Research – Length of High Intensity Intervention for ABI, SCI and Amputees

Brief	In order to develop business rules for the amount of funding to include as a capacity building support within the Participant Budget Model, the following information will assist us: • For the following disability groups: Acquired Brain injury, including Traumatic Brain Injury (TBI), stroke, brain tumour AND spinal injury AND amputations as separate groups. • What is considered best practice in terms of: a) The length of time for which high intensity therapy supports are considered effective after onset? b) How long does high intensity rehab continue post spinal cord injury or amputation? There is a period of time (previously termed 'spontaneous recovery') when it is considered that the brain is more amenable to learning new information/skills after a brain injury. In the past it was accepted that this period of relatively rapid learning would then be followed by a plateau, when limited new learning was possible. c) What is the current thinking regarding: i) whether there is a plateau; and ii) when this point is reached for brain injuries? We are considering the possibility of 5 years as an appropriate time to cease high intensity rehabilitation, and "switch" to maintenance/monitoring supports for brain injuries; and 2 years for spinal cord injuries or amputations. d) Is there any research evidence for this? e) Does this align with research and length of time for improvement post acquired injury?
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Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters.

The contents of this document are OFFICIAL

1 Contents

2 Summary

- Because randomised controlled trials (RCTs) often have limited funding, interventions are rarely delivered past the 12 month mark. Because of this, we can only make assumptions about the effectiveness of rehabilitation for TBI past these timeframes.
    - The consensus is, the earlier intervention occurs the better.
    - The timeline and level of recovery differs between patients. Therefore, the length of rehabilitation should be guided by the patient's needs.
- Most commonly, the plateau for TBI improvement is around the 2 year mark. However, various studies have put the range anywhere from 6 months to 2 years.

- Most spinal cord injury (SCI) cases reach a plateau by 9 months after injury. However, additional recovery may occur up to 12–18 months.
- There is no agreement on duration and intensity of intervention in the acute and post-acute phases of SCI
    - Most studies implement intervention over 6 to 12 weeks.
    - Rehabilitation should be implemented when patients are medically stable and can tolerate the required intensity.

- Unable to determine a timeframe for plateau in relation to amputees, however, the time needed to progress through rehabilitation phases is consistently reported to be between 12 and 18 months.

3 Traumatic Brain Injury

3.1 Length of time high therapy supports are effective

Systematic reviews investigating intensive multidisciplinary rehabilitation (in the post-acute stage) on average implement the intervention for less than 6 months and follow up study participants anywhere between 6-24 months. Refer to Table 1 for more details.

The length of time over which rehabilitation may have its effects (always many months and usually several years) is usually longer than any funded research project [1].

Benefits of neurological rehabilitation typically accrue over several years, rather than over weeks or months. RCTs are typically conducted over a much shorter time. Definitive RCTs in this area should be funded to include follow-up over three to five years but this is rarely possible under existing funding programmes. Furthermore, studies with long follow up periods tend to have high dropout rates, leading to less meaningful results due to smaller sample [2].

For patients engaged in rehabilitation, intervention should be offered as intensively as possible and should begin as early as possible, although the balance between intensity and cost-effectiveness has yet to be determined [2].

3.2 Recovery Plateau

Review of the existing TBI cognitive recovery literature indicates that recovery does indeed occur after TBI and that recovery curves are likely to be differentially sensitive to both recovery domain and time [3]. Most studies have employed global measures of functional outcome including: vocational status, Glasgow Outcome Scale, the Disability Rating Scale, the Community Integration Questionnaire, and the Functional Independence Measure [3].

Recovery is detectable, asymptotic (when more than 3 points are measured), and commonplace after TBI. Studies remain ambiguous about the pace of change over time and the point at which a plateau in recovery is achieved [3]. Expressly, some studies observe continued recovery as late as **2 years** post injury [4-6] while others note no further recovery after **1 year** [3, 7], while still others indicate full recovery as early as **6 months** post injury [8, 9]. The discrepancies between findings may be attributable to the disparity across studies with regard to both study design and outcome measures [10].

Longer term longitudinal studies investigating post injury outcomes have shown mixed results. Newcombe [11] found that veterans who had had a head injury in the showed no

evidence of deterioration many years after injury. This might have been due to the expert and systematic care they received very soon after the injury. But other researchers found that a proportion of patients deteriorated when assessed 10-20 years later. In contrast, Dams-O'Connor, Ketchum [12] found a decline in functioning and decreased independence 5 years post injury. Similar results were also found by Millar, Nicoll [13] and Olver, Ponsford [14], however, a percentage of patients did make improvements. Furthermore, Ponsford, Downing [2] assessed patients at 2, 5 and 10 years post injury and found that problems that were evident at two years post-injury persisted until 10 years post-injury.

Rate of improvement varies from person to person. Currently, we don't know the exact reason why the rate is different between people. However, age, pre-injury health, abilities and severity of injury have an impact on recovery.

3.3 Impairment two years after brain injury

Research from the TBI Model System program offers information about recovery from a moderate to severe TBI at 2 years after injury [15].

- About 30% of people need some amount of assistance from another person.
    - This may be during the day, at night, or both. Over time, most people can move around again without help.
- Trouble with thinking is common.
    - This includes how fast a person can think. It also includes forming new memories. The severity of these problems varies.
- About 25% of people have major depression.
    - In some cases, it's caused directly by the brain injury. In addition, people with TBI are also dealing with major changes in their lives caused by the trauma, including changes in employment, driving, and living circumstances.
- Just over 90% of people live in a private home.
    - Of those who were living alone when they were injured, almost half go back to living alone.
- About 50% of people can drive again, but there may be changes in how often they drive or when.
- About 30% of people have a job, but it may not be the same job they had before the injury.

4 Spinal Cord Injury

4.1 Length of time high therapy supports are effective

A systematic review by Burns, Marino [16] sought to answer various questions relating the type and timing of acute and subacute SCI. The results found that the evidence base is limited for many fundamental questions related to rehabilitation following acute and subacute SCI and there is no agreement in relation to timing, intensity and response [16]. These knowledge gaps include the timing of rehabilitation, nature of rehabilitation (specific interventions), therapeutic dose (intensity, frequency, and duration), role and impact of patient and injury characteristics, cost-effectiveness and efficiency of alternative interventions [16].

Of the studies included in the systematic review, the intervention lasted anywhere from 6 to 12 weeks [16]. This is likely because of similar reasons mentioned above for TBI (i.e. lack of funding for trials). Follow up was up to 12 months.

Recommendations arising from this review include [17, 18]:

- Rehabilitation be offered to patients with acute SCI **when they are medically stable and can tolerate required rehabilitation intensity.** (Grade: Weak Recommendation; No included studies)
- Offer body weight–supported treadmill training as an option for ambulation training in addition to conventional overground walking, dependent on resource availability, context, and local expertise. (Grade: Weak Recommendation; Low Evidence)
- Individuals with acute and subacute cervical SCI be offered functional electrical therapy as an option to improve hand and upper extremity function. (Grade: Weak Recommendation; Low Evidence)
- Based on the absence of any clear benefit, suggest not offering additional training in unsupported sitting beyond what is currently incorporated in standard rehabilitation. (Grade: Weak Recommendation; Low Evidence)

4.2 Recovery Plateau

In the clinical management of spinal cord injury (SCI), neurological outcomes are generally determined at 72 h after injury using American Spinal Cord Injury Association scoring system [19]. This time-point has shown to provide a more precise assessment of neurological impairments after SCI [20]. One important predictor of functional recovery is to determine whether the injury was incomplete or complete. As time passes, SCI patients experience some spontaneous recovery of motor and sensory functions. Most of the functional recovery occurs during the first 3 months and in most cases reaches a plateau by 9 months after injury [19, 21, 22]. However, additional recovery may occur up to 12–18 months post-injury [19, 21, 22]. Long term outcomes of SCI are closely related to the level of the injury, the severity of the primary injury and progression of secondary injury.

5 Amputation

5.1 Length of time high therapy supports are effective

Unable to locate precise intensity and duration of multidisciplinary interventions for amputees. However, the US Department of Veterans Affairs have developed a clinical practice guideline for lower limb amputation [23]. For the purpose of the guideline, the postoperative continuum is separated into "phases". These include

1) Preoperative phase
2) Immediate postoperative phase
3) Pre-prosthetic rehabilitation phase
4) Prosthetic training phase. A study by Johannesson, Larsson [24] found that 64% of participants obtained good function with their prosthesis within 6 months.
5) Rehabilitation and prosthesis follow up phase

The advancement through these phases is largely individualized, however the time needed to progress is consistently reported to be between **12 and 18 months** [23].

The NSW Agency for Clinical Innovation states that follow-up should occur regularly in the initial period for example, fortnightly/monthly for a few months, then 3-monthly, then 6-monthly [25]. Once the residual limb has stabilised, follow-up should occur, at minimum, on an annual basis. This plan may vary depending on the needs of the person [25].

5.2 Recovery Plateau

Unable to locate any details relating to a recovery plateau for amputees in the literature. It is clear however, the length of time often required before maintenance intervention should be implemented.

Table 1. Studies of rehabilitation following TBI, SCI or amputation

Author	Aim/Objective	Methods	Results	Level & Quality of evidence
Turner-Stokes, Pick [1]	To assess the effects of multi-disciplinary rehabilitation following ABI in adults 16 to 65 years of age.	**Systematic Review** RCTs comparing multi-disciplinary rehabilitation versus routinely available local services or lower levels of intervention; or trials comparing an intervention in different settings, of different intensities or of different timing of onset. 16 to 65 years of age, with ABI from any cause.	19 studies involving 3480 people. Mild brain injury: information and advice were usually more appropriate than intensive rehabilitation. Variable intervention length. Often less than 6 months. 6-12 months was the most common length of study/follow-up period. Patients with moderate to severe brain injury who received more intensive rehabilitation showed earlier improvement, and that earlier rehabilitation was better than delayed treatment. Strong evidence supports the provision of cognitive rehabilitation in an environment in which patients receive predominantly group-based rehabilitation alongside a peer group of others who are facing similar challenges. Rehabilitation for brain injury is such an individualised and long-term process that research studies do not necessarily facilitate general conclusions.	Level: 1 Quality: High Rehabilitation for brain injury is an individualised and long term process that research studies do not necessarily facilitate general conclusions.

Table 1. Studies of rehabilitation following TBI, SCI or amputation

Author	Aim/Objective	Methods	Results	Level & Quality of evidence
Königs, Beurskens [26]	Review evidence on the effects of timing and intensity of neuro-rehabilitation on the functional recovery of patients with moderate to severe TBI.	**Systematic Review and Meta-analysis** Prospective controlled clinical trials Eleven articles were included Two independent authors performed data extraction and risk of bias analysis using the Cochrane Collaboration tool Patients with moderate to severe TBI compared with usual care.	6 RCTs, 1 quasi-randomized trial, and 4 controlled trials revealed consistent evidence for a beneficial effect of early onset neuro-rehabilitation in the trauma centre and intensive neuro-rehabilitation in the rehabilitation facility on functional outcome compared with usual care. Meta-analytic quantification revealed a large-sized positive effect for early onset rehabilitation programs (d =1.02; P<.001) and a medium-sized positive effect for intensive Neuro-rehabilitation programs (d= 0.67; P<.001) compared with usual care. Intervention duration was a maximum of 6 months. Intensity was at least 20 therapy hours per week (i.e., 4-5 therapy hours per day, during 4-5d/week).	Level: I Quality: Moderate Early onset neuro-rehabilitation in the trauma centre and more intensive neuro-rehabilitation in the rehabilitation facility have beneficial effects on the functional recovery of patients with TBI compared with usual care. ***Optimal timing and intensity of neuro-rehabilitation remains unknown.*** More research is needed to determine the gain of early and intensive neuro-rehabilitation in younger patients, with greater potential for neural plasticity and functional recovery and a longer period for return on personal, societal, and economic investment.
Ponsford, Downing [2]	To examine aspects of function, previously shown to be affected following TBI, over a span of 10 years.	**Longitudinal Follow up Study** All participants (moderate to severe TBI) received inpatient rehabilitation, during which they typically received 3–5 h daily of physiotherapy, occupational therapy and speech therapy, neuropsychological	141 patients with TBI were assessed at two, five, and 10 years post-injury. Fatigue and balance problems were the most common neurological symptoms, with reported rates decreasing only slightly during the 10-year period.	Level: II Quality: Moderate There is a need for rehabilitation programs to put a greater focus on the cognitive, behavioural, psychological, and social problems

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		assessment, and social work services. This was generally followed by outpatient or community based rehabilitation, with continuing therapy as needed. Therapy services were received over an average **9 month period**, although there was considerable variability according to individual needs. The Structured Outcome Questionnaire was used to assess participant outcomes.	Mobility outcomes were good in more than 75% of patients, with few participants requiring aids for mobility. Changes in cognitive, communication, behavioural, and emotional functions were reported by approximately 60% of the sample at all-time points. Levels of independence in activities of daily living were high during the 10-year period, and as many as 70% of subjects returned to driving. Nevertheless, approximately 40% of patients required more support than before their injury. Only half the sample returned to previous leisure activities and fewer than half were employed at each assessment time post-injury. Older age at injury did not substantially alter the pattern of changes over time, except in employment. Overall, problems that were evident at two years post-injury persisted until 10 years post-injury.	that impede community participation.
Khan, Amatya [27]	To assess the effectiveness of multidisciplinary rehabilitation in people after primary brain tumour treatment, especially the types of approaches that	**Systematic Review** Adults aged 18 years and older. Confirmed diagnosis of brain tumour, regardless of time of onset or disease stage according to the WHO	Only a single study included. N = 106 (with gliomas): treatment group = 53, control group= 53 Treatment group: individualised high-intensity outpatient multidisciplinary rehabilitation programme, up to 3 one-hour sessions of interrupted therapy/week, comprising half-hour	Level: II Quality: Moderate

Table 1. Studies of rehabilitation following TBI, SCI or amputation

Author	Aim/Objective	Methods	Results	Level & Quality of evidence
	are effective (settings, intensity).	classification of tumours of the central nervous system. All RCTs and controlled clinical trials. Only multidisciplinary interventions were included. Timing of outcome measures The time points for outcome assessments and follow-up were: Short term (immediately after intervention or up to three months) and Long term (greater than three months) from the start of the intervention.	blocks of therapy sessions (occupational, social, psychological, and physiotherapy), 2 to 3 times per week for 6 to 8 weeks. Assessment time points: baseline, 3 months, and 6 months 'Low-level' evidence to support high-intensity ambulatory (outpatient) multidisciplinary rehabilitation in reducing short- and long-term motor disability (continence, mobility and locomotion, cognition), when compared with standard outpatient care.	

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