Body Weight Supported Treadmill Training for Spinal Cord Injury

Plain language summary

When people have a spinal cord injury (SCI), it often affects their walking. Some people need help to walk, or walking aides (like walking frames), and some cannot walk at all. Those who can walk may have problems with: balance, coordination, small steps, one leg doesn't move or moves differently to the other.

Body weight supported treadmill training (BWSTT) aims to improve walking in patients with SCI. It trains them to walk more normally through repeated practice. It involves a harness to hold the patient over a treadmill. This supports their weight to make it easier to practice walking. Different methods can be used to help move the patient's legs, such as:

- Two physiotherapists move one of the patient's legs each
- The patient's legs are strapped into a machine (robot) that moves their legs
- Electrical currents are used to trigger movement in leg muscles

There is not enough evidence to assess whether the benefits and harms of BWSTT are better, worse, or the same as other types of walking training.

Body Weight Supported Treadmill Training for Spinal Cord Injury

Evidence summary

Overview

The most comprehensive, up-to-date, high quality systematic review (SR)[1] identified four randomised controlled trials (RCTs) investigating the effectiveness of BWSTT in improving walking function for people with SCI. The studies found no difference in effect between BWSTT and other locomotor training strategies. However, small sample sizes and methodological flaws in the design of these studies lead the authors of the SR to conclude that there was insufficient evidence to determine whether the benefits and harms of BWSTT are better, worse or the same as other locomotor training strategies.

In what clinical conditions is this intervention indicated for use?

Approved indications: unknown
The SR used for this report included patients with a traumatic spinal cord injury, with any level of traumatic incomplete lesion, that is with an AIS (ASIA [American Spinal Injury Association] Impairment Scale) score of B, C or D, regardless of the duration of illness (acute or chronic SCI) or level of initial walking capacity.

What is the effectiveness of this intervention (short and long term benefits) for both complete and incomplete SCI?

There was insufficient evidence to assess the benefits of BWSTT (with or without electrical stimulation or robotics) on walking function after SCI when compared to all other training approaches.

What is the effect of this intervention on mobility, function, quality of life and return to work for SCI?

Mobility: insufficient evidence to determine the effect of BWSTT on mobility
Function: insufficient evidence to determine the effect of BWSTT on function
Quality of life: not investigated
Return to work: not investigated

If it is effective, what is the correct "dose" or training regime – time on machine, time since injury?

Not Applicable

What is the cost-effectiveness of this intervention for SCI?

Not investigated by included studies

Which patient groups/conditions are excluded from this intervention?

Non-approved indications: unknown
The SR used for this report excluded patients with an AIS score of A (complete SCI)

What are the risks associated with use of this intervention?

Safety of exercise: insufficient evidence to determine the effect of BWSTT on safety of exercise

Transport Accident Commission & WorkSafe Victoria

Evidence Service

Body Weight Supported Treadmill Training for Spinal Cord Injury

Evidence Review

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Driss Ait Ouakrim, Emma Donoghue

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BACKGROUND

Since the early nineties and the publication of the first studies in body-weight supported treadmill training (BWSTT) for spinal cord injury (SCI), there has been a growing interest in this technique and its potential benefits[2]. SCI rehabilitation strategies are based on the principle that locomotor functions may improve by repetitive practice of walking, due to mechanisms of neuroplasticity.[1, 3-5] Many studies assessing treadmill-based training, or more sophisticated automated electromechanical gait machines, have reported positive results in terms of patients' walking capacity and wellbeing[2]. These findings however were mainly based on evidence from case reports and cohort studies.

In Australia, about 300–400 new cases of SCI from traumatic and non-traumatic causes occur each year[6]. The decreased mortality and improvements in life expectancy have resulted in an increasing prevalence of patients living with SCI[6]. The age-standardised SCI incidence rate for Australia is 14.5 per million persons and by 2021 the prevalent population is predicted to be between 10,500 and 12,000. Based on 2005 cost estimates, the ongoing costs associated with the long-term care of the prevalent population are estimated to be nearly A$500 million per year[6].

In order to develop policies for the use of BWSTT in patients with complete or incomplete SCI, the Transport Accident Commission and WorkSafe Victoria (TAC/WSV) Health Services Group requested a review of the evidence supporting BWSTT techniques and strategies in terms of effectiveness, cost and potential associated risks.

QUESTIONS

This Evidence Review sought to find the most up-to-date, high quality source of evidence to answer the following questions regarding Body Weight Supported Treadmill Training (BWSTT) (with or without electrical stimulation or robotics) in comparison to other locomotor training techniques, for spinal cord injury (SCI).

- In what conditions is this intervention indicated?
- What is the effectiveness (short and long term benefits) for both complete and incomplete SCI?
- What is the effect of this intervention on mobility, function, quality of life and return to work for SCI?
- If it is effective, what is the correct "dose" or training regime – time on machine, time since injury?
- What is the cost-effectiveness of this intervention for SCI?
- Which patient groups/conditions are excluded from this intervention?
- What are the risks associated with use of this intervention?

METHODS

Methods are outlined briefly below. More detailed information about the methodology used to produce this report is available in Appendices 1 and 2. All appendices are located in the Technical Report accompanying this document.

A comprehensive search of Medline, Embase, the Cochrane Library, Compendex (Engineering), Pedro and Sportsdiscus (sporting) was undertaken in December 2010 to identify relevant synthesised research (i.e. evidence-based guidelines (EBGs), systematic reviews (SRs), health technology assessments (HTAs)), and any relevant randomised controlled trials (RCTs) and controlled clinical trials (CCTs). A comprehensive search of the internet, relevant websites and electronic health databases was also undertaken (see Appendix 2, Tables A2.2-A2.4 for search details). Reference lists of included studies were also scanned to identify relevant references.

Studies identified by the searches were screened for inclusion using specific selection criteria (see Appendix 2, Table A2.1). Synthesised evidence (EBGs, SRs and HTAs) that met the selection criteria were reviewed to identify the most up-to-date and comprehensive source of evidence, which was then critically appraised to determine whether it was of high quality. This process was repeated for additional sources of evidence, if necessary, until the most recent, comprehensive and high quality source of evidence was identified. Findings from the best available source of evidence were compared to other evidence sources for consistency of included references and findings.

The available synthesised evidence was mapped (see Table 2), and the algorithm in Table 1 was followed to determine the next steps necessary to answer the clinical questions.

Table 1. Further action required to answer clinical questions

Is there any synthesised research available? (e.g. EBGs, HTAs, SRs, RCTs)				
Yes			No	
Is this good quality research?			Are RCTs available?	
Yes		No	Yes	No
Is it current (within 2 years)?				
Yes	No			
No further action	Update existing SR	Undertake new SR	Undertake new SR	Consider looking for lower levels of evidence

Data on characteristics of all included studies were extracted and summarised (see Appendix 4). The most recent, relevant, high quality systematic review was used to address the questions posed above.

RESULTS

A search of electronic databases conducted in December 2010 yielded 380 potentially relevant journal articles. After reviewing the title, abstract or full text, six SRs[1, 7-11], five RCTs[2, 5, 12-14], and one CCT[15] were found that met the selection criteria. Internet searches yielded no additional references. On closer inspection, one SR[7] and one RCT[13] were excluded as they had only been published as abstracts for conferences and there was not enough information to properly assess the risk of bias in each of these studies. The RCT[13] was also excluded as it reported on a mixed group of spinal and stroke patients and it was not possible to separate out results for the SCI patients. An additional SR paper was excluded[9] as it was one of two papers that reported findings from the same SR, we only included one of these papers[1].

Searches yielded a total of nine studies (four SRs[1, 8, 10, 11], four RCTs[2, 5, 12, 14] and one CCT[15]; see Table 2) of BWSTT for SCI published between 2000 and 2010 that met our selection criteria (see Appendix 2 Table A2.1 for selection criteria). A list and summary of included studies can be found in Appendices 3 and 4, respectively.

Table 2. Evidence map of identified studies by study-type

Synthesised Studies		Primary studies	TOTAL
EBGs	SRs & HTAs		
0	4 SRs	4 RCTs, 1CCT	9

Although the focus of this Evidence Review was on BWSTT for both complete and incomplete SCI, none of the identified SRs included RCTs of patients with complete SCI.

Of the three most recent systematic reviews identified,[1, 10, 11] only one (Mehrholz et al[1]) assessed all the interventions of interest. The SR by Swinnen et al[10] excluded functional electrical stimulation and BWS systems without robot-assisted gait training. Similarly the SR by Wessels et al[11] excluded trials that included co-interventions (i.e. BWSTT with FES). Although the Mehrholz SR[1] was not the most recent, it was used as the basis of this report (see Table 3) due to its greater relevance to the question and the fact that it reviewed all of the RCTs included in the more recent SRs by Swinnen[10] and Wessels[11]. Quality appraisal also found this to be a high quality systematic review with a low risk of bias (see Appendix 5, Table A5.1).

An additional RCT that was not included in any of the selected SRs was identified (Nooijen et al., 2009[14]). This study was an update of an RCT[2] quality appraised and included in the SR by Mehrholz et al.,[1] therefore, quality appraisal was not performed on Nooijen et al.[14] Also, this RCT update[14] reported on different gait-related outcomes to those reported in the original study[2] and found no statistically significant difference between locomotor training strategies for any of the gait parameters assessed, which was consistent with its previous findings[2].

Table 3. Key information from most recent, comprehensive, high quality systematic review

Mehrholz J, Kugler J, Pohl M. Locomotor training for walking after spinal cord injury. Cochrane database of systematic reviews (Online). 2008(2):CD006676.	
Study design	Systematic Review
Scope	**Patient/population:** four trials involving 222 participants. Patients of any gender and any age with a traumatic spinal cord injury with any level of traumatic incomplete lesion, that is with an AIS impairment of B, C or D, regardless of the duration of illness (acute or chronic SCI) or level of initial walking ability. **Intervention:** trials that compared locomotor training (over-ground gait training, hybrid strategies using BWS and functional electrical stimulation, automated electromechanical devices or robots). **Control:** any other exercise or no treatment **Outcomes assessed:** Primary • speed of walking (measured by the 10-meter or 15-meter walking speed, either fastest or casual walking speed) • walking capacity (defined as the capacity to cover a distance in a defined time, for example distance walked in six minutes) Secondary • level of independence of walking (measured by the Functional Independence Measure) • Safety of exercises (determined by the incidence of adverse effects during the study period) • Rates of dropouts or withdrawals for any reason during the study period
Effectiveness (short and long term benefits) of BWSTT for both complete and incomplete SCI	There was insufficient evidence to assess the benefits of BWSTT (with or without electrical stimulation or robotics) on walking function after SCI when compared to all other training approaches.
Effect of BWSTT on mobility, function, quality of life and return to work for SCI?	**Bodyweight supported treadmill training vs. all other training approaches** Speed of walking: insufficient evidence to determine effect Walking capacity: insufficient evidence to determine effect Independence of walking: insufficient evidence to determine effect Quality of life: not investigated Return to work: not investigated **Robotic-assisted locomotor training vs. all other training approaches** Speed of walking: insufficient evidence to determine effect Walking capacity: not investigated Independence of walking: not investigated Quality of life: not investigated Return to work: not investigated **FES and BWSTT vs. all other training approaches** Speed of walking: insufficient evidence to determine effect Walking capacity: not reported (intervention and control groups not comparable at baseline) Independence of walking: not investigated Quality of life: not investigated Return to work: not investigated

If BWSTT is effective: correct "dose" or training regime – time on machine, time since injury?	Not Applicable
Cost-effectiveness of BWSTT for SCI	Not reported
Which patient groups/conditions are excluded from BWSTT?	Patients with complete SCI
Risks associated with use of BWSTT	**Bodyweight supported treadmill training vs. all other training approaches** Safety of exercise: insufficient evidence to determine effect **Robotic-assisted locomotor training vs. all other training approaches** Safety of exercise: insufficient evidence to determine effect **FES and BWSTT vs. all other training approaches** Safety of exercise: insufficient evidence to determine effect
Conclusion/Recommendation	"There is insufficient evidence from RCTs to conclude that any one locomotor training strategy improves walking function more than another for people with SCI. Research in the form of large RCTs is needed to address specific questions about the type of locomotor training which might be most effective in improving walking function of people with SCI."
Recommendation category	Insufficient evidence
Quality assessment results	This systematic review was well conducted and considered to have a low risk of bias (see Appendix 5, Table A5.1 for quality appraisal)
Our comments/summary	This study is a high quality systematic review. It includes four RCTs assessing the effect of BWSTT on walking capacity of SCI patients. The review reports that all four trials failed to detect a difference in effect between BWSTT approaches and any other training modality. It also notes that the RCTs were based on small samples and subject to several methodological shortcomings, which limit the validity of their results. Overall, the authors state that there is insufficient evidence to conclude that any one approach to locomotor training is more, less or equally as effective as any other for improving the walking function of people with SCI.

Findings

Based on the analysis of pooled estimates of 4 RCTs included in a high quality systematic review, there is insufficient evidence to conclude whether the benefits and harms of BWSTT are better, worse or the same as other locomotor training strategies.

DISCUSSION & CONCLUSION

There are a limited number of studies that compare BWSTT with other forms of locomotor training. The most comprehensive, recent, high quality SR[1] compared different locomotor training strategies in the following way: BWSTT versus all other training approaches; robotic-assisted locomotor training versus all other training approaches; and, functional electrical stimulation (FES) and BWSTT versus all other training approaches. Regarding the questions posed in this Evidence Review, this SR found that there is not enough evidence to conclude wether BWSTT (with or without electrical stimulation or robotics) is more, less or equally as effective as other locomotor training approaches in terms of mobility, function and safety. The SR contained no information in regards to quality of life, return to work, or cost effectiveness.

DISCLAIMER

The information in this report is a summary of that available and is primarily designed to give readers a starting point to consider currently available research evidence. Whilst appreciable care has been taken in the preparation of the materials included in this publication, the authors and the National Trauma Research Institute do not warrant the accuracy of this document and deny any representation, implied or expressed, concerning the efficacy, appropriateness or suitability of any treatment or product. In view of the possibility of human error or advances of medical knowledge the authors and the National Trauma Research Institute cannot and do not warrant that the information contained in these pages is in every aspect accurate or complete. Accordingly, they are not and will not be held responsible or liable for any errors or omissions that may be found in this publication. You are therefore encouraged to consult other sources in order to confirm the information contained in this publication and, in the event that medical treatment is required, to take professional expert advice from a legally qualified and appropriately experienced medical practitioner.

CONFLICT OF INTEREST

The TAC/WSV Evidence Service is provided by the National Trauma Research Institute. The NTRI does not accept funding from pharmaceutical or biotechnology companies or other commercial entities with potential vested interest in the outcomes of systematic reviews.

The TAC/WSV Health Services Group has engaged the NTRI for their objectivity and independence and recognises that any materials developed must be free of influence from parties with vested interests. The Evidence Service has full editorial control.

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