Pragmatic multicentre stepped-wedge cluster randomised trial to investigate the effectiveness of community-based falls prevention programme for older adults with falls risk in Singapore: a protocol paper

Pey June Tan,1 Mimaika Luluina Ginting,1 Zoe Zon Be Lim,1 Nivedha Balachandar,1 Rehena Sultana,2 Muntaz Mohamed Kadir,1 Tianma Xu,3 Noor Hafizah Ismail,4 Joyce Kwee Yong Yap,4 Sweet Fun Wong,5 Joanne Yoong,6,7 David Bruce Matchar,8 Keith Hill,9 Chek Hooi Wong1,8

ABSTRACT

Introduction Falls are an important public health issue with consequences that include injuries, quality of life reduction and high healthcare costs. Studies show that falls prevention strategies are effective in reducing falls rate among community-dwelling older adults. However, the evaluation for effectiveness was usually done in a controlled setting with homogeneous population, and thus may not be generalisable to a wider population. This study aims to evaluate the impact of community falls prevention programmes with group-based strength and balance exercises, on falls risk and health outcomes for older adults with falls risk in Singapore.

Methods and analysis This is a pragmatic closed cohort stepped-wedge cluster randomised trial design study, which involves sequential crossover of clusters from the waitlist control condition to the intervention condition, with the sequence of crossover randomly determined. The intervention will be sequentially rolled out to 12 clusters (a minimum of 5 participants/cluster), over 6 time periods with 8-week intervals in Central and North regions of Singapore. The primary analysis will be conducted under the intention-to-treat principle. A general linear mixed model or generalised estimating equation analysis appropriate for a multilevel longitudinal study incorporating an appropriate error distribution and link function will be used. Markov model will be developed to estimate the incremental cost per quality-adjusted life years and incremental cost per fall prevented from the implementation of falls prevention strategies from a societal perspective. Conditional on there being clinically relevant differences in short-term outcomes, we will implement simulation modelling to project the long-term divergence in trajectories for outcomes and costs using the Markov model.

Ethics and dissemination Ethics approval has been obtained. Results will be disseminated in publications and other relevant platforms.

Trial registration number NCT04788251.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This pragmatic study will generate real-world evidence on the effectiveness of community-based falls prevention intervention in an Asian country.
⇒ Compared with the traditional parallel cluster randomised controlled trial design, a sequential roll-out of the intervention in a stepped-wedge design enables a more efficient study and implementation resource allocation, amid the logistical constraints in a COVID pandemic.
⇒ The study started during the COVID pandemic in Singapore where restrictions were put in place for the numbers of people allowed in a room with additional safety protocols to be put in place. These restrictions may limit the number of planned recruitment of 12 community sites as clusters and participants.
⇒ The study actively engaged community-based stakeholders in community site managers and programme implementers for study design and implementation. However, there was limited involvement for the general public.
⇒ The productivity measures will be limited to loss of productivity from individuals in formal employment in the economic evaluation. The value of time will not be otherwise captured but will be noted as a significant limitation.

INTRODUCTION

Falls are a major public health concern as 30%–39% of community-dwelling adults above 60 years had a fall in a 12 month period, of which 30% resulted in injuries, and 15% of emergency visits are due to falls.1,2 In Singapore, fall prevalence was found to be 19% in a nationally representative sample of...
community-dwellers aged 60 years and older. In addition, 76% of trauma cases presented at emergency departments in Singapore were due to falls.

It is well established that falls have a multifactorial aetiology. Falls prevention guidelines published by the American and British Geriatrics Society and the Centers for Disease Control and Prevention (CDC) Injury Centre address the multiple risk factors for falls. There is strong evidence that falls prevention interventions incorporating structured strength and balance training are effective in preventing falls among the community-dwelling older adults. These exercises have been found to reduce the rate of falls, risk of falling, fractures and injuries in systematic reviews and meta-analysis of randomised controlled trials (RCTs). It can be implemented either as a single intervention or embedded within a multiple-component or multifactorial intervention design.

However, the evidence for effectiveness of falls prevention interventions in Asia is less robust. These studies are often ‘efficacy’ trials conducted in controlled research settings with homogeneous populations, thus may not be generalisable to the wider populations. There is also a paucity of studies in the implementation and sustainability of locally adapted community-based falls prevention interventions in Asian countries such as Singapore. Translation of evidence-based interventions to the community setting is often inhibited by limited expertise and resources. Recognising this, implementation guidelines recommend for interventions to be tailored to local needs and context. For instance, Asians’ close family ties and high reliance on family caregivers may require adaptations to the messaging and delivery of interventions.

In this study, we will examine the effectiveness of community-based falls prevention interventions in Singapore. Two programmes are included in this study to be evaluated in a real-world setting as a single condition. The first programme is Otago Exercise, which has been shown to be effective in reducing the number of falls and falls-related injuries by 35% as well as mortality. The second programme is Stepping On, which has shown to reduce falls risk by 31%. Both programmes contain evidence-based group exercises for muscle strength and balance for falls prevention in older adults. The primary aim of the study is to evaluate the effectiveness of community-based falls prevention programmes (intervention) in reducing falls risk for older adults with falls risk in Singapore. Falls risk, in this study, is defined from falls literature to include: (1) measures of physical performances (Timed Up and Go (TUG) and Short Physical Performance Battery (SPPB)) and (2) fear of falling (Falls Efficacy Scale–International (FES-I)). Second, we aim to evaluate the impact of the intervention on other health outcomes (falls, loneliness, health-related quality of life, subjective health, falls-related protective behaviours, productivity loss, falls-related healthcare utilisation and costs). We hypothesise that those who have received the intervention would have reduced falls risk (ie, higher physical performance and lower fear of falling) and improved health outcomes compared with those who are waitlist controls.

A real-world approach is adopted to improve applicability of the findings post study and to enable continuous delivery amid the COVID pandemic. We use a pragmatic stepped-wedge cluster randomised trial (SWCRT) design to allow for an efficient study and implementation resource allocation in community site training and roll-out of programmes. A stepped sequential roll-out is advantageous due to the logistical constraints of the COVID pandemic when compared with a traditional parallel cluster RCT. SWCRT is increasingly used to study the effectiveness of a growing range of interventions, health programmes or policies, which are implemented at a cluster level and with impacts measured on individuals. SWCRT has also been used in various settings, including hospitals, community sites, schools, workplace or in geographically defined areas. We use the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) as a reporting guideline (online supplemental material 1: SPIRIT Checklist).

METHOD AND ANALYSIS

Trial design and setting

This is a closed cohort SWCRT, which involves sequential crossover of clusters from the waitlist control condition to the intervention condition, with the sequence of crossover randomly determined. All participants will be identified at the start of the study and participate from the start until end of study without changing clusters. Pre-existing community sites of senior activity centres in Singapore will be recruited as clusters in this study. These sites are frequently used for community-based activities where structured classes and programmes for community-dwelling older adults are conducted. This is to encourage applicability of the study findings and training to continue beyond the duration of this study. The trial will be implemented in two regions, that is, Central and North of Singapore. Each region will have six geographically defined clusters with a minimum of five participants per cluster. The intervention will be sequentially rolled out to the 12 clusters over 6 time periods (allocated randomised sequences every 8 weeks). One cluster from each region will switch, in a stepwise manner, from a control condition to an intervention condition every 8 weeks. Due to the nature of a closed cohort and allocated step length, most participants and clusters will be waitlisted into the control condition until the cluster’s randomly allocated crossover point. Once participants and community site (cluster) cross over to the intervention condition, both participants and community site will remain within the intervention condition for follow-up with no further crossover. All 12 clusters will receive the intervention by the end of the SWCRT (figure 1). The study is planned to be rolled out from September 2021 to October 2022.
A higher number of participants will be recruited for the last two clusters (ie, the fifth and sixth clusters) to account for potential drop-outs, as these clusters will have the longest waiting period.

Assignment of interventions
Allocation and blinding
The unit of randomisation is the cluster. The six clusters in the Central region will be randomly assigned to Otago Exercise intervention’s initiation schedules (C1, C2, C3, C4, C5 and C6), and the six clusters in the North region will be randomly assigned to Stepping On intervention’s initiation schedules (N1, N2, N3, N4, N5 and N6). A trial statistician will develop computer-generated randomisation schedule for both regions and clusters. Once randomised, initiation schedules cannot be changed (figure 1). However, if a cluster becomes unavailable prior to recruitment, it may be replaced with a new cluster outside of the randomised list, if available.

Outcome assessors will be blinded throughout the period of the study. Target population will be blinded until the intervention is initiated. Implementers (ie, trainers and administrators delivering the programmes) will be blinded until 4 months prior to the commencement of the intervention to enable operational preparation.

Participants
Eligibility criteria for participants
Inclusion criteria are individuals aged 60 years and above; lives in the community in the Central or North region of Singapore; Singaporean or Singapore Permanent Resident; understands conversational English or Mandarin; able to walk independently in the community with or without assistive devices (only single-point walking aids are allowed, eg, umbrella, cane and walking stick); answered ‘Yes’ to any of 3 falls risk screening questions (adapted from US CDC-STEADI) of ‘Did you have a fall in the past 12 months?’, ‘Are you concerned about falling?’ and ‘Do you feel like you are going to fall when getting up or walking?’.

Exclusion criteria are self-reported history of diagnosed dementia and severe neuromuscular or cardiovascular conditions (ie, stroke in the past 6 months, heart failure, acute myocardial infarction and Parkinson’s disease); had chest pains when doing exercise; had a recent (less than 3 months prior to study enrolment) major surgery or undergoing renal dialysis or active cancer treatment; scored less than 7 on the Abbreviated Mental Test; participating in other falls prevention interventions or trials in the past 3 months; or have been told by a doctor not to exercise due to health issues.

Participant timeline
Recruitment
Potential participants will be identified through multiple recruitment sources, including dissemination of flyers by participating community partners and recruitment roadshows by the study team at the community sites. Potential participants have the option to either self-screen or be screened by staff (researchers, surveyors and community partners). Self-screening is done by scanning the QR code on the recruitment flyer, which takes participants to the study web application (web-app) containing study information, contact details and screening questions. Older adults who respond ‘Yes’ to at least one of the three screening questions are classified as having falls risk and will be asked to indicate their name, contact information and consent to be contacted for eligibility assessment.

Consent
Informed consent will be taken by trained study team members or surveyors. Each participant will be given sufficient time to read the informed consent document covering the study responsibilities, risks, benefits and expectations, and the opportunity to clarify and ask...
questions (online supplemental material 2: example of consent form).

If eligible participants agree to be enrolled, written informed consent will be taken. Participants will be asked to commit at least 12 months to the study, and will be also informed of the possibility of waiting up to 9 months for their intervention to commence, depending on the cluster randomisation schedule. Participants will be allocated to a nearby or preferred cluster to improve uptake of intervention. If their preferred cluster’s recruitment is full, they will be given their next preferred cluster. All recruitment materials and consent forms are available in both English and Mandarin.

Study assessments
Study participants will first undergo the Community Falls Assessment (CFA). The CFA will be conducted by trained research nurses at participating community sites for a comprehensive assessment of participants’ falls risk factors and their eligibility to participate in the intervention. Assessment includes sociodemographic profile, falls history in the past 12 months, general health, sarcopenia, cognition, physical performance measures, frailty and osteoporosis.

The CFA is developed based on recommendations by United States CDC and Singapore Ministry of Health Falls Prevention guidelines, and verified with geriatricians experienced in community-based falls prevention in Singapore. Those who are unsuitable for the intervention, as assessed by the medical team, will drop out from the study and be referred for further follow-up with appropriate healthcare professionals.

When assessed as safe to participate, participants will be scheduled for a baseline research assessment and allocated to clusters. The subsequent follow-up research assessments and falls diary checks will be done in 8-week intervals at the community sites. (figure 2)

Participants will receive tokens of appreciation for each completed follow-up assessment and falls diary record to improve adherence to the study. Surveyors will call or send phone text reminders prior to assessments. Participants may choose to drop out at any point and/or investigators may withdraw participants from the study for safety reasons. Reasons for loss to follow-up will be documented, and data collected until the point of drop out will be used in analysis.

Intervention condition
Participants recruited to the Central region clusters will receive Otago Exercise and those recruited to the North region will receive Stepping On. Otago Exercise is a single-component (ie, exercise only) intervention for falls prevention that aims to improve strength and balance in the lower limbs. Stepping On is a multi-component intervention, which incorporates exercise with other falls prevention techniques and delivered using behavioural change tools. In this study, implementation of the intervention has been adapted to fit the local context. Details of the intervention are described using the TIDieR checklist (online supplemental material 3).

Strategies to increase intervention adherence include: (1) delivering programmes at community sites within close proximity to participants’ homes, (2) providing phone call reminders for classes, (3) motivating participants to practice exercises regularly at home and (4) encouraging participants to attain 80% attendance to the 7-week classes to be considered as having completed the intervention. Participants will be requested not to participate in other falls prevention programmes during the course of the study. Participants may discontinue the intervention if they experience significant pain or discomfort, or choose to withdraw. In such cases, details on reasons for intervention non-attendance, intervention non-completion or withdrawal will be documented.

Control condition
Individuals who have not initiated the intervention are waitlisted controls with usual care. Those in usual care will have access to falls educational resources comprising a video on falls prevention and links to other publicly available resources.

Outcomes
Mobility is the primary outcome used in this study as measured using the TUG. Secondary outcomes include balance and fear of falling, as measured by the SPPB and FES-I, respectively. Other outcomes include falls, subjective health, health-related quality of life, falls-related protective behaviours, productivity loss, loneliness, falls-related healthcare utilisation and costs. Outcome variables will be collected every 8 weeks (table 1), except for falls-related protective behaviours which will be done at two time-points: (1) immediately prior to the introduction of the intervention and (2) immediately after the 7-week group exercise classes (first phase of intervention).

Primary outcome for sample size calculation
Timed Up and Go
The TUG test is assessed as time needed for an individual to stand from a seated position from a chair, walk 3 m at their comfortable and safe pace, turn around, walk back to the chair and return to a seated position. It is a quick and commonly used functional tool to predict falls risk, functional decline and global health decline of older adult. A faster time indicates a better performance with a cut-off point of ≥13.5 s used to identify those at increased risk of falls in community setting.

Secondary outcomes
Short Physical Performance Battery
The SPPB is a short battery to assess balance, gait, strength and endurance by examining the ability to stand with the feet together in the side-by-side, semi-tandem and tandem positions, time to walk 8 feet and time to rise from a chair and return to the seated position 5 times. A summary score (range: 0–12) will be calculated from all the assessments, with higher score indicating a better
performance. It has been shown to predict recurrent falls, disability, mortality as well as institutionalisation.

**Falls Efficacy Scale–International**

The FES-I is a 16-item questionnaire for fear of falling, defined as an ongoing concern about falling that limits the performance of activities of daily living. It assesses concerns about the possibility of falling when performing 16 activities with a 4-point Likert scale. The scores are added up to calculate a total score that ranges from 16 to 64, with a higher score indicating a greater fear of falling.

**Other outcomes**

**Falls and injurious falls**

A fall is defined as an unintentional coming to rest on the ground, floor or other lower level, whereby lower
level is taken as a threshold of less than 0.5 m (eg, from standing to floor, from standing to bed/sofa/furniture and from sitting to chair/toilet to floor).30 31 Participants will complete a monthly falls diary with daily entry either via a mobile application (mobile-app) developed for this study or monthly phone calls from a surveyor. The falls diary will include data on falls events, nature of falls, falls-related injuries and falls-related medical services used.

**Subjective health**

The subjective health will be measured with a question asking participant’s general health using a 5-point self-rated Likert scale (excellent, very good, good, fair and poor).

**The 5-level EuroQol 5-dimension**

The 5-level EuroQol 5-dimension (EQ-5D-5L) instrument will be used to assess health-related quality of life in 5 dimensions (ie, mobility, self-care, usual activities, pain or discomfort, and anxiety or depression), whereby each dimensions will be scored on a 5-point rating scale: no problems, slight problems, moderate problems, severe problems and extreme problems.32 Scores will be combined and converted to single index value. A EuroQol Visual Analogue Scale (EQ VAS) will be included to record a quantitative measure of self-rated health (range: 0–100), with 0 being the worst possible health and 100 the best health.

**24-item Falls Behavioural Scale**

The Falls Behavioural Scale will be used to assess individual’s awareness and practice of behaviours that could potentially protect against falling (falls-related protective behaviours).33 34 In this study, we will include 24 statements that describe day-to-day behaviours and actions, both habitual and intentional, that if not done safely, can place an individual at undue risk of falling.35 Participants will respond with a four-point Likert scale. Higher score indicates safer behaviours.33 34

---

**Table 1** List of measures and variables, data collection time-points and mode of collection

<table>
<thead>
<tr>
<th>Measurement Tool</th>
<th>Mode of collection</th>
<th>Allocation</th>
<th>Post allocation</th>
</tr>
</thead>
<tbody>
<tr>
<td>TUG</td>
<td>RA</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>SPPB</td>
<td>RA</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>16-item FES-I</td>
<td>RA</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Falls</td>
<td>RA; FD</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Subjective health</td>
<td>RA</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>EQ-5D-5L</td>
<td>RA</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>24-item FaB Scale</td>
<td>RA</td>
<td>X‡</td>
<td>X‡</td>
</tr>
<tr>
<td>UCLA Loneliness Scale 3-item</td>
<td>RA</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CSRI</td>
<td>RA</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>WPAI-GH</td>
<td>RA</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Sociodemographic data</td>
<td>RA</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Blood pressure and heart rate</td>
<td>RA</td>
<td>X</td>
<td>X‡</td>
</tr>
<tr>
<td>Hand grip strength</td>
<td>RA</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Snellen Score</td>
<td>RA</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>GDS-7</td>
<td>RA</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Modified Sallis Social Support Scale</td>
<td>RA</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Adapted Fried Guralnik with Functional Comorbidity Index</td>
<td>RA</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>SARC-F Scale</td>
<td>RA</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PASE</td>
<td>RA</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>10-item CD-RISC</td>
<td>RA</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

*Follow-up time-points refer to data collection time-points following baseline (T1, T2, ..., T6).

†The 24-item FaB Scale will be collected only at two time-points, that is, (1) immediately prior to intervention introduction and (2) immediately after the 7-week classes (first phase of intervention).

‡Blood pressure and heart rate will be collected at every time-points as part of the safety protocol.

CD-RISC, Connor-Davidson Resilience Scale; CSRI, Client Service Receipt Inventory; EQ-5D-5L, 5-level EuroQol 5-dimension; FaB, Falls Behavioural; FD, falls diary; FES-I, Falls Efficacy Score–International; GDS-7, 7-item Geriatric Depression Scale; PASE, Physical Activity Scale for the Elderly; RA, research assessment; SARC-F, Strength, Assistance with walking, Rising from a chair, Climbing stairs and Falls; SPPB, Short Physical Performance Battery; TUG, Timed Up and Go; UCLA, University of California, Los Angeles; WPAI-GH, Work Productivity and Activity Impairment Questionnaire–General Health.
**Baseline variables**

**Sociodemographic data**

Sociodemographic data includes birth year, gender, marital status, education level, employment status and living arrangement.

**Blood pressure and heart rate**

Blood pressure and heart rate will be measured using an automatic blood pressure monitor. Participants will be asked to rest for 5 min before the measurement and to sit in a chair with both feet flat on the ground and back straight. The measurement will be done one time.

**Hand grip strength**

Hand grip strength will be measured using JAMAR hand grip dynamometer. Participants will be asked to sit on a chair with feet rest firmly on floor. We will record the participant’s hand dominance. Participants will be asked to squeeze the dynamometer as tightly as possible for the best result until the number stops rising. Three measurements will be recorded, with a 10–20 s rest in between.

**Snellen Score**

This test is done to assess the sharpness of vision of both eyes, known as visual acuity. Participants will be asked to discern diminishing sizes of alphabets, numbers or shapes at a specified distance of 6 m. We will test the participant’s right and left eyes, and record the visual acuity without (unaided visual acuity) and with glasses (aided visual acuity). Normal visual acuity is 6/6.

**Seven-item Geriatric Depression Scale**

The Geriatric Depression Scale (GDS) is used to screen and assess depression in the elderly. In this study, we will use a shortened seven-item GDS, which has been validated and have a good test performance for screening major depressive disorders in elderly in Singapore.

**Modified Sallis Social Support Scale**

The Sallis Social Support for Exercise is used to measure the perceived social support to exercise behaviours from family and friends. In this study, we select four items from the original questions and include the domestic helper as one of the social support for participants. Participants will rate how often their family, friends and domestic helper have said or done things related to supporting them to exercise in a 6-point rating scale: none, rarely, a few times, often, very often and does not apply.

**Adapted Fried Guralnik with Functional Comorbidity Index**

An assessment of comorbidities in relation to physical function that counts the presence or absence of anxiety, arthritic, back pain, chronic lung diseases (ie, asthma and COPD), depression, diabetes, hearing problems, heart conditions, hyperlipidaemia, hypertension, incontinence, neurological diseases (ie, stroke, epilepsy and migraine), kidney diseases, osteoporosis and eyesight problems (ie, cataract).

**SARC-F scale**

The Strength, Assistance with walking, Rising from a chair, Climbing stairs and Falls (SARC-F) Scale includes components of strength, assistance walking, rise from a chair, climb stairs, and falls. This is assessed to reflect health status changes associated with the consequences of sarcopenia. The scale score range from 0 to 10, with healthy status scored as 0–3.

**The Physical Activity Scale for the Elderly**

The Physical Activity Scale for the Elderly (PASE) is a self-reported questionnaire used to quantify the duration, frequency, exertion level and amount of physical activity done by the participants over the past 7 days. PASE scores (0–400) are calculated from weights and frequency values for each of 12 types of activity.

**10-item Connor Davidson Resilience Scale**

The 10-item Connor Davidson Resilience Scale consists of 10 statements describing different aspects of resilience. The scale measures hardiness, with items corresponding to flexibility, sense of self-efficacy, ability to regulate emotion, optimism and cognitive focus under stress. Higher scores (range: 0–40) reflect greater resilience and ease in bouncing back from adversity.

**Sample size**

The approach for sample size calculations for parallel group RCTs is to calculate the sample size that would be needed if individuals were to be randomised (N). Then, this unadjusted sample size is multiplied by the design effect (1 + (n – 1) ρ) to correct for clustering, where n is the number of subjects within a cluster and ρ is the intra-cluster correlation. For an analysis of covariance (ANCOVA) design, the sample size for a clustered parallel group design is multiplied by a factor (1 – r^2); where r = np/(1 + (n – 1) ρ). Using a similar approach for stepped-wedge designs, the derived design effect (DE) was:
where \( k \) is the number of steps, \( b \) is the number of baseline measurements and \( t \) is the number of measurements after each step. After correcting for adjusted DE, the new sample size becomes \( N_w' = N_w - \rho \) DSW. The \( \rho \) is assumed to be 0.05 to maximise the sample size inflation.

For sample size calculation, we aim to achieve a moderate effect size of 0.40–0.45 using the primary outcome of the TUG test. With the assumption of two-sided \( \alpha \) as 0.05, 80% power, a total minimum sample size of 60 participants in 12 clusters with an average of 5 participants per cluster per time period would allow the detection of an effect size of \( \Delta/\sigma = 0.43 \) (moderate effect size) between control and intervention conditions for the TUG test. The study will target to recruit up to 86 participants to allow for 30% attrition.

### Statistical analysis

Descriptive statistics will be presented for all baseline and outcome variables. Primary analysis will be done on the overall effectiveness of community-based falls prevention programmes with group strength and balance exercises as a whole (Otago and Stepping On) with intervention condition (after introduction of programme) versus control condition (before introduction of programme). The analysis will not specifically compare Otago with Stepping On. The primary analysis will be conducted under the intention-to-treat (ITT) principle. As per ITT, all participants allocated to intervention at baseline will be included in the primary analysis. We will also include per-protocol analysis, including only those who adequately completed the intervention, defined as completing at least 80% of the 7-week classes as per study protocol, as part of the sensitivity analysis. A general linear mixed model or generalised estimating equation analysis, appropriate for a multilevel (cluster and individual) longitudinal study, with a random effect for the cluster and a fixed time effect for every step will be used in the analysis of all outcomes. Subgroup analysis will be conducted to identify association within age, gender, physical performance and fear-of-falling groups. Analysis results will be reported as mean change or OR with (95% CI) based on different time points, clusters and intervention conditions. Missing values will be imputed if at least 85% data are available. Missing values will be imputed using Multivariate Imputation by Chained Equation for primary outcome TUG and a sensitivity analysis will be done after missing value imputation.

A Markov model will be developed to estimate the incremental cost per quality-adjusted life years and incremental cost per fall prevented from the implementation of the intervention from a societal perspective. The falls referral pathways will be simulated to estimate and compare the probabilities of getting into various health states (eg, falls, visit to emergency department hospitalisation and death) in the presence versus absence of the intervention. In the lifetime model, costs and health utility will be discounted at 3%. Univariate and multivariate probabilistic sensitivity analyses will be conducted to test model uncertainty.

Economic modelling will be done to compare costs and immediate outcomes between the intervention and control conditions. Conditional on there being clinically relevant differences in short-term outcomes, we will proceed to implement simulation modelling to project the long-term divergence in trajectories for outcomes and costs using the Markov model.

### Patient and public involvement

Members of the public in the North and Central regions will only be involved in the recruitment of potential participants. Implementers will be involved in engaging their network of older adults in the community, providing the intervention sites and implementing the intervention. Both research assessments and the intervention will be piloted in community-dwelling older adults with varying educational levels, in both English and Mandarin. Feedback will be used to assess feasibility, improve logistics and reduce research questionnaire and performance measures burden on the participants. Trial results will be available as peer reviewed journal and media publications, and reports to support dissemination to the public.

### Data collection, management, monitoring and quality assurance

All surveyors involved in data collection will be trained by study team members. Training includes a detailed overview of the physical performance measures, as well as an item-by-item discussion of the questionnaires. A recording of the training session and a comprehensive training manual will be provided to surveyors for their reference. In addition, all surveyors will be required to pass a competency test for conducting the physical performance measures before data collection.

All data except the falls diary will be collected via face-to-face surveys by the study team and trained surveyors, and entered electronically in a closed access web-app platform at the participating community sites. Falls diary data will be entered electronically, either by surveyor via the web-app or by participants via the closed access mobile-app. The data entry screens will resemble the approved survey questions submitted to the local ethics committee, the Domain Specific Review Board (DSRB).

The electronic platform will be a dedicated platform developed for this study, and will be compliant to all prevailing data security and privacy regulations governed by local healthcare information system governance and personal data protection act. System logic will be imposed in the web-app algorithm to ensure data integrity, such as valid values, compulsory fields, skip patterns and scoring algorithm. Data entered via the web-app and mobile-app will be stored in the secured cloud database and will be available for viewing through the electronic platform.

The type of activity that an individual user may undertake...
Table 2  Expected SAE and UPRITSO

<table>
<thead>
<tr>
<th>Reportable events</th>
<th>Timeline for report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected SAE</td>
<td>Reportable to DSRB as soon as possible but not later than 7 calendar days after first knowledge by the investigator, and follow-up report within 8 calendar days of making the initial report</td>
</tr>
<tr>
<td>► Falls related or possibly related to the intervention that resulted in, or contributed to death</td>
<td></td>
</tr>
<tr>
<td>► Events related or possibly related to the intervention that were life-threatening:</td>
<td></td>
</tr>
<tr>
<td>− Falls with major injuries (fractures)</td>
<td></td>
</tr>
<tr>
<td>− Falls that required inpatient hospitalisation or prolongation of existing hospitalisation</td>
<td></td>
</tr>
<tr>
<td>− Cardiovascular complications (stroke and heart attack)</td>
<td></td>
</tr>
<tr>
<td>► Falls that resulted in, or contributed to persistent or significant disability or incapacity</td>
<td></td>
</tr>
<tr>
<td>UPRITSO</td>
<td>Reportable to DSRB as soon as possible, but not later than 15 calendar days after first knowledge by the PI</td>
</tr>
<tr>
<td>► Only problems involving local* deaths that are related/possibly related to the intervention regardless of expectedness</td>
<td></td>
</tr>
<tr>
<td>► Life-threatening problems not resulting in death that are unexpected and related/possibly related to the intervention</td>
<td></td>
</tr>
<tr>
<td>► All other problems that are unexpected and related/possibly related to the intervention</td>
<td></td>
</tr>
</tbody>
</table>

*Local deaths are defined as those within institutions under the oversight of DSRB.

DSRB, Domain Specific Review Board; PI, principal investigator; SAE, serious adverse event; UPRITSO, unanticipated problems involving risks to subjects or others.

will be regulated by the access rights associated with the user’s identification and password.

Data quality will be ensured through a variety of mechanisms. On-site observations will be conducted during selected research assessment sessions to examine the proper conduct and documentation of the assessments. All data entered by surveyors will be checked by the study team for consistency and completeness. An audit trail will be established through documentation in the web-app (as notes and system activity logs for all data modified) and email communications.

Data extracted will be de-identified and the codes to participant identifiable data will be encrypted, password-protected and stored in a separate data file. All softcopy data will be saved in a designated password-protected corporate laptop and an encrypted electronic database accessible only to the study team. If there is a need to transfer de-identified data to other parties outside the study team and collaborators, data will be encrypted and password protected. Data transfer will be governed under a research collaboration agreement and/or service agreement and/or data sharing agreement. Hardcopy documents with identifiable information will be stored in a secure and locked cabinet accessible only to the study team. All data will be maintained for a period of 6 years after completion of the study.

There will be no independent Data Monitoring Committee for this trial. Both exercise interventions have relatively low risk as they have been widely implemented in other populations, and shown to reduce falls and to be safe to implement.14 15 Trial conducts will be monitored by the study team and externally by the DSRB and sponsor. A random audit will be performed by the DSRB to assess whether the trial is conducted as per the approved protocol and adhere to local policies and regulations. A trial progress report will be submitted to the sponsor annually.

An interim analysis will be performed at mid-point of data collection to formally monitor the accumulating data in the trial. Interim analysis will only be done if there is sufficient sample size for any significant statistical interpretation.

Adverse events reporting

In this study, an adverse event (AE) will be defined as any untoward medical occurrence in a participant which does not necessarily have a causal relationship with the intervention (note: the intervention involved in this study is the community-based falls prevention programme). A serious AE (SAE) will be defined as any untoward medical occurrence due to biomedical research, which results in death, is life threatening, requires inpatient hospitalisation or prolongs existing hospitalisation, results in or contributes to persistent or significant disability/incapacity or results in or contributes to a congenital anomaly/birth defect. Unanticipated problems involving risks to subjects or others (UPRITSO) is a problem that is (1) unexpected, (2) related or possibly related to participation in research and (3) suggests that the research places subjects or others at greater risk of harm. If participants follow the directions of the study team and they are physically injured due to the procedure given under the plan of this study, the Geriatric Education and Research Institute will compensate the medical expenses for the treatment of that injury.
All AEs occurring during and after participant’s involvement in the intervention and until the study completion will be recorded. The study team, surveyor and programme implementers will be trained to identify and report AEs. Using the AEs reporting form, the person in contact will inform the study team, who will then relay the information to the principal investigator and Data Safety Monitoring Board. AEs will be reviewed immediately and a decision will be made if the participant is to continue or cease participation in the study. If the adverse event is related and precludes the participant from continuing, they will be officially withdrawn from the study. If the adverse event is unrelated or a temporary condition, and the participant is medically cleared to remain or continue in the study, they will not be withdrawn. Expected SAE and UPRITSO must be reported to the DSRB. Table 2 describes the expected SAE and UPRITSO that will be monitored throughout the study.

ETHICS AND DISSEMINATION
Research ethics approval
This study is approved by the DSRB of National Healthcare Group, Singapore (protocol ID: 2020/01193, date of approval: 23 March 2021). The DSRB’s research policies are based on local and international ethical guidelines, including the Belmont Report, Declaration of Helsinki and Ministry of Health Singapore Code of Ethical Practice in Human Biomedical Research.

Protocol amendments
Protocol modifications that affect the study conduct, potential risk, benefit and safety of the participant will require a formal amendment of the protocol. Any amendments to the protocol described in this paper will be approved by the DSRB and agreed on by the Sponsor, National Medical Research Council, Ministry of Health Singapore.

Dissemination policy
The study team will submit a yearly progress report outlining the scientific progress and study results to the sponsor. A final report will be released to the sponsor within 3 months from the end of study period. We expect to disseminate study findings, journal publication/s or newspapers. Publications arising from the study will be made publicly available no later than 12 months after the official date of publication. The copy of the publication will be deposited in the institution’s open access repository, in accordance to the applicable open access policy. We will follow the recommended guideline by International Committee of Medical Journal Editor in defining the role of authors and contributors for publication.

Contributors
PJT and MLG contributed equally to this paper and drafted the initial manuscript. CHW, PJT, KH, DBM, NH, SFW and TX conceived the research idea and developed the theory and framework for this study. CHW is the lead principal investigator (PI) who has overall responsibility for the design and conduct of the study. NH and SFW are the site PIs for Central and North regions, respectively. PJT, ZZBL, MLG, NB, RS and JY were involved in the methodological design and plan for this study. PJT, MLG, NB, ZZBL and MMK were involved in designing the data collection tools and acquisition of data. RS is the study statistician who designed and wrote the analysis plan. NB and MLG created the figures in the manuscript. All authors (PJT, MLG, CHW, ZZBL, RS, NB, MMK, TX, NH, JKYY, SFW, JY, DBM and KH) contributed to the study development and reviewed, commented and edited the manuscript and have read and agreed to the submitted manuscript. KH and DBM provided guidance and are advisors to the study.

Funding
This work is supported by National Medical Research Council, Singapore, under National Innovation Challenge on Active and Confident Ageing (award no.: MOH/NC/F1/2017).

Competing interests
None declared.

Patient and public involvement
Patients and/or the public were involved in the design, conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication
Not applicable.

Provenance and peer review
Not commissioned; externally peer reviewed.

Data availability statement
All data relevant to the study are included in the article or uploaded as supplementary information.

Supplemental material
This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access
This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

ORCID iDs
Mimaika Luluina Ginting http://orcid.org/0000-0002-0319-8097
David Bruce Matchar http://orcid.org/0000-0003-3020-2108
Chok Hooi Won http://orcid.org/0000-0002-3048-0477

REFERENCES

Author affiliations
1 Geriatric Education and Research Institute, Singapore
2 Centre for Quantitative Medicine, Duke-NUS Medical School, Singapore
3 Health and Social Sciences Cluster, Singapore Institute of Technology, Singapore
4 Department of Continuing and Community Care, Tan Tock Seng Hospital, Singapore
5 Population Health & Community Transformation, Khoo Teck Puat Hospital, Singapore
6 Center for Economic and Social Research, University of Southern California, Los Angeles, California, USA
7 Research for Impact, Singapore
8 Health Services and Systems Research, Duke-NUS Medical School, Singapore
9 Rehabilitation Aging and Independent Living (RAIL) Research Centre, School of Primary and Allied Health Care, Monash University, Melbourne, Victoria, Australia


33. Clemson L, Cumming RG. The falls behavioural (FaB) scale for the older person. Sydney: The University of Sydney, 2003.


### Standard Protocol Items: Recommendations for Intervventional Trials (SPIRIT) Checklist

<table>
<thead>
<tr>
<th>Section/item</th>
<th>Item No</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Administrative information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A Pragmatic Multi-Centre Stepped Wedge Cluster Randomised Trial to Investigate the Effectiveness of Community-based Falls Prevention Programme for Older Adults with Falls Risk in Singapore: Protocol Paper</td>
</tr>
<tr>
<td>Trial registration</td>
<td>2a&amp;2b</td>
<td>Trial identifier and registry name. If not yet registered, name of intended registry.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All items from the World Health Organization Trial Registration Data Set.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ClinicalTrials.gov ID NCT04788251. Study progress has been updated to the registry, approved, and released in the registry on 03 January 2022. Link: <a href="https://register.clinicaltrials.gov/prs/app/action/SelectProtocol?sis=S000AK81&amp;selectaction=Edit&amp;uid=U0005XMP&amp;ts=2&amp;cx=b73pf5">https://register.clinicaltrials.gov/prs/app/action/SelectProtocol?sis=S000AK81&amp;selectaction=Edit&amp;uid=U0005XMP&amp;ts=2&amp;cx=b73pf5</a></td>
</tr>
<tr>
<td>Protocol version</td>
<td>3</td>
<td>Date and version identifier</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Funding</td>
<td>4</td>
<td>Sources and types of financial, material, and other support</td>
</tr>
<tr>
<td></td>
<td></td>
<td>This work was supported by National Medical Research Council, Singapore, under National Innovation Challenge on Active and Confident Ageing (Award No.: MOH/NIC/F1/2017).</td>
</tr>
<tr>
<td>Roles and responsibilities</td>
<td>5a</td>
<td>Names, affiliations, and roles of protocol contributors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Refer to author lists and contribution statement.</td>
</tr>
<tr>
<td></td>
<td>5b</td>
<td>Name and contact information for the trial sponsor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>National Medical Research Council, Singapore, under National Innovation Challenge on Active and Confident Ageing, NIC(PO): <a href="mailto:NIC_Ageing@moh.gov.sg">NIC_Ageing@moh.gov.sg</a></td>
</tr>
</tbody>
</table>
Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities

Study sponsor and funders have no role in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication.

Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)

There will be no independent Data Monitoring Committee for this trial. Both exercise interventions have relatively low risk as they have been widely implemented in other populations, and shown to reduce falls and to be safe to implement. Data Safety Monitoring Board will oversee the adverse events reporting.

Introduction

Background and rationale

6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

Refer to Introduction

6b Explanation for choice of comparators

Refer to Introduction, and Method and Analysis: Control group

Objectives

7 Specific objectives or hypotheses

The study has two aims. First, we aim to evaluate the effectiveness of the intervention in reducing falls risk (measures of physical performance and fear of falling) for older adults with falls risk in Singapore. Second, we aim to evaluate the impact of the intervention on other health outcomes (falls, loneliness, health-related quality of life, subjective health, falls-related protective behaviours, falls-related healthcare utilisation and costs). We hypothesise that those who have received the intervention would have reduced falls risk (i.e. higher physical performance and lower fear of falling) and improved health outcomes compared to those who are wait list controls.
<table>
<thead>
<tr>
<th>Trial design</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)</td>
<td></td>
</tr>
<tr>
<td>Refer to Method and Analysis: Trial Design and Setting</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Methods: Participants, interventions, and outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study setting</strong></td>
</tr>
<tr>
<td>Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained</td>
</tr>
<tr>
<td>Refer to Method and Analysis: Trial Design and Setting</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Eligibility criteria</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)</td>
<td></td>
</tr>
<tr>
<td>Refer to Method and Analysis: Participants</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interventions</th>
<th>11a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventions for each group with sufficient detail to allow replication, including how and when they will be administered</td>
<td></td>
</tr>
<tr>
<td>Refer to Method and Analysis: Intervention Condition</td>
<td></td>
</tr>
</tbody>
</table>

| 11b |
| Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) |
| Refer to Method and Analysis: Intervention Condition and Adverse Events Reporting |

| 11c |
| Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) |
| Refer to Method and Analysis: Intervention |

| 11d |
| Relevant concomitant care and interventions that are permitted or prohibited during the trial |
| Refer to Participants: Eligibility criteria for participants |

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended</td>
<td></td>
</tr>
<tr>
<td>Refer to Method and Analysis: Outcomes</td>
<td></td>
</tr>
</tbody>
</table>
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)

Refer to Method and Analysis: Participant Timeline and Figure 2. |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations

Refer to Method and Analysis: Sample Size. |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size

Refer to Method and Analysis: Participant timeline – Recruitment. |

**Methods: Assignment of interventions (for controlled trials)**

| Allocation: |  |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Refer to Method and Analysis: Assignment of Interventions – Allocation and Blinding |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned

Refer to Method and Analysis: Assignment of Interventions – Allocation and Blinding |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions

Refer to Method and Analysis: Assignment of Interventions |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how

Refer to Method and Analysis: Assignment of Interventions – Allocation and Blinding |
| 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial  
*Refer to Method and Analysis: Assignment of Interventions – Allocation and Blinding* |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol  
*Refer to Method and Analysis: Data collection, management, and quality assurance. Data collection forms are available upon request.* |
| 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols  
*Refer to Method and Analysis: Participants – Study Assessments.* |
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol  
*Refer to Method and Analysis: Data collection, management, and quality assurance.* |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol  
*Refer to Method and Analysis: Data analysis* |
| 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses)  
*Refer to Method and Analysis: Data analysis* |
| 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)  
*Refer to Method and Analysis: Data analysis* |
<table>
<thead>
<tr>
<th>Section</th>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data monitoring</td>
<td>21a</td>
<td>Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed. Refer to Method and Analysis: Data collection, management, and quality assurance. There will be no independent Data Monitoring Committee for this trial. Both exercise interventions have relatively low risk as they have been widely implemented in other populations, and shown to reduce falls and to be safe to implement.</td>
</tr>
<tr>
<td>Harms</td>
<td>21b</td>
<td>Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial. Refer to Method and Analysis: Data collection, management, and quality assurance.</td>
</tr>
<tr>
<td>Auditing</td>
<td>22</td>
<td>Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct. Refer to Method and Analysis: Adverse Events Reporting.</td>
</tr>
<tr>
<td></td>
<td>23</td>
<td>Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor. Refer to Method and Analysis: Data collection, management, and quality assurance.</td>
</tr>
<tr>
<td>Ethics and dissemination</td>
<td>24</td>
<td>Plans for seeking research ethics committee/institutional review board (REC/IRB) approval. Refer to Ethics and Dissemination: Research Ethics Approval.</td>
</tr>
<tr>
<td>Protocol amendments</td>
<td>25</td>
<td>Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators). Refer to Ethics and Dissemination: Protocol Amendments.</td>
</tr>
<tr>
<td>Consent or assent</td>
<td>26a</td>
<td>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32). Refer to Methods and Analysis: Participant Timeline – Consent.</td>
</tr>
<tr>
<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td><strong>Not applicable.</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Confidentiality 27

How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial

*Refer to Method and Analysis: Data collection, management, and quality assurance.*

<table>
<thead>
<tr>
<th>Declaration of interests 28</th>
<th>Financial and other competing interests for principal investigators for the overall trial and each study site</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No competing interests.</strong></td>
<td></td>
</tr>
</tbody>
</table>

Access to data 29

Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators

*Refer to Method and Analysis: Data collection, management, and quality assurance.*

Ancillary and post-trial care 30

Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

*If participants follow the directions of the study team and they are physically injured due to the procedure given under the plan of this study, the Geriatric Education and Research Institute will compensate the medical expenses for the treatment of that injury.*

Dissemination policy 31a

Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions

*Refer to Ethics and Dissemination: Dissemination Policy*

<table>
<thead>
<tr>
<th>31b</th>
<th>Authorship eligibility guidelines and any intended use of professional writers</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Refer to Ethics and Dissemination: Dissemination Policy</em></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>31c</th>
<th>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Refer to Ethics and Dissemination: Dissemination Policy</em></td>
<td></td>
</tr>
</tbody>
</table>

Appendices
<table>
<thead>
<tr>
<th>Informed consent materials</th>
<th>32</th>
<th>Model consent form and other related documentation given to participants and authorised surrogates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Available upon request.</td>
</tr>
<tr>
<td>Biological specimens</td>
<td>33</td>
<td>Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not applicable.</td>
</tr>
</tbody>
</table>
INFORMED CONSENT FORM

1. Study Information

Protocol Title:
Falls Prevention Evaluation and Development for Older Adults in the Community (FREDA)

Contact Details:

Principal Investigator
Name:
Tel:
Email:

Study Coordinator
Tel:
Email:

KTPH Principal Investigator
Name:
Tel:
Email:

KTPH Study Coordinator
Tel:

Study Sponsor:
Ministry of Health of Singapore, Grant Call on Falls Prevention National Innovation Challenge on Active and Confident Ageing (Award No.: MOH/NIC/F1/2017)

2. Purpose of the Research Study
You are invited to participate in a research study. It is important to us that you first take time to read through and understand the information provided in this sheet. Nevertheless, before you take part in this research study, the study will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must sign this informed consent form. You will be given a copy of this consent form to take home with you.

You are invited because you are aged 60 years and above, living in the North region of Singapore, walk independently (with or without assistive devices), understand conversational English or Chinese, are a Singaporean citizen or PR and were identified to be at risk for falls.

This study aims to find out the effectiveness of the Stepping On programme on fall risk and other health outcomes among community-dwelling older adults in Singapore. Stepping On is a group-based programme with weekly classes on exercise and falls prevention. It is conducted by trained programme leaders and focuses on balance, strength training and other safety strategies to prevent falls.

This study will recruit 100 participants from the North region of Singapore over a period of 2 months. In total, a maximum of 200 participants from the North and Central regions will be involved in this study.

3. What procedures will be followed in this study
If you take part in this study, you will be required to participate in all study activities (listed below) that will occur over the next 1 year. These activities will be conducted at a site of your choice.
Please note that you will only be told the start date of your exercise programme by the study team after you have consented to participate. This is because we have randomized the site to start in 1 of 6 possible dates. Randomization means that each site is assigned to one of the six start dates by chance, like tossing a coin or rolling dice.

This means that you can only start your exercise programme when it becomes available in your neighborhood. The exercise programme will be made available based on a fixed schedule to start either in Nov 2021, Jan 2022, Mar 2022, Apr-May 2022, Jun 2022, Aug 2022. Depending on the selected location, you may have to wait for up to 9 months for your exercise programme to start. While waiting, you will still receive a no-cost health examination by our clinical team, access to fall prevention education materials, 2-monthly follow-up study assessment(s) and reimbursed for your participation while you wait.

If you agree to take part in this study, you will be asked to complete:

- **Community Falls Assessment (CFA) (1 x 45-60 mins):** This is a health examination for fall risk conducted by the community health team to understand your health status, level of fall risk and assess if you are safe to participate in the group-based exercise programme. This will be conducted at a community nurse post. It would include tests for your blood pressure, eyesight, physical function, height and weight, footwear safety, osteoporosis risk and memory. You may require one additional visit to the community site before being certified as fit for participation in the Stepping On programme, if you are at high risk of falls or if deemed necessary by the community health team. You will receive a personalized report with referrals and recommendations if needed. You will have to follow up with these referrals separately from the research study. Kindly note that you can proceed with the study and exercise programme only after being certified as safe for participation by the community health team.

- **Stepping On programme:** This programme consists of
  - 7 classes (2 hours each) (Week 1-7) on exercise and fall prevention conducted at a community site in your neighborhood and
  - 3 follow-up sessions comprising of–
    1. A home visit (1 hour) (Week 11) (optional) to assess for hazards that may cause falls. This will only occur if you are willing and able to have your trainer and/or classmates (other older adult participants in this study) visit your house. This can be replaced by a phone call if you prefer. Both the home visit and phone call mentioned here are optional.
    2. A 1-hour booster session (1 hour) (Week 19) that acts as a refresher for you to revise techniques learnt at the weekly sessions, and
    3. A short telephone call (~10min) (Week 31) from the programme trainer to remind you of Fall Prevention strategies and exercises and to discuss any concerns you may have regarding falls.

You will be required to attend at least 6 weekly classes (80% attendance rate) to be considered as having adequately completed the exercise intervention. We will provide reminders to help you with your appointments. There will be one brief feedback survey at the end of the Stepping On programme. Please note that researchers may sit in a few of these sessions if your class is agreeable to it. The observation sessions are to study the way the class is carried out and factors affecting its effectiveness. No audio or video recording will be carried out and your identity will be masked in any photos taken during these observation sessions.

- **Health Survey and Physical Performance Tests (7 times x 30-45min):** These assessments will be conducted once every 2 months (and once at the end of the Stepping On programme) for 7 times over the study period by a research assistant or a contracted surveyor (estimated dates shown below). The assessments include physical performance tests and questions on health, falls and quality of life. If you are unable to
complete this assessment in one visit, we will schedule a second appointment. We will provide reminders to help you with your appointments at these estimated times.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment 1</td>
<td>Sep – Nov 2021</td>
</tr>
<tr>
<td>Assessment 2</td>
<td>Dec 2021 – Jan 2022</td>
</tr>
<tr>
<td>Assessment 3</td>
<td>Feb – Mar 2022</td>
</tr>
<tr>
<td>Assessment 4</td>
<td>Apr – May 2022</td>
</tr>
<tr>
<td>Assessment 5</td>
<td>Jun – Jul 2022</td>
</tr>
<tr>
<td>Assessment 6</td>
<td>Aug – Sep 2022</td>
</tr>
<tr>
<td>Assessment 7</td>
<td>Oct – Nov 2022</td>
</tr>
</tbody>
</table>

- **FREDA Web-Application:** Upon enrollment into the programme, you will be invited to download our optional FREDA Web-App onto your smart phones. This can be used to record your falls and remind you of your study appointments. It will also contain useful resources on falls risks and exercises.

- **Falls Diaries:** This diary is used to record your falls during your time in this study (1 year). You will be given the option to either record this on the using the FREDA Web-app on your phones, or to receive monthly phone calls from contracted surveyors. Each daily entry should take less than 5 min to complete. We will provide a telephone reminder if we have not received the diaries.

Please note that you may be contacted by the study team for a follow-up interview after your Stepping On programme ends. There will be a separate consent-taking process for this, should you be interested in participating.

There will not be any incidental findings arising from this research. “Incidental findings” are findings that have potential health or reproductive importance to research participants like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study.

Any individually-identifiable data obtained during the course of this study will be stored and analysed for the purposes of this study and will not be used for future biomedical research.

4. **Your Responsibilities in This Study**

If you agree to participate in this study, you should be prepared to follow the advice given to you by the study team and undergo all the procedures that are outlined above. You are also requested not to participate in any other fall prevention programmes or trials during the study period.

5. **What Is Not Standard Care or is Experimental in This Study**

The study is being conducted because Stepping On has been proven to be effective in reducing the number of falls and fall-related injuries worldwide. But there is little evidence of the effectiveness of the Stepping On programme to reduce risk of falls in Singapore. We hope that your participation will help us to determine whether this Stepping On programme is suitable to prevent falls for older adults in Singapore.

The use of randomization (study group selection by chance) is only done for research studies. All procedures elaborated under Section 3 are carried out for research purposes only.

6. **Possible Risks and Side Effects**

Stepping On may have the following side effects or risks: fatigue and/or soreness. If you feel uncomfortable at any time during any of the research procedures, please inform a member of
the study team. If you experience any new symptoms, please contact the Principal Investigator as soon as possible. To reduce the risk of any possible injuries, the exercise programmes will be conducted in small groups by trained facilitators trained looking out for your safety. Also, you will be given handouts to refer to while performing the exercises at home.

You will be allowed to skip any question that you do not feel comfortable addressing to reduce any psychological stresses you may face due to participation in this trial.

Furthermore, to ensure that any data collected from you is kept private and confidential, all hardcopy data will be kept under lock-and-key by the study team and all softcopy data (collected via FREDAA Web-App) will be stored and transferred in means compliant to iHIS and national PDPA regulations.

As you cannot take part in other fall prevention programmes for the entire duration of our study, you will be provided with falls prevention education resources which include recommendations to reduce your fall risk while waiting for your programme to start. However, if you do not wish to proceed with the study or do not feel fit to participate in regular exercises, while waiting for your programme to start, please inform a member of the study team to opt out of the study and/or for further advice.

7. Possible Benefits from Participating in the Study

You may reasonably expect to benefit from this programme through improved physical performance in terms of strength and balance, improved balance confidence, reduced fear of falling, increased fitness, physical activity, social health, and decreased falls. Furthermore, you may expect indirect benefits such as increased knowledge and awareness on falls risks and fall prevention strategies from this study.

8. Costs & Payments if Participating in the Study

If you take part in this study, the following will be provided at no charge to you: the 7-week Stepping On programme, CFA, Health and Physical Performance Surveys, FREDAA Web-Application and Falls Diaries. Please note that the research is funded and costings related to this study will be borne under the study sponsor.

However, please note that you will have to bear the cost of any visits made to polyclinics or other healthcare institutions made using the referrals generated at the CFA.

You will be reimbursed for your time and transportation costs as follows:

- For each Health and Physical Performance Survey you complete, you will receive a $30 NTUC shopping voucher.

- If you complete the electronic Falls Diaries, you will receive additional NTUC vouchers for target number of completed diaries. A $10 NTUC voucher will be given for every 60 consecutive days of diary entries completed on time (ie. within 1 week of the end of the month). Please note that you will not receive reimbursements if you opt to report falls via monthly phone calls instead.

- If you do not complete the study for any reason, you will only be paid for each visit you complete.

9. Voluntary Participation

Your participation in this study is voluntary. You may stop participating in this study at any time. There will be no consequences should you decide not to take part in this study or to stop your participation. If you decide to stop taking part in this study, please inform the Principal Investigator or a representative of the study team.

If you withdraw from the study, you will be required to provide reason(s) of termination to our representative of the study team.
However, the data that have been collected until the time of your withdrawal will be kept and analyzed. The reason is to enable a complete and comprehensive evaluation of the study.

The Investigator and/or the Sponsor of this study may stop your participation in the study at any time if they decide that it is in your best interests. They may also do this if you do not follow instructions required to complete the study adequately. If you have other medical problems or side effects, the research team will decide if you may continue in the research study.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you will be informed in a timely manner by the Principal Investigator or his/her representative.

10. Compensation for Injury

If you follow the directions of the research team in charge of this study and you are physically injured due to the procedure given under the plan for this study, the Geriatric Education and Research Institute will pay the medical expenses for the treatment of that injury.

Payment for management of the normally expected consequences of your treatment will not be provided by the Geriatric Education and Research Institute.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

11. Confidentiality of Study Records

Your participation in this study will involve the collection of “Personal Data”. “Personal Data” means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. This includes medical conditions, medications, investigations and treatment history.

Information and “Personal Data” collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available.

However, the Sponsoring company (Ministry of Health), Regulatory Agencies and NHG Domain Specific Review Board and Ministry of Health will be granted direct access to your original study records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you are authorising (i) the collection, access to, use and storage of your “Personal Data”, and (ii) the disclosure to authorised service providers and relevant third parties.

Data collected and entered into the Case Report Forms are the property of the Geriatric Education and Research Institute and Khoo Teck Puat Hospital. In the event of any publication regarding this study, your identity will remain confidential.

Research arising in the future, based on your “Personal Data”, will be subject to review by the relevant institutional review board.

Any information containing your “Personal Data” that is collected for the purposes described in this Informed Consent Form will not be transferred out of Singapore.

By participating in this research study, you are confirming that you have read, understood and consent to the Personal Data Protection Notification available at https://www.geri.com.sg/Documents/NHG_Personal_Data_Protection_Policy_GERI.pdf

12. Who To Contact if You Have Questions

If you have questions or injuries during the course of this study, you may contact the study coordinator at xxx or the principal investigator, Dr Chek Hooi Wong at xxx during office hours (Mon-Fri, 9-6pm).

The study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.
If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research subject, you may contact the NHG Domain Specific Review Board Secretariat at xxx. You can also find more information about participating in clinical research, the NHG Domain Specific Review Board and its review processes at www.research.nhg.com.sg.

If you have any complaints or feedback about this research study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.

13. Consent to be Contacted for Future Research

You will be asked for permission to be contacted in the future for participation in research studies that you may be suitable for.

If you agree to be contacted, your information and contact details will be entered and stored in a secured database in the Geriatric Education and Research Institute (GERI) and at Khoo Teck Puat Hospital (KTPH). Your information and contact details will not be released to any parties outside GERI or KTPH without your permission. When investigators from GERI or KTPH identify you to be suitable for a particular research study, the investigators or authorised personnel from GERI or KTPH will contact you to inform you about the research study.

If you do provide consent for use in future studies, your contact details will be stored in a secure location at GERI for up to 6 years after study completion for general research. Your decision to be contacted for future research studies is completely voluntary and separate from your decision to participate in this study.

Your decision will not affect your medical care or any benefits to which you are entitled. You may change your mind at any time by contacting the study coordinator at xxx during office hours (Mon-Fri, 9-6pm).
CONSENT FORM

Protocol Title:
Falls Prevention Evaluation and Development for Older Adults in the Community (FREDA)

Contact Details:

Principal Investigator               Study Coordinator
Name: ____________________________ Tel: ____________________________
Tel: ____________________________ Email: ____________________________
Email: ____________________________

KTPH Principal Investigator          KTPH Study Coordinator
Name: ____________________________ Tel: ____________________________
Tel: ____________________________ Email: ____________________________
Email: ____________________________

I voluntarily consent to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand, I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction. I have also been informed and understood the alternative treatments or procedures available and their possible benefits and risks.

By participating in this research study, I confirm that I have read, understood and consent to the Geriatric Education and Research Institute Personal Data Protection Notification.

Consent to be Contacted for Future Research

☐ Yes, I agree to be contacted for future research that I may be eligible for.
   I agree to be contacted via:
   ☐ Phone ____________________________
   ☐ Mail ____________________________
   ☐ Email ____________________________
   ☐ Others ____________________________

☐ No, I do not agree to be contacted for future research.

Name of Participant ____________________________ Signature ____________________________ Date ____________________________
**Witness Statement**

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant/the participant’s legally acceptable representative signing this informed consent form has the study fully explained in a language understood by him/her and clearly understands the nature, risks and benefits of his/her participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant/the participant’s legally acceptable representative giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

_________________________   ________________________________  ___________________
Name of Witness Signature Date

1. In accordance with Section 6(d) of the Human Biomedical Research Act and Regulation 25 of the Human Biomedical Research Regulations 2017, appropriate consent must be obtained in the presence of a prescribed witness who is 21 years of age or older, and has mental capacity. The witness must be present during the entire informed consent discussion, and must not be the same person taking the appropriate consent. The witness may be a member of the team carrying out the research.

2. However, if the participant/the participant’s legally acceptable representative is unable to read, and/or sign and date on the consent form, an impartial witness should be present instead. The impartial witness should not be a member of the study team.

**Impartial Witness Statement**

I, the undersigned, certify to the best of my knowledge that the participant signing this informed consent form had the study fully explained in a language understood by him/her and clearly understands the nature, risks and benefits of his/her participation in the study.

_________________________   ________________________________  ___________________
Name of Impartial Witness Signature Date

**Investigator Statement**

I, the undersigned, certify that I explained the study to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of his/her participation in the study.

_________________________   ________________________________  ___________________
Name of Investigator / Person administering consent Signature Date
## TIDieR Checklist of Community-based Falls Prevention Interventions

<table>
<thead>
<tr>
<th>TIDieR Item</th>
<th>Intervention at Central Region</th>
<th>Intervention at North Region</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Brief Name</td>
<td>Modified Otago Exercise Programme: A community group-based programme focusing on progressive strength and balance training.</td>
<td>Stepping On Programme: A community group-based programme focusing on a variety of falls prevention topics.</td>
</tr>
<tr>
<td>2 Why</td>
<td>Intervention targets poor strength and balance to prevent falls.</td>
<td>Intervention targets a variety of known falls risk factors (e.g. poor strength and balance, medication side effects or misuse, home and community hazards, bone health, and poor vision) to prevent falls. Additionally, it uses adult learning principles and group-based learning to effect behaviour change in the participants.</td>
</tr>
<tr>
<td>3 What (Materials)</td>
<td>Participants will be provided with ankle weights (for exercise progression), and an exercise booklet (for reference and logging of daily exercises).</td>
<td>Participants will be provided with ankle weights (for exercise progression), a folder containing learning materials from all sessions and homework handouts (for logging of daily exercises).</td>
</tr>
<tr>
<td>4 What (Procedures)</td>
<td>The intervention has 2 phases: 1. Classes: Participants learn, practice and progress on 5 strength and 12 balance exercises in a 1-hour session that will be conducted twice-weekly for 7 weeks at community sites. Participants must attain 80% attendance to adequately complete the intervention, and are encouraged to exercise at home ≥2 times per week. 2. Follow-up: Participants will be encouraged to continue practicing the learnt exercises at home for at least 3 months after the last weekly session.</td>
<td>The intervention has 2 phases: 1. Classes: Participants learn about different falls prevention techniques from invited experts, practice and progress on 3 strength and 4 balance exercises, and review their homework in 2-hour sessions that will be conducted weekly for 7 weeks at community sites. Participants are encouraged to do the exercises at home. Participants must attain 80% attendance to adequately complete the intervention. 2. Follow-up: Participants will receive home visit/phone call (Week 11), a booster session (Week 19) and 1 phone call (Week 31) by the programme leaders. In these sessions, programme leaders will revise strategies taught in weekly sessions and ensure participants’ adherence to taught strategies.</td>
</tr>
<tr>
<td>5</td>
<td>Who provided</td>
<td>Health extenders (allied health professionals or volunteers) who have been trained and certified in leading the Later Life Training Otago Exercise Programme.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>6</td>
<td>How delivered</td>
<td>All sessions to be conducted face-to-face in an interactive group setting (5-10 participants) at a community site. Sessions will be aided by pre-recorded videos demonstrating the exercises.</td>
</tr>
<tr>
<td>7</td>
<td>Where delivered</td>
<td>All sessions will be conducted at participating community sites in the Central region of Singapore.</td>
</tr>
<tr>
<td>8</td>
<td>When and How much</td>
<td>Intervention consists of 1-hour twice-weekly classes for 7 weeks (14 sessions).</td>
</tr>
<tr>
<td>9</td>
<td>Tailoring</td>
<td>Group sessions will progress depending on the pace of the class. Exercises and any advice to manage falls risk provided will be tailored for each individual wherever possible.</td>
</tr>
<tr>
<td>10</td>
<td>Adaptations from original Programme</td>
<td>Delivery of programme will be adapted to a group-based approach, conducted by trained health extenders in community settings, and given over a shorter period as compared to the original programme (original programme is given one-to-one by physiotherapist at participant’s home, over a one-year period).</td>
</tr>
<tr>
<td>11</td>
<td>Assessment of Fidelity (Planned)</td>
<td>All health extenders are trained to ensure safe and effective delivery of the intervention, overseen by a physiotherapist. Also, physiotherapist will conduct ad hoc fidelity checks for certain sessions, based on a pre-defined fidelity checklist.</td>
</tr>
</tbody>
</table>