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Effectiveness of Senior Dance on risk factors for falls in older adults (DanSE): a study protocol for a randomised controlled trial

Marcia R Franco,[1] Catherine Sherrington,[2] Anne Tiedemann,[2] Leani S Pereira,[3] Monica R Perracini,[4] Claudia R S Faria,[1] Rafael Z Pinto,[1] Carlos M Pastre[1]

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For numbered affiliations see end of article.

Correspondence to
Marcia R Franco;
marciarfranco@gmail.com

ABSTRACT

Introduction: Strong evidence shows that exercise is effective to improve fall risk factors among older people. However, older people's participation and adherence to exercise programmes is suboptimal. Type of exercise and apathy are reported to be barriers to exercise participation, suggesting that new effective interventions are needed. The primary aim of this randomised controlled trial is to investigate the effect of Senior Dance plus brief education for falls prevention on balance among people aged 60 years or over, compared with a control group receiving only brief education.

Methods and analysis: This single-blind randomised controlled trial will involve 82 community-dwelling older people aged 60 years or over who are cognitively intact. Participants allocated to the intervention group will attend a single educational class on strategies to prevent falls, and will participate in a 12-week, twice-weekly group-based programme of Senior Dance. The Senior Dance consists of different choreographies, which include rhythmic and simple movements with rhythmic folk songs. Participants allocated to the control group will attend the same educational class that intervention group participants will receive, and will be instructed not to take part in any regular exercise programme. The primary outcome will be single-leg stance with eyes closed. Secondary outcomes include: Short Physical Performance Battery, Falls Efficacy Scale, Trail Making Test and the Montreal Cognitive Assessment. Continuous outcomes will be reported using mean (SD) or median (IQR), depending on the distribution of the data. The linear regression approach to analysis of covariance will be used to compare the mean effect between groups. All patients will be included in the analyses following an intention-to-treat approach.

Ethics and dissemination: Ethics approval has been granted by the Human Ethics Committee of the São Paulo State University (CAAE 48665215.9.0000.5402). Outcomes will be disseminated through publication in peer-reviewed journals and presentations at conferences.

Trial registration number: NCT02603523, Pre-results.

Strengths and limitations of this study

- Single-blind randomised controlled trial (blinded assessors) and intention-to-treat analysis.
- Investigates a promising alternative to traditional structured exercise programmes that has the potential to improve older people's participation and adherence to exercise programmes.
- The intervention under investigation can be widely implemented into health services attended by older people living in the community.
- One limitation of this study is the lack of blinding of participants and therapists delivering the intervention due to the nature of the intervention.

INTRODUCTION

Falls among older people are an important public health concern worldwide, leading to deaths, hospitalisation, long-term disability, loss of independence, poor quality of life, fear of falling and nursing home admission.[1–4] Around one-third of people aged 65 years or over fall at least once each year, and those who fall once are more likely to fall again.[5 6] The direct and indirect healthcare costs associated with falls are extensive.[7 8]

Many risk factors for falls and related injuries have been identified. Balance and cognitive impairments, and muscle weakness are important risk factors for falls.[9–11] Since most of these risks factors for falls are modifiable, they are commonly the target of health interventions. Impaired performance on balance tests is a particularly strong predictor of falls in older people.[12–15] Balance or postural control in particular depends on the interaction of multiple systems such as biomechanical, motor coordination and sensory organisation.[16] With advancing age, changes in these systems make the postural control mechanism less efficient.[17 18] Older people

show a larger centre of pressure displacements and sway velocity in bipedal stance and single-leg stance compared with young adults.[19–22]

Systematic reviews with meta-analysis show that well-designed, structured exercise programmes are effective in improving fall risk factors and in preventing falls among community-dwelling older people.[23 24] Exercise programmes that target balance have been found to have greater fall prevention effects than those that do not.[25] A recent systematic review with meta-analysis confirms that balance training interventions for older adults (ie, exercises aiming at improving postural control by challenging the alignment of the body's centre of gravity) improve balance test performance.[25]

However, older people's participation and adherence to exercise programmes is suboptimal.[11] Pooled estimates of adherence to falls prevention programmes, derived from systematic reviews, vary from 21% to 74%.[26 27] Another study including 5681 older people found that only around 21% of older people adhere to public health recommendations for participation in strength or balance activities, falling in the lower limit of the estimates derived from systematic reviews.[28] From a health policy perspective, non-adherence to long-term therapies severely compromises the effectiveness of treatment leading to excessive healthcare costs.[29]

A recent qualitative systematic review published by our group including 132 studies revealed that apathy or disinterest is commonly reported as a barrier to physical activity participation.[30] In another study, we found that exercise type is highly likely to influence older people's decision on whether or not to engage in exercise programmes.[31] The results of these studies, when interpreted together, suggest that new effective interventions are required to attract more older people to start and continue to participate in exercise that is effective in preventing falls.

Dancing is a promising alternative to traditional structured exercise programmes as it may provide a safe and fun way of targeting balance. Previous studies show that some older people consider dancing an interesting and joyful activity that provides opportunity for socialisation.[32 33] Systematic reviews investigating the effects of dancing on risk factors for falls report beneficial effects on balance, gait, strength and dynamic mobility.[34 35] The paucity of randomised clinical trials investigating dancing among community-dwelling older adults, as well as the low methodological quality of existing studies, does not allow definitive conclusions to be made on the real effects of the different types of dancing on risk factors for falls. A recent well-designed randomised clinical trial found that social dancing did not prevent falls or risk factors for falls among retirement village residents.[36] Future studies are required to explore the impact of different types of dance in different settings.

Senior Dance is becoming increasingly popular among the older population in Brazil.[37] Senior Dance classes consist of different choreographies, which include rhythmic and simple movements with rhythmic folk songs. The concentration required to learn the choreographies challenges balance, motor coordination and cognitive function. The present study is a randomised clinical trial aiming to investigate the Senior Dance effect on balance, mobility and cognitive function, compared with a control group, among older people living in the community.

METHODS

Trial design

We will conduct a single-blind parallel randomised controlled trial in a university facility that belongs to the Faculty of Science and Technology from the São Paulo State University (UNESP)—Presidente Prudente campus. The design of the trial is illustrated in the figure 1. The protocol conforms to the Consolidated Standard of Reporting Trials (CONSORT) statement.[38] The trial has been registered at ClinicalTrials.gov (NCT02603523).

Participants

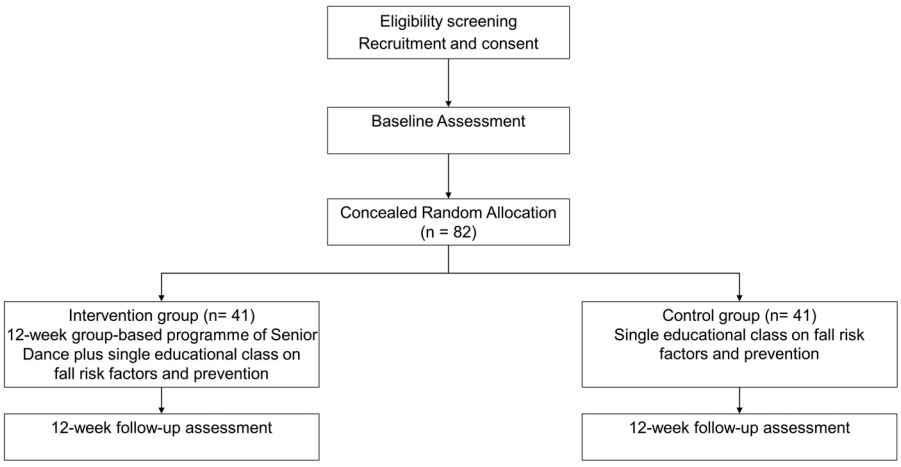
A total of 82 participants will be recruited via advertisements in local newspapers, health centres and community organisations in the urban area of Presidente Prudente, Brazil from January 2016 to June 2017. Participants will be considered eligible if they are community-dwelling, aged 60 years or over and cognitively intact (defined as a minimum score of 24 points on the Mini Mental Status Examination—MMSE).[39] We will exclude participants if they have had a previous stroke with severe neurological impairment, a progressive neurological disease, a severe visual deficiency, dizziness or vertigo for <3 months, any acute pain, an inability to maintain a standing position, even with the use of a walking aid or other device, or any illness that the physician considers as an exercise contraindication (eg, uncontrolled angina, acute coronary disease).

Participants who are currently participating in regular exercise programmes including strength training and balance challenge, such as supervised group exercise, Tai Chi, Yoga or any dance activity, will also be excluded. We will not exclude participants if their regular exercise regime is limited to walking, water-based exercise or any other form of therapy that does not include the exercises described above, as there is no evidence that these types of exercise are effective to prevent falls among older adults.[24] With the exception of the cognitive impairment criterion for eligibility that requires the face-to-face application of the MMSE, the lead investigator (MRF) will determine whether prospective participants fulfil the eligibility criteria during initial telephone contact.

Randomisation

Participants who meet the eligibility criteria and sign the informed consent form will have baseline data collected

Figure 1 Trial design.



prior to the randomisation procedure. To ensure allocation concealment, randomisation to groups (senior dance or control group) will be undertaken by an investigator (RZP) not involved in recruitment using a computer-generated randomisation schedule.

Intervention group

Participants allocated to the intervention group will attend a 1-hour single educational class on strategies to prevent falls among older people, and will participate in a 12-week, twice-weekly group-based programme of Senior Dance. Each dance class will last for an hour, and the number of participants per class will range from 10 to 15. Senior Dance-certified instructors who have the same level of training and expertise will lead the classes. The Senior Dance classes are at a moderate-level intensity, and consist of different choreographies, which include rhythmic and simple movements with rhythmic folk songs. During the classes, participants will practise the movements while sitting or standing, quickly or slowly, in circles, individually, in pairs or in small groups. The concentration required to learn the choreographies challenges balance, motor coordination and cognitive function.

Control group

Participants allocated to the control group will attend the same educational class on strategies to prevent falls

Table 1 Intervention description using the Template for Intervention Description and Replication (TIDieR) checklist

1. Brief name	Effects of Senior Dance on risk factors for falls (DanSE)
2. Why	Strong evidence demonstrates that specific types of exercise are effective for preventing falls among older people. However, older people's participation and adherence to such exercise programmes is suboptimal. Type of exercise and apathy are reported to be barriers to exercise participation, suggesting that new effective interventions are needed.
3. What materials	Participants will not receive any materials.
4. What procedures	Participants allocated to the intervention group will attend a 1-hour single educational class on strategies to prevent falls among older people, and will participate in supervised Senior Dance classes in groups of 10–15 participants per class.Participants allocated to the control group will attend a 1-hour single educational class on strategies to prevent falls among older people in groups of 10–15 participants per session.
5. Who provided	Senior Dance-certified instructors who have the same level of training and expertise will lead the classes.
6. How	Both the educational class on strategies to prevent falls among older people and the Senior Dance classes will be delivered face to face in a group.
7. Where	The intervention will be delivered to community-dwelling older people living in Presidente Prudente, São Paulo, Brazil.
8. When and how much	Participants allocated to the intervention group will attend a 1-hour single educational class on strategies to prevent falls among older people, and will participate in a 12-week, twice-weekly group-based programme of Senior Dance. Each dance class will last for an hour and will be at a moderate-intensity level.Participants allocated to the control group will only attend a 1-hour single educational class on strategies to prevent falls among older people, and will be instructed to not take part in any structured exercise programme during the study period.
9. Tailoring	The intervention will be delivered in a group and will not be individually tailored to participants.

among older people that intervention group participants will receive, and will be instructed not to take part in any regular exercise programmes such as supervised group exercise, Tai Chi, Yoga or any dance activity during the study period. At the end of the study, they will be offered Senior Dance classes, twice a week, during 12 weeks.

The 1 table summarises the contents of both interventions according to the Template for Intervention Description and Replication (TIDieR) checklist.

Outcome measures

Data will be collected at baseline prior to randomisation and at the follow-up (12 weeks after randomisation), by an assessor blinded to group allocation.

A 12-week intervention should be enough time to detect an impact of the dance intervention on our outcome measures based on previous published clinical trials investigating the effect of dancing on risk factors for falls.[40 41] One of these studies found that the group that received 12 weeks of dance showed better results on muscle strength compared with a control group.[41]

Primary outcome

Balance outcomes will be used due to the importance of balance as a risk factor for falls. Single-leg stance with eyes closed without the use of a walking aid will be the primary outcome measure. Participants will be asked to choose a leg to stand on, flex the opposite knee allowing the foot to clear the floor and balance on one leg for up to 60 s. Participants will be given at least two attempts and the best time will be recorded and analysed as a continuous measure. The choice of single-leg stance as the primary outcome was based on the fact that it is a highly functional test, since transient balance on a single limb is needed for a number of activities, such as normal gait, turning, stair climbing and dressing. Single-leg stance with eyes closed is a challenging and reliable test[42] that has been previously used in studies investigating dance among the older population.[40]

Secondary outcomes

There will be four secondary outcome measures:

- Short Physical Performance Battery: the domains related to gait speed, chair stand and balance tests will be analysed separately.[43] The gait speed will be measured by recording the time spent to walk 4 m at a comfortable pace. The chair stand test will be measured by recording the time spent to complete five repetitions of the sit-to-stand test. The balance tests include the sum of time able to stand in the three standing balance positions (feet side by side, feet in semitandem and in tandem positions) with the addition of the single-leg stance with eyes closed. The ability to stand for up to 10 s at each balance position will be recorded, and the final measure will be up to 40 s.
- Falls Efficacy Scale—International (FES-I): to measure falls self-efficacy or concerns about falling while undertaking daily tasks.[44]
- Trail Making Test (TMT): to evaluate cognitive function.[45] The test consists of two parts (A and B). Part A measures processing speed and involves participants connecting consecutive numbers (eg, 1-2-3). Part B is a measure of executive function of 'task shifting' and involves participants connecting alternating letters and numbers in order (eg, 1-A-2-B). The difference in time between the two parts (B minus A) will be calculated to isolate the executive component of this test.
- The Montreal Cognitive Assessment (MoCA): to also evaluate cognitive function.[46] The MoCA is a one-page 30-point test, which contains the following cognitive domains: visuospatial, executive, sustained attention, concentration, working memory, short-term memory recall, language and orientation.

Additional information collected at baseline will include demographic information (age, gender, educational level, working status), previous history of falls, and information about medical conditions and use of medications. This information will be collected to enable a description of the sample's baseline characteristics and to obtain values to enter as covariates in the models comparing groups at follow-up.

To investigate the participant's perceptions on the benefits and barriers to exercise participation, the Exercise Benefits and Barriers Scale will also be applied.[47] We will also collect data on adherence and adverse effects. The Senior Dance instructor will record class attendance at each session using an adherence questionnaire,[48] and adverse events associated with the intervention will be recorded in the follow-up after study completion. Participants who do not attend the dance class will be contacted by telephone in an attempt to promote participant retention and complete follow-up.

Sample size

As described above, the primary outcome measure will be the single-leg stance with eyes closed. A total sample of 82 participants (41 per group) will be required to detect a between-group difference of 1.93 s (SD of 2.87 s)[49] with 80% power and a significance level of 5%, allowing 15% dropouts.

Data integrity and analysis

Data integrity will be monitored by regularly scrutinising data files for omissions and errors. The statistical software SPSS V.20.0 (IBM Corporation, Somers, New York, USA) will be used for data analysis. Dichotomous and categorical data will be reported using frequency (proportion), while continuous data will be reported using mean (SD) or median (IQR), depending on the distribution of the data. The linear regression approach to analysis of covariance will be used to compare the mean effect between the intervention and control groups. In this model,

group will be included as the independent variable, the post-treatment outcomes as dependent variables and the pretreatment outcomes as covariates. The level of significance will be set at $p<0.05$. All patients will be included in the analyses following an intention-to-treat approach. Participants will be given an anonymous study ID to protect confidentiality, and only study investigators will have access to the final trial data set.

DISCUSSION

The popularity of dancing is increasing among the older population. Previous systematic reviews report a beneficial effect of dancing on risk factors for falls, such as balance, gait and strength.[34 35] However, the low methodological quality of existing studies does not allow one to reach definitive conclusions about the real therapeutic effect of dancing on risk factors for falls. Methodological flaws commonly reported in this area include lack of concealed allocation and non-use of an intention-to-treat approach when analysing the data.[34] Importantly, both methodological flaws have been reported to inflate effect sizes of clinical trials.[50 51]

This study is the first randomised controlled trial testing the effectiveness of Senior Dance on risk factors for falls among older people. Our results will provide information on the real benefits provided by this type of physical activity, and can be used to guide the decision-making process of health professionals, especially physiotherapists, when prescribing exercise regimens for the older population. If the intervention proves to be effective, future larger randomised clinical trials should be conducted to investigate the effect of Senior Dance on the incidence of falls over the long term.

DISSEMINATION

Outcomes will be disseminated through publication in peer-reviewed journals and presentations at international conferences.

Author affiliations
[1]Faculdade de Ciências e Tecnologia, UNESP—Univ Estadual Paulista, Presidente Prudente, São Paulo, Brasil
[2]The George Institute for Global Health, Sydney Medical School, The University of Sydney, Sydney, New South Wales, Australia
[3]Department of Physical Therapy, Post Graduate Program in Rehabilitation Sciences, School of Physical Education, Physical Therapy and Occupational Therapy, Universidade Federal de Minas Gerais (UFMG), Belo Horizonte, Minas Gerais, Brazil
[4]Department of Physical Therapy, Universidade Cidade de São Paulo (UNICID), São Paulo, Brazil

Twitter Follow Anne Tiedemann @AnneTiedemann1

Collaborators MRF.

Contributors MRF with input from the other investigators conceived and received funding to conduct this study. CS, AT, LSP, MRP, CRSF, RZP and CMP commented on the various versions of this study protocol. MRF, CRSF and RZP were involved in the recruitment and data collection. MRF, CMP and RZP will conduct the analyses. All authors approved the final manuscript.

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