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, Mimaika Luluina Ginting, Zoe Zon Be Lim, Nivedha Balachandar, Rehena Sultana, Mumtaz Mohamed Kadir, Tianma Xu, Noor Hafizah Ismail, Joyce Kwee Yong Yap, Sweet Fun Wong, Joanne Yoong, David Bruce Matchar, Keith Hill, Chek Hooi Wong

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. 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)).

METHOD AND ANALYSIS

Trial design and setting
This is a closed cohort stepped-wedge cluster randomised trial (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 the 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. Data are collected from all participants via research assessments occurring once every 8 weeks (at T0, T1, ..., T6). These will be conducted ±1 week of exact date. Shaded grey cells represent clusters which have switched to the intervention condition. White cells represent clusters in the control condition. SWCRT, stepped-wedge cluster randomised trial.

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 road-shows 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). 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. 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). 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. Participants will respond with a four-point Likert scale. Higher score indicates safer behaviours.

### 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></td>
</tr>
<tr>
<td>GDS-7</td>
<td>RA</td>
<td>X</td>
<td></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></td>
</tr>
<tr>
<td>PASE</td>
<td>RA</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>10-item CD-RISC</td>
<td>RA</td>
<td>X</td>
<td></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.
Health. In this study, this instrument will be used to assess the effect of falling on participant’s ability to work and perform regular activities. This instrument will be used only for participants who are employed.

Productivity loss

Productivity loss will be collected using the Work Productivity and Activity Impairment Questionnaire–General Health. In this study, this instrument will be used to assess the effect of falling on participant’s ability to work and perform regular activities. This instrument will be used only for participants who are employed.

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 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 − r²); 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 \( N_{sw}^{*} = N_0 - \rho \). 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 (e.g., 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...
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.\textsuperscript{14, 15} Trial conduct 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.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Expected SAE and UPRITSO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reportable events</strong></td>
<td><strong>Timeline for report</strong></td>
</tr>
<tr>
<td>Expected SAE &gt; Falls related or possibly related to the intervention that resulted in, or contributed to death</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>
</tbody>
</table>
| &gt; Events related or possibly related to the intervention that were life-threatening:  
- Falls with major injuries (fractures)  
- Falls that required inpatient hospitalisation or prolongation of existing hospitalisation  
- Cardiovascular complications (stroke and heart attack)  
| &gt; Falls that resulted in, or contributed to persistent or significant disability or incapacity | |
| UPRITSO &gt; Only problems involving local* deaths that are related/possibly related to the intervention regardless of expectedness | 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 |
| &gt; Life-threatening problems not resulting in death that are unexpected and related/possibly related to the intervention | |
| &gt; All other problems that are unexpected and related/possibly related to the intervention | Reportable to DSRB as soon as possible, but not later than 15 calendar days after first knowledge by the PI |

*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.
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, methods and results in appropriate platforms, such as symposia, national, international or regional professional meetings or conferences, 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.

Author affiliations

1Geriatric Education and Research Institute, Singapore

2Centre for Quantitative Medicine, Duke-NUS Medical School, Singapore

3Health and Social Sciences Cluster, Singapore Institute of Technology, Singapore

4Department of Continuing and Community Care, Tan Tock Seng Hospital, Singapore

5Population Health & Community Transformation, Khoo Teck Puat Hospital, Singapore

6Center for Economic and Social Research, University of Southern California, Los Angeles, California, USA

7Research for Impact, Singapore

8Health Services and Systems Research, Duke-NUS Medical School, Singapore

9Rehabilitation Aging and Independent Living (RAIL) Research Centre, School of Primary and Allied Health Care, Monash University, Melbourne, Victoria, Australia

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, JKY, 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/NIC/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 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.


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


