

Research recommendations for review questions:

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

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

Also applicable for the following review questions:

B.2 What cognitive rehabilitation interventions are effective and acceptable for adults/children and young people with complex rehabilitation needs after traumatic injury?

B.3 What psychological and psychosocial rehabilitation interventions are effective and acceptable for adults/children and young people with complex rehabilitation needs after traumatic injury?

B.4 What rehabilitation interventions relating to participation in society (e.g., return to work, education or training) are effective and acceptable for adults/children and young people with complex rehabilitation needs after traumatic injury?

Research question

What is the effectiveness of intensive rehabilitation programme in adults with complex rehabilitation needs after a traumatic injury?

Why this is important?

- Standard care rehabilitation for individuals with the most severe injuries and complex rehabilitation needs is provided as a prolonged therapy (over many months), often lacks coordination, and generally is associated with poor outcomes.
- There is emerging evidence from military studies that intensive inpatient or outpatient rehabilitation programmes comprising a holistic package (e.g. physical, cognitive, psychological interventions) positively impact outcomes (e.g. function, pain, quality of life and mental health outcomes).
- Clinical experience also indicates that periodic intensive rehabilitation delivered at the time point that is deemed most beneficial for the patient (e.g. when a patient can commence weight bearing on all limbs; when a patient is returning to work or higher level function) is associated with improvements in outcomes.
- Currently, it takes months to achieve outcomes that could be achieved within weeks with an intensive rehabilitation programme. This negatively impacts an individual's recovery and has a detrimental impact on their quality of life and general wellbeing for many months. An individual might also be dependent on care for many months.
- Intensive rehabilitation is potentially associated with high intervention costs; also there may be a need for more than one programme of intensive rehabilitation. However, it may reduce future health and care costs due to a quicker recovery.

Table 82: Research recommendation rationale

Research question	
Why is this needed	
Importance to ‘patients’ or the population	At some recovery point, depending on factors such as weight-bearing, psychological state, number and pattern of injuries, immobilisation period, and healing rate, a concentrated rehabilitation block may be helpful for a patient. Intensive, coordinated rehabilitation improves the functional outcome of patients with complex trauma in the months post-injury, speeds up recovery, leads to improvements in their health-related quality of life and general well-being, and increases the chance of their returning to work early. It can also improve outcomes for carers of those affected by traumatic injury.
Relevance to NICE guidance	High - The committee were unable to issue definite recommendations on intensive rehabilitation due to a lack of evidence and potential resource implications. The committee used expert testimony and findings from exploratory economic analysis to make weak recommendations in this area. By conducting research in this area, it is hoped that a more definitive NICE guidance on intensive rehabilitation can be issued in future iterations of this guideline.
Relevance to the NHS	High - It already exists for some NHS patient groups, e.g. amputees (Clinical Commissioning Group, level 2b funding). The committee explained that there is a trade-off between patient outcomes and resource use. Intensive rehabilitation has high intervention costs with a potential for more than one programme of intensive rehabilitation. Intensive rehabilitation leads to quicker recovery, better outcomes, and potentially lower future health and care costs. It is essential to identify whether providers could reconfigure their services to provide short programmes of intensive rehabilitation rather than prolonged therapy input and whether that would represent an effective and cost-effective practice to the NHS.
National priorities	<ul style="list-style-type: none"> • Research into the intensity of rehabilitation following traumatic injury is important to the NHS long-term plan by promoting high quality care which is safe, effective and focused on patient experience. Personalised care plans focused on the return to full function employment feature in the NHS long-term plan. Also, The Principles and Expectations for Good Adult Rehabilitation – June 2015 focused on peoples’ needs not diagnosis, includes vocational outcomes and people’s changing needs.

Research question	
Current evidence base	At the time of searching there were no RCTs or cohort studies in the literature.
Equality	Intensive rehabilitation is already available for some NHS patient groups, e.g. amputees. All people with complex trauma deserve to receive optimal care, just like other patient groups, to achieve the best possible outcomes.
Feasibility	Ideally, a prospective multi-centre randomised study for adults (aged 18 years and above) with complex rehabilitation needs resulting from traumatic injury that required admission to hospital with randomisation to either intensive rehabilitation or control will be conducted. However, such a trial may be challenging to run because the majority of potential participating trauma units will not be set up to provide intensive rehabilitation. A prospective comparative cohort study will allow trauma units to continue with their current protocols and should have little impact on their practice.
Other comments	• None.

NHS: National Health Service; NICE: National Institute for Health and Care Excellence; RCT: randomised controlled trial

Table 83: Research recommendation modified PICO table

Criterion	Explanation
Population	<ul style="list-style-type: none"> Adults (aged 18 years and above) with complex rehabilitation needs resulting from traumatic injury that requires admission to hospital
Intervention	<ul style="list-style-type: none"> Periodic intensive rehabilitation (in ≤3 week blocks) in addition to standard care rehabilitation
Comparator	<ul style="list-style-type: none"> Standard care rehabilitation services
Outcomes	<ul style="list-style-type: none"> Overall quality of life (validated scales) Patient acceptability (any direct measure) Changes in activity of daily living (validated scales) Changes in mood (validated scales) Return to work Return to education Resource use i.e. acute length of stay in trauma unit, hospital re-admissions, outpatient visits, primary and community care visits Cost-effectiveness
Study design	<ol style="list-style-type: none"> Randomised controlled trial Prospective comparative cohort study (minimum sample size ≥ 100 per arm)
Timeframe	<ul style="list-style-type: none"> >12 months
Additional information	None.

Research question

What is the effectiveness of intensive rehabilitation programme in children and young people with complex rehabilitation needs after a traumatic injury?

Why this is important?

- Standard care rehabilitation for individuals with the most severe injuries and complex rehabilitation needs is provided as a prolonged therapy (over many months), varies across trauma centres, often lacks coordination, and particularly after discharge may be associated with long waits and poor outcomes.
- There is emerging evidence from military studies (involving some individuals aged below 18 years) and studies in children and young people with acquired brain injury that intensive inpatient or outpatient rehabilitation programmes comprising a holistic package (e.g. physical, cognitive, psychological interventions) positively impact outcomes (e.g. function, pain, quality of life and mental health outcomes).
- Clinical experience also indicates that periodic intensive rehabilitation delivered at the time point that is deemed most beneficial for the patient (e.g. when a patient can commence weight bearing on all limbs; when a patient is returning to nursery, education or higher level function) is associated with improvements in outcomes.
- Currently, it takes months to achieve outcomes that could be achieved within weeks with an intensive rehabilitation programme. This negatively impacts an individual's recovery; prolongs hospital stays and has a detrimental impact on their quality of life and general wellbeing for many months. An individual might also be dependent on care for many months.
- Intensive rehabilitation is potentially associated with high intervention costs; also there may be a need for more than one programme of intensive rehabilitation. However, it may reduce length of inpatient stay, future health and care costs due to a quicker recovery.

Table 84: Research recommendation rationale

Research question	
Why is this needed	
Importance to 'patients' or the population	At some recovery point, depending on factors such as weight-bearing, psychological state, number and pattern of injuries, immobilisation period, and healing rate, a concentrated rehabilitation block may be helpful for a patient. Intensive, coordinated rehabilitation improves the functional outcome of patients with complex trauma in the months post-injury, speeds up recovery, leads to improvements in their health-related quality of life and general well-being, and increases the chance of their returning to nursery, education or work early. It can also improve outcomes for carers of those affected by traumatic injury.
Relevance to NICE guidance	High - The committee were unable to issue definite recommendations on intensive rehabilitation due to a lack of evidence and potential resource implications. The committee used expert testimony and findings from exploratory economic analysis to make weak recommendations in this area. By conducting research in this area, it is hoped that a more definitive NICE guidance on intensive rehabilitation can be issued in future iterations of

Research question	
	this guideline.
Relevance to the NHS	High - It already exists for some NHS patient groups, e.g. amputees (Clinical Commissioning Group, level 2b funding). The committee explained that there is a trade-off between patient outcomes and resource use. Intensive rehabilitation has high intervention costs with a potential for more than one programme of intensive rehabilitation. Intensive rehabilitation leads to quicker recovery, better outcomes, and potentially lower future health and care costs. It is essential to identify whether providers could reconfigure their services to provide short programmes of intensive rehabilitation rather than prolonged therapy input and whether that would represent an effective and cost-effective practice to the NHS.
National priorities	<ul style="list-style-type: none"> Research into the intensity of rehabilitation following traumatic injury is important to the NHS long-term plan by promoting high quality care which is safe, effective and focused on patient experience. Personalised care plans focused on the return to full function employment feature in the NHS long-term plan. Also, The Principles and Expectations for Good Adult Rehabilitation – June 2015 focused on peoples' needs not diagnosis, includes vocational outcomes and people's changing needs.
Current evidence base	At the time of searching there were no RCTs or cohort studies in the literature.
Equality	Intensive rehabilitation is already available for some NHS patient groups, e.g. amputees. All people with complex trauma deserve to receive optimal care, just like other patient groups, to achieve the best possible outcomes.
Feasibility	Ideally, a prospective multi-centre randomised study for children and young people (aged below 18 years) with complex rehabilitation needs resulting from traumatic injury that required admission to hospital with randomisation to either intensive rehabilitation or control will be conducted. However, such a trial may be challenging to run because the majority of potential participating trauma units will not be set up to provide intensive rehabilitation. A prospective multi-centre comparative cohort study will allow trauma units to continue with their current protocols and should have little impact on their practice.
Other comments	<ul style="list-style-type: none"> None.

NHS: National Health Service; NICE: National Institute for Health and Care Excellence; RCT: randomised controlled trial

Table 85: Research recommendation modified PICO table

Criterion	Explanation
Population	<ul style="list-style-type: none"> Children and young people (aged below 18 years) with complex

Criterion	Explanation
	rehabilitation needs resulting from traumatic injury that requires admission to hospital
Intervention	<ul style="list-style-type: none"> • Periodic intensive rehabilitation (in 3 week blocks) in addition to standard care rehabilitation
Comparator	<ul style="list-style-type: none"> • Standard care rehabilitation services
Outcomes	<ul style="list-style-type: none"> • Overall quality of life (validated scales) • Patient and family acceptability (any direct measure) • Changes in activity of daily living (validated scales) • Changes in mood (validated scales) • Return to nursery, education or work • Resource use i.e. acute length of stay in trauma unit, hospital re-admissions, outpatient visits, primary and community care visits • Cost-effectiveness
Study design	<ol style="list-style-type: none"> 1. Randomised controlled trial 2. Prospective comparative cohort study (minimum sample size \geq 100 per arm)
Timeframe	<ul style="list-style-type: none"> • >12 months
Additional information	None.

Research question

What are the benefits and harms of using thoracic lumbar sacral orthoses in older people with thoraco-lumbar vertebral fractures?

Why this is important

The thoracolumbar spine is the most commonly injured segment of the spinal column. Older people are particularly vulnerable to vertebral fractures due to osteoporosis. Many spinal injuries are managed conservatively without operative intervention. Historically, orthoses, such as the thoracic lumbar sacral orthosis, have been used as a conservative treatment strategy for thoraco-lumbar vertebral fractures. The evidence base for their benefit is heterogeneous and generally of low quality. Side effects, poor tolerance and increased hospital length of stay have been reported with their use, particularly in older people, and yet they remain commonly used in current practice. Establishing the true benefit or harms of these devices would allow better informed clinical decision making and could have important effects upon quality of life for people with spinal injuries.

Table 86: Research recommendation rationale

Research question	
Why is this needed	
Importance to 'patients' or the population	High – The use of spinal orthoses for the conservative management of thoraco-lumbar injuries is widespread.
Relevance to NICE guidance	High – The committee were unable to issue any recommendation on the use of thoracic lumbar sacral orthoses (TLSO) due to evidence only being found in younger people, which conflicted with the committee's knowledge and experience. By conducting research in this area, it is hoped that clearer NICE guidance on this can be issued.
Relevance to the NHS	Medium – The use of TLSO as a treatment

Research question	
	strategy has been reported to result in increased length of hospital stay. The orthoses themselves can also be expensive and the socio-economic consequences of their use have not been fully established.
National priorities	Research into the use of TLSO in older people following spinal injury is important to the NHS long-term plan by promoting high quality care which is safe, effective and focused on patient experience.
Current evidence base	At the time of searching there were no RCTs or cohort studies that met our inclusion criteria in the literature for this population.
Equality	The evidence located for TLSO was largely found in younger people. The committee discussed that TLSO were well-tolerated for young people, but that they could increase the risk of adverse events and increased length of hospital stay in older people. By conducting research in the older population, the benefits and harms of TLSO can be quantified which will clarify the best non-surgical treatment options for people over 65 years old.
Feasibility	Ideally a prospective multi-centre randomised study for patients ≥ 65 years of age with thoraco-lumbar fractures who are being managed conservatively with randomisation to either thoracic lumbar sacral orthosis or control. However, such a trial may have difficulties recruiting adequate numbers due to the risk of side effects, poor tolerance and increased length of hospital stay. A prospective or retrospective comparative cohort study will allow trauma units to continue with their current spinal injury protocols and should have little impact on their practice.
Other comments	None

TLSO: Thoracic lumbar sacral orthoses

Table 87: Research recommendation modified PICO table

Criterion	Explanation
Population	Older adults (aged ≥ 65 years) with thoraco-lumbar vertebral fractures as a result of traumatic injury that required admission to hospital and are being managed non-operatively.
Intervention	Thoracic lumbar sacral orthoses
Comparator	No orthosis
Outcomes	<ul style="list-style-type: none"> • Patient acceptability (any direct measure) • Mobility (validated scales) • Pain (Numerical rating scale, visual assessment scale) • Overall quality of life (validated scales) • Activities of daily living (validated scales)
Study design	<ol style="list-style-type: none"> 1. Randomised controlled trial 2. Prospective comparative cohort study (minimum sample size ≥ 100 per arm)

Criterion	Explanation
	3. Retrospective comparative cohort study (minimum sample size \geq 100 per arm)
Timeframe	0 months to 18 months
Additional information	None