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

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3 **Effectiveness of senior dance on risk factors for falls in older adults (DanSE):**  
4 **study protocol for a randomised controlled trial**  
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## 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 programs is suboptimal. Type of exercise and apathy have been reported to be barriers to exercise participation, suggesting that new effective interventions are needed. The primary aim of this randomized controlled trial is to investigate the effect of Senior Dance plus brief education for falls prevention (intervention group) on balance among people aged 60 years or over, compared to a control group receiving only brief education.

**Methods and analysis:** This single blind randomized 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 program of Senior Dance. 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 program. The primary outcome will be single-leg stance with eyes closed. Secondary outcomes include: Short Physical Performance Battery, Falls Efficacy Scale (FES-I), Trail Making Test part A and B, and the Montreal Cognitive Assessment (MoCA). Dichotomous and categorical data, data with normal distribution and non-normal distribution will be reported using frequency (proportion), mean (standard deviation) and median (interquartile range), respectively. The linear regression approach to analysis of covariance will be used to compare the mean effect between intervention and control group. All patients will be included in the analyses following an intention-to-treat approach.

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3 **Ethics and dissemination:** Ethics approval has been granted by the Human Ethics  
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5 Committee of the São Paulo State University (CAAE 48665215.9.0000.5402).  
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7 Outcomes will be disseminated through publication in peer-reviewed journals and  
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9 presentations at conferences.  
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11 **Trial registration number:** The trial has been registered at ClinicalTrials.gov  
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13 (NCT02603523).  
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15 **Key words:** geriatric medicine, preventive medicine, older people, accidental falls  
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## STRENGTHS AND LIMITATIONS OF THIS STUDY

- Randomised controlled trial with blinded assessors and intention-to-treat analysis.
- Investigates a promising alternative to traditional structured exercise programs that has the potential to improve older people's participation and adherence to exercise programs.
- The intervention under investigation can be transferable to routine clinical practice in the aged care health service setting.
- 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, hospitalization, 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 health care 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]

As most of these risks factors for falls are modifiable, they are commonly the target of health interventions. Systematic reviews with meta-analysis show that well-designed,

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3 structured exercise programs are effective in improving fall risk factors and in  
4 preventing falls among community-dwelling older people.[12, 13] However, older  
5 people's participation and adherence to exercise programs is suboptimal. Estimates of  
6 adherence to falls prevention programs derived from systematic reviews, vary from 21%  
7 and 74% [14, 15]. From a health policy perspective, non-adherence to long-term  
8 therapies severely compromises the effectiveness of treatment leading to excessive  
9 health care costs.[16]  
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14 A recent qualitative systematic review published by our group including 132 studies  
15 revealed that apathy or disinterest is commonly reported as a barrier to physical activity  
16 participation.[17] In another study we found that exercise type is highly likely to  
17 influence older people's decision on whether or not to engage in exercise programs.[18]  
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19 The results of these studies, when interpreted together, suggest that new effective  
20 interventions are required.  
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36 Dancing is a promising alternative to traditional structured exercise programs. Previous  
37 studies show that older people consider dancing an interesting and joyful activity, that  
38 provides opportunity for socialization.[19, 20] Systematic reviews investigating the  
39 effects of dancing on risk factors for falls report beneficial effects on balance, gait,  
40 strength and dynamic mobility.[21, 22] Nevertheless, the lack of randomized clinical  
41 trials as well as the low methodological quality of the existing studies do not allow  
42 reaching definitive conclusions on the real effects of dance on risk factors for falls.[21]  
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54 Senior Dance is becoming increasingly popular among the older population in  
55 Brazil.[23] Senior Dance classes consist of different choreographies, which include  
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3 rhythmic and simple movements with rhythmic folk songs. The concentration required  
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5 to learn the choreographies challenges balance, motor coordination and cognitive  
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7 function. The present study is a randomized clinical trial aiming to investigate the  
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9 Senior Dance effect on balance, mobility and cognitive function, compared with a  
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11 control group, among older people living in the community.  
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## 14 15 16 **METHODS**

### 17 18 **Trial design**

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20 We will conduct a single-blind randomized controlled trial in a university facility that  
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22 belongs to the Faculty of Science and Technology from the São Paulo State University  
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24 (UNESP) - Presidente Prudente campus. The design of the trial is illustrated in Figure 1.  
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26 The protocol conforms to Consolidated Standard of Reporting Trials (CONSORT)  
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28 statement.[24] The trial has been registered at ClinicalTrials.gov (NCT02603523).  
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### 34 35 **Participants**

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37 A total of 82 participants will be recruited via advertisements in local newspapers,  
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39 health centers and community organizations in the urban area of Presidente Prudente,  
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41 Brazil.

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43 Participants will be considered eligible if they are community-dwelling aged 60 years or  
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45 over and cognitively intact (defined as a minimum score of 24 points on the Mini  
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47 Mental Status Examination - MMSE).[25] We will exclude participants if they have a  
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49 previous stroke with severe neurological impairment, a progressive neurological  
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51 disease, a severe visual deficiency, dizziness or vertigo for less than 3 months, any acute  
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53 pain, an inability to maintain a standing position, even with the use of a walking aid or  
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3 other device, or any illness that the physician considers as an exercise contra-indication  
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5 (e.g. uncontrolled angina, acute coronary disease).  
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10 Participants who are currently participating in regular exercise programs including  
11 strength training and balance challenge, such as supervised group exercise, Tai Chi,  
12 Yoga, or any dance activity will also be excluded. We will not exclude participants if  
13 their regular exercise regime is limited to walking, water-based exercise or any other  
14 form of therapy that does not include the exercises described above, as there is no  
15 evidence that these types of exercise are effective to prevent falls among older  
16 adults.[12] With the exception of the cognitive impairment criterion for eligibility that  
17 requires the face-to-face application of the MMSE, the lead investigator (MRF) will  
18 determine whether prospective participants fulfil the eligibility criteria during initial  
19 telephone contact.  
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### 33 34 **Randomization**

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36 Participants who meet eligibility criteria and signed the Informed Consent Form will  
37 have baseline data collected prior to the randomization procedure. To ensure allocation  
38 concealment, randomisation to groups (senior dance or control group) will be  
39 undertaken by an investigator (RZP) not involved in recruitment using a computer-  
40 generated randomization schedule.  
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### 51 **Intervention group**

52 Participants allocated to the intervention group will attend a one-hour single educational  
53 class on strategies to prevent falls among older people, and will participate in a 12-  
54 week, twice-weekly group-based program of Senior Dance. Each dance class will last  
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3 for an hour, and the number of participants per class will range from 10 to 15. Senior  
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5 Dance-certified instructors that have the same level of training and expertise will lead  
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7 the classes. The Senior Dance classes consist of different choreographies, which include  
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9 rhythmic and simple movements with rhythmic folk songs. During the classes,  
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11 participants will practise the movements while sitting or standing, quickly or slowly, in  
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13 circles, individually, in pairs or in small groups. The concentration required to learn the  
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15 choreographies challenges balance, motor coordination and cognitive function.  
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### 20 21 **Control group**

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23 Participants allocated to the control group will attend the same educational class on  
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25 strategies to prevent falls among older people that intervention group participants will  
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27 receive, and will be instructed not to take part in any regular exercise programs such as  
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29 supervised group exercise, Tai Chi, Yoga, or any dance activity during the study period.  
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31 At the end of the study, they will be offered Senior Dance classes, twice a week, during  
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33 12 weeks.  
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### 38 39 **Outcome measures**

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41 Data will be collected at baseline prior to randomization and at the follow-up (12-week  
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43 after randomization), by an assessor blinded to group allocation.  
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### 47 48 ***Primary outcome***

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50 Single-leg stance with eyes closed without the use of walking aid will be the primary  
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52 outcome measure. Participants will be asked to choose a leg to stand on, flex the  
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54 opposite knee allowing the foot to clear the floor, and balance on one leg for up to 60  
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56 seconds. We will record the time participants will be able keep this position, and results  
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3 will be analysed as a continuous measure. The choice of single-leg stance as the primary  
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5 outcome was based on the fact that it is a highly functional test, since transient balance  
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7 on a single limb is needed for a number of activities, such as normal gait, turning, stair  
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9 climbing and dressing. Single-leg stance with eyes closed is a challenging and reliable  
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11 test [26] that has been previously used in studies investigating dance among the older  
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13 population.[27]  
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### 15 16 17 18 ***Secondary outcomes*** 19

20 There will be four secondary outcomes measures:  
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- 22 - Short Physical Performance Battery: the domains related to gait speed, chair  
23 stand and balance tests will be analysed separately.[28] The gait speed will be  
24 measured by recording the time spent to walk 4-m at fast pace. The chair stand  
25 test will be measured by recording the time spent to complete five repetitions of  
26 the sit-to-stand test. The balance tests include the sum of time able to stand in  
27 the three standing balance positions (feet side by side, feet in semi tandem and in  
28 tandem positions) with the addition of the single-leg stance with eyes opened  
29 The ability to stand for up to 10 seconds at each balance position will be  
30 recorded, and the final measure will be up to 40 seconds.  
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32 - Falls Efficacy Scale – International (FES-I): to measure falls self-efficacy or  
33 concerns about falling while undertaking daily tasks.[29]  
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35 - Trail Making Test (TMT): to evaluate cognitive function.[30] The test consists  
36 of two parts (A and B). Part A measures processing speed and involves  
37 participants connecting consecutive numbers (e.g., 1-2-3). Part B is a measure of  
38 executive function of ‘task shifting’ and involves participants connecting  
39 alternating letters and numbers in order (e.g., 1-A-2-B). The difference in time  
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3 between the two parts (B minus A) will be calculated to isolate the executive  
4 component of this test  
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7 - The Montreal Cognitive Assessment (MoCA): to also evaluate cognitive  
8 function.[31] The MoCA is a one-page 30-point test, which contains the  
9 following cognitive domains: visuospatial, executive, sustained attention,  
10 concentration, working memory, short-term memory recall, language and  
11 orientation.  
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20 Additional information collected at baseline will include demographic information  
21 (age, gender, educational level, working status), previous history of falls, and  
22 information about medical conditions and use of medications. This information will  
23 be collected to enable a description of the sample's baseline characteristics and to  
24 obtain values to enter as covariates in the models comparing groups at follow-up.  
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34 To investigate participant's perceptions on the benefits and barriers to exercise  
35 participation, the Exercise Benefits and Barriers Scale will also be applied.[32] We  
36 will also collect data on adherence and adverse effects. The Senior Dance instructor  
37 will record class attendance at each session using an adherence questionnaire [33],  
38 and adverse events associated with the intervention will be recorded in the follow-  
39 up after study completion.  
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#### 47 **Sample size**

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49 As described above, the primary outcome measure will be the single-leg stance with  
50 eyes closed. A total sample of 82 subjects (41 per group) will be required to detect a  
51 between-group difference of 1.93 seconds (standard deviation of 2.87-seconds) [34]  
52 with 80% power and a significance level of 5%, allowing 15% dropouts.  
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### Data integrity and analysis

Data integrity will be monitored by regularly scrutinising data files for omissions and errors. The statistical software SPSS version 20.0 (IBM Corporation, Somers, NY, USA) will be used for data analysis. Dichotomous and categorical data, data with normal distribution and non-normal distribution will be reported using frequency (proportion), mean (standard deviation) and median (interquartile range), respectively. The linear regression approach to analysis of covariance will be used to compare the mean effect between intervention and control group. In this model, group will be included as the independent variable, the post-treatment outcomes as dependent variables and the pre-treatment 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.

### 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.[21, 22] However, the low methodological quality of existing studies do not allow reaching 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.[21] Importantly, both methodological flaws have been reported to inflate effect sizes of clinical trials.[35, 36]

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5 This study is the first randomized controlled trial testing the effectiveness of Senior  
6 Dance on risk factors for falls among older people. Our results will provide  
7 information on the real benefits provided by this type of physical activity, and can  
8 be used to guide the decision making process of health professionals, especially  
9 physiotherapists when prescribing exercise regimens for the older population. The  
10 results generated in this study can also be of use for both health and insurance policy  
11 makers in their decision-making regarding funding and treatment options.  
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### 23 **ETHICS AND DISSEMINATION**

24 Ethics approval has been granted by the Human Ethics Committee of the São Paulo  
25 State University (CAAE 48665215.9.0000.5402), and outcomes will be disseminated  
26 through publication in peer-reviewed journals and presentations at international  
27 conferences.  
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36 **CONTRIBUTORS:** MRF with input from the other investigators conceived and  
37 received funding to conduct this study. CS, AT, LP, MRP, CSF, RZP and CMP  
38 commented on the various versions of this study protocol. MRF, CSG and RZP were  
39 involved in the recruitment and data collection. MRF, CMP and RZP will conduct  
40 the analyses. All authors approved the final manuscript.  
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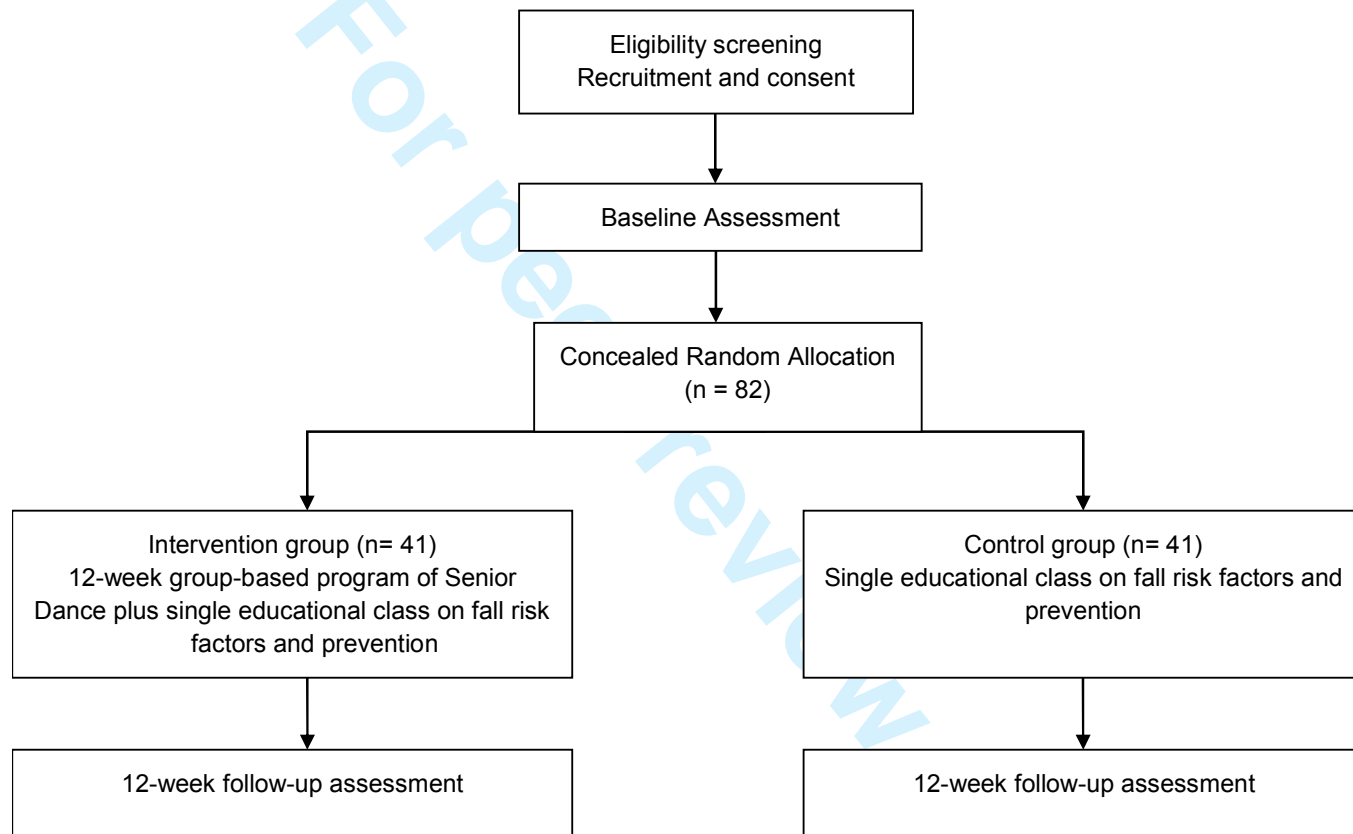
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Figure 1. Trial design



# BMJ Open

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

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Manuscripts

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3 **Effectiveness of senior dance on risk factors for falls in older adults (DanSE):**  
4 **study protocol for a randomised controlled trial**  
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9 Marcia R Franco<sup>1</sup>, Sherrington C<sup>2</sup>, Tiedemann A<sup>2</sup>, Pereira LS<sup>3</sup>, Perracini MR<sup>4</sup>, Faria  
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## 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 programs 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 randomized 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 to a control group receiving only brief education.

**Methods and analysis:** This single blind randomized 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 program 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 program. 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 (standard deviation) or median (interquartile range), 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).

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3 Outcomes will be disseminated through publication in peer-reviewed journals and  
4 presentations at conferences.  
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7 **Trial registration number:** The trial has been registered at ClinicalTrials.gov  
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9 (NCT02603523). Protocol issue date: January 29, 2016.  
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11 **Key words:** geriatric medicine, preventive medicine, older people, accidental falls  
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For peer review only

## 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 programs that has the potential to improve older people's participation and adherence to exercise programs.
- 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, hospitalization, 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 health care 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] As most of these risks factors for falls are modifiable, they are commonly the target of health interventions. Systematic reviews with meta-analysis show that well-designed, structured exercise programs are effective in improving fall risk factors and in preventing falls among community-dwelling older people.[12, 13] However, older people's participation and adherence to exercise programs is suboptimal.[11] Pooled estimates of adherence to falls prevention programs derived from systematic reviews, vary from 21% and 74% [14, 15]. 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.[16] From a health policy perspective, non-adherence to long-term therapies severely compromises the effectiveness of treatment leading to excessive health care costs.[17]

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

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3 participation.[18] In another study we found that exercise type is highly likely to  
4 influence older people's decision on whether or not to engage in exercise programs.[19]  
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6 The results of these studies, when interpreted together, suggest that new effective  
7 interventions are required to attract more older people to commence and continue to  
8 participate in exercise that is effective in preventing falls.  
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16 Dancing is a promising alternative to traditional structured exercise programs. Previous  
17 studies show that some older people consider dancing an interesting and joyful activity,  
18 that provides opportunity for socialization.[20, 21] Systematic reviews investigating the  
19 effects of dancing on risk factors for falls report beneficial effects on balance, gait,  
20 strength and dynamic mobility.[22, 23] The paucity of randomized clinical trials  
21 investigating dancing among community-dwelling older adults as well as the low  
22 methodological quality of existing studies, do not allow definitive conclusions to be  
23 made on the real effects of the different types of dancing on risk factors for falls. A  
24 recent well-designed randomized clinical trial found that social dancing did not prevent  
25 falls or risk factors for falls among retirement village residents.[24] Future studies are  
26 required to explore the impact of different types of dance in different settings.  
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43 Senior Dance is becoming increasingly popular among the older population in  
44 Brazil.[25] Senior Dance classes consist of different choreographies, which include  
45 rhythmic and simple movements with rhythmic folk songs. The concentration required  
46 to learn the choreographies challenges balance, motor coordination and cognitive  
47 function. The present study is a randomized clinical trial aiming to investigate the  
48 Senior Dance effect on balance, mobility and cognitive function, compared with a  
49 control group, among older people living in the community.  
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## METHODS

### Trial design

We will conduct a single-blind parallel randomized 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. The protocol conforms to Consolidated Standard of Reporting Trials (CONSORT) statement.[26] The trial has been registered at ClinicalTrials.gov (NCT02603523).

### Participants

A total of 82 participants will be recruited via advertisements in local newspapers, health centers and community organizations 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).[27] 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 less than 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 contra-indication (e.g. uncontrolled angina, acute coronary disease).

Participants who are currently participating in regular exercise programs including strength training and balance challenge, such as supervised group exercise, Tai Chi,

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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.[13] 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.

### **Randomization**

Participants who meet eligibility criteria and signed the Informed Consent Form will have baseline data collected prior to the randomization 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 randomization schedule.

### **Intervention group**

Participants allocated to the intervention group will attend a one-hour single educational class on strategies to prevent falls among older people, and will participate in a 12-week, twice-weekly group-based program 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 that 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

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3 standing, quickly or slowly, in circles, individually, in pairs or in small groups. The  
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5 concentration required to learn the choreographies challenges balance, motor  
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7 coordination and cognitive function.  
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### 10 11 **Control group**

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14 Participants allocated to the control group will attend the same educational class on  
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16 strategies to prevent falls among older people that intervention group participants will  
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18 receive, and will be instructed not to take part in any regular exercise programs such as  
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20 supervised group exercise, Tai Chi, Yoga, or any dance activity during the study period.  
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22 At the end of the study, they will be offered Senior Dance classes, twice a week, during  
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24 12 weeks.  
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30 The Table summarizes the contents of both interventions according to the TIDieR  
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32 checklist.  
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### 36 **Outcome measures**

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38 Data will be collected at baseline prior to randomization and at the follow-up (12-week  
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40 after randomization), by an assessor blinded to group allocation.  
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46 A 12-week intervention should be enough time to detect an impact of the dance  
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48 intervention on our outcome measures based on previous published clinical trials  
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50 investigating the effect of dancing on risk factors for falls.[28, 29] One of these studies  
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52 found that the group that received 12 weeks of dance showed the better results on  
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54 muscle strength compared to a control group.[29]  
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### ***Primary outcome***

Single-leg stance with eyes closed without the use of 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 seconds. 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 [30] that has been previously used in studies investigating dance among the older population.[28]

### ***Secondary outcomes***

There will be four secondary outcomes measures:

- Short Physical Performance Battery: the domains related to gait speed, chair stand and balance tests will be analysed separately.[31] The gait speed will be measured by recording the time spent to walk 4-m at fast 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 semi tandem and in tandem positions) with the addition of the single-leg stance with eyes opened. The ability to stand for up to 10 seconds at each balance position will be recorded, and the final measure will be up to 40 seconds.
- Falls Efficacy Scale – International (FES-I): to measure falls self-efficacy or concerns about falling while undertaking daily tasks.[32]

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3 - Trail Making Test (TMT): to evaluate cognitive function.[33] The test consists  
4 of two parts (A and B). Part A measures processing speed and involves  
5 participants connecting consecutive numbers (e.g., 1-2-3). Part B is a measure of  
6 executive function of ‘task shifting’ and involves participants connecting  
7 alternating letters and numbers in order (e.g.,1-A-2-B). The difference in time  
8 between the two parts (B minus A) will be calculated to isolate the executive  
9 component of this test  
10  
11 - The Montreal Cognitive Assessment (MoCA): to also evaluate cognitive  
12 function.[34] The MoCA is a one-page 30-point test, which contains the  
13 following cognitive domains: visuospatial, executive, sustained attention,  
14 concentration, working memory, short-term memory recall, language and  
15 orientation.  
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32 Additional information collected at baseline will include demographic information  
33 (age, gender, educational level, working status), previous history of falls, and  
34 information about medical conditions and use of medications. This information will  
35 be collected to enable a description of the sample’s baseline characteristics and to  
36 obtain values to enter as covariates in the models comparing groups at follow-up.  
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45 To investigate participant’s perceptions on the benefits and barriers to exercise  
46 participation, the Exercise Benefits and Barriers Scale will also be applied.[35] We  
47 will also collect data on adherence and adverse effects. The Senior Dance instructor  
48 will record class attendance at each session using an adherence questionnaire [36],  
49 and adverse events associated with the intervention will be recorded in the follow-  
50 up after study completion. Participants who do not attend the dance class will be  
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3 contacted by telephone as an attempt to promote participant retention and complete  
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5 follow-up.  
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### 8 9 **Sample size**

10 As described above, the primary outcome measure will be the single-leg stance with  
11 eyes closed. A total sample of 82 subjects (41 per group) will be required to detect a  
12 between-group difference of 1.93 seconds (standard deviation of 2.87-seconds) [37]  
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14 with 80% power and a significance level of 5%, allowing 15% dropouts.  
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### 20 21 **Data integrity and analysis**

22 Data integrity will be monitored by regularly scrutinising data files for omissions  
23 and errors. The statistical software SPSS version 20.0 (IBM Corporation, Somers,  
24 NY, USA) will be used for data analysis. Dichotomous and categorical data will be  
25 reported using frequency (proportion), while continuous data will be reported using  
26 mean (standard deviation) or median (interquartile range), depending on the  
27 distribution of the data. The linear regression approach to analysis of covariance will  
28 be used to compare the mean effect between intervention and control group. In this  
29 model, group will be included as the independent variable, the post-treatment  
30 outcomes as dependent variables and the pre-treatment outcomes as covariates. The  
31 level of significance will be set at  $p < 0.05$ . All patients will be included in the  
32 analyses following an intention-to-treat approach. Participants will be given an  
33 anonymous study ID to protect confidentiality, and only study investigators will  
34 have access to the final trial dataset.  
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### 53 54 55 **DISCUSSION**

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3 The popularity of dancing is increasing among the older population. Previous  
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5 systematic reviews report a beneficial effect of dancing on risk factors for falls, such  
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7 as balance, gait and strength.[22, 23] However, the low methodological quality of  
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9 existing studies do not allow reaching definitive conclusions about the real  
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11 therapeutic effect of dancing on risk factors for falls. Methodological flaws  
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13 commonly reported in this area include lack of concealed allocation and non-use of  
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15 an intention to treat approach when analysing the data.[22] Importantly, both  
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17 methodological flaws have been reported to inflate effect sizes of clinical trials.[38,  
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25 This study is the first randomized controlled trial testing the effectiveness of Senior  
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27 Dance on risk factors for falls among older people. Our results will provide  
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29 information on the real benefits provided by this type of physical activity, and can  
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31 be used to guide the decision making process of health professionals, especially  
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33 physiotherapists when prescribing exercise regimens for the older population. If the  
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35 intervention proves to be effective, future larger randomised clinical trials should be  
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37 conducted to investigate the effect of Senior Dance on the incidence of falls over the  
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39 long-term.  
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#### 45 **ETHICS AND DISSEMINATION**

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47 Ethics approval has been granted by the Human Ethics Committee of the São Paulo  
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49 State University (CAAE 48665215.9.0000.5402), and outcomes will be disseminated  
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51 through publication in peer-reviewed journals and presentations at international  
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3 **CONTRIBUTORS:** MRF with input from the other investigators conceived and  
4 received funding to conduct this study. CS, AT, LP, MRP, CSF, RZP and CMP  
5 commented on the various versions of this study protocol. MRF, CSG and RZP were  
6 involved in the recruitment and data collection. MRF, CMP and RZP will conduct  
7 the analyses. All authors approved the final manuscript.  
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16 **COMPETING INTERESTS:** None declared.  
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Table. 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 programs 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 one-hour single educational class on strategies to prevent falls among older people, and will participate in supervised Senior Dance classes in groups of 10 to 15 participants per class. Participants allocated to the control group will attend a one-hour single educational class on strategies to prevent falls among older people in groups of 10 to 15 participants per session.
5. Who provided	Senior Dance-certified instructors that 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 one-hour single educational class on strategies to prevent falls among older people, and will participate in a 12-week, twice-weekly group-based program of Senior Dance. Each dance class will last for an hour and will be at a moderate-intensity level.

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Participants allocated to the control group will only attend a one-hour single educational class on strategies to prevent falls among older people, and will be instructed to not take part in any structured exercise program during the study period.

9. Tailoring

The intervention will be delivered in a group and will not be individually tailored to participants.

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Figure. Trial design

For peer review only



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 3
	2b	All items from the World Health Organization Trial Registration Data Set	Page 3 Page 13 Table 1
Protocol version	3	Date and version identifier	Page 3
Funding	4	Sources and types of financial, material, and other support	Page 13
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 13 Page 1
	5b	Name and contact information for the trial sponsor	Page 13
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 13
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 5
	6b	Explanation for choice of comparators	Page 6
Objectives	7	Specific objectives or hypotheses	Page 7

1				
2	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 7
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8	<b>Methods: Participants, interventions, and outcomes</b>			
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10	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 7
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14	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 7
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18	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 8 Page 9
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21		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
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25		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 11
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30		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 9
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33	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 9 Page 10
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41	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 9 Page 17
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45	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 11
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49	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 7
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53	<b>Methods: Assignment of interventions (for controlled trials)</b>			
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55	Allocation:			Page 8
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2	Sequence	16a	Method of generating the allocation sequence (eg, computer-	Page 8
3	generation		generated random numbers), and list of any factors for stratification.	
4			To reduce predictability of a random sequence, details of any planned	
5			restriction (eg, blocking) should be provided in a separate document	
6			that is unavailable to those who enrol participants or assign	
7			interventions	
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9	Allocation	16b	Mechanism of implementing the allocation sequence (eg, central	Page 8
10	concealment		telephone; sequentially numbered, opaque, sealed envelopes),	
11	mechanism		describing any steps to conceal the sequence until interventions are	
12			assigned	
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14	Implementation	16c	Who will generate the allocation sequence, who will enrol participants,	Page 8
15			and who will assign participants to interventions	
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18	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial	Page 9
19	(masking)		participants, care providers, outcome assessors, data analysts), and	
20			how	
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22		17b	If blinded, circumstances under which unblinding is permissible, and	NA
23			procedure for revealing a participant's allocated intervention during	
24			the trial	
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27	<b>Methods: Data collection, management, and analysis</b>			
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29	Data collection	18a	Plans for assessment and collection of outcome, baseline, and other	Page 9
30	methods		trial data, including any related processes to promote data quality (eg,	Page 10
31			duplicate measurements, training of assessors) and a description of	Page 11
32			study instruments (eg, questionnaires, laboratory tests) along with	
33			their reliability and validity, if known. Reference to where data	
34			collection forms can be found, if not in the protocol	
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36		18b	Plans to promote participant retention and complete follow-up,	Page 11
37			including list of any outcome data to be collected for participants who	
38			discontinue or deviate from intervention protocols	
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41	Data	19	Plans for data entry, coding, security, and storage, including any	Page 12
42	management		related processes to promote data quality (eg, double data entry;	
43			range checks for data values). Reference to where details of data	
44			management procedures can be found, if not in the protocol	
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46	Statistical	20a	Statistical methods for analysing primary and secondary outcomes.	Page 12
47	methods		Reference to where other details of the statistical analysis plan can be	
48			found, if not in the protocol	
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50		20b	Methods for any additional analyses (eg, subgroup and adjusted	NA
51			analyses)	
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53		20c	Definition of analysis population relating to protocol non-adherence	Page 12
54			(eg, as randomised analysis), and any statistical methods to handle	
55			missing data (eg, multiple imputation)	
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**Methods: Monitoring**

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 11
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA

**Ethics and dissemination**

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 13
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 12
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 13
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 12
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA

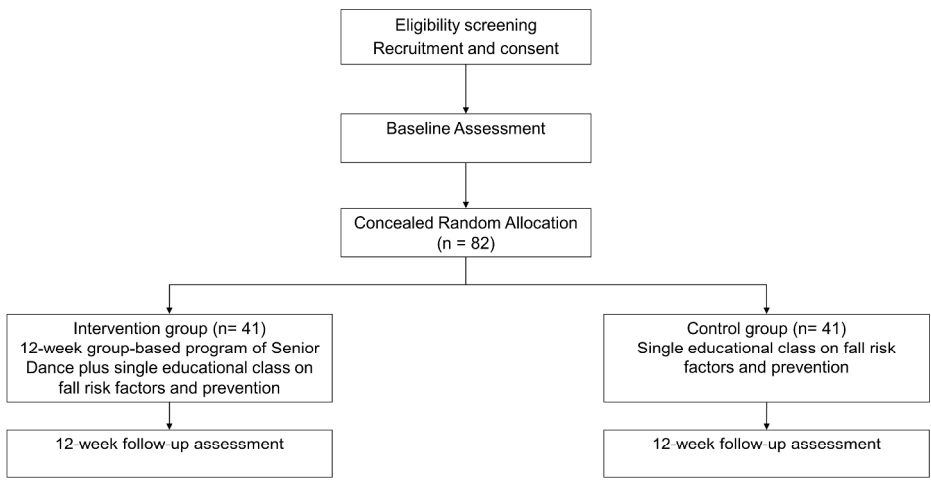
1 2 3 4 5 6 7 8 9 10 11 12 13	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 13
14 15 16 17 18 19 20 21 22 23		31b	Authorship eligibility guidelines and any intended use of professional writers	NA
		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Page 13

### Appendices

24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Doc in Portu_ guese
	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

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# BMJ Open

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

Journal:	<i>BMJ Open</i>
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<b>Primary Subject Heading</b>:	Geriatric medicine
Secondary Subject Heading:	Public health, Sports and exercise medicine
Keywords:	GERIATRIC MEDICINE, PREVENTIVE MEDICINE, PRIMARY CARE

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Manuscripts

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3 **Effectiveness of senior dance on risk factors for falls in older adults (DanSE):**  
4 **study protocol for a randomised controlled trial**  
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9 Marcia R Franco<sup>1</sup>, Sherrington C<sup>2</sup>, Tiedemann A<sup>2</sup>, Pereira LS<sup>3</sup>, Perracini MR<sup>4</sup>, Faria  
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## 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 programs 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 randomized 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 to a control group receiving only brief education.

**Methods and analysis:** This single blind randomized 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 program 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 program. 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 (standard deviation) or median (interquartile range), 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).

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3 Outcomes will be disseminated through publication in peer-reviewed journals and  
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5 presentations at conferences.  
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7 **Trial registration number:** The trial has been registered at ClinicalTrials.gov  
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9 (NCT02603523). Protocol issue date: January 29, 2016.  
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11 **Key words:** geriatric medicine, preventive medicine, older people, accidental falls  
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## 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 programs that has the potential to improve older people's participation and adherence to exercise programs.
- 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, hospitalization, 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 health care 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] As 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 organization.[16] With advancing age, changes in these systems make the postural control mechanism less efficient.[17, 18] Older people show larger center 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 programs are effective in improving fall risk factors and in preventing falls among community-dwelling older people.[23, 24] Exercise programs 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

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3 older adults (i.e. exercises aiming at improving postural control by challenging the  
4 alignment of the body's center of gravity) improve balance test performance.[25]  
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10 However, older people's participation and adherence to exercise programs is  
11 suboptimal.[11] Pooled estimates of adherence to falls prevention programs derived  
12 from systematic reviews, vary from 21% and 74% [26, 27]. Another study including  
13 5681 older people found that only around 21% of older people adhere to public health  
14 recommendations for participation in strength or balance activities, falling in the lower  
15 limit of the estimates derived from systematic reviews.[28] From a health policy  
16 perspective, non-adherence to long-term therapies severely compromises the  
17 effectiveness of treatment leading to excessive health care costs.[29]  
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29 A recent qualitative systematic review published by our group including 132 studies  
30 revealed that apathy or disinterest is commonly reported as a barrier to physical activity  
31 participation.[30] In another study we found that exercise type is highly likely to  
32 influence older people's decision on whether or not to engage in exercise programs.[31]  
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34 The results of these studies, when interpreted together, suggest that new effective  
35 interventions are required to attract more older people to commence and continue to  
36 participate in exercise that is effective in preventing falls.  
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47 Dancing is a promising alternative to traditional structured exercise programs as it may  
48 provide a safe and fun way of targeting balance. Previous studies show that some older  
49 people consider dancing an interesting and joyful activity, that provides opportunity for  
50 socialization.[32, 33] Systematic reviews investigating the effects of dancing on risk  
51 factors for falls report beneficial effects on balance, gait, strength and dynamic  
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3 mobility.[34, 35] The paucity of randomized clinical trials investigating dancing among  
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5 community-dwelling older adults as well as the low methodological quality of existing  
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7 studies, do not allow definitive conclusions to be made on the real effects of the  
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9 different types of dancing on risk factors for falls. A recent well-designed randomized  
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11 clinical trial found that social dancing did not prevent falls or risk factors for falls  
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13 among retirement village residents.[36] Future studies are required to explore the impact  
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15 of different types of dance in different settings.  
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21 Senior Dance is becoming increasingly popular among the older population in  
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23 Brazil.[37] Senior Dance classes consist of different choreographies, which include  
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25 rhythmic and simple movements with rhythmic folk songs. The concentration required  
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27 to learn the choreographies challenges balance, motor coordination and cognitive  
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29 function. The present study is a randomized clinical trial aiming to investigate the  
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31 Senior Dance effect on balance, mobility and cognitive function, compared with a  
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33 control group, among older people living in the community.  
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## 38 **METHODS**

### 39 **Trial design**

40  
41 We will conduct a single-blind parallel randomized controlled trial in a university  
42  
43 facility that belongs to the Faculty of Science and Technology from the São Paulo State  
44  
45 University (UNESP) - Presidente Prudente campus. The design of the trial is illustrated  
46  
47 in the Figure. The protocol conforms to Consolidated Standard of Reporting Trials  
48  
49 (CONSORT) statement.[38] The trial has been registered at ClinicalTrials.gov  
50  
51 (NCT02603523).  
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## Participants

A total of 82 participants will be recruited via advertisements in local newspapers, health centers and community organizations 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 less than 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 contra-indication (e.g. uncontrolled angina, acute coronary disease).

Participants who are currently participating in regular exercise programs 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.

## Randomization

1  
2  
3 Participants who meet eligibility criteria and signed the Informed Consent Form will  
4  
5 have baseline data collected prior to the randomization procedure. To ensure allocation  
6  
7 concealment, randomisation to groups (senior dance or control group) will be  
8  
9 undertaken by an investigator (RZP) not involved in recruitment using a computer-  
10  
11 generated randomization schedule.  
12

### 13 14 15 16 **Intervention group**

17  
18 Participants allocated to the intervention group will attend a one-hour single educational  
19  
20 class on strategies to prevent falls among older people, and will participate in a 12-  
21  
22 week, twice-weekly group-based program of Senior Dance. Each dance class will last  
23  
24 for an hour, and the number of participants per class will range from 10 to 15. Senior  
25  
26 Dance-certified instructors that have the same level of training and expertise will lead  
27  
28 the classes. The Senior Dance classes are at a moderate level intensity, and consist of  
29  
30 different choreographies, which include rhythmic and simple movements with rhythmic  
31  
32 folk songs. During the classes, participants will practise the movements while sitting or  
33  
34 standing, quickly or slowly, in circles, individually, in pairs or in small groups. The  
35  
36 concentration required to learn the choreographies challenges balance, motor  
37  
38 coordination and cognitive function.  
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### 45 **Control group**

46  
47 Participants allocated to the control group will attend the same educational class on  
48  
49 strategies to prevent falls among older people that intervention group participants will  
50  
51 receive, and will be instructed not to take part in any regular exercise programs such as  
52  
53 supervised group exercise, Tai Chi, Yoga, or any dance activity during the study period.  
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1  
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3 At the end of the study, they will be offered Senior Dance classes, twice a week, during  
4  
5 12 weeks.  
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10 The Table summarizes the contents of both interventions according to the TIDieR  
11  
12 checklist.  
13

### 14 15 16 **Outcome measures**

17  
18 Data will be collected at baseline prior to randomization and at the follow-up (12-week  
19  
20 after randomization), by an assessor blinded to group allocation.  
21  
22

23  
24 A 12-week intervention should be enough time to detect an impact of the dance  
25  
26 intervention on our outcome measures based on previous published clinical trials  
27  
28 investigating the effect of dancing on risk factors for falls.[40, 41] One of these studies  
29  
30 found that the group that received 12 weeks of dance showed the better results on  
31  
32 muscle strength compared to a control group.[41]  
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### 38 39 **Primary outcome**

40  
41 Balance outcomes will be used due to the importance of balance as a risk factor for  
42  
43 falls. Single-leg stance with eyes closed without the use of walking aid will be the  
44  
45 primary outcome measure. Participants will be asked to choose a leg to stand on, flex  
46  
47 the opposite knee allowing the foot to clear the floor, and balance on one leg for up to  
48  
49 60 seconds. Participants will be given at least two attempts and the best time will be  
50  
51 recorded, and analysed as a continuous measure. The choice of single-leg stance as the  
52  
53 primary outcome was based on the fact that it is a highly functional test, since transient  
54  
55 balance on a single limb is needed for a number of activities, such as normal gait,  
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3 turning, stair climbing and dressing. Single-leg stance with eyes closed is a challenging  
4  
5 and reliable test [42] that has been previously used in studies investigating dance among  
6  
7 the older population.[40]  
8  
9

### 10 11 *Secondary outcomes*

12  
13  
14 There will be four secondary outcomes measures:

- 15  
16 - Short Physical Performance Battery: the domains related to gait speed, chair  
17 stand and balance tests will be analysed separately.[43] The gait speed will be  
18 measured by recording the time spent to walk 4-m at fast pace. The chair stand  
19 test will be measured by recording the time spent to complete five repetitions of  
20 the sit-to-stand test. The balance tests include the sum of time able to stand in  
21 the three standing balance positions (feet side by side, feet in semi tandem and in  
22 tandem positions) with the addition of the single-leg stance with eyes opened  
23  
24 The ability to stand for up to 10 seconds at each balance position will be  
25 recorded, and the final measure will be up to 40 seconds.  
26  
27 - Falls Efficacy Scale – International (FES-I): to measure falls self-efficacy or  
28 concerns about falling while undertaking daily tasks.[44]  
29  
30 - Trail Making Test (TMT): to evaluate cognitive function.[45] The test consists  
31 of two parts (A and B). Part A measures processing speed and involves  
32 participants connecting consecutive numbers (e.g., 1-2-3). Part B is a measure of  
33 executive function of ‘task shifting’ and involves participants connecting  
34 alternating letters and numbers in order (e.g.,1-A-2-B). The difference in time  
35 between the two parts (B minus A) will be calculated to isolate the executive  
36 component of this test  
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3 - The Montreal Cognitive Assessment (MoCA): to also evaluate cognitive  
4 function.[46] The MoCA is a one-page 30-point test, which contains the  
5 following cognitive domains: visuospatial, executive, sustained attention,  
6 concentration, working memory, short-term memory recall, language and  
7 orientation.  
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16 Additional information collected at baseline will include demographic information  
17 (age, gender, educational level, working status), previous history of falls, and  
18 information about medical conditions and use of medications. This information will  
19 be collected to enable a description of the sample's baseline characteristics and to  
20 obtain values to enter as covariates in the models comparing groups at follow-up.  
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28  
29 To investigate participant's perceptions on the benefits and barriers to exercise  
30 participation, the Exercise Benefits and Barriers Scale will also be applied.[47] We  
31 will also collect data on adherence and adverse effects. The Senior Dance instructor  
32 will record class attendance at each session using an adherence questionnaire [48],  
33 and adverse events associated with the intervention will be recorded in the follow-  
34 up after study completion. Participants who do not attend the dance class will be  
35 contacted by telephone as an attempt to promote participant retention and complete  
36 follow-up.  
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### 49 **Sample size**

50 As described above, the primary outcome measure will be the single-leg stance with  
51 eyes closed. A total sample of 82 subjects (41 per group) will be required to detect a  
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3 between-group difference of 1.93 seconds (standard deviation of 2.87-seconds) [49]  
4  
5 with 80% power and a significance level of 5%, allowing 15% dropouts.  
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8

### 9 10 **Data integrity and analysis**

11 Data integrity will be monitored by regularly scrutinising data files for omissions  
12 and errors. The statistical software SPSS version 20.0 (IBM Corporation, Somers,  
13 NY, USA) will be used for data analysis. Dichotomous and categorical data will be  
14 reported using frequency (proportion), while continuous data will be reported using  
15 mean (standard deviation) or median (interquartile range), depending on the  
16 distribution of the data. The linear regression approach to analysis of covariance will  
17 be used to compare the mean effect between intervention and control group. In this  
18 model, group will be included as the independent variable, the post-treatment  
19 outcomes as dependent variables and the pre-treatment outcomes as covariates. The  
20 level of significance will be set at  $p < 0.05$ . All patients will be included in the  
21 analyses following an intention-to-treat approach. Participants will be given an  
22 anonymous study ID to protect confidentiality, and only study investigators will  
23 have access to the final trial dataset.  
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### 43 **DISCUSSION**

44 The popularity of dancing is increasing among the older population. Previous  
45 systematic reviews report a beneficial effect of dancing on risk factors for falls, such  
46 as balance, gait and strength.[34, 35] However, the low methodological quality of  
47 existing studies do not allow reaching definitive conclusions about the real  
48 therapeutic effect of dancing on risk factors for falls. Methodological flaws  
49 commonly reported in this area include lack of concealed allocation and non-use of  
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3 an intention to treat approach when analysing the data.[34] Importantly, both  
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5 methodological flaws have been reported to inflate effect sizes of clinical trials.[50,  
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7 51]  
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10  
11 This study is the first randomized controlled trial testing the effectiveness of Senior  
12  
13 Dance on risk factors for falls among older people. Our results will provide  
14  
15 information on the real benefits provided by this type of physical activity, and can  
16  
17 be used to guide the decision making process of health professionals, especially  
18  
19 physiotherapists when prescribing exercise regimens for the older population. If the  
20  
21 intervention proves to be effective, future larger randomised clinical trials should be  
22  
23 conducted to investigate the effect of Senior Dance on the incidence of falls over the  
24  
25 long-term.  
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### 30 31 32 **ETHICS AND DISSEMINATION**

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34 Ethics approval has been granted by the Human Ethics Committee of the São Paulo  
35  
36 State University (CAAE 48665215.9.0000.5402), and outcomes will be disseminated  
37  
38 through publication in peer-reviewed journals and presentations at international  
39  
40 conferences.  
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45  
46 **CONTRIBUTORS:** MRF with input from the other investigators conceived and  
47  
48 received funding to conduct this study. CS, AT, LP, MRP, CSF, RZP and CMP  
49  
50 commented on the various versions of this study protocol. MRF, CSG and RZP were  
51  
52 involved in the recruitment and data collection. MRF, CMP and RZP will conduct  
53  
54 the analyses. All authors approved the final manuscript.  
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3 **COMPETING INTERESTS:** None declared.  
4  
5  
6

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

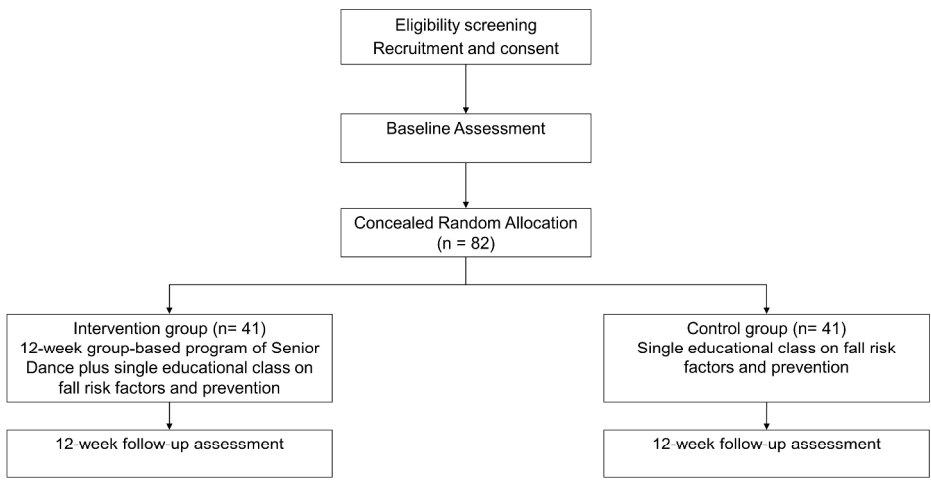
1. Brief name	Effects of Senior Dance on Risk Factors for Falls (DanSE)
2. Why	Strong evidence demonstrates that specific types of exercise are effective for preventing falls among older people. However, older people's participation and adherence to such exercise programs is suboptimal. Type of exercise 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 one-hour single educational class on strategies to prevent falls among older people, and will participate in supervised Senior Dance classes in groups of 10 to 15 participants per class. Participants allocated to the control group will attend a one-hour single educational class on strategies to prevent falls among older people in groups of 10 to 15 participants per session.
5. Who provided	Senior Dance-certified instructors that 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

- 1  
2  
3 and the Senior Dance classes will be delivered face to face in a group.  
4  
5 7. Where The intervention will be delivered to community-dwelling older people living  
6 in Presidente Prudente, São Paulo, Brazil.  
7  
8 8. When and how much Participants allocated to the intervention group will attend a one-hour single  
9 educational class on strategies to prevent falls among older people, and will  
10 participate in a 12-week, twice-weekly group-based program of Senior  
11 Dance. Each dance class will last for an hour and will be at a moderate-  
12 intensity level.  
13 Participants allocated to the control group will only attend a one-hour single  
14 educational class on strategies to prevent falls among older people, and will  
15 be instructed to not take part in any structured exercise program during the  
16 study period.  
17  
18 9. Tailoring The intervention will be delivered in a group and will not be individually  
19 tailored to participants.  
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Figure. Trial design



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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 3
	2b	All items from the World Health Organization Trial Registration Data Set	Page 3 Page 13 Table 1
Protocol version	3	Date and version identifier	Page 3
Funding	4	Sources and types of financial, material, and other support	Page 13
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 13 Page 1
	5b	Name and contact information for the trial sponsor	Page 13
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 13
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 5
	6b	Explanation for choice of comparators	Page 6
Objectives	7	Specific objectives or hypotheses	Page 7

1				
2	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 7
3				
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### Methods: Participants, interventions, and outcomes

9	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 7
10				
11	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 7
12				
13				
14	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 8 Page 9
15		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
16		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 11
17		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 9
18				
19	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 9 Page 10
20				
21	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 9 Page 17
22				
23	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 11
24				
25	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 7
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### Methods: Assignment of interventions (for controlled trials)

53	Allocation:			Page 8
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2	Sequence	16a	Method of generating the allocation sequence (eg, computer-	Page 8
3	generation		generated random numbers), and list of any factors for stratification.	
4			To reduce predictability of a random sequence, details of any planned	
5			restriction (eg, blocking) should be provided in a separate document	
6			that is unavailable to those who enrol participants or assign	
7			interventions	
8				
9	Allocation	16b	Mechanism of implementing the allocation sequence (eg, central	Page 8
10	concealment		telephone; sequentially numbered, opaque, sealed envelopes),	
11	mechanism		describing any steps to conceal the sequence until interventions are	
12			assigned	
13				
14	Implementation	16c	Who will generate the allocation sequence, who will enrol participants,	Page 8
15			and who will assign participants to interventions	
16				
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18	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial	Page 9
19	(masking)		participants, care providers, outcome assessors, data analysts), and	
20			how	
21				
22		17b	If blinded, circumstances under which unblinding is permissible, and	NA
23			procedure for revealing a participant's allocated intervention during	
24			the trial	
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27	<b>Methods: Data collection, management, and analysis</b>			
28				
29	Data collection	18a	Plans for assessment and collection of outcome, baseline, and other	Page 9
30	methods		trial data, including any related processes to promote data quality (eg,	Page 10
31			duplicate measurements, training of assessors) and a description of	Page 11
32			study instruments (eg, questionnaires, laboratory tests) along with	
33			their reliability and validity, if known. Reference to where data	
34			collection forms can be found, if not in the protocol	
35				
36		18b	Plans to promote participant retention and complete follow-up,	Page 11
37			including list of any outcome data to be collected for participants who	
38			discontinue or deviate from intervention protocols	
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41	Data	19	Plans for data entry, coding, security, and storage, including any	Page 12
42	management		related processes to promote data quality (eg, double data entry;	
43			range checks for data values). Reference to where details of data	
44			management procedures can be found, if not in the protocol	
45				
46	Statistical	20a	Statistical methods for analysing primary and secondary outcomes.	Page 12
47	methods		Reference to where other details of the statistical analysis plan can be	
48			found, if not in the protocol	
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50		20b	Methods for any additional analyses (eg, subgroup and adjusted	NA
51			analyses)	
52				
53		20c	Definition of analysis population relating to protocol non-adherence	Page 12
54			(eg, as randomised analysis), and any statistical methods to handle	
55			missing data (eg, multiple imputation)	
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**Methods: Monitoring**

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 11
	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA

**Ethics and dissemination**

24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 13
	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA
	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 8
		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 12
	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 13
	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 12
	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA

1 2 3 4 5 6 7 8 9 10 11 12 13	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 13
14 15 16 17 18 19 20 21 22 23		31b	Authorship eligibility guidelines and any intended use of professional writers	NA
24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Page 13

### Appendices

14 15 16 17 18 19 20 21 22 23	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Doc in Portu_ guese
24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.