Research Proposal

Title

Efficacy of strengthening or balance exercises in a Falls & Balance Program

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Research Site and Department

St John of God Berwick Hospital, Outpatient Department

Background

Falls have a recurring prevalence within Australia, with studies reporting falls as the leading cause of injury and death-related hospitalisations in Australia (42%) (Australian Institute of Health & Welfare, 2021). The Australian Institute of Health and Welfare have highlighted the increasing hospitalisations caused by falls have increasing by 7% each year. Additionally, AIHW found that an increase in age led to an increased risk in fall related hospitalisations as 58% of hospitalisations and 94% of deaths were for the ages 65 and above. As a result, it is important to determine the most effective interventions that prevent falls and promote physical activity in our aging population.

Research demonstrates the importance of participating in physical activity to maintain sensorimotor system and postural control, as it diminishes with age (Tiedemann, Sherrington, Close & Lord, 2011). Exercise can target muscle strength, power, balance and coordination to reduce the increased risk of falling. It is found that performing only strength training without participating in balance-targeted exercises is not effective in preventing falls (Lord, Sherrington

& Menz, 2003). However, strength training has been shown to lead to improvements in balance that may demonstrate a benefit to the falls-risk population (Nejc, Loefler, Cvecka, Sedliak & Kern, 2013). In order for strength training to lead to improvements in balance, the exercises must focus on lower-limb or postural muscles, have limited upper-limb support and be provided moderate-high intensity.

It is important to examine reliable and valid outcome measures found in the literature to inform such an appropriate exercise intervention considering a combination of factors such as strength and balance for reducing the risk of falls. These outcome measures include the Timed Up and Go Test (TUG), Berg Balance Scale (BBS), Clinical Test of Sensory Integration and Balance and 6-meter-walk-test (6MWT). The TUG assesses balance, gait speed and functional ability that would be required for older people in their everyday lives. It is a key test that is used for falls risk screening and to detect if older adults are at an increased risk of falling (Beauchet et al., 2011). It is widely used due to its high intra- and inter-rater reliability. Another outcome measure that assesses physical balance is the Berg Balance Scale. It is an effective assessment that detects falls as it also has high reliability and reproducible results (Muir et al., 2008). This test is more sensitive in patients who have multiple falls and stroke survivors.

St John of God (SJG) Berwick Hospital currently offers an outpatient falls and balance program to patients across a 6-week period. Patients will require to attend 1.5 hours, 2 sessions per week with a combination of Physiotherapy, Exercise Physiology and Occupational Therapy services. A combination of exercise and education is tailored to the current individual needs of each patient in attendance. As clinicians, there is a growing concern that aging contributes significantly to falls risk and lack of education for patients on how to reduce their falls. There is no current research that assesses whether strength or balance interventions are more beneficial than the other for reducing falls risks. Thus, to find the most effective exercises that can target these falls-risk factors, SJG Berwick Hospital is aiming to revise the current falls and balance program to

determine whether strength or balance exercises leads to greater improvements in outcome measures across a 6-week period.

Aim

The purpose of this study is to evaluate whether strength or balance exercises leads to greater improvements in outcomes in patients who complete a 6-week falls and balance program in outpatient setting at SJG Berwick Hospital.

Method

Study Design and sample size

This study will be a single-blinded block allocation trial. The study will be conducted at outpatient clinic at SJG Berwick Hospital in Victoria.

Previous study done by Kristensen et al. (2019) suggested that a sample of 18 participants to achieve 80% power, 5% Type 1 error with ICC of 0.9 for the outcome measure TUG. Therefore the aim is to achieve a sample size of 50 participants (25 participants per group) and allow for 25% loss to follow up.

Recruitment of study participants, inclusion and exclusion criteria

A flyer will be displayed each ward at SJG Berwick Hospital to promote the Falls & Balance program (Appendix 1). Patients can contact the outpatient department if they wish to participate in this study.

Patients are eligible for inclusion in the study if they:

i. Referred to Falls & Balance program at SJG Berwick Hospital (Appendix 2)
ii. Over the age of 65
iii. Had a least one mechanical fall in the last 12 months prior to the commencement of the program

iv. Able to read and speak in English
v. Able to provide written consent

Patients are excluded if they:

i. Have Parkinson disease
ii. Had stroke in the last six months
iii. Have multiple sclerosis
iv. Had recent spinal surgery in the last six months
v. Have peripheral neuropathy
vi. Unable to participate one hour of exercise during the study period
vii. Have missed more than two consecutive sessions in the program

Allocation concealment and blinding

Participants will be randomized to either strengthening or balance group using a time-block method. Each block will be eight weeks (56 days). In the first block, participants will be allocated to the strengthening group and in the second block participants will be allocated to the balance group. The recruitment will stop when the sample size is reached.

Participants

Therapists who are delivering the Falls & Balance Program will issue the Patient Information Sheet for potential participants who wish to participate in this study (Appendix 3). If potential participants are eligible to participate in this study after an initial assessment completed by physiotherapist and occupational therapist, they will have 7 days to consider and will then complete the consent form (Appendix 4). Participants will only be informed that they will receive one hour of exercises plus 30 minutes of occupational therapy intervention twice a week for 6 weeks. They will not be informed of the type of the exercise (strength or balance). Participants can attend another session if they miss one session. However they will be excluded from the study if they miss two sessions consecutively.

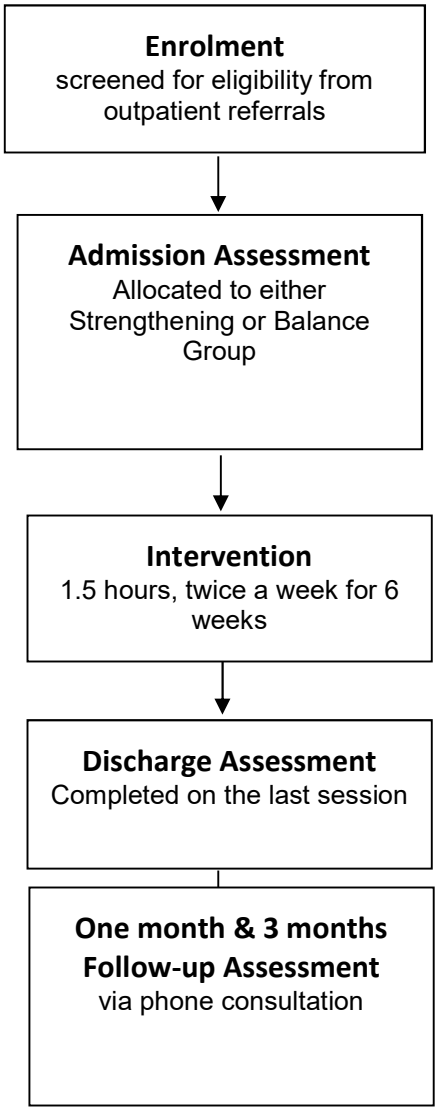
Therapists

Physiotherapists, exercise physiologists and, occupational therapists who work in outpatient clinic at SJG Berwick Hospital will participate in this study. Blinding of the treating therapists is not possible due to the nature of the intervention. However, they will be asked not to discuss the group allocation with participants. Each therapist will be trained in the treatment protocol to ensure the consistency of the intervention. All therapists will require to document each therapy session in the participants medical file in accordance with the hospital documentation requirements.

Assessors

Physiotherapists, exercise physiologists, occupational therapists who deliver the interventions of the Falls & Balance program will also be the assessors to complete the outcome measurements on initial, discharge, at 1 month and 3-month follow up.

Figure 1. Flow chart of the recruitment process.



Group Allocation

Strengthening Group

Participants who are allocated to the strengthening group will receive one hour of lower limbs strengthening exercises and 30 minutes of occupational therapy session twice a week for 6 weeks. Participants will receive a home exercise program on discharge.

Balance Group

Participants who are allocated to the balance group will receive one hour of balance exercises and 30 minutes of the same occupational therapy session as the strengthening group twice a week for 6 weeks. Participants will receive the same home exercise program on discharge.

Treatment Intervention

Exercises

Participants will complete a sixty minutes of exercise in each session. The exercises have been prescribed based off the Otago Exercise Program. This program consists of 23 strength and balance exercises that has shown to produce a 35-40% reduction in falls of participants and improvements in balance (Campbell, 2003). All participants will complete the same warm up exercises for both Strengthening and Balance group. Then the main exercises will be allocated to the respective groups which include targeting the strength of knee extensors, knee flexors, hip adductors, ankle plantarflexors (Figure 2.) and the balance exercises including knee bends, walking backwards, walking and turning around, walking sideways, tandem stance, tandem walk and one leg stance (Figure 3.). The groups will begin by being prescribed 10 repetitions as per the OEP and progressed by increasing repetitions and/or weights. Participants will be given a standard home exercise program on completion of the program. Participants may experience some discomfort after exercising such as delayed onset muscle soreness which is no difference to any exercise intervention.

Therapists will monitor participants' comfort in each session and will modify the dosage of the exercises if required.

On completion of the program, participants will receive a home exercise program that they can continue at home (Figure 4).

Occupational Therapy

Participants in each group will receive the same thirty minutes of occupational education session, delivered by an occupational therapist. The topics of each education is outlined in Figure 5.

Outcome Measures

Outcome measures including functional and self-reported measures will be collected on the initial assessment and on discharge. In addition, number of falls and self-reported measures will be collected at one month and 3-month follow up via a phone consultation.

The primary outcome measure will be TUG. Secondary outcome measures will include knee extensors strength, 6MWT, Health Quality of Life Measure (EQ-5D-5L), Falls Efficacy Scale (FES) and BBS.

Primary Outcome

TUG

The TUG is commonly used as a measure of mobility in older populations. The time taken for participants to rise from a chair, walk 3 meters and cross a line drawn on the floor, turn around and return to the chair is recorded. Time is measured in seconds with a stopwatch, and participants are seated on a 450mm height chair. Participants are instructed to walk at their comfortable pace. Then participants will commence the test on the instruction of 'ready-go' and the time of the test is started as soon as the participant's back has left the back rest. The time is stopped when the participants return and their buttocks touch the chair. Participants will have one practice trial followed by one timed trial. The test has showed excellent test-retest reliability (Intraclass Correlation Coefficient (ICC)= 0.80 to 0.97) and validity in inpatient orthopaedic populations (Mizner et al., 2011; Young, Wessel, Stratford, & Macdermid, 2008).

Secondary Outcomes

Knee Extensor Strength

Knee extensor strength will be measured by a hand-held dynamometer (Commander PowerTrack II) using the belt-resistance method. A hand-held dynamometer is inexpensive, portable, easy to use and commonly used in clinical settings. Measurement of quadriceps strength with a hand-held dynamometer and belt-resistance in a population of older adults has good intra- and inter-reliability with ICC between 0.70 and 0.90 (Ford-Smith, Wyman,

Elswick, & Fernandez, 2001; Kollock, Onate, & Van Lunen, 2010; Schache et al., 2015; Thorborg & Bandholm, 2013). The method used in this study is adapted from the report by Holm et al. (2010) where participants will be positioned at the end of the plinth with a hip angle of 90° and a knee angle of 60° (Figure 5). This position most closely corresponds to the joint position where maximal quadriceps force can be generated, and is therefore selected to measure the maximum capacity for force generation of the knee extensors (Becker & Awiszus, 2001; Lienhard et al., 2013; Thorstensson, Grimby, & Karlsson, 1976). To ensure a correct knee angle of 60°, the center of a 360° plastic goniometer is placed over the lateral femoral epicondyle. The proximal arm is aligned with the lateral midline of the femur with use of the greater trochanter as a reference, and the distal arm is aligned with the lateral midline of the fibula with use of the lateral malleolus as a reference. A belt is attached to the plinth and the patient's ankle is perpendicular to the lower leg, 5 cm above the lateral malleolus (Bohannon, Kindig, Sabo, Duni, & Cram, 2012). The transducer is then placed at the front of the ankle under the belt to measure the knee-extension force. The participants is instructed to contract "as forcefully as possible for three seconds," and verbal encouragement is provided during the contractions. Three contractions will be performed, each separated by a 60-second rest, and the greatest value will be used for data analysis. The knee extensor force will be recorded in newton (N) and it will then be normalized to the participant's body weight (kg) to allow for comparison between participants and intervention groups.

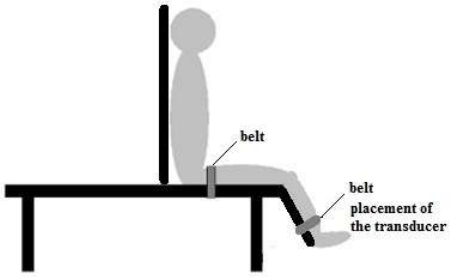


Figure 5. Diagram of the plinth set up for quadriceps strength testing

Health-related Quality of Life Measure (EQ-5D-5L) (Appendix 5)
It is a self-reported measure of health status. It consists of 5 domains include mobility, personal care, usual activities, pain/discomfort and anxiety/depression in ordinal scale (no problems, slight, moderate, severe and extreme) developed by the EuroQol group in 2010. The lower the score the better it is for patient's function, pain and anxiety level. It is a standard outcome measurement used in rehabilitation setting at St Joh of God Berwick Hospital. This tool has excellent test-retest reliability with ICC 0.7 and with moderate effect size in responsiveness (Feng et al., 2021)

Six Minute Walk Test (Appendix 6)
The 6MWT is a timed test that measures how far patients can walk in six minutes. It is a strong predictor of functional ambulation in total knee arthroplasty population (Ko, Taylor, Harris, Crosbie, & Yeo, 2013). This test has strong responsiveness to change over time as well as high test-retest reliability with an ICC of 0.94. (Kennedy, Stratford, Riddle, Hann, & Gollish, 2008; Ouellet & Moffet, 2002).

Falls Efficacy Scale (Appendix 7)
The Falls Efficacy Scale is a 16-item questionnaire that is able to predict the risk of falling in the community (Cruz-Diaz et al., 2015). It is a valid and reliable tool for measuring a fear of falling in an older population. It is used to evaluate physical, social and functional related concerns about falling. The score can range from 16 to 64, meaning complete absence of concern to extreme concern respectively. This outcome measure demonstrates more precise results that any other questionnaire that targets fear of falling because it looks at concerns relating to a variety of measures such as activities of daily living and functional tasks. It is also great for the measuring change over time from treatment.

Berg Balance Scale (Appendix 8)

The BBS is a widely used outcome measure to assess dysfunctions of balance in older populations as it is easy to complete and requires little equipment. It is a 14-item outcome measure including tests such as sit to stand, transferring to a chair, standing with feet together and standing on 1 leg. The aim of this test is to evaluate postural control, stability, and sensory strategies through static and dynamic activities. It is measured by a 5-point ordinal scale with 0 demonstrating the inability to complete the task and 4 as independent. The maximum score that a participant can score is 56, demonstrating high level of balance. It has a high test-retest (ICC=0.91) and intra-evaluator reliability (ICC=0.97) (Lima et al., 2018). The BBS is a valid measure for predicting falls in various populations and has a moderate to high reliability. However, the use of the BBS alone is not able to predict falls risk, and when used with other balance assessments, such as the TUG, will provide a better representation of falls risk prediction (Neuls et al., 2011).

Patient Specific Functional Scale (PSFS) (Appendix 9)

The Patient-Specific Functional Scale (PSFS) is a self-reported, patient-specific measure, designed to assess functional change among patients with varying levels of independence (Stratford et al., 1995). According to Stratford at al., (1995), "Patients are asked to identify up to five important activities they are unable to perform or are having difficulty with as a result of their problem. In addition to identifying the activities, patients are asked to rate, on an 11-point scale, the current level of difficulty associated with each activity." The PSFS considers the most affected and valuable aspects of their life at the time of assessment, which indicates the patient-centred component of the program. The PSFS is proven to be a valid and responsive outcome measure for individuals with back and neck issues as well as upper extremity and knee dysfunctional problems (Horn et al., 2012).

Adherence of the intervention

Attendance will be recorded in the medical file each time when participants attend the program session.

Data Analysis

Once this proposal has been approved the Human Research Ethics Committee, this study will be registered under ANZCTR before the recruitment of the first participant. Participants' personal details such as name and date of birth will be de-identified. Demographic data such as age, gender and outcome measures will be collected for data analysis. Those data will be retrieved from the SJG Berwick Hospital medical records from Health Information Department.

All data will be analysed using computer software SPSS. The characteristics of each group at baseline (on initial assessment) will be compared using t-test for continuous parametric data and chi-squared tests for categorical data.

Analysis of superiority between two treatment groups will be completed for the outcomes using independent sample t-test. Categorical data including adherence of the intervention will be described using the mode and range, and comparison between two treatment groups will be done using chi-squared tests.

All analysis will include intention-to-treat (ITT) analysis and per-protocol (PP) which will be used to assess the robustness of this trial. The last observation carried forward method will be used for ITT analysis meaning that any missing data will be replaced by the previous observed outcome. The per-protocol analysis will include participants who completed assessment both at discharge, one-month and three month follow up. The treatment effect of both intervention groups will then analysed with the use of a linear model statistic on both primary and secondary outcomes. CONSORT guidelines will be used for reporting this trial.

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