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Intensive Balance Training for Adults With Incomplete Spinal Cord Injuries: Protocol for an Assessor-Blinded Randomized Clinical Trial

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Abstract

Background

Impaired reactive balance control can lead to increased falls in people with neurological impairments. Perturbation-based balance training (PBT), which involves repetitive exposure to destabilizing external perturbations, improves the ability to take reactive steps in older adults and individuals who have had a stroke.

Objective

The objective is to investigate whether PBT or conventional intensive balance training (CIBT) results in greater improvements in reactive stepping ability in individuals with chronic incomplete spinal cord injury (iSCI).

Design

The design consists of an assessor-blind randomized clinical trial comparing the efficacy of 2 balance training programs (PBT and CIBT) matched for training duration (thrice weekly for 8 weeks).

Setting

A tertiary spinal cord injury rehabilitation center is used as the setting.

Participants

Participants include 24 adults with iSCI classified as a C or D on the American Spinal Association Impairment Scale, who are able to stand independently and exhibit moderate trunk control.

Intervention

Both PBT and CIBT involve 24 sessions, each 1 hour long, of individualized static and dynamic balance tasks. However, PBT includes external, unexpected balance perturbations provided manually by the trainer at a frequency of roughly 1 per training minute.

Measurements

The primary outcome is the ability to recover balance using a single step during the Lean-and-Release test, a novel method of assessing reactive balance. Secondary outcomes include a number of clinical balance and gait assessments, and the number of falls experienced in a 6-month follow-up period. Semi-structured interviews are conducted 3 months after training completion to gain insight into the participants' perceptions of the impact of the interventions.

Limitations

A control group receiving "standard care" for balance training is not included.

Conclusions

This trial will provide physical therapists with insight into the efficacy of 2 forms of balance training for individuals with iSCI.

Among individuals with incomplete spinal cord injury (iSCI), about 75% will experience at least 1 fall each year, usually while walking.[1] Falls can lead to serious injuries and hospital admissions.[2] Impaired balance control likely contributes to the high fall rate; consequently, improving balance should be a goal of SCI rehabilitation. Despite their significant inpatient length of stay,[3] individuals with motor iSCI spend just a mean (standard deviation) of 2.0 (2.0) hours of their total stay on balance training,[4] a time allocation inconsistent with their high fall risk.[1,5]

Research specifying effective modes of balance training for individuals with iSCI is limited.[6] Prior studies have examined the effects of the following interventions on balance ability: divided-attention stepping tasks,[7] visual feedback,[8,9] virtual reality,[10] locomotor training,[11–14] and locomotor training combined with intermittent hypoxia.[15] In general, these studies have focused on anticipatory balance strategies, which involve muscle activation in anticipation of preventing a loss of balance before a voluntary movement.[16] In contrast, reactive balance control describes the ability to recover balance after an unexpected balance

perturbation, and can involve keeping the feet in place (ankle or hip strategies) or taking 1 or more steps to increase the size of the base of support.[16–18] This last strategy is referred to as reactive stepping, which, if compromised, can increase fall risk.[19,20] To our knowledge, no study has attempted to train reactive balance in people with iSCI, despite the existence of effective programs that target reactive balance strategies in other populations. Perturbation-based balance training (PBT) is a reactive balance–focused intervention that has demonstrated efficacy in both older adults[21] and individuals who have had a stroke.[22] Following PBT, these individuals show fewer multistep reactions, less need for assistance to recover balance, and faster step reaction time.[21,22] It is unknown if PBT will be as effective for individuals with iSCI because the spinal cord plays an important role in controlling balance reactions.[23,24] If PBT can successfully address the impaired reactive balance control of people with iSCI,[25] the incidence of falls might be reduced.[19,20]

PBT involves repetitive exposure to balance perturbations, applied by the researcher, during standing and walking tasks. The goal for participants is to achieve improved control of reactive stepping (eg, faster reaction time).[21,22] One method of assessing reactive balance is called the Lean-and-Release test, which simulates a forward fall in a safe environment.[26] Currently, reactive balance control is not commonly assessed in SCI research[27] or clinical practice.[28,29] Given the importance of reactive balance control in fall prevention,[30] a measure of reactive stepping should be included in intervention studies targeting upright balance and mobility.

Here we outline the protocol for a single-site, assessor-blinded, randomized clinical trial that compares the efficacy of PBT with that of conventional intensive balance training (CIBT), where participants practice balance-related tasks without external perturbations. We use an equal-dose approach, where the intensity (ie, challenge), frequency, and duration of sessions, and the total duration of the training program are the same, because assessing the dose-response relationship of balance training is not a study aim. The aim of this protocol is to evaluate the efficacy of administering external perturbations to train the reactive stepping response; hence, the only difference between the interventions is the addition of external perturbations in PBT. The primary objective is to determine if PBT results in greater improvement in reactive stepping ability when compared with CIBT. Secondary objectives include comparing the 2 training methods on: (1) clinical measures of balance and walking; and (2) the number of participants who experience 1 or more falls in the 6 months following completion of training. We hypothesize that when compared with CIBT, PBT will result in improved reactive stepping ability, improved scores on clinical outcomes, and fewer participants experiencing a fall in the follow-up period.

Methods

Study Design

A single-site, assessor-blinded randomized clinical trial (ClincalTrials.gov identifier NCT02960178, first published November 2016) is being conducted over 3 years at the Lyndhurst Centre, Toronto Rehabilitation Institute, University Health Network, a tertiary rehabilitation hospital. This protocol (version 4, June 23, 2017) was approved by the institutional Research Ethics Board in accordance with the Declaration of Helsinki (1964). Changes to the protocol are submitted as amendments. Data collection began in February 2017. All participants provide informed consent prior to the initiation of study procedures. Participants are assigned a unique identifier, which is used on all study-related documentation to protect confidentiality. Participants complete 2 baseline assessments spaced 2 weeks apart. At the second baseline assessment, participants are randomized into PBT or CIBT in matched pairs by a researcher not affiliated with the trial using blocked randomization (block size 4) and sequentially numbered, opaque envelopes. Participants are matched by age (≥60 years or <60 years) and injury severity (American Spinal Injury Association Impairment Scale [AIS] rating C or D). Hence, if a participant aged less than 60 years with an AIS C impairment is randomized into PBT, the next participant who is less than

60 years old with an AIS C impairment is entered into CIBT.[31] The participants then attend 24 training sessions (thrice weekly over 8 weeks), with one midpoint (after 4 weeks) and one final (after 8 weeks) assessment. Participants are followed for 6 months post-training, with follow-up phone calls occurring every 3 weeks, and follow-up assessments occurring at 3 and 6 months post-training. Table 1 outlines when each study component occurs in accordance with the SPIRIT guidelines.[32]

Participants

Participants are recruited through posted flyers, therapy staff at the Lyndhurst Centre, and a central recruitment database. The database contains the contact information of previous Lyndhurst inpatients willing to be contacted about research studies. Individuals with AIS C or D SCI, a moderate level of trunk control (defined by scoring ≥2 on item #8 on the Berg Balance Scale: Reaching Forward with Outstretched Arms While Standing[33]), and independent standing ability are eligible for this study. Screening for inclusion is completed in person, and the study physician is contacted for consultation as needed to clarify participant eligibility. Inclusion and exclusion criteria for study participation are detailed in Table 2.

Sample Size

Baseline data from 11 participants with iSCI were used to determine sample size. The mean (standard deviation) of the proportion of trials where participants were able to recover balance using a single step during the Lean-and-Release test was 0.36 (0.42). Using 0.5 as a clinically relevant goal for the difference between groups and power of 0.8, we calculated a sample size of 11 participants per group.[34] We selected an increase of 0.5 as a clinically relevant change based on our baseline data. An increase of 0.5 would mean that most participants in the PBT group are able to recover from the perturbation with a single step following the training. We will enroll a total of 24 participants (n = 12 per group) to account for participant attrition.

Interventions

Participants in PBT and CIBT groups attend 24 training sessions (3 times per week for 8 weeks) with a researcher who has a background in physical therapy or kinesiology. Training sessions are 1 hour in duration, with rest breaks taken during that hour as requested by the participant or specified by the researcher. All participants wear a safety harness that does not support weight, but prevents a fall to the ground. The harness is secured overhead to a free-standing frame measuring 2 × 4 m (Prism Medical Ltd, Concord, Ontario, Canada), which permits movement in both the anterior-posterior and medial-lateral directions. The amount of time spent with the harness secured to the frame can be gradually reduced over the intervention, at the discretion of the researchers (see supplementary material online, available at https://academic.oup.com/ptj). This is done to reduce the likelihood of the participant feeling dependent on the frame, and enables practice of real-world tasks, such as stairs and walking outdoors on uneven surfaces. Participants can continue with their routine leisure activities, but are asked not to begin a new exercise regimen during the 8-week intervention.

A researcher records the tasks completed during each session using a training log (see supplementary material online). Tasks are divided into 5 categories: stable, quasi-mobile, mobile, unpredictable, and participant-selected (Tab. 3). Participants prefer individualized rehabilitation programs to standardized protocols, and want to be actively involved with the goal-setting process.[35] Further, the saliency of the training, which is important for the promotion of neuroplasticity,[36] is facilitated by individualizing the activities. Refer to the supplemental materials for example training sessions.

Although the 2 groups perform similar training tasks, only the PBT group receives external perturbations from a researcher. About 1 perturbation is delivered every minute of training, thereby ensuring about 45 perturbations per session, allowing time for set up and rest breaks. Perturbations in the anterior, posterior, and lateral directions are provided via the harness or a safety belt worn at hip (if performing tasks outside

the harness). The perturbations are strong enough to elicit a change in the participant's base of support (ie, a step reaction); this method of eliciting a perturbation has previously been used in the stroke literature.[37] The researchers providing PBT have a background in physical therapy and/or kinesiology. They have received training from physical therapists who use PBT in stroke rehabilitation. The researchers also attend PBT and CIBT sessions together, especially during the participants' initial 3 to 5 sessions to ensure a consistent response from the participants.

In addition to the tasks practiced, researchers document how many step reactions occur. Step reactions are classified as either a 1-step, multistep, or fall. One-step reactions occur when only 1 step is needed to recover balance (a second step may be used for realignment). Multistep reactions occur when more than 1 step is needed to recover balance independently. A fall occurs when the participant requires assistance to prevent a fall. Participants also rate the level of challenge they experience during each task using a visual analog scale (VAS) (0–10: 0 = very easy, 10 = very challenging [would fall without assistance]) used in a previous study.[14] Training tasks rated more than or equal to 7 are deemed adequately challenging for PBT and CIBT because a rating of 7 was previously associated with a loss of balance or increased attentional demands.[14] Tasks rated less than 7 are modified to increase the challenge.

Outcome Measures

The primary outcome for this study is the ability to recover balance using a single step during the Lean-and-Release test (an outcome that has been previously used in older adults[21]): recovering with a single step demonstrates a higher level of balance control than using multiple steps.[38] The Lean-and-Release test quantifies reactive stepping ability.[26] Participants lean forward from the ankles such that 8% to 12% of their body weight is supported by a horizontal cable that extends from their waist to a metal frame behind them. A uniaxial force transducer (MLP-100-CO-C; Transducer Techniques, Temecula, CA, USA) is attached to the cable for measuring the leaning load. An analog-to-digital converter (PowerLab 16SP and Lab Chart 7; ADInstruments Inc., Colorado Springs, CO, USA) is used to monitor the force transducer signal during the experiment to control the leaning load. To elicit a step reaction, the cable is released at an unexpected time. We aim to complete 10 trials of the Lean-and-Release test per assessment; depending on the tolerance of the participant; however, fewer (ie, 5–9 trials) can be completed. Three false trials (ie, mechanism is not released) are interspersed with the 10 release trials in an attempt to reduce the initiation of anticipatory balance strategies. The behavioral response elicited is documented as a 1-step reaction, multistep reaction, or a fall. Parameters of the Lean-and-Release test have demonstrated reliability in other populations, including people with Parkinson disease[39] and older adults.[21] Currently, no minimal detectable change (MDC) can be calculated for this measure in the SCI population due to a lack of data. Instead, we use an increase in the proportion of 1-step reactions of 0.5 as a clinically relevant change, as outlined above.

The secondary study outcomes include clinical measures that are administered 6 times over the study period (see Tab. 1). Two clinical measures of balance are administered by a physical therapist blinded to group allocation. If unblinding occurs the therapist informs the research team, and the occurrence of unblinding (if any) will be disclosed at the time of publication. Unblinding is unlikely to occur because the assessor does not work in the environment in which PBT and CIBT occur, and participants are instructed not to disclose group allocation to the assessor. If the MDC for any of the following balance measures in the iSCI population was unknown, we calculated it, when possible, using the formula $MDC_{95} = SEM \times 1.96 \times \sqrt{2}$, where MDC_{95} is the MDC at a 95% CI and SEM is the standard error of measurement[40]:

1. The Mini-Balance Evaluation Systems Test (mini-BESTest) assesses 4 balance control systems (anticipatory, reactive, sensory, and dynamic) during standing and walking.[41,42] Twenty-eight is the highest possible score.[42] The mini-BESTest is a valid measure of balance for individuals with iSCI[41]

and has previously been used in this population.[45] We calculated the MDC_{95} for this scale, using the SEM from a preexisting data set collected in iSCI,[44] as 5 points.

2. The Community Balance and Mobility Scale (CBMS) measures high-level, ambulatory balance[45,46] and is a valid measure for iSCI.[45] The highest possible score is 96 points.[46] The MDC_{95} for this measure, which we calculated with preexisting data collected in SCI,[45] is 13 points.

At each assessment the following measures are administered by a researcher:

3. The Activities-specific Balance Confidence (ABC) scale asks participants to rate their confidence in performing 16 standing and walking tasks without losing their balance (0% = no confidence, 100% = complete confidence).[47] The ABC scale is both valid and reliable in people with chronic iSCI, and the MDC_{95} is 15%.[44]

4. The Falls Efficacy Scale International (FES-I) measures participants' concern about falling during 16 functional activities,[48] and although its psychometric properties have not been evaluated in the SCI population, it has been used in previous research in people with iSCI.[49] The FES-I has a total possible score of 64, with scores less than or equal to 22 indicating a low concern of falling and scores greater than 22 suggesting a high concern.[50]

5. Spatiotemporal parameters of gait are measured using the Zeno Walkway (Model 485, Ver. J; Prokinetics, Havertown, PA, USA). Participants walk across the pressure-sensitive walkway, without gait aids if feasible, under 3 conditions: self-selected walking speed, fast walking speed, and tandem walking. Spatiotemporal parameters (ie, double support time, step length, cadence, and spatial and temporal symmetry) are extracted. MDC_{95} values for gait parameters in this population are as follows: 0.17 m for step length, 0.69 seconds for double support time, 0.17 m/s for speed, and 13 steps/min for cadence.[51]

Participants are followed for 6 months postintervention. Every 3 weeks participants are contacted by a researcher (J.U.) to discuss any changes in their health, medications, physical activity levels, or fear of falling, and any falls they experienced during the previous 3 weeks. A fall is defined as unintentionally coming to rest on the floor, ground, or another lower-level surface.[52] At the onset of the follow-up period, participants are given a falls survey,[53] either on paper or through an electronic link (Qualtrics Survey Software, Dallas, TX, USA) according to their preference. Participants are asked to complete the survey within 24 hours of falling; however, if the participant forgets to complete the survey, it is completed at the time of the next phone follow-up. The survey gathers details of the fall, including the location, time, injuries, and possible cause (see supplemental materials).

Adverse Events

The risks of participating in this study are presumed to be no greater than a typical physical therapy session. In the case of an adverse event, the participant will receive medical treatment at no cost to them. If the allocated intervention results in worsening of a participant's condition, or the participant requests to stop the intervention, the participant will be withdrawn from the trial without consequences. Serious adverse events and strategies to resolve them will be reported to the Research Ethics Board.

Data Analyses

Data are entered by a single researcher (J.U.) into a database stored on a secure research network. Data entries are double-checked by a second researcher. All investigators will have access to the final trial data set. Demographic information, injury-related data, number of 1-step and multistep reactions experienced during training, as well as performance on the clinical and self-report measures (raw scores and change from baseline) will be reported as mean (standard deviation) or median (IQR) values, as appropriate. The

number of falls experienced by each participant during the follow-up period will be extracted from completed fall surveys. Details reported in the fall surveys, such as location of fall, will be reported descriptively.

To compare the primary outcome between the PBT and CIBT groups, the mean change in proportion of trials in which balance was recovered using a single step on the Lean-and-Release test will be compared with a Chi Square test of independence. Similarly, Chi Square tests of independence will be used to compare, between groups, the proportion of participants who experienced a fall during the follow-up period, the proportion who achieved the threshold for a MDC on each clinical measure, and the mean change in proportion reporting a low/high concern of falling on the FES-I. If a participant withdraws from the training program, we continue to complete the assessments at the prescribed time points if the participant is willing (ie, intention-to-treat). If a participant misses an assessment, we will implement a complete case analysis, which means that only observed scores will be included in analyses.[54] This analysis is a commonly used method to manage data that are missing completely at random.[54] To confirm that PBT resulted in more practice of reactive stepping than CIBT, the mean number of 1-step and multistep reactions recorded during training will be compared between groups with a matched-pair *t* test. Alpha will be set to .05.

Knowledge Translation Plan

The findings from this study can have an immediate impact on the rehabilitation of individuals with iSCI; hence, an effective knowledge translation (KT) strategy is warranted. The goals of our KT plan are to: (1) inform future research in the area of balance training post-iSCI; (2) increase knowledge users' awareness of study outcomes and the need to measure and train balance in SCI rehabilitation; and (3) enable knowledge users to implement study findings by providing instructional tools such as manuals, instructional videos, web-based resources, and on-site training modules. One member of the research team (C.S.), who has expertise in knowledge mobilization in SCI rehabilitation, is directing the integrated and end-of-project KT activities.

Anticipated knowledge users include physical therapists who work in SCI rehabilitation, health care administrators, SCI rehabilitation researchers, and individuals with iSCI and their families. To ensure our findings are relevant to clinicians, physical therapists are involved throughout the research process. Therapist involvement includes generating the research question to address a knowledge gap, ensuring clinical feasibility, collecting data (ie, blinded assessors), and, should the results be positive, implementing PBT in the clinical environment. Three individuals with iSCI provided participant perspective as the study protocol was developed. Hospital administrators were approached to ensure the proposed research fitted with the institutional emphasis on fall prevention. Furthermore, the majority of study activities take place in the clinical environment at the Lyndhurst Centre, where clinicians, administrators, and individuals with SCI can observe PBT/CIBT, thus facilitating interest and dialogue about the research.

End-of-project KT strategies include: (1) creation of an online manual and instructional videos about effective balance training and assessment techniques customized for SCI; (2) on-site or web-based training for rehabilitation centers interested in implementing a focused balance training program for SCI; (3) publication of the results in scientific journals; and (4) presentations at conferences attended by researchers and clinicians. The long-term impact will be evaluated by the numbers of journal article citations, downloads of the training manual, views of instructional videos, and centers that request training.

Role of the Funding Source

The funder was not involved with study design, collection, analysis, interpretation, or writing of reports.

Discussion

The trial results will contribute to improved rehabilitation practices for the recovery of upright balance after iSCI. To date, the recovery of balance reactions has not been a focus of SCI rehabilitation. Our study findings will shed light on the feasibility and efficacy of a novel method to train reactive stepping. Physical therapists are commonly responsible for assessing and training balance[29]; thus, developing and testing novel training methods will provide clinicians with additional ways to address the high fall risk of their clients with iSCI.

This trial's focus on reactive balance control is a strength, because intact reactive balance is crucial for fall prevention.[19,20] This study uses strong rehabilitation research methodologies, because it is a randomized clinical trial with blinded assessors.[55] Another strength is the comprehensive KT plan including integrated and end-of-project initiatives, which will accelerate the translation of study findings into clinical practice. Implementation of new approaches and knowledge into physical therapy practice can be challenging;[56] hence, it is important to incorporate both knowledge creation and translation into a dynamic process so that each can influence the other.[57] One weakness of this study is the lack of a control group that implements "standard care" for balance training. Both the PBT and CIBT groups receive 24 hours of balance training during this trial—a dosage exceeding that reported in inpatient rehabilitation for iSCI.[4] Another potential limitation is the choice of the primary outcome, because the psychometric properties of a single step recovery during the Lean-and-Release test have not been established in SCI, although this outcome has been used with older adults.[21] From the data collected during this trial, we will be able to evaluate the Lean-and-Release test's validity, test-retest reliability, and possibly predictive validity for falls, if the sample size proves adequately large, among the iSCI population.

In conclusion, the study results, along with the KT plans in place, will help advance the assessment and training of reactive balance control in the iSCI population, potentially leading to fewer falls and improved clinical outcomes.

Author Contributions and Acknowledgments

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Ethics Approval

This protocol (version 4, June 23, 2017) was approved by the institutional Research Ethics Board in accordance with the Declaration of Helsinki (1964).

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Disclosures

The authors completed the ICJME Form for Disclosure of Potential Conflicts of Interest. J. Unger, K. Chan, C.Y. Scovil, and K.E. Musselman reported a grant received to their institution. B.C. Craven receives consulting fees from the Rick Hansen Institute, unrelated to the enclosed trial. No other authors reported any conflicts of interests.

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Figures and Tables

Table 1.

Study Timeline[a]

	Study Period						
	Enrollment		Post-Enrollment			Follow-Up	
	−t0	Baseline 1	Baseline 2	Midpoint	Final	3 Months	6 Months
Eligibility screen	X						
Consent	X	X					
Allocation			X				
PBT							
CIBT							
Lean-and-release		X	X	X	X	X	X
Zeno		X	X	X	X	X	X
Mini-BESTest[b]		X	X	X	X	X	X
CB&M[b]		X	X	X	X	X	X
ABC Scale		X	X	X	X	X	X
FES-I		X	X	X	X	X	X
Researcher contact[c]							

[a]Study time points defined. Table adapted from Chan et al.[32] ABC Scale = Activities-specific Balance Confidence Scale; CB&M = Community Balance and Mobility Scale; CIBT = conventional intensive balance training; FES-I = Falls Efficacy Scale—International; Mini-BESTest = Mini-Balance Evaluation Systems Test; PBT = perturbation-based training. X indicates the time point(s) at which each outcome measure is completed.

[b]Indicates an outcome measure administered by a blinded physical therapist.

[c]The solid black horizontal line indicates an activity that is ongoing throughout more than 1 time period.

Table 2.

Trial Inclusion and Exclusion Criteria[a]

Inclusion Criteria	Exclusion Criteria
1. ≥18 y old 2. Traumatic or nontraumatic, nonprogressive SCI 3. More than 1 y postinjury 4. Able to stand independently (without any gait aid) for 30 s 5. Moderate level of trunk control as defined by the ability to reach ≥2 inches forward with an outstretched arm when standing unsupported (ie, a score ≥2 on the Berg Balance Scale Reaching Forward task)	1. Severe spasticity affecting the lower extremities, defined as spasticity in 1 or more joints that prevents participant from standing upright in a neutral position (score of 3 or 4 on the Modified Ashworth Scale) 2. Lower extremity contractures that prevent achieving a neutral hip and ankle position or knee extension in upright standing upon observation 3. A pressure injury higher than grade 2 on the pelvis or trunk where the safety harness will be applied 4. Untreated orthostatic hypotension, hypertension, or cardiac arrhythmias (atrial or ventricular) 5. A prior lower extremity fragility fracture 6. Any other condition (besides SCI) that would significantly affect balance or walking (eg, stroke, vestibular impairment, or vision loss)

Open in a separate window

[a]SCI = spinal cord injury.

Table 3.

Balance Training Tasks[a]

Category	Task Examples
Stable	Standing still, weight shifting, tandem stance
Quasi-mobile	Stepping, tap ups, walking in place
Mobile	Walking, side stepping, turning
Unpredictable	Kicking, throwing, cued walking (fast, slow, etc)
Participant-selected	Painting, gardening, stairs

[a]Examples of tasks included in each category of balance training.