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

Table 7: Review protocol for physical rehabilitation interventions in adults

ID	Field	Content
0.	PROSPERO registration number	CRD42019135299
1.	Review title	Rehabilitation packages and programmes for adults
2.	Review question	2.1a: What physical rehabilitation interventions are effective and acceptable for adults with complex rehabilitation needs after traumatic injury?
3.	Objective	To evaluate the effectiveness of physical rehabilitation interventions among adults with complex rehabilitation needs after traumatic injury
4.	Searches	The following databases will be searched: • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE Searches will be restricted by: • Date: 1995 onwards as there has been significant change in practice since then • English language • Human studies The full search strategies for MEDLINE database will be published in the final review.
5.	Condition or domain being studied	Complex rehabilitation needs resulting from traumatic injury '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: • Vocational or educational social support for the person to return to their pervious functional level,

ID	Field	Content
		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 Traumatic injury is defined as 'traumatic injury as injury that requires admission to hospital at the time of injury.'
6	Population	Inclusion: Adults (aged 18 years or above) with complex rehabilitation needs resulting from traumatic injury that required admission to hospital Exclusion: • Adults with complex rehabilitation needs resulting from traumatic brain injury (including anoxic brain injury, for example, drowning and strangulation) • Adults with traumatic injuries who do not have complex rehabilitation needs and/or do not require admission to hospital • Adults with complex rehabilitation needs resulting from traumatic injury who are admitted to the ICU
7	Intervention	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: • 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)

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		• 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) Exclusion: • 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	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). 2) Studies that employ the same intervention program as listed under 'interventions' but vary it in terms of any of the following: • Frequency • Intensity • Timing
9	Types of study to be included	• Systematic review of RCTs • Randomised controlled trial If no RCT data are available for an intervention, evidence from the followings will be considered in order • 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	Study design:

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		• Cross-over design • Case-controls • Cross-sectional • Case series and case reports • Audits Language: • Non-English Publication status: • Abstract only
11	Context	Settings - Inclusion: All inpatient, outpatient and community settings in which rehabilitation services following traumatic injury are provided Exclusion: • Accident and emergency departments • Critical care units • Prisons
12	Primary outcomes (critical outcomes)	Critical: • Patient acceptability (any direct measure) • Changes in mobility (any measure) • Upper limb function (DASH, ARMA) Timeframe for the follow-up will be 0 to18 months. This will be grouped into short-term (0 to 6 months) and long-term (> 6 to 18 months).
13	Secondary outcomes (important outcomes)	Important: • Return to work or education • Pain [e.g., VAS] • Overall quality of life [EURO-QoL 5D 3L, SF-36, SF-12, SF-6D, SFMA]

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		• Changes in activity of daily living (COPM, Barthel ADL index, Katz, PSMS, OARS, PAT, EADL-Test, GAS, FIMFAM) Timeframe for the follow-up will be 0 to18 months. This will be grouped into short-term (0 to 6 months) and long-term (>6 to 18 months).
14	Data extraction (selection and coding)	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).
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	NGA STAR software will be used for generating bibliographies/citations, study sifting and data extraction. If pairwise meta-analyses are undertaken, they will be performed using Cochrane Review Manager (RevMan). 'GRADEpro' will be used to assess the quality of evidence for each outcome.
17	Analysis of sub-groups	No subgroups were specified for this question for stratification of the data, but if there is heterogeneity, we will look at the following subgroups to try to identify the source of it: • Upper limb / lower limb • People with pre-existing physical and/or mental health conditions (including substance misuse), physical and learning disability • Age below 65 years / age above 65 years • Frail / not frail • Vulnerable adults or those who require safeguarding
18	Type and method of review	Intervention
19	Language	English
20	Country	England
21	Anticipated or actual start date	23/10/2019

ID	Field	Content
22	Anticipated completion date	01/11/2020
23	Stage of review at time of this submission	Review stage / Started / Completed Preliminary searches ☑ ☑ Piloting of the study selection process ☑ ☑ Formal screening of search results against eligibility criteria ☑ ☑ Data extraction ☑ ☑ Risk of bias (quality) assessment ☑ ☑ Data analysis ☑ ☑
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.

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29	Other registration details	-
30	Reference/URL for published protocol	https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=135299
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; CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; COPM: Canadian Occupational Performance Measure; 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; NG: Nasogastric; NGA: National Guideline Alliance; NHS: National health service; NICE: National Institute for Health and Care Excellence; OARS: Older Americans Resources and Services; PAT: Performance ADL test; PEG: Percutaneous endoscopic gastrostomy; PHQ-9: 9 item Patient Health Questionnaire; PSMS: Physical Self-maintenance Scale; RCT: randomised controlled trial; RIG: Radiologically inserted gastrostomy; 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