Study Protocol

Evaluating the feasibility of providing a newly developed multifactorial falls prevention programme for community-dwelling patients after stroke.

Protocol Version and Date: 1.1_2018-03-05

Short Title: The Fall Monty Activity Programme (FallMAP) Feasibility Study

REC Reference: HRE2018-0104

Funder: Curtin University

Protocol Summary

Short title:	The Fall Monty Activity Program Feasibility Study
Protocol version:	1.1
Protocol date:	2018-03-05
Chief Investigator:	Dr. Lex D. de Jong
Sponsor:	Curtin University
Funder:	Curtin University
Study design:	An exploratory mixed-method phase I feasibility study with a pre-post design.
Study aim:	To evaluate the feasibility of providing a newly developed multifactorial falls prevention programme ('the Fall Monty Activity Programme') for community-dwelling patients after stroke.
Specific objectives:	1) to explore the participants' and the therapists' experiences (barriers, enablers) on the *acceptability* (e.g. appropriateness, satisfaction, safety), *implementation* (e.g. execution, factors affecting implementation ease) and *practicality* (e.g. ability of participants and staff to carry out the interventions) of the programme. 2) to explore whether participating in the programme can positively influence the participants' fear of falling, quality of life, balance and mobility and social engagement.
Study population/size:	10 community-dwelling patients after stroke.
Study duration:	12 months

2. Plain Language Summary

Between 45-73% of people who have had a stroke fall over in the months and years following their stroke. Falls not only lead to physical harm such as hip fractures, but they may also lead to an increased fear of falling and a subsequent downwards spiral of inactivity that impedes people to perform their everyday activities (such as walking, household and leisure activities). This cascade of problems can lead to reduced social participation and reduced quality of life.

Research has shown that exercises for strength and balance can help both older people and patients after stroke to get fitter, healthier, improve their balance capacity and help them prevent having falls. Other key elements in reducing the risk of falls are home safety interventions and falls prevention education. Research has further suggested that 'safe landing' strategies may help to reduce people's fear of falling and reduce how seriously and how frequently people injure themselves from a fall. All this knowledge from previous research has prompted falls prevention researchers from Curtin University to developed a new, therapist led exercise and multifactorial falls prevention programme called the *Fall Monty Activity Programme (FallMAP).* This programme aims to aid in functional recovery and reduce falls by combining a mix of activities such as falls education, strength and balance exercises, and activities that teach people how to get up from the floor and how to fall safely. The programme also includes a social activity (morning or afternoon tea) after each session. Especially because people with residual impairments following a stroke have an increased risk of a fall we have decided to test the feasibility of this programme in a small group of people after stroke.

The aim of this study is to evaluate the feasibility of providing the FallMAP to community-dwelling patients (n = 10) after stroke. We want to explore the participants' and the therapists' experiences (barriers, enablers) on the *acceptability* (e.g. appropriateness, satisfaction, safety), *implementation* (e.g. execution, factors affecting implementation ease) and *practicality* (e.g. ability of participants and staff to carry out the interventions) of the programme, and explore whether participating in the programme can positively influence the participants' fear of falling, quality of life, balance and mobility and social engagement.

Especially because people with residual impairments following a stroke have an increased risk of a fall we have decided to test the feasibility of this programme in a small group of people after stroke. This study is a first step in establishing whether the different components of the FallMAP are acceptable and practical for both patients after stroke and staff who deliver the program. In particular, it is important to evaluate if it is feasible to provide the seven combined components as one comprehensive programme. Secondly, we want to explore whether participating in the programme can positively influence the participants' fear of falling, quality of life, balance and mobility and social engagement. If this feasibility study suggests the programme can work in the clinical setting, then a definitive randomised controlled trial will be proposed in order to look at whether the full programme is effective at reducing falls in patients after stroke.

3. Protocol contacts

Chief Investigator (CI):

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The CI (Lex D. de Jong) (PhD, MSc PT, BASc PT) is a Research Fellow with over 15 years of clinical experience and experience of managing and organising quantitative and qualitative research projects. The PI has ample experience in designing trials, preparing ethics applications and trial registration, training assessors and clinical staff in administering assessments and interventions, preparing standard operating procedures, case report forms, day-to-day trial management, planning and performance of baseline and follow-up actions, financial control, data management, data analysis, and preparing manuscripts for publication. In the past two years the CI has taken four qualitative courses and has led two mixed-method research studies which included activities such as organising and moderating focus groups, performing in-depth interviews, and performing qualitative data analysis using thematic analyses.

Co-investigator 1:

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The CI (Anne-Marie Hill) (PhD, B App Sc; M Sc; Grad Cert.Uni. Cert) is an Associate Professor who previously held an NHMRC Early Career Fellowship in the area of falls prevention. She is currently leading falls prevention projects in community, residential care and post joint replacement populations. She has worked extensively in health department hospitals and has extensive clinical (gerontological physiotherapy) and education experience, is a member of the WA Health Department Falls External Advisory Group and is conducting two falls prevention trials in WA, sited within WA Health Department settings. She has PhD students working in this area and also works with clinical staff in WA to assist in translation of falls prevention evidence into practice. She is experienced at leading large randomised trials in WA (currently CIA of a NHMRC funded RCT being conducted in WA) and has conducted extended qualitative and quantitative studies.

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4. Background

Annually, 15 million people worldwide - and 377,000 Australians - suffer a stroke.(1),(2) A stroke can cause muscle weakness, sensory loss, reduced attention, and abnormalities of vision and spatial awareness.(3) These impairments in body functions pose a significant challenge to maintaining balance and can impact on recovering functional activities (such as gait) and preventing falls. Patients after stroke have a very high risk of falling, with incidence rates reported to be as high as 45-73% in the chronic phase post-stroke.(4),(5),(6),(7) Due to ageing of the population and improvements in post stroke life expectancy the societal impact of falls after stroke is growing,(8) for both patients and their carers.(9) Falls not only lead to physical harm such as hip fractures,(10) but they may also lead to an increased fear of falling(11) and a subsequent downwards spiral of inactivity that can put people closer to or below the critical 'thresholds' of performance necessary for everyday activities.(12) This cascade of problems leads to reduced social participation,(13) and reduced quality of life.
Exercise as a single intervention is a well established evidence based approach to falls prevention in community-dwelling older people(14) and to improving balance capacity in patients after stroke.(15) Multifactorial approaches (which typically include group and home-based exercise programs, home safety interventions and Tai Chi exercises) can also reduce the rate of falls(16) in the general older population, but are underexplored(17) in patients after stroke. Because all people with residual impairments following a stroke are considered at increased risk of a fall(4) and stroke survival has increased,(8) more research in this population is urgently needed.(17)

Exercise interventions targeted on strength and dynamic balance which have evidence for effective use within falls prevention services are the group based Falls Management Exercise (FaME)(18) programme and the Otago home exercise programme.(19) Recent systematic reviews and meta-analyses have further provided some preliminary evidence that innovative gamified exercises ('virtual reality','Exergames') can improve balance and falls risk factors after stroke.(20) However, although it has been established that regular participation in physical activities and exercise is integral to reduce the risk of falls,(21),(22) other key elements are falls prevention education,(23) and providing a home falls hazard evaluation.(24),(25) Patients after stroke also value inclusion of a social element.(26),(27) A novel approach would be to include safe landing/falling techniques as a component to a multifactorial approach as a means to teach individuals how to fall in such a manner to reduce injury.(28) Research has suggested that falls involve a predictable series of responses which facilitate safe landing,(29) and that fall-related impact forces can be reduced by appropriate volitional arrest strategies.(30) To date, research into such safe landing/falls technique strategies has only included older subjects on one occasion.(31) Adding this latter component to a multifactorial falls prevention intervention may help to further reduce the fear of falling and reduce how seriously and how frequently older people or people after stroke injure themselves from a fall. Research is warranted to verify the effectiveness and suitability of these strategies for at-risk populations.(28)

The *Fall Monty Activity Programme (FallMAP)* is a novel therapist led exercise and multifactorial falls prevention programme recently designed by the falls prevention research team at Curtin University specifically for use in patients after stroke to aid in functional

recovery and reduce falls. The programme includes *four* interventions that are based on best available evidence (i.e. falls prevention education, FaME group based exercise programme, Otago home exercise programme, and a home falls hazard evaluation) and *three* components that have not previously been investigated as part of multifactorial falls prevention approach (i.e. Exergames, safe landing/falls technique training - which includes teaching people how to move if on the floor and how to safely get up from the floor-, and a social activity undertaken after the exercise sessions). This programme aims to increase falls prevention knowledge, increase strength and balance, evaluate home falls hazards, teach individuals how to land safely in case of a fall, how to move on the floor and how to get up again. The delivery mode of the programme provides participants an opportunity to train and socially interact with support from a small group of peers. Feasibility of delivering this multifactorial programme requires investigation.

5. Study Aims and Objectives

Study Aim

The aim of this research project is to evaluate the feasibility of providing a newly developed multifactorial falls prevention programme for community-dwelling patients (n = 10) after stroke.

Study Objectives

1) to explore the participants' and the therapists' experiences (barriers, enablers) on the *acceptability* (e.g. appropriateness, satisfaction, safety), *implementation* (e.g. execution, factors affecting implementation ease) and *practicality* (e.g. ability of participants and staff to carry out the interventions) of the programme,

2) to explore whether participating in the programme can positively influence the participants' fear of falling, quality of life, balance and mobility and social engagement.

6. Method

Study Design

This is an exploratory mixed-method phase I feasibility study with a pre-post design.

Participants, Sample Size and Eligibility Criteria

A convenience sample of 10 patients after stroke will be recruited.

Participants are eligible for participation if they 1) are over 50 and more than 6 months post-stroke, 2) live in the community, 3) have good cognition (MMSE ≥ 25 points) and 4) are able to walk at least three times weekly outside their home without hands on supervision (with or without the use of a walking aid). Participants will be excluded if they 1) have medical issues preventing them from participating in moderate to vigorous strength and balance exercises

and 2) have receptive aphasia impacting on ability to follow instructions and 3) are unable to provide informed consent.

Intervention

The programme delivered during this feasibility study will consist of a total of 12 multifactorial falls prevention group exercise sessions. Each session is 90-100 minutes in duration, followed by a 20-30 minute social activity (2 hours in total). The sessions will be offered over a period of 8 weeks, with one session in one week and two sessions in the next. Each session will comprise (a mix of) seven program components of the intervention:

1) *Falls prevention education*: Fifteen minutes of each session will be spent on an existing educational programme(23) that is framed on the principles of changes to health behaviour. This part of the programme is aimed to alert patients to their personal risk of falls, raise their knowledge about falls epidemiology and falls prevention. The educational information will be aimed specifically at patients after stroke.

2) *FaME group-based exercises* for strength and dynamic balance (these include some basic Tai Chi exercises). Fifteen minutes of every other training session will be spent on this part of the programme.

3) *(Preparing for) home exercises*. Selected components of both the FaME group-based exercise programme and the Otago home exercise programme will be practised in order to prepare participants to perform these at home for 10-20 minutes per day for the duration of the intervention.

4) *Interactive, virtual reality gamefied exercises*. This part of the program comprises a Kinect-based Exergame system (http://mirarehab.com/product) which will be used to transform existing physical therapy strength and balance exercises into fun video-games. This element is to improve enjoyment, and encourage adherence to the exercise component of the programme. In groups of two or three, participants will spend 30 minutes using this system between them. Each participant's training time and training level will be tailored to the individual, with the aim to gradually increase training impact.

5) *Getting on and off the floor / floorwork / safe landing & falls technique activities*. In groups of two or three participants, and over 12 sessions in stepwise progression of duration and difficulty, 30 minutes per session will be spent on exploring feelings of being balanced and off-balance, feelings of falling, and teaching participants how to fall safely, how to move if on the floor, and how to safely get up from the floor. A bespoke training programme (as based on similar programmes used in stroke rehabilitation) will be used. To ensure safety, all these activities/exercises will be tailored to the individual, supervised and guided on a one-to-one basis.

6) *Home falls hazard evaluation.* Participants will be issued with the Stay on Your Feet® Home Safety Checklist (booklet) and they will be asked to make their home and surrounding environment safer according to this checklist. Actions taken and barriers addressed will be discussed during (one of the) falls prevention education sessions.

7) *A social activity after the exercise session:* Participants will be invited to enjoy a (20-minute) morning/afternoon tea and socially engage with the other participants/therapists after

each session. Peer to peer support activities of sharing and phone contact will be encouraged.

The intervention will be delivered by two qualified and trained health professionals: a physiotherapist and a exercise physiologist. They will deliver the programme to 5 participants at the time, so in total two groups will be organised. Although all the activities will be delivered during a group session, exercises and activities can (and will) be tailored to (and be performed at the discretion of) the individual participants where necessary.

The detailed schedule of the FallMAP sessions is presented in Appendix 1.

Setting

The FallMAP sessions will be delivered in room 201 of the Curtin Health and Wellness Centre, Building 404 on the Bentley Campus. The Health and Wellness Centre has easy access in terms of public transport, (limited) patient parking and physical access.

The main research activities will be performed at the School of Physiotherapy and Exercise Science, Faculty of Health Sciences, Building 208, room 3508 (CI).

Quantitative data collection

Participants who are willing and eligible to participate will be invited to undergo a one-hour baseline assessment in the week prior to commencement of the FallMAP programme. During this assessment eligibility will need to be confirmed. The first test during this baseline assessment will be the Standardised Mini-Mental State Examination (SMMSE; see Appendix 2). Only if the participant meets the criterion of ≥ 25 points on the SMMSE he/she will be allowed to continue with the remainder of the baseline assessment. Participants who score below 25 points will be informed that they are not eligible to enrol due to scoring below this level on the test. The researcher will advise participants to contact their GP to discuss the result. The one-hour outcome assessment will take place within one week of completing the programme.

Participant characteristics

The following participant characteristics will be collected during the baseline assessment: age (years), gender (male/female), time post-stroke (months), side of lesion (left/right), type of lesion (ischemic/hemorrhagic), self-rated health status (poor, fair, good, very good, excellent), the number of different prescribed medications, if the participant has discussed falls with their health provider (yes/no), if the participant is undertaking/has undertaken any healthy ageing or falls prevention activities (yes/no), recent falls history (fall in the past 12 months, yes/no; injured as a result of a fall, yes/no), and if the participant is able to stand up from the floor without assistance (yes/no).

Outcome measures

The following outcome measures will be administered both at the baseline and outcome assessment:

Questionnaires:

1) a bespoke semi-structured survey about the participants' falls prevention knowledge (11 true/false/unsure knowledge statements about falls and falls prevention).

2) the Short Falls-Efficacy Scale-International (FES-I). The FES-I is a validated and reliable 7-item tool which measures confidence in performing a range of activities of daily living without falling.

3) The European Quality of Life 5 Dimensions Health Questionnaire (EQ-5D-5L)(32) measures health based on a descriptive system that defines health in terms of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.

4) the Stroke Impact Scale (SIS) assesses stroke-specific quality of life. The SIS is reliable, valid and sensitive to change.(33)

Balance and Mobility tests:

5) the Functional Ambulation Classification (FAC) classifies functional ambulation in patients undergoing physical therapy.(34),(35)

6) The Berg Balance Test (36) is a psychometrically sound measure of balance impairment for use in poststroke assessment. Given the floor and ceiling effects it is recommended that it is used in conjunction with other balance measures.

7) the 4-Square Step Test (37) is a reliable and valid clinical test of dynamic standing balance with high sensitivity and specificity.

8) the 5-Times Sit-to-Stand Test (38) is a functional mobility test that has excellent reliability as a measurement tool that correlates with knee flexors muscle strength.(39) (40)

All assessments will be conducted by an experienced physiotherapist.

During the intervention period the participants will be monitored for their adherence to the group exercise programme (attendance register kept by the therapists). The participants will also be asked to keep a record of the time they spend on their home exercise programme, and their fall events (with subsequent injuries) during the intervention period (self-reported through diary, see Appendix 3).

Quantitative data collection

During the outcome assessment participants will be individually interviewed about their experiences with the programme by an experienced physiotherapist who was not involved in delivering the FallMAP sessions. Family members involved with the patient will also be invited to consent (see Appendix 4) an interview. The Patient Information Statement for the family members can be found in Appendix 5.

Depending on the group a one-hour focus group may be undertaken. The topics guide for the interviews can be found in Appendix 6.

Semi-structured individual interviews of up to an hour's duration each will be held with the two staff members (instructors of the FallMAP sessions) within 2 weeks after all intervention

sessions have been completed. The topics guide for these interviews can be found in Appendix 7.

Study Data and Data Collection Procedures

The data collected during this study will consist of six paper questionnaires, physical (balance and lower limb strength) tests, audio-recordings (in-depth interviews), field notes (observations during the exercise classes), an attendance register and self-report diaries (home-exercise compliance and falls events). All assessments will take place in the exercise venue.

Baseline assessment

First the participants will be asked to provide written informed consent. Then the assessor (a research physiotherapist) will check the participant's level of cognition (duration: 10 minutes). If sufficient for participation (SMMSE ≥25 points) the participant characteristics will be collected (duration 10 minutes) followed by the six questionnaires (duration 20 minutes). Finally, the three physical tests will be administered (duration 20 minutes). All questionnaires and physical tests can be found in Appendix 2.

Outcome assessment

After the final (12th) FallMAP session each participant will be invited to undergo a one-hour outcome assessment. The research physiotherapist will repeat the five questionnaires (duration 20 minutes) and the three physical tests (20 minutes). Finally, the in-depth interview will take place (duration: 20-30 minutes).

Staff interviews will take place within two weeks of the final FallMAP session.

Screening, Recruitment and Consent Procedures

Identification and screening of participants

Participants will be identified and recruited through promotion of the project to out-patients from the researchers' local network and (if needed) promotion through the *Council on the Ageing* (COTA WA; http://www.cotawa.org.au/) and *Injury Matters* (https://injurymatters.org.au/) newsletters.

Recruitment procedures

The main method of recruitment consists of handing out information about the study and an example of the informed consent form to identified and potentially eligible participants. The Participant Information Statement (Appendix 8) and Consent Form (Appendix 9) for the study will be available only in English. Following receipt of the information about the study participants can contact the CI if they would like to participate.

People in the networks of the researchers can be active physiotherapists that know patients, and who may approach patients who they think are eligible to, and might benefit from, participation. To avoid the potential for coercion it will be made explicitly clear to these 'recruiting' active physiotherapists that when they hand out the Patient Information Statement

they must explain to each potential participant that they are not obliged to participate, and if they choose not to participate or withdraw after the start of participation, their medical care and legal rights will not be affected.

Consent procedures

Signed consent (Appendix 9) will be sought prior to the baseline assessment, and only when the researcher has ensured that the participant has accessed and understood the information provided. Each participant will be asked to sign two informed consent forms; one will be retained in the Investigator Site File, and one will be provided to the participant. The right to refuse or withdraw (from) participation without giving reasons will be respected.

7. Statistical Considerations

As this is a feasibility study the analyses will be primarily descriptive.

Quantitative data analysis

The quantitative data collected during this study (participant characteristics, participant questionnaires, physical tests, compliance, number of fall incidents, data completion) will be analysed and presented descriptively in terms of means (standard deviations), medians (interquartile ranges) and categories. Data completeness will also be ascertained of the instruments and any potential bias in the completion data to inform the choice of instruments in a future trial.

Qualitative data analysis

All in-depth interviews will be recorded, fully transcribed verbatim, anonymised and coded. Transcripts will not be returned to participants for comments or corrections. The analysis will be performed using thematic analysis, which is a method for identifying, analysing and reporting patterns ('themes') within data.(41) Thematic analysis focuses on similarities and differences and results in the organisation of the data from codes into (candidate) themes (42). The analysis will be performed by two of the authors (LDdJ, JF-C) with all authors agreeing the final themes. Quotes illustrating each theme will be identified for use in the publication(s).

Assessment of the feasibility to progress to a full trial

Following the completion of the qualitative interviews the research team members will have a discussion about the practicality of the study design, its impact on and acceptability to, both patients after stroke and professionals, and the acceptability and applicability of the outcome measures for the intervention. The conclusions from this discussion will inform the development of a definitive RCT. The progression criteria to judge the feasibility of progressing to a full trial are:

1. ≥70% of the participants complete 9 of the 12 group sessions (compliance)
2. <10% of serious adverse events (SAEs) deemed due to the intervention.

8. Risks and benefits

Risks

During this research study the participants will be exposed to balance challenging exercises, and exercises that can result in muscular fatigue. Recent research has shown that older people are at increased risk of falling following intensive endurance exercise bouts,(43) through exercise induced alterations in respiration and muscular fatigue. The same will be true for people who have had a stroke. Increased muscular fatigue may exacerbate existing gait and balance difficulties, further increasing the risk of falls. It is therefore essential that participants are offered a targeted and appropriately balanced exercise programme which is gently increased in duration / exercise load.

Benefits

In the longer term, participating in this study may have positive impacts on the participants' gait and balance, both physically but also psychologically, in terms of increasing confidence and lessening fear of falling which may have resulted in the adoption of falls risk behaviour, such as abnormal gait and postural balance and slower walking speeds. This study will add to an emerging body of work that is using fear of falling as assessed by a widely validated cross cultural tool (the Falls Efficacy Scale-International) to address the gap in knowledge of how to manage fear of falling successfully in patients after stroke. Participating in this study may further raise awareness amongst the participants of their risk of falling, and may motivate them to continue performing healthy ageing activities that are also good for falls prevention after the study. A potential third benefit for participants of this study is that it will enable them to draw on the existing knowledge about how older adults have low levels of self-perceived risk of falls and generally lack the willingness to take up existing falls prevention strategies.

Withdrawal of participants

Participants have the right to withdraw from the study at any time for any reason, and without giving a reason. Should a participant decide to withdraw from the study, he/she will be asked if they would be happy for the reason for the decision to withdraw to be recorded. The investigator also reserves the right to withdraw participants from the study in the event of inter-current illness, adverse events (AE), serious adverse events (SAE), or if it is judged that it is in the participant's best interests.

9. Adverse Events Reporting

For the purpose of this study, an adverse event (AE) is defined as any untoward medical occurrence in a participant to whom the study procedure or intervention has been administered, including occurrences which are not necessarily caused by or related to that intervention. An AE, therefore, does not necessarily have a causal relationship with the intervention. Medical conditions/diseases present before starting the intervention are only considered adverse events if they worsen after having started participating in the intervention. An AE that is not listed in the study protocol as an expected occurrence in the circumstances of this study is being considered an unexpected AE.

As described in the risks paragraph above, expected adverse events during participation in this study include the following:
- slips, trips and falls and its consequences: cuts and abrasions, soft tissue injury, fracture.
- muscular/joint pain associated with the above or with increased physical activity.

All AEs judged by the reporting exercise instructor as having reasonable causal relationship to a study procedure or the intervention qualifies as a 'related AE'. The expression *"reasonable causal relationship"* means to convey in general that there is evidence or argument to suggest a causal relationship. An assignment of causality should be made by the exercise instructor responsible for conducting the FallMAP sessions using the definitions in the table below. All AEs judged as having a reasonable suspected causal relationship to a study procedure or the intervention (i.e. definitely, probably or possibly related) are considered to be related AEs. If required, the opinion of the participant's own GP will be sought. In the case of discrepant views on causality between the investigator and others, all parties will discuss the case. In the event that no agreement is made, Curtin University's HREC will be informed of both points of view.

Relationship	**Description**
Unrelated	There is no evidence of any causal relationship
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the study procedure). There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant treatment).
Possible	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the study procedure). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant treatments).
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definitely	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.
Not assessable	There is insufficient or incomplete evidence to make a clinical judgement of the causal relationship.

Any untoward occurrence (whether expected or not) that results in death, is life-threatening (refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe), requires hospitalisation, results in persistent or significant disability or incapacity or is otherwise considered medically significant by the participant's own GP is considered a Serious Adverse Event (SAE). SAEs exclude any pre-planned hospitalisations not associated with clinical deterioration, routine treatment or monitoring of the studied indication not associated with any deterioration in condition, or elective or scheduled treatment for pre-existing conditions that did not worsen during the study.

AE/SAE Reporting

Before the start of each FallMAP session, participants will be asked whether they have experienced any AEs or SAEs. Any AEs or SAEs reported on the falls diaries will also be assessed. All reported AEs and SAEs will be recorded in the patient's case report form and assessed for causality and seriousness. For safety reasons, the CI (LDdJ) and the exercise instructors will discuss any recorded related AEs and SAEs reported by the exercise instructors during the sessions or as reported by the participants during their 12 weeks of participation. All related AEs and SAEs will be reported to all investigators and Curtin's Human Research Ethics Committee (HREC) by the CI within five working days of their occurence. The research team will monitor any trends in related AEs and SAEs and bring the programme to a close, should this be deemed necessary.

To reduce the possibility of AEs and SAEs during the project the exercise deliverers (physiotherapist) will be qualified to deliver exercise programs to older people and ensure the exercises undertaken by the exercise participants are safe and clearly understood.

10. Risk Management

Any incident (including falls) of a participant during their visit to the Health and Wellness Centre (including the FallMAP exercise sessions) will be handled in accordance with the general emergency procedures of the venue (see Appendix 10). This procedure is in line with Curtin University's Incident and Hazard Reporting procedure: (https://healthandsafety.curtin.edu.au/event_and_hazard/index.cfm).

11. Data Handling & Record Keeping

The information collected during this research study will be mainly re-identifiable (coded). The audio-recordings of the interviews will be transcribed and the transcripts will subsequently be anonymised. As such the qualitative data is non-identifiable (anonymous).

Any information collected will be treated as confidential and used only in this study unless otherwise specified. All source data relating to consented study participants will be stored and processed in line with Curtin University requirements. All source data held in paper form (Case Report Forms) will be scanned and securely stored in a locked filing cabinet in the research office at Curtin University as soon as possible after data collection.

Scans of the paper versions of data will be saved on Curtin University's R-drive. These data will also be entered into a computer spreadsheet, and backed up, on Curtin University's R-drive. Only the CI and will have access to this secure area. All source data held in audio-form (in-depth interviews with participants and staff) will be uploaded to Curtin University's R-drive as soon as the PI is back at their work base. Copies held on the audio recorders will be deleted as soon as they are uploaded successfully. All copies of audio recordings will be destroyed once they are successfully transcribed, anonymised and backed up. All qualitative data will be stored on Curtin University's R-drive to which only the PI and CI will have access.

All data and consent forms collected during this study will be kept under secure conditions at Curtin University for 25 years after the research has ended and then it will be destroyed.

12. Ethics & Regulatory Issues

The conduct of this study will be in accordance with the recommendations as described in the *National Statement on Ethical Conduct in Research* (2007, updated May 2015). Favourable ethical opinion from the Human Research Ethics Office (HREC) of Curtin University approval will be sought prior to commencement of the study. Information sheets will be provided to all eligible subjects and written informed consent obtained prior to any study procedures.

Confidentiality

Personal data will be regarded as strictly confidential. To preserve anonymity, any data leaving the site will identify participants by their initials and a unique study identification code only. All study records will be kept at Curtin University in a locked filing cabinet with restricted access.

Study Report / Publications

The data will be the property of the CI. Publication will be the responsibility of the CI. It is planned to publish this study in peer review articles and to present data at national and international meetings. Individuals will not be identified from any publication. Participants will be informed about the study, including a lay summary of the results.

13. References

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