Yoga-based exercise to prevent falls in community-dwelling people aged 60 years and over: study protocol for the Successful AGEing (SAGE) yoga randomised controlled trial

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ABSTRACT

Introduction Falls significantly reduce independence and quality of life in older age. Balance-specific exercise prevents falls in people aged 60+ years. Yoga is growing in popularity and can provide a high challenge to balance; however, the effect of yoga on falls has not been evaluated. This trial aims to establish the effect on falls of a yoga exercise programme compared with a yoga relaxation programme in community-dwellers aged 60+ years.

Method and Analysis This randomised controlled trial will involve 560 community-dwelling people aged 60+ years. Participants will be randomised to either: (1) the Successful AGEing (*SAGE*) yoga exercise programme or (2) a yoga relaxation programme. Primary outcome is rate of falls in the 12 months post randomisation. Secondary outcomes include mental well-being, physical activity, health-related quality of life, balance self-confidence, physical function, pain, goal attainment and sleep quality at 12 months after randomisation. The number of falls per person-year will be analysed using negative binomial regression models to estimate between-group difference in fall rates. Generalised linear models will assess the effect of group allocation on the continuously scored secondary outcomes, adjusting for baseline scores. An economic analysis will compare the cost-effectiveness and cost-utility of the two yoga programmes.

Ethics and dissemination Protocol was approved by the Human Research Ethics Committee at The University of Sydney, Australia (approval 2019/604). Trial results will be disseminated via peer-reviewed articles, conference presentations, lay summaries.

Trial registration number The protocol for this trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12619001183178).

INTRODUCTION

Approximately, one in three community-dwelling people aged 65+ years fall each year,[1] making falls an important public health issue. Every fall has the potential to be a life-changing event with possible devastating consequences, such as ongoing disability, admission to a residential aged care facility and even death. Globally, 37.3 million falls occur each year that are severe enough to require medical attention,[2] demonstrating that strategies to prevent falls have the potential for huge population health and economic impact.

A recently updated Cochrane systematic review of exercise interventions to prevent falls in community-dwelling people aged 60+ years,[3] identified 108 trials and concluded that exercise can reduce falls by up to 34%. Another systematic review found that exercise programmes with a high challenge to balance and high dose have the greatest effect on falls and that general physical activity programmes, such as walking, are not effective.[4] These reviews identified no trials that evaluated the effect of yoga-based exercise on falls. However, yoga-based exercise can provide a high challenge to balance and can be practiced in a group or home setting, making it worthy of analysis as a strategy to prevent falls. The growing availability of yoga studios in many countries and the ability to access classes online provide the ideal means for programme scale-up and broad implementation for maximum public health impact.

Yoga is an increasingly popular leisure time activity among middle-aged and older people,[5] and can improve both physical and mental health. Previous research[6] showed that yoga is well received by older people compared with other exercise types, since it can be easily modified for individuals with a range of functional abilities and clinical conditions. Yoga is associated with documented health benefits including reduced

hypertension,[7] reduced chronic back pain and disability,[8] improved balance, health status, gait and leg strength,[6 9 10] mental well-being and quality of life.[11]

There is also evidence suggesting the potential beneficial impact of yoga on falls. Our pilot trial[12] and systematic review[10] demonstrated that well-designed yoga-based exercise is safe for older people to undertake and improves balance and mobility. Yoga is also recommended as a fall prevention activity for older adults in exercise prescription guidelines,[13] despite no evidence of effect on falls. No randomised controlled trials to date have been designed to detect the effect of yoga on falls over the long term.

To address this evidence gap, we will conduct a randomised controlled trial to investigate the effect of the Successful AGEing (SAGE) yoga programme, a 40-week group-based, yoga exercise programme, on falls over 12 months compared with a seated, yoga relaxation programme, in community-dwellers aged 60+ years. Yoga classes will be delivered either face-to-face, or online via the internet during the period of social distancing restrictions resulting from the COVID-19 pandemic. Additionally, we aim to measure the effects of yoga on mental well-being, physical activity, health-related quality of life, balance confidence, physical function, pain, goal attainment and sleep. We will also evaluate the cost-effectiveness and cost-utility of the yoga exercise programme and explore uptake and acceptability in order to guide future scale-up if effective.

METHODS AND ANALYSIS
Trial design
We will conduct a two-arm parallel, pragmatic randomised controlled trial. The trial design is illustrated in figure 1. This trial is designed according to the CONsolidated Standards Of Reporting Trials (CONSORT) statement[14] and reported according to the Standard
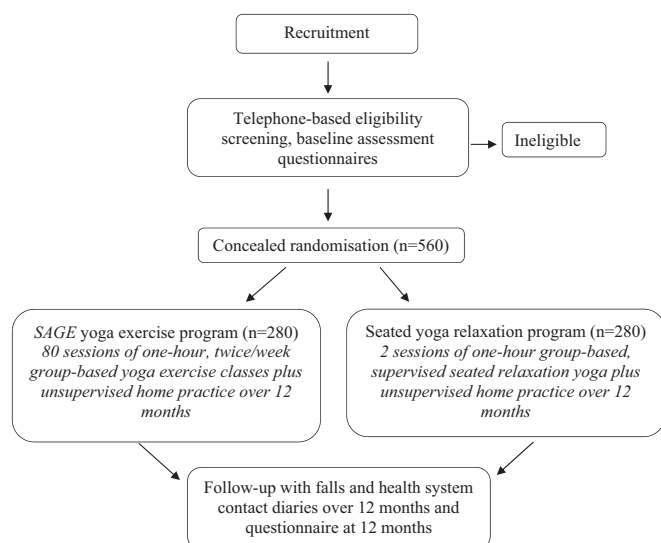
Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement[15] and with reference to the Template for Intervention Description and Replication (TIDieR) checklist.[16]

Participants
Participants will be recruited from metropolitan Sydney, Australia for face-to-face classes and from throughout the eastern states of Australia for the online classes. Community-based recruitment will be accomplished through advertisements in local newspapers, community centres, social media and through contact with community organisations, such as the Country Women's Association, Men's Sheds, Rotary and Probus.

Eligible participants will be aged 60 years and over; living independently at home; not currently participating in yoga and have not regularly participated in yoga, at least once/week, during the past year; and able to travel to an intervention location for face-to-face classes or able to access online classes via the internet. Potential participants will be excluded if they: are 'house-bound' (not been outside independently in the past month); have a cognitive impairment (scoring 4 or less on the 8-point Memory Impairment Screen)[17]; have insufficient English language skills to fully participate; self-assessed inability to walk 10 metres unassisted; have a progressive neurological disease (eg, Parkinson's disease) or have a self-reported medical condition precluding exercise (eg, unstable cardiac disease). Participants will be enrolled after being screened over the telephone for eligibility, providing written informed consent and completing the baseline questionnaire.

Randomisation
Participants will be randomly assigned (1:1) to either the group-based SAGE yoga exercise programme or to a seated yoga relaxation programme. Participants will be randomised after they have provided consent and completed all baseline measures. The trial will use a centralised web-based randomisation system using REDCap (Research Electronic Data Capture) within The University of Sydney license to ensure concealment of allocation to groups. The group allocation system will use a computer-generated random number schedule with randomly permuted block sizes of two and four and will use stratification to ensure balance by yoga studio/instructor.

Group-based SAGE yoga exercise programme
The SAGE yoga exercise programme emphasises standing yoga postures that challenge balance, improve leg strength and stability, along with breathing and relaxation practice and techniques. Postures can be modified to cater to individuals with varying functional abilities and to ensure safety. The balance challenge of each posture will increase as participants develop skill and confidence. The SAGE programme is based on a Hatha/Iyengar style of yoga where postures are held for relatively long periods of time and involve static postures rather than a flow

Figure 1 Trial design.

(Vinyasa) yoga, making it simpler for older adults to learn. Props, such as blocks, straps, chairs and bolsters, can be used to modify certain postures to cater for all levels of ability. Adherence to the supervised *SAGE* yoga sessions will be recorded by yoga instructors who will keep class attendance records. More detail is provided in table 1.

Participants will be invited to take part in 80, free of charge, 1-hour classes, on a twice-weekly basis, over a 12-

month period. The 1-hour classes will include: (1) introduction to the class focus for the day, discussion of new topics and/or demonstration of new poses (5 min), (2) physical poses aimed at improving balance and leg strength (40–45 min), (3) relaxation/meditation (5–10 min) and (4) question time and discussion of home practice (5 min). Participants will also be instructed to complete a 20-min unsupervised yoga programme, based on the class content, at least twice weekly. This

Table 1	Intervention description using the template for intervention description and replication (TIDieR) checklist
1. Brief name	Group-based *SAGE* yoga exercise programme to prevent falls in community-dwelling people compared with yoga relaxation programme.
2. Why	Falls among older people are a major health issue worldwide. One in three older people fall each year, often resulting in significant injuries and ongoing disability. Exercise that challenges balance is proven to prevent falls. Yoga-based exercise provides a high degree of challenge to balance, making it a logical choice for investigation as a fall prevention strategy. Yoga studios are widely available in many countries, providing a structure for future programme scale-up and broad implementation.
3. What materials	► 12 monthly fall calendars either returned in reply-paid, pre-addressed envelopes or completed online. ► Participants allocated to the *SAGE* yoga exercise programme may use props to assist with performing the yoga poses, including blocks, chairs, walls, straps, bolsters and blankets. ► *SAGE* yoga exercise programme participants will also receive a booklet comprising detailed descriptions of yoga postures to complete unsupervised at least twice per week. ► Instructors receive a programme manual that details the content and structure of both the *SAGE* yoga exercise programme and the seated yoga relaxation programme. ► Participants allocated to the seated yoga relaxation programme will receive printed instructions illustrating breathing techniques and simple-seated relaxation yoga postures to be completed unsupervised at home at their own discretion. ► Participants allocated to the *SAGE* yoga exercise programme delivered online will use Zoom, a freely available online livestream application, to access classes and will use WhatsApp a freely available online messaging service to connect with class members and their instructor.
4. What procedures	The intervention group will participate in the *SAGE* yoga exercise programme delivered in local yoga studios or online. Participants will be advised to complete two classes weekly for 40 weeks over 12 months. They will also be advised to complete at least two unsupervised sessions of the *SAGE* yoga programme per week. The control group will attend two group-based workshops, delivered in local yoga studios or online, to learn the seated yoga relaxation programme which they will undertake unsupervised at home as often as they prefer. Access to both yoga programmes will be provided free of charge and participants will require their own transport to travel to the face-to-face classes.
5. Who provided	Approximately eight yoga teachers with certificate qualifications and experience working with older people and who have received specific training in the trial background, intervention content, and trial procedures will deliver the *SAGE* yoga classes and the workshops for the seated yoga relaxation group.
6. How	For the *SAGE* yoga exercise programme, face-to-face or online classes will occur over 12 months. Participants allocated to the seated yoga relaxation programme will attend two face-to-face or online workshops in total.
7. Where	The *SAGE* yoga exercise classes and the two yoga relaxation programme workshops will be delivered in established local yoga studios within metropolitan Sydney, Australia or online via the Zoom app.
8. When and how much	The *SAGE* yoga exercise programme will be delivered twice per week, for 1-hour duration, for 40 weeks in total over 12 months. Participants allocated to this group will be encouraged to also complete an unsupervised yoga programme for at least two extra 20-min sessions each week. Participants allocated to the seated yoga relaxation programme will attend two one-hour workshops. They will then complete the programme at home, unsupervised at their own discretion.
9. Tailoring	The *SAGE* yoga exercise programme will be tailored to the individual's capabilities and conditions. The yoga postures will be modified with the use of props to ensure safety. The workshops provided to the seated yoga relaxation group will be tailored to each participant's ability.

duration and frequency are in accordance with fall prevention guidelines, which state that exercise to prevent falls should be ongoing, and of a high dose.[4] Classes will either be attended face-to-face or online, and will be taught by yoga instructors with nationally or internationally recognised yoga qualifications and experience working with older people who are also specifically trained to deliver the *SAGE* programme. Online classes address the need for social distancing during the global COVID-19 pandemic.

Participants attending the face-to-face *SAGE* programme will attend yoga classes in trial-specific groups of between 10 and 20 people at established yoga studios in Sydney, Australia. Participants taking part in the online *SAGE* programme will access the classes via Zoom, a free online livestream app that can be accessed with a computer, smartphone or tablet. The research team will offer virtual help (via phone call) to assist Zoom set up. Participants will be advised to have their camera on so that the instructor is able to view their participation and provide feedback on poses. Prior to online classes commencing, participants will have the option of a one-on-one Zoom meeting with their yoga instructor to discuss any health issues and precautions regarding their participation in the yoga programme. Participants will also be able to ask questions throughout the class. Class-specific *WhatsApp* groups will also be available for participants to join, in order to foster social cohesion and connection between online class members, which in turn encourages programme adherence.[18]

Seated yoga relaxation programme

Participants allocated to the seated yoga relaxation programme will attend two 1-hour workshops, either face-to-face or online via Zoom, involving 10–20 participants to learn the programme. Yoga instructors with nationally or internationally recognised yoga qualifications and experience working with older people will teach the yoga relaxation programme which will focus on seated stretching exercises for the lower back, hips, neck, shoulders and chest and breathing and relaxation techniques. Participants will be instructed to practice the relaxation programme at home at their own discretion. The yoga relaxation programme was included as the comparator group in order to enhance recruitment and retention in the trial by ensuring that all participants received some form of yoga programme. The relaxation programme includes a focus on breathing and stretching movements performed in a seated position in order to minimise the likely impact on falls and the secondary outcomes.

Outcomes

Primary outcome

The primary outcome will be the rate of falls in the 12 months after randomisation. A fall will be defined as 'an unexpected event in which the participant comes to rest on the ground, floor, or lower level, as a result of a loss of balance'.[19] Participants will complete 12 monthly falls calendars either in a paper-based format or via online survey, as preferred by the participant. The participants who choose the paper-based format will return the calendar to the research centre at the end of each month in a reply-paid, pre-addressed envelope. If calendars are not completed, participants will be telephoned to ask about their fall history for that month.

All reported falls will be followed up with a phone call by a research assistant blinded to study group allocation to obtain further details about the fall and any related consequences. This method for collecting fall-related data has been successfully used in previous research[20] and is recommended as best practice by the Prevention of Falls Network Europe (ProFaNE), an EU-funded collaboration for fostering consensus with fall prevention research.[19]

Secondary outcomes

The secondary outcomes will be: (1) mental well-being, assessed using the Warwick-Edinburgh Mental Well-being Scale[21]; (2) physical activity, assessed with the Incidental and Planned Exercise Questionnaire[22]; (3) health-related quality of life, assessed using the EQ-5D-5L questionnaire[23]; (4) balance self-confidence, assessed with the Activity-specific Balance Confidence scale-simplified[24]; (5) physical function, assessed with the lower limb function subscale of the Late Life Function and Disability Instrument[25]; (6) sleep quality, assessed with The Pittsburg Sleep Quality Index[26]; (7) goal attainment, measured with the Goal Attainment Scale[27]; and (8) pain, assessed with the following three questions: *'Are you currently troubled by pain or discomfort, either all the time or on and off?'; 'Have you had this pain or discomfort for more than 3 months?'; 'Does this pain affect your daily activities? (1=not at all, 2=a little bit, 3=moderately, 4=quite a lot, 5=extremely)'*. All secondary outcomes will be measured at baseline and 12 months after randomisation.

Adverse events

For the purpose of this trial, an adverse event (AE) will be defined as an unwanted and usually harmful outcome (eg, fall, seizure, cardiac event). The event may or may not be related to the intervention, but occurs while the person is participating in the intervention that is, while they are doing yoga exercises. If any research staff member witnesses or becomes aware of a participant reporting an AE, they will notify the Research Manager within 12 hours. If a serious adverse event (SAE) occurs, the Research Manager will notify the Data and Safety Monitoring Board (DSMB), who will be convened to monitor SAE within 48 hours.

Data management

We will use a custom-built and secure REDCap database hosted by The University of Sydney to collect participant

data. Participants will complete the study survey either in a paper-based format posted to participants or via an online survey link. All study documentation will be stored securely in either locked filing cabinets (paper files) or electronically (electronic database files) with access granted only to authorised study team members.

To ensure confidentiality, the final dataset will contain re-identifiable information only. All publications associated with the study results will involve de-identified data so participant confidentiality will be maintained. Demographic information linking the participant to the data will be stored on a separate file. Only the lead investigator will have access to this information at the conclusion of the study.

Analysis of outcomes

The number of falls per person-year will be analysed using negative binomial regression models to estimate the between-group difference in fall rates after 1 year (primary outcome).[28] Generalised linear models will assess the effect of group allocation on continuously scored secondary outcomes (mental well-being, physical activity, quality of life, balance confidence, physical function, pain, goal attainment, sleep), adjusting for baseline scores.

Planned subgroup analyses will assess the differential effects of the intervention by baseline self-reported balance ability and history of falls. Secondary analyses will use instrumental variable regression to estimate the complier average causal effect for the primary outcome, falls, in people who adhered to at least 80% of supervised yoga sessions. We will conduct exploratory analyses to investigate the impact of controlling for exposure to physical activity. Predictors of acceptability and adherence will be identified with multivariable modelling techniques. Missing data for the primary outcome will not be imputed. Analyses will follow a pre-specified statistical analysis plan, will be conducted while masked to group allocation and will use an intention-to-treat approach. Analyses will use the Stata software package, College Station, Texas, and will be overseen by an experienced biostatistician.

The economic evaluation will take a health and community care funder perspective, and will include benefits related to falls prevented and Quality Adjusted Life Years (QALY) gained. Using mean costs and mean health outcomes in each trial arm, the incremental cost/QALY of the group-based *SAGE* yoga exercise programme compared with the seated yoga relaxation programme will be calculated and plotted on a cost-effectiveness plane. Bootstrapping will be used to estimate a distribution around costs and health outcomes, and to calculate the CIs around the incremental cost-effectiveness ratios. One-way sensitivity analysis will be conducted around key variables, and a probabilistic sensitivity analysis will be conducted to estimate the joint uncertainty in all parameters; a cost-effectiveness acceptability curve will be plotted to measure the probability that an intervention is cost-effective, given a decision maker's willingness to pay for each additional QALY gained. We will collect intervention cost data (staff costs, consumables, capital costs), health and community service contact (recorded on monthly calendars), fall rates and utility-based quality of life.

Sample size

A total of 560 participants (280/group) will provide 80% power to detect as significant, at the 5% level, a 30% lower fall rate for group-based *SAGE* yoga exercise programme participants than seated yoga relaxation programme participants (ie, IRR =0.70). Sample size calculations used a simulation approach in Stata 13 and coefficients from previous studies: alpha (a measure of over-dispersion in the negative binomial regression model) was assumed to be 0.65.[29] We assumed a control group rate of falls of 0.75 falls/person year over the 12-month follow-up as this was the fall rate in a large trial with similar recruitment methods.[30] The 0.70 value for IRR was chosen, as this was the size of effect on the fall rate from Tai Chi in a similar population.[30] An average follow-up period of 11 months (rather than the planned 12 months) was used in these calculations to account for loss to follow-up.

This sample size is expected to be sufficient to detect between-group differences of 10–15% for the secondary outcome measures. These calculations used the *sampsi* command in Stata 13 and PASS 13, and conservatively allow for 20% loss to follow-up, although we have achieved lower loss to follow-up in past trials using similar recruitment/follow-up methods.[31 32]

Patient and public involvement

The trial design, rationale and intervention content were informed by patient and public experiences and preferences, obtained through formal participant feedback in previous studies and during the process of obtaining the endorsement of the trial by Australia and New Zealand Musculoskeletal (ANZMUSC) Clinical Trials Network. Members of the public have assisted with recruitment of participants to the research through community organisations.

DISCUSSION

This trial is important as it addresses the urgent public health challenge of preventing falls in older people. Falls are common and costly in older age and the ageing of the global population means the burden of falls is rapidly increasing. This trial is the first internationally to rigorously examine the evidence about the effectiveness and cost-effectiveness of a yoga-based exercise programme on falls in people aged 60 years and over.

Exercise that challenges balance is known to prevent falls, yet to date, population-wide uptake and ongoing participation in such exercise programmes have been low. A greater choice of effective programmes that offer feasible and cost-effective scalability, and better implementation strategies

are needed to increase population-wide participation in effective fall prevention exercise programmes.

Yoga is growing in popularity among older people and warrants investigation as a potential strategy for preventing falls. If found to be effective and cost-effective, this yoga programme could be implemented affordably nationally and internationally to improve the health and independence of many older people.

ETHICS AND DISSEMINATION

The trial protocol was approved by the Human Research Ethics Committee at The University of Sydney, Sydney, Australia (approval number 2019/604). The results of this trial will be disseminated via peer-reviewed journal articles, presentations at international conferences and participant newsletters. The trial has been endorsed by the Australia and New Zealand Musculoskeletal (ANZMUSC) Clinical Trials Network indicating its high clinical priority and quality, importance to consumers, clinicians and policy makers and its potential to improve consumer outcomes. The protocol manuscript adheres to the ANZMUSC governance and publication policies, as will further trial-related manuscripts.

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Contributors AT, CS and SL conceived the study. All authors contributed to the study design, implementation methods, refinement of the study protocol and approved the final manuscript.

Competing interests RS and SY are practicing yoga instructors.

Ethics approval University of Sydney, Human Research Ethics Committee (approval number 2019/604).

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Data availability statement Data sharing not applicable as no datasets generated and/or analysed for this study.

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