

Feasibility of Ballistic Strength Training to Improve Mobility of Inpatients with Traumatic Brain Injury: A Study Protocol

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ABSTRACT

Traumatic brain injury is a major cause of mortality and long-term disability, often resulting in limited mobility. Limited mobility is associated with poor community participation and reduced health-related quality of life. Mobility, particularly walking, requires rapid force generation, which can be improved using ballistic strength training. This study aims to investigate the feasibility of ballistic strength training for improving mobility in people recovering from traumatic brain injury in an inpatient rehabilitation setting. The feasibility study will use a quasi-experimental single group pre-test–post-test design. We will recruit inpatients with first-ever, moderate-to-severe traumatic brain injury, less than 6 months post-injury. We plan to measure recruitment capability, attendance, the incidence of adverse events, acceptability of the intervention, and ability to perform exercises. Preliminary effects of the intervention will be measured as a change in self-selected walking speed, change in walking capacity, and participant perceived difference in walking ability. The data will be descriptively analysed. In this study protocol, we outline the rationale for implementing a feasibility study to test the feasibility of ballistic strength training for inpatients who have experienced traumatic brain injuries.

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INTRODUCTION

Traumatic brain injury (TBI) often results in complex clinical presentations, and rehabilitation teams perceive this condition to be one of the most challenging to treat (McNamee et al., 2009; Røe et al., 2019). In New Zealand, TBI is a major cause of disability and death (Te Ao et al., 2015), with substantial economic costs for society (Te Ao et al., 2014). In 2010, men and women in the 40- to 49-year-old age group had the highest prevalence of TBI in New Zealand (Te Ao et al., 2015). Survivors of moderate-to-severe TBI may have long-term healthcare needs, with associated costs running into billions of dollars (Centers for Disease Control and Prevention, 2022; Ma et al., 2014; Prang et al., 2012).

Impact of TBI on mobility outcomes

People recovering from moderate-to-severe TBI present with manifold, multi-system physical, cognitive, and neurobehavioral impairments (Riggio & Wong, 2009; Walker & Pickett, 2007). These impairments often result in limited mobility (Walker & Pickett, 2007; Williams & Willmott, 2012), including slower walking speed, reduced walking distance, and impaired quality of gait (Katz et al., 2004; McFadyen et al., 2003; Williams et al., 2009). Walker and Pickett (2007) report that more than

one-third of patients with TBI continue to display neuro-motor abnormalities two years after acute rehabilitation. People with limited mobility struggle to navigate their homes and community environments, often suffering from falls and limited participation (Lasry et al., 2017; Williams & Schache, 2010). Restoring walking skills is often the main long-term rehabilitation goal for people recovering from moderate-to-severe TBI, as being able to walk will enhance their performance in activities of daily living and participation in recreational activities (Katz et al., 2004; Wilson et al., 2019).

Aspects of walking ability can be measured in terms of endurance and speed. Reduced walking endurance can restrict a person's ability to perform daily activities, from crossing a road to accessing the community (Charrette et al., 2016; Mossberg & Fortini, 2012). Walking speed is a particularly important outcome in neurological populations because it is relevant to community ambulation (Andrews et al., 2010). Walking speed also inversely correlates with the risk of falls (Fritz & Lusardi, 2009), with slower walking speeds being associated with more frequent falls (Morone et al., 2014; Tilson et al., 2012). Klima et al. (2019) report that patients with TBI have a mean walking velocity of 0.96 m/s, significantly slower than age-matched controls and speeds reported in published norms (Bohannon,

1997). People aged between 20 and 69 years have a normal walking speed between 1.2 m/s and 1.55 m/s (Bohannon & Andrews, 2011).

A key research priority for individuals with TBI is to develop, evaluate, and implement interventions for optimising independent function and participation (Nalder et al., 2018). Muscle weakness has been identified as the leading cause of walking limitation for most people with neurological conditions (Nadeau et al., 1999; Williams et al., 2013). Muscle weakness is usually treated using conventional strength training methods, which follow the overload principle of slow and heavy resistance. However, conventional strength training does not promote rapid force generation, which is needed for walking (Williams et al., 2019; Williams, Kahn et al., 2014). Consequently, walking ability in people with neurological conditions does not seem to respond to conventional strength training (Dorsch et al., 2018; Williams, Kahn, et al., 2014). Therefore, current interventions to rehabilitate walking may not be specific enough to the task of walking (Williams, Kahn, et al., 2014).

Ballistic strength training

Ballistic strength training (BST) is a type of strength training performed at high velocity with lighter loads and high repetition (Williams et al., 2016). BST is a task-focused approach healthy athletes use to improve muscle strength, maximal power generation, and functional ability (Newton et al., 2006). Recently, BST has shown potential as a therapeutic tool for improving mobility outcomes in neurologic populations (Hendrey et al., 2018; Van Vulpen et al., 2017). However, research on the use of BST in patients with neurological conditions, including TBI, is relatively novel, and evidence is limited.

Currently, most research on the use of BST in adult neurologic populations focuses on participants who were at least 6 months post-injury. These studies on BST found that combining BST principles with conventional leg strengthening exercises resulted in increased power generation with increased peak jump height and peak velocities (Williams, Clark, et al., 2014). BST appears to improve muscle strength and power generation. BST is safe, feasible, and effective in neurological conditions, including adults with stroke, Parkinson's disease, and multiple sclerosis (Cordner et al., 2020).

The impact of BST on mobility outcomes during the early inpatient TBI rehabilitation phase is of particular interest because BST is highly task specific. This task-specificity plays an important role in improving functional outcomes (Anthony & Brown, 2016; Hendrey et al., 2018). In a randomised feasibility trial investigating the use of BST in participants who were less than 6 months post-stroke (median = 56 days), Hendrey et al. (2018) report that BST improved self-selected walking speed and muscle power generation. However, their study used a small sample size, and the results cannot be generalised to the TBI population.

Inpatient rehabilitation can be optimised using evidence-based interventions to improve mobility following TBI. There is a need for high-quality research to inform clinical practice, particularly when considering the current lack of high-quality evidence to

inform interventions for improving mobility outcomes. We will add to the current body of evidence by examining whether BST can improve mobility outcomes of inpatients with TBI less than 6 months post-injury. A feasibility trial will provide preliminary information on whether BST can work for inpatients with TBI by measuring acceptability, safety, and preliminary effects (Harvey, 2018; Orsmond & Cohn, 2015). A feasibility trial will also inform the translation of BST into clinical practice and lay the foundation for future larger definitive trials (Harvey, 2018).

METHODS AND ANALYSIS

Research aim

To establish the feasibility of implementing BST to improve mobility outcomes following moderate-to-severe TBI in an inpatient rehabilitation setting.

Study objectives

Our primary objective is to establish the feasibility of implementing BST in an inpatient rehabilitation setting by:

1. Determining the recruitment rate of participants by investigating the eligibility and subsequent uptake of participants.
2. Establishing the safety of BST by recording adverse events.
3. Determining training attendance per participant.
4. Determining participant acceptance of the intervention.
5. Evaluating clinical feasibility by determining the following:
 - (a) the ability of participants to complete BST exercises using participant logs.
 - (b) the ability of participants to develop skills during BST exercises.

Our secondary objective is to examine the preliminary effects of BST on the following mobility outcomes:

1. Determining changes in self-selected walking speed.
2. Determining changes in walking capacity.
3. Determining participants' perceived impression of change in walking ability.

Study design

The proposed feasibility study will use a quasi-experimental single group pre-test–post-test design (O1 X O2). A quasi-experimental study is ideal for maximising sample size in proof-of-concept studies where participants are not randomly assigned to experimental groups (Harris et al., 2006). In this study, pre-test measurements will be taken (O1), the intervention (X) will be implemented, and post-test measurements will be taken (O2) to examine preliminary effects on mobility outcomes.

This feasibility study will be a non-randomised pilot study without a control group (Eldridge et al., 2015). The feasibility of BST will be established using the following criteria as specified by Orsmond and Cohn (2015): recruitment capability, training attendance, safety, participant acceptability of the intervention, and preliminary evaluation of participant response to the intervention.

Research setting

The study will be conducted in a 33-bed specialist acquired brain injury rehabilitation centre that provides interdisciplinary care to inpatients in Auckland, New Zealand.

Study population

Eligibility criteria

Inclusion criteria for participants are adults, 18–65 years of age, with first-ever diagnosis of moderate-to-severe TBI, fewer than 6 months post-injury. Participants will have had independent, unaided baseline mobility before TBI; and after TBI, will be able to walk with standby assistance of one therapist for at least 14 m (the use of mobility aids and orthoses is permitted). Participants must be able to understand written and spoken English.

Exclusion criteria include: Individuals unwilling or unable to give informed consent; Severe cognitive or behavioural problems that prevent assessment and participation; Medically unstable and unable to perform cardiovascular exercise; Recent spinal surgery in the last 6 weeks or orthopaedic injuries restricting weight bearing; Lower limb muscle weakness from a peripheral cause (e.g., peripheral nerve injuries); Previously diagnosed central nervous system disorder (e.g., previous moderate to severe TBI, multiple sclerosis, or Parkinson's disease); Individuals who are able to walk independently, unaided, with a self-selected walking speed of faster than 1.55 m/s.

Sampling method

Sample size

The study will take place over 6 months. Even though feasibility studies do not require a powered sample (Orsmond & Cohn, 2015), we asked a statistician to estimate the ideal sample size. The power analysis showed that for parametric tests such as a paired *t*-test with a large effect size of 0.6, using G*Power 3.1.9.2, at an alpha level of 5% and a power of 80%, a sample size of 23 would be required. To allow for attrition, we will aim to include 27 participants.

Recruitment

Physiotherapists at the rehabilitation centre will screen ambulatory inpatients for eligibility. We will determine whether a participant can provide informed consent for each prospective participant. Each potential participant will be assessed using an interdisciplinary model in line with the rehabilitation centre's policy. A medical officer will sign off on the potential participant's ability to provide informed consent. An independent representative from the rehabilitation centre will invite eligible prospective participants. Potential participants will receive a participant information sheet and an informed consent form, and will be given time to consider the trial and ask questions. Those willing to participate in the study will be asked to sign the written informed consent form. Participants will be consecutively enrolled as they consent to participate. Participants can withdraw at any stage without negatively affecting their treatment. Participants will be informed that, should they wish to withdraw during the study, the data collected cannot be erased and may still be used in the final analysis.

Intervention

Following enrolment and baseline assessments, participants

will have two 30 min BST sessions per week instead of the usual conventional physiotherapy sessions. Participants will attend BST sessions for at most 4 weeks, which is dependent upon and reflective of the typical inpatient length of stay. The BST exercise programme has been peer reviewed and validated by an expert in the field, Professor Gavin Williams, and two neurology lecturers at the Department of Physiotherapy, University of Pretoria. Each BST session will be performed in the therapy gym at the rehabilitation centre. Each participant will be directly supervised by a physiotherapist or a physiotherapy assistant trained in the BST exercise programme to ensure correct technique and appropriate progression. The proposed BST exercise programme is based on the theoretical framework designed for neurologic rehabilitation (Williams, Clark et al., 2014; Williams et al., 2019). The BST exercise programme will comprise two parts, each with four exercises. Each participant will perform the same exercises, and the progression of exercises will be individualised. Part A includes low resistance (below body weight) exercises performed on a reclined slide-board. Part B comprises bodyweight exercises performed in parallel bars using equipment such as a mini trampoline, with or without upper limb support, and additional resistance. The BST exercise programme and progression principles are similar to the BST exercise programme used by Hendrey et al. (2018) in a stroke population. First, the aim will be to ensure the correct movement pattern is achieved. Thereafter, speed of movement will be increased as a progression. The desired speed of movement will be set to one beat per second, the usual time for a typical gait cycle. As per consultation with an expert in BST, Professor Gavin Williams, we will use a metronome to provide auditory feedback. Finally, load will be increased as a progression (by increasing the incline in Part A or by adding external resistance in Part B), without altering speed and quality of movement.

The level of intensity will be set to the maximum level the participant can manage while maintaining the correct lower limb alignment, using the correct technique and desired range of motion. Each exercise will be performed for 2 min, during which the participant will be encouraged to perform as many repetitions as possible. Although the BST programme will strengthen all major lower limb muscle groups, we will target the three muscle groups critical for power generation during forward propulsion when walking. These three muscle groups include the ankle plantar flexors used during push-off in terminal stance, hip flexors at toe-off to accelerate the leg through swing phase, and hip extensors at initial contact (Neptune et al., 2008; Requião et al., 2005).

Therapists will demonstrate exercises and assist participants where necessary. We will keep an exercise log for each participant to capture the assistance and progression level required for each exercise. There will be at least 48 hours between each BST session. The severity of adverse events will be recorded using the Common Terminology Criteria for Adverse Events (CTCAE v5) (US Department of Health and Human Services, 2017). As the study's primary aim is to establish feasibility, the study will be terminated early if the supervisors judge there are excessive adverse events or complaints. Participants will continue to receive routine physiotherapy care on the remaining five days of the week.

Data collection, management, and analysis

Demographic characteristics

Participant demographic information will be extracted from medical records and captured in Microsoft Excel spreadsheets. Information will pertain to participants' date of TBI, date of admission to the rehabilitation centre, classification of injury (moderate or severe; severity will be determined by the medical team of the rehabilitation centre according to the initial Glasgow Coma Scale score and the length of Post Traumatic Amnesia), mechanism of injury, age, gender, and orthopaedic injuries (weight-bearing restrictions).

Pre-test–post-test outcome measures

The use of mobility aids, orthoses, and/or amount of assistance required will be recorded on the pre-test and post-test assessment sheets. A trained and accredited user will score the locomotion item of the Functional Independent Measure (FIM) for comparison between pre-test and post-test analysis.

Pre-test outcome measures

We will complete the following baseline assessments:

10-metre Walk Test (10mWT): A performance measure used to assess self-selected walking speed, also known as comfortable walking speed. A dynamic start and stop will be used. A total distance of 14 m will be used, of which the middle 10 m will be timed. The participants will be allowed to use mobility aids and orthoses. Self-selected walking speed (m/s) will be calculated by dividing the distance (10 m) by the time (s) taken to walk the distance.

6 Minute Walk Test (6MWT): To measure functional walking capacity, we will determine how far (m) a participant can walk in 6 min. The 6MWT is a self-paced walking test. A 50 m track will be used with the assessor walking behind the participant. Participants may use mobility aids and orthoses. Data will be recorded in spreadsheets. The 6MWT evaluates if a person can increase their activity level and then maintain a moderate level of physical activity over a period representative of activities of daily living (Mossberg & Fortini, 2012).

Post-test outcome measures

After completing the intervention, we will repeat the 10mWT and 6MWT.

10-metre Walk Test (10mWT): Minimal detectable change of > 0.05 s is considered clinically relevant; this change is also greater than assessor error (Watson, 2002). In our study, a minimum worthwhile change in self-selected speed of 0.175 m/s will be considered statistically significant (Fulk et al., 2011).

6 Minute Walk Test (6MWT): TBI population-specific normative values have not been clearly defined in the current literature. Clinically meaningful changes in distance are between 14 m and 30.5 m for adults with pathology (Bohannon & Crouch, 2017) and between 45 m and 54 m following stroke (Tyson & Connell, 2009). In our study, as indicative of improved endurance in post-stroke populations, a clinically meaningful change of 34.4 m in distance will be used (Tang et al., 2012).

The following measures will also be completed after the intervention.

Visual Analogue Scale (VAS): To evaluate participant acceptance of BST (Sekhon et al., 2017). Participants will be asked to rate their agreement with the statement 'I find the BST exercise programme acceptable' using a 10-point VAS ranging from 0 (I totally disagree) to 10 (I totally agree). Using a ruler, the score will be determined by measuring the distance (mm) on the 10 cm line between the "totally disagree" anchor and the participant's mark (providing a range of scores from 0 to 100). Higher scores show greater acceptability (Lamontagne et al., 2014; Tverdal et al., 2018). In our study, a score of more than 5/10 will indicate acceptance of the intervention.

Global Rating of Change Scale (GROC): To determine each participant's perceived change in walking ability following the intervention. GROC is a generic 15-point ordinal scale, ranging from -7 to +7, with positive scores showing improvement and negative scores showing regression. Participants who answer between -4 and +4 will be considered to perceive minimal or no change (stable/not improved). Participants who answer +5 or more will be considered to perceive clinically important change or marked improvement. Traditionally, a cut-off of +3 is deemed to represent a minimal change, and participants who answer +4 or more perceive a marked improvement (Jaeschke et al., 1989). We chose a ≥ 5 cut-off for two reasons: all patients during this early time frame after TBI will likely experience some change in walking ability. We are interested in identifying changes in aspects of mobility that are more than just 'minimally' important. A score of ≥ 5 , 'a good deal better', may reflect a bigger improvement than 'somewhat' or 'moderately' better, which would indicate 'minimally important' improvement (Fulk & Echterhach, 2008; Fulk et al., 2011).

Feasibility measures

We will establish feasibility using data from screening (number of eligible and recruited participants with reasons for exclusion), participant BST exercise logs, and pre-test–post-test assessment sheets. We will use the exercise logs to record the number of sessions attended, the level of assistance required for each exercise, and skills acquisition. Skills acquisition refers to how much help the participant requires to achieve the desired speed of movement during exercises, as well as whether the participant can perform the exercise. Reports of discomfort or adverse effects will also be captured. We will screen the participants' clinical notes to identify any adverse events.

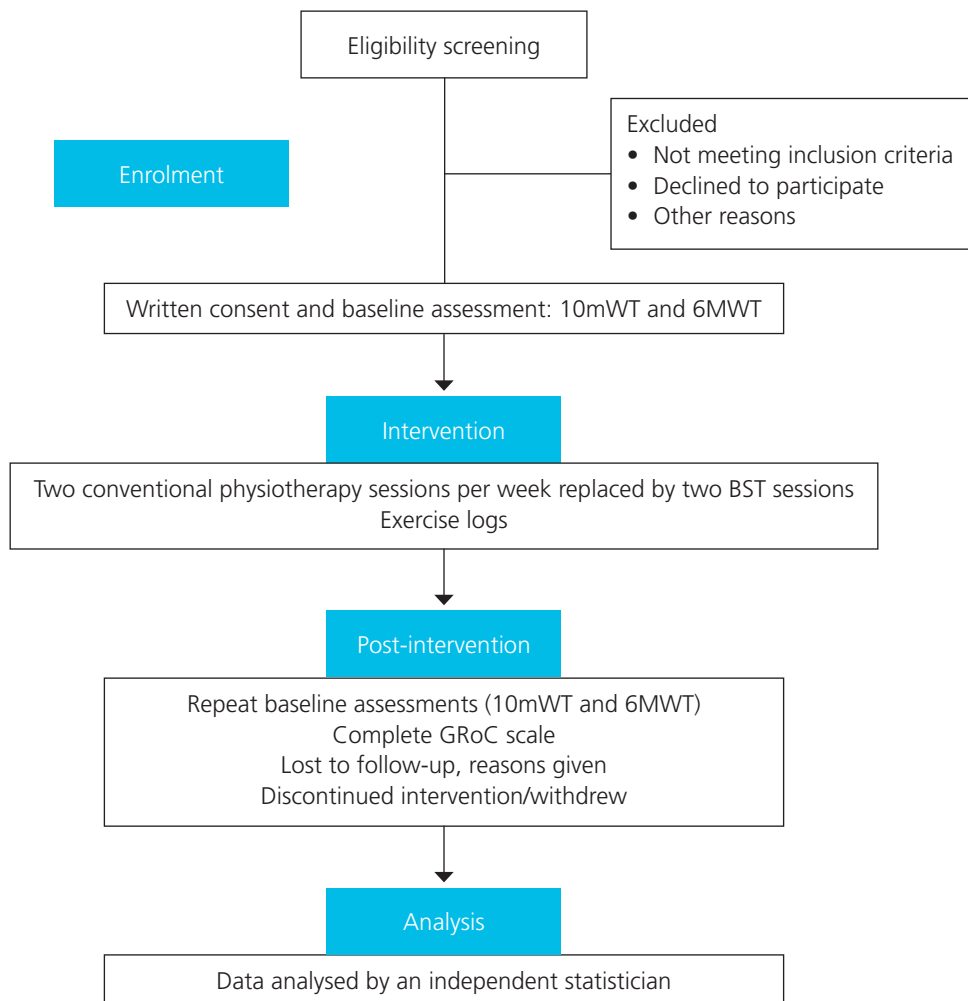
To enhance rigour, an independent physiotherapist or physiotherapy assistant will conduct the pre-test–post-test assessments. The same assessor will be used for pre-test and post-test assessments where practicable. Assessors will be trained in the research methodology, and assessors will use standardised instructions to complete the outcome measures. Guidelines for managing patients during COVID-19 will be adhered to during the trial. See Figure 1 for details of the flow of participants through the proposed study.

Data management

Each participant will be assigned a unique alpha-numerical code, which we will use on anonymised study forms and in the electronic database. Only approved personnel will have access to the study forms. Study-specific source documents will be stored in the secure electronic cloud-based system used by the

Figure 1

Participant Flow Diagram of the Proposed Ballistic Strength Training Feasibility Study



Note. GROC = Global Rating of Change scale; 6MWT = 6 minute walk test; 10mWT = 10-metre walk test.

rehabilitation centre. These records will be stored according to good clinical practice for 10 years from the last intervention. Anonymised data will be irreversibly stripped of the unique participant code and any other identifiers. Anonymised data will be held securely, password protected, and retained indefinitely by the researcher.

Data analysis

The data will be analysed in consultation with an independent statistician using Microsoft Excel spreadsheets and Windows statistical software. The data will be descriptively analysed, and we will report appropriate means, medians, standard deviations, confidence intervals, frequencies, and proportions. Data will be graphically represented where applicable. If the recruited sample size and collected data allow, paired *t*-tests may be performed to determine changes between pre-test and post-test mobility outcome measures. If inferential tests are performed, a *p* value of 0.05 will be set.

Based on Campbell et al. (2020), we will use a traffic light system to evaluate whether the feasibility study could progress

to a full-scale randomised controlled trial. Green indicates implementation is feasible and the study design will require minor or no change. Amber will indicate an element requires major modification before progressing, and red will indicate it is not feasible to progress with this design. Table 1 summarises the progression criteria for each objective.

DISCUSSION

This protocol outlines the procedure we will follow to test the feasibility of BST to improve the mobility of inpatients with moderate-to-severe TBI. Best-practice guidelines recommend testing the feasibility and acceptability of trial procedures before undertaking a definite trial. The feasibility study will reveal any potential issues related to recruitment, safety, and participant acceptance of BST as an intervention. We will also assess the preliminary efficacy of BST for improving mobility. We will investigate self-selected walking speed, walking capacity, and participants' perceived impression of change in walking ability. This study will generate data and experience to guide future trials.

Table 1*Traffic Light Progression Criteria for Each Element of the Proposed Ballistic Strength Training Feasibility Study*

Progression criteria	Measurement	Green	Amber	Red
Recruitment capability	Number of participants recruited	15–20	10–15	< 10
	Proportion of eligible participants consented	> 70%	50–69%	< 50%
Attendance	Number of BST sessions attended per participant	> 75%	50–75%	< 50%
Participant safety	AEs: incidence, type, and severity	Minor modifications made to BST to accommodate discomfort	AEs in a large proportion of the sample size	Occurrence of serious AEs
Intervention acceptability	Participants' acceptance: VAS	Most participants (> 50%) find BST acceptable (> 5/10)	Conflicting views on acceptance of BST, or major revisions needed	Most participants (> 50%) find BST unacceptable (< 5/10), or changes required are unfeasible
Clinical feasibility	Participants' ability to complete BST	Most participants can complete BST	Participation possible with minor adjustments	Most participants cannot complete BST
	Skills acquisition: assistance and speed of movement Data collected from participant exercise logs	Most (> 50%) of participants do not require assistance and achieve skills acquisition	< 50% of participants require assistance Conflicting results on skills acquisition	Most (> 50%) participants require assistance, which may be unfeasible. Exercises require unfeasible changes
Indication of effect on mobility outcome measures	Self-selected walking speed (if completed \geq 75% of BST sessions)	Clinically important change between pre-test and post-test	Minimally clinically important change between pre-test and post-test	No change between pre-test and post-test
	Walking capacity (if completed \geq 75% of BST sessions)	Clinically important change between pre-test and post-test	Minimally clinically important change between pre-test and post-test	No change between pre-test and post-test
	Participants' perception of change in walking ability: GRoC	Most GRoC scores are between +5 to +7	Most GRoC scores are between +3 to +5	Most GRoC scores are < 3

Note. This table was adapted from Campbell et al. (2020). AE = adverse event; BST = ballistic strength training; GRoC = Global Rating of Change scale; VAS = Visual Analogue Scale.

TRIAL REGISTRATION AND DISSEMINATION

The trial is registered on the Australian New Zealand Clinical Trials Register (ACTRN12621001073897). The results of this study will be shared via publication in a peer-reviewed academic journal. The BST exercise programme and progression principles will accompany the results in a peer-reviewed international journal as a supplementary appendix. All participants will be offered a lay summary of the results.

DISCLOSURES

The authors have no conflicts of interest to declare. HQH Fitness New Zealand has sponsored a Total Gym Jump Trainer for this study. The equipment sponsor will have no role in the study

design, data collection, analysis, or interpretation of results. The research project received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

PERMISSIONS

Ethical permission has been obtained from the following Ethics Committees: The Faculty of Health Sciences Research Ethics Committee, University of Pretoria (reference number 399/2021), and the Health and Disability Ethics Committee of New Zealand (reference number 21/CEN/238). The research study will be conducted according to the declaration of Helsinki. Formal Māori consultation was completed for this study. The principles of the Treaty of Waitangi and the guidelines on health research involving Māori participants (Te Ara Tika) will be applied.

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CONTRIBUTIONS OF AUTHORS

IG: Conceptualization, methodology manuscript drafting, manuscript review, and editing. DJM: Supervision, conceptualisation, initial manuscript review, and editing. AvH: Supervision, conceptualisation, initial manuscript review, and editing.

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