans resources and services; PAT: Performance ADL test; PEDS-QL: Paediatric quality of life inventory; PEG: Percutaneous endoscopic gastrostomy; PHQ-9: 9 item patient health questionnaire; PSMS: Physical self-maintenance scale; RCT(s): randomised controlled trial(s); RIG: Radiologically inserted gastrostomy; RoB: risk of bias; SCIM: Spinal cord independence measure; SF-12: 12 item short-form survey; SF-36: 36 item short-form survey; SF-6D: 6-dimension short-form; VAS: Visual analogue scale; WeeFIM; Paediatric functional independence measure