PROTOCOL DESCRIPTION

**1. TITLE**

**GUCCI (GEM UNIT CIRCUIT CLASS INTERVENSION)- Program**

**2. STUDY INVESTIGATORS**

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**3. BACKGROUND**

Hospitalization of older adults appears to result in functional decline mostly likely due to reduced activity level (1). Bed rest and low level of mobility were common occurrences during hospitalization of older adults (2). On average, these hospitalized older adults only spend 43 min a day standing or walking and 80% of their hospital stay is spent in bed (3). While it is acknowledged that bed rest and inactivity are detrimental for mobility and function, it is often observed that patients in the Geriatric Evaluation and Management (GEM) Unit are inactive during day hours.

Physiotherapists play a crucial role in maximising patient mobility and independence through the prescription and delivery of exercise programmes. The type and intensity of exercise are important factors in determining patient outcome (4). Systematic reviews have found that weight bearing and targeted task specific exercises can improve balance (5) and decrease falls (6) in older people.

Usual physiotherapy care provided in GEM unit consists of one-to-one individualised session. Exercises provided in groups via circuit training have shown benefits in improving balance in older people in the inpatient setting (7). Very little is known about the delivery of circuit class (therapy provided to more than 2 participants, involving a tailored intervention program with a focus on practice of functional task received in group setting (8)) in older people admitted to GEM unit who have multiple co-morbidities and reduced physical capacity.

This study sought to determine if additional exercise provided via circuit training improves balance and functional outcome more than usual physiotherapy alone in adults undergoing rehabilitation in GEM unit.

**4. AIMS & HYPOTHESIS**

**Aims:**

**1)** Investigate the feasibility of running exercise via circuit training in GEM unit.

**2)** To investigate whether additional exercise provided via circuit training improves outcomes including composite balance measure (CBM), balance outcome measure for elder rehabilitation (BOOMER), functional independence measure (FIM), reduce falls, length of stay and hospital readmission within 1 month of discharge than usual physiotherapy

**Hypothesis:**

Exercise provided via circuit training in addition to usual physiotherapy will be feasible and will improve balance and functional outcome compared to usual physiotherapy alone.

**5. METHOD**

**Study type/design**

A two group, parallel, randomised control trail conforming to CONSORT guidelines, with blinded assessment, concealed allocation and intention-to treat analysis will be conducted with patients admitted to the GEM unit at RBWH.

A total of 96 participants will be randomly allocated to one of the two groups via concealed allocation. An offsite investigator not involved in participant recruitment, assessment or delivery of the intervention will undertake randomisation. All participants will continue to receive usual physiotherapy. Participants will be assessed at admission and discharge.

**Population:** Participants aged 65 years or older and more admitted to GEM unit will be eligible to participate in the study. Participants admitted to the GEM unit will be screened and invited to participate in the study by treating physiotherapist. Once they fulfil the eligibility criteria the treating physiotherapist will ask the patients if it is permissible for a member of the research team to approach them to ask about a research study. Once the patient has given permission, a research team member will approach the patient with requirement document and the consent form. Participants who are not able to consent, next to kin will be contacted by a research team member to obtain consent. 48 hrs will be provided for participants/next to kin for consideration of the participation. Written information and consent will be provided by a member of research team, if they meet the eligibility criteria.

**Inclusion criteria:**

Aged 65 years and older, can stand at least 30 sec without assistance, may require maximum of one person assistance to complete functional task such as sit to stand or walking, can follow simple commands with mini- mental score of 17 and above, able to participate in weight bearing exercises.

**Exclusion criteria:** Medically unstable, pre-morbid non- ambulant, admitted to palliation, weight- bearing restriction, inappropriate behaviour or cognition for group therapy.

**6. INTERVENTION**

Participants in the **experimental group** will participate in circuit classes 3 sessions /week x 45 min each session in addition to their usual physiotherapy. The circuit group will consist of 6 different stations with each station comprising an exercise to be maintained for 5 minutes in a standing position. All exercises will be tailored to individual participants by senior therapist. Progression of exercise will be decided by senior physiotherapist depending on capability of participants to perform exercise safely. Participants will be encouraged to complete their exercise station with minimal supportive aids or equipment. Participants in the experimental group will continue to receive usual physiotherapy.

Participants in the **control group** will receive usual physiotherapy which consists of one to one physiotherapist prescribed exercises program delivered by either the ward physiotherapist or physiotherapist assistant. Exercise programs are individualised to patient needs and will include exercises such as bed exercises, targeted strengthening exercises, functional exercises or walking program.

**7**. **OUTCOME MEASURES (blinded assessor)**

*All outcome measures will be measured by a blinded assessor at study admission and before hospital discharge.*

**Primary Measure:**

**Composite Balance measure: (**CBM): Comprises five standing balance tests: Feet apart, feet together, semi tandem, tandem, and single leg stance. Each test will be performed without any hand support and timed up to max of 10 sec each. The sum of all tests is =/50. This test is based on SPPB (short physical Performance battery) (9) score and has been found to predict falls in inpatient rehabilitation (10)

**Secondary Measure:**

**Balance Outcome Measure for Elder Rehabilitation (BOOMER)**: Comprises of four previously validated tests including timed up and go, functional reach, step test, and standing balance test of feet together eyes closed. Test results are scored using a 5 point ordinal scale (0-4) with a maximum of 16 (11).

Other secondary outcome measure include Functional Independent Measure (FIM)(12), length of stay (LOS), number of circuit classes attended and repetition of exercises, falls during hospital stay will be retrieved from medical chart. 1-month hospital readmission rates will be collected via records and phone call to participants.

**8. SAMPLE SIZE AND STATISTICAL ANALYSIS**

Based on a previous study investigating circuit training in older adults undergoing rehabilitation a between group difference in the primary measure, the Short Physical Performance battery (SPPB) score, of a mean change of 1 and standard deviation of 1.7, aiming for a beta error rate of 0.20 and an alpha error rate of 0.05 for a 2 tailed test, 40 subject per group are required. Allowing for 20 % drop out due to the frailty of the population, 48 participants per group are required.

**Statistical Analysis :** Data will be checked for normality prior to analysis. Descriptive statistics will be undertaken to describe the sample. Between group analyses, either independent t-test or non- parametric Kruskal-Wallis test will be used to compare the composite balance score, BOOMER, FIM, and LOS, between groups over time. Hospital readmission and number of falls will be compared between group by a chi square crosstabs.

**9. STUDY PLAN**

Participants who are admitted to GEM unit will be screened for participation by the treating physiotherapist. The criteria for screening will be based on eligibility criteria. Once the participants are eligible for participating in the project, the treating therapist will ask the participant permission if it is permissible for a member of the research team to approach them to ask about a research study. The research member will approach the participant with the information and consent sheet explaining the details about the project. It will be made very clear to participants that the process of random allocated means (by chance) which means that one of the consequence may be that they may not, in fact, receive the treatment being tested and this will continue till you are discharge from the GEM unit. Details of the information sheet and consent form will be provided to each participants to read in their time. A member of the research team will visit the participant after 48 hrs. to collect the consent sheet. If in the beginning it was found that the patient does not have cognitive capacity to consent thru mini-mental state exam, then next to kin will be approached for the consent and results will be collected after 48 hrs.

Once the consent form is collected participant will be randomly allocation to one of the two groups.

Randomisation will be concealed from consent designee research staff. Participants will be then visited by blinded assessor for the initial collection of outcome measures. Once the admission outcome measure is completed participants will start their intervention depending on the group (intervention or control) they are allocated. They will continue either with intervention or usual care till they are discharge. Just before the discharge the blinded assessor will collect the discharge outcome. Once participants are discharged, a member of the research team will follow up either by medical health record or via a phone call to confirm, if there was any hospital re-admission with in a period of one month from the date of discharge.

**10. ETHICAL ISSUES**

**10.1 Recruitment**

All participants who are admitted to GEM unit will be screened for the eligibility criteria by the treating physiotherapist. Once they fulfil the eligibility criteria the treating physiotherapist will ask the patients if it is permissible for a member of the research team to approach them to ask about a research study. Once the patient has given permission, a research team member will approach the patient with requirement document and the content form. Participants who are not able to consent, next to kin will be contacted by a research team member to obtain consent. 48 hrs will be provided for participants/next to kin for consideration of the participation.

**10.2 Consent**

All participants will provide their own written informed consent or have this provided by a next of kin. All participants will be screened using the Mini- mental state exam to determine cognitive capacity. Only those scoring at least 17 and above will be deemed as having sufficient capacity to provide individual informed consent. People whose primary language is other than English will be eligible to participate in this study if their English is sufficient to understand the study requirements and provide informed consent.

**10.3 Benefits and Risks**

Participants will be explained about the benefits of participating in the project, which range from improvement in muscle strength, balance and confidence to manage their daily activities easily. These benefits will also reduce falls and possibly reduce length of stay in hospital.

Participants will also be explained about the minor risks associated with the project such as muscle soreness. During high intensity exercise there is always the risk of heart attack or fall, however explaining that they will be tested before exercise, monitor them very closely during exercise and have emergency procedure in place. Also explaining that exercising in hospital is safer than exercising by own.

**10.4 Data management**

Only investigators involved in this study will have access to information collected in this study. Participant information collected by the research team will be re-identifiable, as we need to be able to identify the patient to ensure the correct information from different sources is entered for that patient. When all information has been entered we will de-identify all data. The information on participants will be stored in both paper copy and electronic files. Paper based data will be stored in a locked filing cabinet in a locked office. Electronic files will be stored on password protected computer. The information stored at the completion of the project will be in a non- identifiable type. The information collected after the completion of the project will be stored for Fifteen years as per protocol. Paper copies will be destroyed in a confidential shredder and data stored on computer will be destroyed using the most up to date available data cleaning software available at the time.

The individual results obtained during this research will be shared ONLY to the individual participants only. For example: when their outcome measure are completed at discharge, participants will be informed about their admission and discharge outcome verbally.

If any participants or family members ask the results of other participants then they will be directed to the consent form which describes that other participant results will NOT be disclose to any other participant.

**11. WITHDRAWL OF THE STUDY TREATMENT (TRAIL)**

In accordance with the Declaration of Helsinki, each subject has the right to withdraw from the study at any time. An investigator also has the right to withdraw subjects from the study in the event of inter current illness, adverse events (AE) or other reasons concerning the health or well being of the participants. The Investigator also has the right to withdraw subjects in the case of lack of compliance.

Following randomization, all efforts will be made to keep the participant in the trial. The participant or their legal surrogate may withdraw from the study if they decide to do so, at any time, irrespective of the reason, or this may be the investigator’s decision. Should a subject decide to withdraw after commencement, or should the Investigator decide to withdraw the subject, all efforts will be made to complete and report the observations up to the time of withdrawal as thoroughly as possible. The reason, date and time of withdrawal will be recorded in the case report form. All treatment discontinuation will be recorded by the investigator in the source notes.

**12. SUPERVISION**

Regular team meetings will be held. Principal investigator and co-principal investigators will review study progress at these meetings, address pertinent issues and identify further actions to be taken. The principal investigator along with co-principal; investigator will ensure via this regular review process that data is managed appropriately (i.e. stored in a de-identified fashion) and that appropriate steps are taken with regard to data cleansing and dissemination of results. A safety committee will be formed by two researcher. They will review the data and any adverse incidents monthly.

**13. DISSEMINATION OF FINDINGS**

The summary outcome of the project will be disseminated to participants if desired by the participants in form of hard copy. A verbal summary of individual results will be provided to participants.

This project may be disseminated via conference presentations and manuscripts. If this occurs collated and de-identified data will be presented. No identifying information will be disseminated or used for other activities.

Positive results will lead to change in core practice of physiotherapy delivery in GEM unit.

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