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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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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.

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

Trial registration number: The trial has been registered at ClinicalTrials.gov (NCT02603523).

Key words: geriatric medicine, preventive medicine, older people, accidental falls

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,

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. Estimates of adherence to falls prevention programs derived from systematic reviews, vary from 21% and 74% [14, 15]. From a health policy perspective, non-adherence to long-term therapies severely compromises the effectiveness of treatment leading to excessive health care costs.[16]

A recent qualitative systematic review published by our group including 132 studies revealed that apathy or disinterest is commonly reported as a barrier to physical activity participation.[17] In another study we found that exercise type is highly likely to influence older people´s decision on whether or not to engage in exercise programs.[18] The results of these studies, when interpreted together, suggest that new effective interventions are required.

Dancing is a promising alternative to traditional structured exercise programs. Previous studies show that older people consider dancing an interesting and joyful activity, that provides opportunity for socialization.[19, 20] Systematic reviews investigating the effects of dancing on risk factors for falls report beneficial effects on balance, gait, strength and dynamic mobility.[21, 22] Nevertheless, the lack of randomized clinical trials as well as the low methodological quality of the existing studies do not allow reaching definitive conclusions on the real effects of dance on risk factors for falls.[21]

Senior Dance is becoming increasingly popular among the older population in Brazil.[23] Senior Dance classes consist of different choreographies, which include

rhythmic and simple movements with rhythmic folk songs. The concentration required to learn the choreographies challenges balance, motor coordination and cognitive function. The present study is a randomized clinical trial aiming to investigate the Senior Dance effect on balance, mobility and cognitive function, compared with a control group, among older people living in the community.

METHODS

Trial design

We will conduct a single-blind 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 Figure 1. The protocol conforms to Consolidated Standard of Reporting Trials (CONSORT) statement.[24] 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.

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).[25] We will exclude participants if they have 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.[12] 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 consist of different choreographies, which include rhythmic and simple movements with rhythmic folk songs. During the classes, participants will practise the movements while sitting or standing, quickly or slowly, in circles, individually, in pairs or in small groups. The concentration required to learn the choreographies challenges balance, motor coordination and cognitive function.

Control group

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

Outcome measures

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

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. We will record the time participants will be able keep this position, and results

will be 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 [26] that has been previously used in studies investigating dance among the older population.[27]

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.[28] 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.[29]
- Trail Making Test (TMT): to evaluate cognitive function.[30] The test consists of two parts (A and B). Part A measures processing speed and involves participants connecting consecutive numbers (e.g., 1-2-3). Part B is a measure of executive function of 'task shifting' and involves participants connecting alternating letters and numbers in order (e.g.,1-A-2-B). The difference in time

between the two parts (B minus A) will be calculated to isolate the executive component of this test

- The Montreal Cognitive Assessment (MoCA): to also evaluate cognitive function.[31] The MoCA is a one-page 30-point test, which contains the following cognitive domains: visuospatial, executive, sustained attention, concentration, working memory, short-term memory recall, language and orientation.

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

To investigate participant´s perceptions on the benefits and barriers to exercise participation, the Exercise Benefits and Barriers Scale will also be applied.[32] We will also collect data on adherence and adverse effects. The Senior Dance instructor will record class attendance at each session using an adherence questionnaire [33], and adverse events associated with the intervention will be recorded in the follow-up after study completion.

Sample size

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

Data integrity and analysis

Data integrity will be monitored by regularly scrutinising data files for omissions and errors. The statistical software SPSS 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]

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

ETHICS AND DISSEMINATION

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

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

COMPETING INTERESTS: None declared.

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REFERENCES:

[1] Gill TM, Allore HG, Holford TR, Guo Z. Hospitalization, restricted activity, and the development of disability among older persons. Jama. 2004;292:2115-24.

[2] Jorstad EC, Hauer K, Becker C, Lamb SE, ProFa NEG. Measuring the psychological outcomes of falling: a systematic review. Journal of the American Geriatrics Society. 2005;53:501-10.

[3] Sartini M, Cristina ML, Spagnolo AM, Cremonesi P, Costaguta C, Monacelli F, et al. The epidemiology of domestic injurious falls in a community dwelling elderly population: an outgrowing economic burden. European journal of public health. 2010;20:604-6.

[4] Tinetti ME, Kumar C. The patient who falls: "It's always a trade-off". Jama. 2010;303:258-66.

[5] Tinetti ME, Speechley M, Ginter SF. Risk factors for falls among elderly persons living in the community. The New England journal of medicine. 1988;319:1701-7.

[6] Gale CR, Cooper C, Aihie Sayer A. Prevalence and risk factors for falls in older men and women: The English Longitudinal Study of Ageing. Age and ageing. 2016.

[7] Craig J, Murray A, Mitchell S, Clark S, Saunders L, Burleigh L. The high cost to health and social care of managing falls in older adults living in the community in Scotland. Scottish medical journal. 2013;58:198-203.

[8] Hartholt KA, Polinder S, Van der Cammen TJ, Panneman MJ, Van der Velde N, Van Lieshout EM, et al. Costs of falls in an ageing population: a nationwide study from the Netherlands (2007-2009). Injury. 2012;43:1199-203.

[9] National Institute for Health and Clinical Excellence (NICE). Falls: Assessment and prevention of falls in older people (NICE clinical guideline 161). Available at: http://wwwniceorguk/guidance/cg161. 2013.

[10] Peel N, Bell RAR, Smith K. Queensland Stay On Your Feet® Community Good Practice Guidelines – preventing falls, harm from falls and promoting healthy active ageing in older Queenslanders. Brisbane: Queensland Health. 2008.

[11] Todd C, Skelton D. What are the main risk factors for falls among older people and what are the most effective interventions to prevent these falls? Copenhagen: World Health Organization (WHO) Regional Office for Europe. 2004.

[12] Gillespie LD, Robertson MC, Gillespie WJ, Sherrington C, Gates S, Clemson LM, et al. Interventions for preventing falls in older people living in the community. The Cochrane database of systematic reviews. 2012;9:CD007146.

[13] Sherrington C, Tiedemann A, Fairhall N, Close JC, Lord SR. Exercise to prevent falls in older adults: an updated meta-analysis and best practice recommendations. New South Wales public health bulletin. 2011;22:78-83.

[14] McPhate L, Simek EM, Haines TP. Program-related factors are associated with adherence to group exercise interventions for the prevention of falls: a systematic review. Journal of physiotherapy. 2013;59:81-92.

[15] Simek EM, McPhate L, Haines TP. Adherence to and efficacy of home exercise programs to prevent falls: a systematic review and meta-analysis of the impact of exercise program characteristics. Preventive medicine. 2012;55:262-75.

[16] World Health Organization (WHO). Adherence to long-term therapies - evidence for action 2003. http://apps.who.int/medicinedocs/en/d/Js4883e/.

[17] Franco MR, Tong A, Howard K, Sherrington C, Ferreira PH, Pinto RZ, et al. Older people's perspectives on participation in physical activity: a systematic review and thematic synthesis of qualitative literature. British journal of sports medicine. 2015;49:1268-76.

[18] Franco MR, Howard K, Sherrington C, Ferreira PH, Rose J, Gomes JL, et al. Eliciting older people's preferences for exercise programs: a best-worst scaling choice experiment. Journal of physiotherapy. 2015;61:34-41.

[19] K N. Life without line dancing and the other activities would be too dreadful to imagine": an increase in social activity for older women. J Women Aging. 2008;20:329-42.

[20] Lima MMS VA. Ballroom Dance as Therapy for the Elderly in Brazil. American Journal of Dance Therapy 2007;29:129-4.

[21] Fernandez-Arguelles EL, Rodriguez-Mansilla J, Antunez LE, Garrido-Ardila EM, Munoz RP. Effects of dancing on the risk of falling related factors of healthy older adults: a systematic review. Archives of gerontology and geriatrics. 2015;60:1-8.

[22] Keogh JW, Kilding A, Pidgeon P, Ashley L, Gillis D. Physical benefits of dancing for healthy older adults: a review. Journal of aging and physical activity. 2009;17:479-500.

[23] Silva AFG BA. O benefício da dança sênior em relação ao equilíbrio e às atividades de vida diárias no idoso. Arquivos Brasileiros de Ciências da Saúde (ABCS). 2015;40:16-21.

[24] Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC medicine. 2010;8:18.

[25] Brucki SM, Nitrini R, Caramelli P, Bertolucci PH, Okamoto IH. [Suggestions for utilization of the mini-mental state examination in Brazil]. Arquivos de neuro-psiquiatria. 2003;61:777-81.

[26] Springer BA, Marin R, Cyhan T, Roberts H, Gill NW. Normative values for the unipedal stance test with eyes open and closed. Journal of geriatric physical therapy. 2007;30:8-15.

[27] Shigematsu R, Chang M, Yabushita N, Sakai T, Nakagaichi M, Nho H, et al. Dance-based aerobic exercise may improve indices of falling risk in older women. Age and ageing. 2002;31:261-6.

[28] Guralnik JM, Simonsick EM, Ferrucci L, Glynn RJ, Berkman LF, Blazer DG, et al. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. Journal of gerontology. 1994;49:M85-94.

[29] Delbaere K, Close JC, Mikolaizak AS, Sachdev PS, Brodaty H, Lord SR. The Falls Efficacy Scale International (FES-I). A comprehensive longitudinal validation study. Age and ageing. 2010;39:210-6.

[30] Tombaugh TN. Trail Making Test A and B: normative data stratified by age and education. Archives of clinical neuropsychology : the official journal of the National Academy of Neuropsychologists. 2004;19:203-14.

[31] Nasreddine ZS, Phillips NA, Bedirian V, Charbonneau S, Whitehead V, Collin I, et al. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. Journal of the American Geriatrics Society. 2005;53:695-9.

[32] Sechrist KR, Walker SN, Pender NJ. Development and psychometric evaluation of the exercise benefits/barriers scale. Research in nursing & health. 1987;10:357-65.

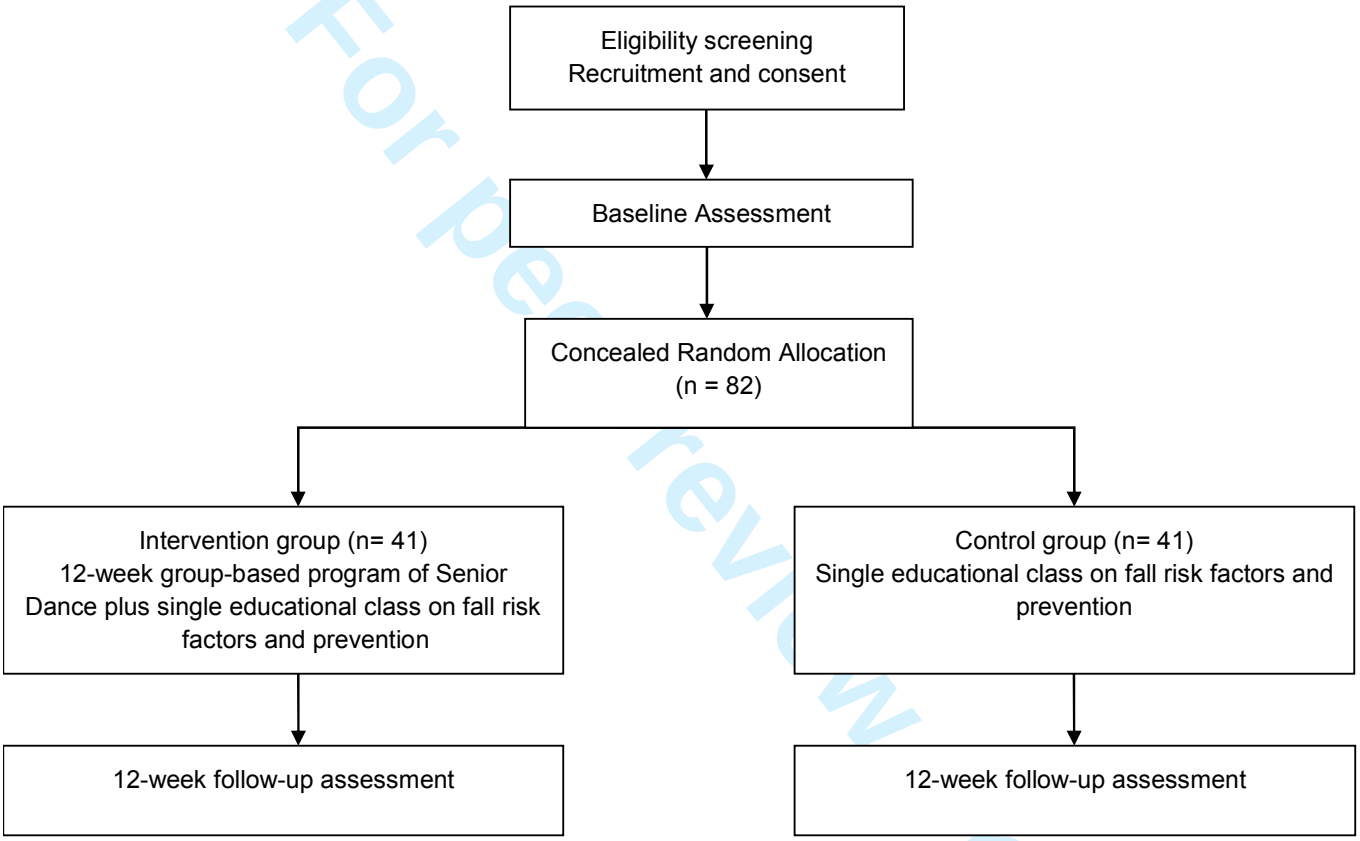
[33] Picorelli AMA PD, Felício DC, Gomes DA, Dias RC, Pereira LSM. Adhesion of older women to a home exercise program post ambulatory training. Fisioterapia & Pesquisa. 2015;22:291-308.

[34] Tiedemann A, O'Rourke S, Sesto R, Sherrington C. A 12-week Iyengar yoga program improved balance and mobility in older community-dwelling people: a pilot randomized controlled trial. The journals of gerontology Series A, Biological sciences and medical sciences. 2013;68:1068-75.

[35] Bollini P, Pampallona S, Tibaldi G, Kupelnick B, Munizza C. Effectiveness of antidepressants. Meta-analysis of dose-effect relationships in randomised clinical trials. The British journal of psychiatry : the journal of mental science. 1999;174:297-303.

[36] Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. Jama. 1995;273:408-12.

Figure 1. Trial design



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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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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

participation.[18] In another study we found that exercise type is highly likely to influence older people´s decision on whether or not to engage in exercise programs.[19] The results of these studies, when interpreted together, suggest that new effective interventions are required to attract more older people to commence and continue to participate in exercise that is effective in preventing falls.

Dancing is a promising alternative to traditional structured exercise programs. Previous studies show that some older people consider dancing an interesting and joyful activity, that provides opportunity for socialization.[20, 21] Systematic reviews investigating the effects of dancing on risk factors for falls report beneficial effects on balance, gait, strength and dynamic mobility.[22, 23] The paucity of randomized clinical trials investigating dancing among community-dwelling older adults as well as the low methodological quality of existing studies, do not allow definitive conclusions to be made on the real effects of the different types of dancing on risk factors for falls. A recent well-designed randomized clinical trial found that social dancing did not prevent falls or risk factors for falls among retirement village residents.[24] Future studies are required to explore the impact of different types of dance in different settings.

Senior Dance is becoming increasingly popular among the older population in Brazil.[25] Senior Dance classes consist of different choreographies, which include rhythmic and simple movements with rhythmic folk songs. The concentration required to learn the choreographies challenges balance, motor coordination and cognitive function. The present study is a randomized clinical trial aiming to investigate the Senior Dance effect on balance, mobility and cognitive function, compared with a control group, among older people living in the community.

METHODS

Trial design

We will conduct a single-blind parallel 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,

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

standing, quickly or slowly, in circles, individually, in pairs or in small groups. The concentration required to learn the choreographies challenges balance, motor coordination and cognitive function.

Control group

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

The Table summarizes the contents of both interventions according to the TIDieR checklist.

Outcome measures

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

A 12-week intervention should be enough time to detect an impact of the dance intervention on our outcome measures based on previous published clinical trials investigating the effect of dancing on risk factors for falls.[28, 29] One of these studies found that the group that received 12 weeks of dance showed the better results on muscle strength compared to a control group.[29]

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]

- Trail Making Test (TMT): to evaluate cognitive function.[33] The test consists of two parts (A and B). Part A measures processing speed and involves participants connecting consecutive numbers (e.g., 1-2-3). Part B is a measure of executive function of 'task shifting' and involves participants connecting alternating letters and numbers in order (e.g.,1-A-2-B). The difference in time between the two parts (B minus A) will be calculated to isolate the executive component of this test
- The Montreal Cognitive Assessment (MoCA): to also evaluate cognitive function.[34] The MoCA is a one-page 30-point test, which contains the following cognitive domains: visuospatial, executive, sustained attention, concentration, working memory, short-term memory recall, language and orientation.

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

To investigate participant´s perceptions on the benefits and barriers to exercise participation, the Exercise Benefits and Barriers Scale will also be applied.[35] We will also collect data on adherence and adverse effects. The Senior Dance instructor will record class attendance at each session using an adherence questionnaire [36], and adverse events associated with the intervention will be recorded in the follow-up after study completion. Participants who do not attend the dance class will be

contacted by telephone as an attempt to promote participant retention and complete follow-up.

Sample size

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

Data integrity and analysis

Data integrity will be monitored by regularly scrutinising data files for omissions and errors. The statistical software SPSS version 20.0 (IBM Corporation, Somers, NY, USA) will be used for data analysis. Dichotomous and categorical data will be reported using frequency (proportion), while continuous data will be reported using mean (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 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, and only study investigators will have access to the final trial dataset.

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.[22, 23] 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.[22] Importantly, both methodological flaws have been reported to inflate effect sizes of clinical trials.[38, 39]

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

ETHICS AND DISSEMINATION

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

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

COMPETING INTERESTS: None declared.

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REFERENCES:

[1] Gill TM, Allore HG, Holford TR, Guo Z. Hospitalization, restricted activity, and the development of disability among older persons. JAMA. 2004;292:2115-24.

[2] Jorstad EC, Hauer K, Becker C, Lamb SE, ProFa NEG. Measuring the psychological outcomes of falling: a systematic review. Journal of the American Geriatrics Society. 2005;53:501-10.

[3] Sartini M, Cristina ML, Spagnolo AM, Cremonesi P, Costaguta C, Monacelli F, et al. The epidemiology of domestic injurious falls in a community dwelling elderly population: an outgrowing economic burden. European journal of public health. 2010;20:604-6.

[4] Tinetti ME, Kumar C. The patient who falls: "It's always a trade-off". JAMA. 2010;303:258-66.

[5] Tinetti ME, Speechley M, Ginter SF. Risk factors for falls among elderly persons living in the community. The New England journal of medicine. 1988;319:1701-7.

[6] Gale CR, Cooper C, Aihie Sayer A. Prevalence and risk factors for falls in older men and women: The English Longitudinal Study of Ageing. Age and ageing. 2016.

[7] Craig J, Murray A, Mitchell S, Clark S, Saunders L, Burleigh L. The high cost to health and social care of managing falls in older adults living in the community in Scotland. Scottish medical journal. 2013;58:198-203.

[8] Hartholt KA, Polinder S, Van der Cammen TJ, Panneman MJ, Van der Velde N, Van Lieshout EM, et al. Costs of falls in an ageing population: a nationwide study from the Netherlands (2007-2009). Injury. 2012;43:1199-203.

[9] National Institute of Clinical Excellence (NICE). Falls: Assessment and prevention of falls in older people (NICE clinical guideline 161). http://nice.org.uk/guidance/cg161. 2013.

[10] Peel N, Bell RAR, Smith K. Queensland Stay On Your Feet® Community Good Practice Guidelines – preventing falls, harm from falls and promoting healthy active ageing in older Queenslanders. Brisbane: Queensland Health. 2008.

[11] Skelton D, Todd C. What are the main risk factors for falls among older people and what are the most effective interventions to prevent these falls? Copenhagen: WHO Regional Office for Europe. 2004.

[12] Sherrington C, Michaleff ZA, Fairhall N, Paul SS, Tiedemann A, Whitney J, et al. Exercise to prevent falls in older adults: an updated systematic review and meta-analysis. British journal of sports medicine. 2016.

[13] Gillespie LD, Robertson MC, Gillespie WJ, Sherrington C, Gates S, Clemson LM, et al. Interventions for preventing falls in older people living in the community. The Cochrane database of systematic reviews. 2012;9:CD007146.

[14] McPhate L, Simek EM, Haines TP. Program-related factors are associated with adherence to group exercise interventions for the prevention of falls: a systematic review. Journal of physiotherapy. 2013;59:81-92.

[15] Simek EM, McPhate L, Haines TP. Adherence to and efficacy of home exercise programs to prevent falls: a systematic review and meta-analysis of the impact of exercise program characteristics. Preventive medicine. 2012;55:262-75.

[16] Merom D, Pye V, Macniven R, van der Ploeg H, Milat A, Sherrington C, et al. Prevalence and correlates of participation in fall prevention exercise/physical activity by older adults. Preventive medicine. 2012;55:613-7.

[17] World Health Organization (WHO). Adherence to long-term therapies - evidence for action 2003. http://apps.who.int/medicinedocs/en/d/Js4883e/; 2003.

[18] Franco MR, Tong A, Howard K, Sherrington C, Ferreira PH, Pinto RZ, et al. Older people's perspectives on participation in physical activity: a systematic review

and thematic synthesis of qualitative literature. British journal of sports medicine. 2015;49:1268-76.

[19] Franco MR, Howard K, Sherrington C, Ferreira PH, Rose J, Gomes JL, et al. Eliciting older people's preferences for exercise programs: a best-worst scaling choice experiment. Journal of physiotherapy. 2015;61:34-41.

[20] Nadasen K. Life without line dancing and the other activities would be too dreadful to imagine": an increase in social activity for older women. Journal of Women and Aging. 2008;20:329-42.

[21] Lima MMS, Vieira AP. Ballroom Dance as Therapy for the Elderly in Brazil. American Journal of Dance Therapy 2007;29:129-4.

[22] Fernandez-Arguelles EL, Rodriguez-Mansilla J, Antunez LE, Garrido-Ardila EM, Munoz RP. Effects of dancing on the risk of falling related factors of healthy older adults: a systematic review. Archives of gerontology and geriatrics. 2015;60:1-8.

[23] Keogh JW, Kilding A, Pidgeon P, Ashley L, Gillis D. Physical benefits of dancing for healthy older adults: a review. Journal of aging and physical activity. 2009;17:479-500.

[24] Merom D, Mathieu E, Cerin E, Morton RL, Simpson JM, Rissel C, et al. Social Dancing and Incidence of Falls in Older Adults: A Cluster Randomised Controlled Trial. PLoS medicine. 2016;13:e1002112.

[25] Silva AFG, Berbel AM. O benefício da dança sênior em relação ao equilíbrio e às atividades de vida diárias no idoso. Arquivos Brasileiros de Ciências da Saúde (ABCS). 2015;40:16-21.

[26] Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC medicine. 2010;8:18.

[27] Brucki SM, Nitrini R, Caramelli P, Bertolucci PH, Okamoto IH. [Suggestions for utilization of the mini-mental state examination in Brazil]. Arquivos de neuro-psiquiatria. 2003;61:777-81.

[28] Shigematsu R, Chang M, Yabushita N, Sakai T, Nakagaichi M, Nho H, et al. Dance-based aerobic exercise may improve indices of falling risk in older women. Age and ageing. 2002;31:261-6.

[29] Holmerova I, Machacova K, Vankova H, Veleta P, Juraskova B, Hrnciarikova D, et al. Effect of the Exercise Dance for Seniors (EXDASE) program on lower-

body functioning among institutionalized older adults. Journal of aging and health. 2010;22:106-19.

[30] Springer BA, Marin R, Cyhan T, Roberts H, Gill NW. Normative values for the unipedal stance test with eyes open and closed. Journal of geriatric physical therapy. 2007;30:8-15.

[31] Guralnik JM, Simonsick EM, Ferrucci L, Glynn RJ, Berkman LF, Blazer DG, et al. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. Journal of gerontology. 1994;49:M85-94.

[32] Delbaere K, Close JC, Mikolaizak AS, Sachdev PS, Brodaty H, Lord SR. The Falls Efficacy Scale International (FES-I). A comprehensive longitudinal validation study. Age and ageing. 2010;39:210-6.

[33] Tombaugh TN. Trail Making Test A and B: normative data stratified by age and education. Archives of clinical neuropsychology : the official journal of the National Academy of Neuropsychologists. 2004;19:203-14.

[34] Nasreddine ZS, Phillips NA, Bedirian V, Charbonneau S, Whitehead V, Collin I, et al. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. Journal of the American Geriatrics Society. 2005;53:695-9.

[35] Sechrist KR, Walker SN, Pender NJ. Development and psychometric evaluation of the exercise benefits/barriers scale. Research in nursing & health. 1987;10:357-65.

[36] Picorelli AMA, Pereira DS, Felício DC, Gomes DA, Dias RC, Pereira LSM. Adhesion of older women to a home exercise program post ambulatory training. Fisioterapia & Pesquisa. 2015;22:291-308.

[37] Tiedemann A, O'Rourke S, Sesto R, Sherrington C. A 12-week Iyengar yoga program improved balance and mobility in older community-dwelling people: a pilot randomized controlled trial. The journals of gerontology Series A, Biological sciences and medical sciences. 2013;68:1068-75.

[38] Bollini P, Pampallona S, Tibaldi G, Kupelnick B, Munizza C. Effectiveness of antidepressants. Meta-analysis of dose-effect relationships in randomised clinical trials. The British journal of psychiatry : the journal of mental science. 1999;174:297-303.

[39] Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. Jama. 1995;273:408-12.

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.

	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.

Figure. Trial design

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

Section/item	Item No	Description	
Administrative information			
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
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 5
	6b	Explanation for choice of comparators	Page 6
Objectives	7	Specific objectives or hypotheses	Page 7

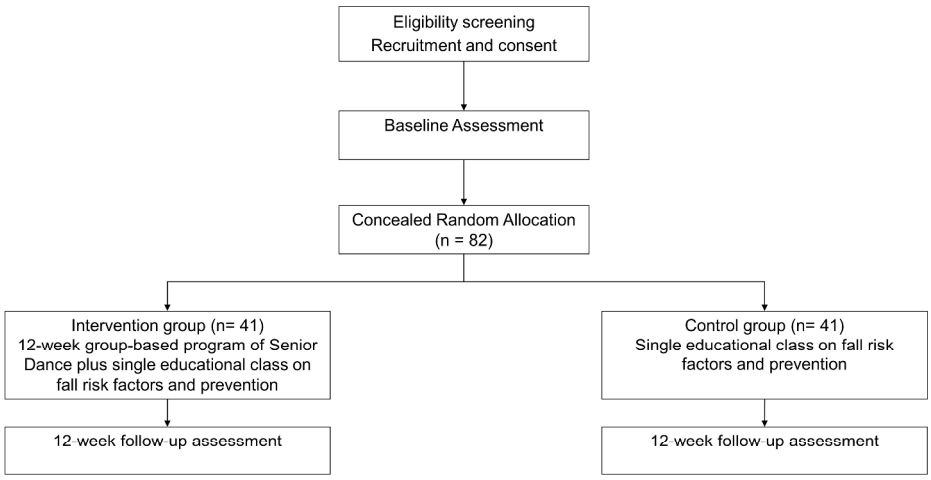
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description 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
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
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 8 Page 9
	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
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 9
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
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
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
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			Page 8

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

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

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
	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			
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" license.



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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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Effectiveness of senior dance on risk factors for falls in older adults (DanSE): 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 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).

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

Trial registration number: The trial has been registered at ClinicalTrials.gov (NCT02603523). Protocol issue date: January 29, 2016.

Key words: geriatric medicine, preventive medicine, older people, accidental falls

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

older adults (i.e. exercises aiming at improving postural control by challenging the alignment of the body's center of gravity) improve balance test performance.[25]

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% [26, 27]. Another study including 5681 older people found that only around 21% of older people adhere to public health recommendations for participation in strength or balance activities, falling in the lower limit of the estimates derived from systematic reviews.[28] From a health policy perspective, non-adherence to long-term therapies severely compromises the effectiveness of treatment leading to excessive health care costs.[29]

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

Dancing is a promising alternative to traditional structured exercise programs as it may provide a safe and fun way of targeting balance. Previous studies show that some older people consider dancing an interesting and joyful activity, that provides opportunity for socialization.[32, 33] Systematic reviews investigating the effects of dancing on risk factors for falls report beneficial effects on balance, gait, strength and dynamic

mobility.[34, 35] The paucity of randomized clinical trials investigating dancing among community-dwelling older adults as well as the low methodological quality of existing studies, do not allow definitive conclusions to be made on the real effects of the different types of dancing on risk factors for falls. A recent well-designed randomized clinical trial found that social dancing did not prevent falls or risk factors for falls among retirement village residents.[36] Future studies are required to explore the impact of different types of dance in different settings.

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

METHODS

Trial design

We will conduct a single-blind parallel 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.[38] The trial has been registered at ClinicalTrials.gov (NCT02603523).

Participants

A total of 82 participants will be recruited via advertisements in local newspapers, health 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

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 standing, quickly or slowly, in circles, individually, in pairs or in small groups. The concentration required to learn the choreographies challenges balance, motor coordination and cognitive function.

Control group

Participants allocated to the control group will attend the same educational class on strategies to prevent falls among older people that intervention group participants will receive, and will be instructed not to take part in any regular exercise programs such as supervised group exercise, Tai Chi, Yoga, or any dance activity during the study period.

At the end of the study, they will be offered Senior Dance classes, twice a week, during 12 weeks.

The Table summarizes the contents of both interventions according to the TIDieR checklist.

Outcome measures

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

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

Primary outcome

Balance outcomes will be used due to the importance of balance as a risk factor for falls. Single-leg stance with eyes closed without the use of 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 [42] that has been previously used in studies investigating dance among the older population.[40]

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.[43] 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.[44]
- Trail Making Test (TMT): to evaluate cognitive function.[45] The test consists of two parts (A and B). Part A measures processing speed and involves participants connecting consecutive numbers (e.g., 1-2-3). Part B is a measure of executive function of 'task shifting' and involves participants connecting alternating letters and numbers in order (e.g.,1-A-2-B). The difference in time between the two parts (B minus A) will be calculated to isolate the executive component of this test

- The Montreal Cognitive Assessment (MoCA): to also evaluate cognitive function.[46] The MoCA is a one-page 30-point test, which contains the following cognitive domains: visuospatial, executive, sustained attention, concentration, working memory, short-term memory recall, language and orientation.

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

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

Sample size

As described above, the primary outcome measure will be the single-leg stance with eyes closed. A total sample of 82 subjects (41 per group) will be required to detect a

between-group difference of 1.93 seconds (standard deviation of 2.87-seconds) [49] with 80% power and a significance level of 5%, allowing 15% dropouts.

Data integrity and analysis

Data integrity will be monitored by regularly scrutinising data files for omissions and errors. The statistical software SPSS version 20.0 (IBM Corporation, Somers, NY, USA) will be used for data analysis. Dichotomous and categorical data will be reported using frequency (proportion), while continuous data will be reported using mean (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 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, and only study investigators will have access to the final trial dataset.

DISCUSSION

The popularity of dancing is increasing among the older population. Previous systematic reviews report a beneficial effect of dancing on risk factors for falls, such as balance, gait and strength.[34, 35] However, the low methodological quality of existing studies 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.[34] Importantly, both methodological flaws have been reported to inflate effect sizes of clinical trials.[50, 51]

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

ETHICS AND DISSEMINATION

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

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

COMPETING INTERESTS: None declared.

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REFERENCES:

[1] Gill TM, Allore HG, Holford TR, Guo Z. Hospitalization, restricted activity, and the development of disability among older persons. Jama. 2004;292:2115-24.

[2] Jorstad EC, Hauer K, Becker C, Lamb SE, ProFa NEG. Measuring the psychological outcomes of falling: a systematic review. Journal of the American Geriatrics Society. 2005;53:501-10.

[3] Sartini M, Cristina ML, Spagnolo AM, Cremonesi P, Costaguta C, Monacelli F, et al. The epidemiology of domestic injurious falls in a community dwelling elderly population: an outgrowing economic burden. European journal of public health. 2010;20:604-6.

[4] Tinetti ME, Kumar C. The patient who falls: "It's always a trade-off". Jama. 2010;303:258-66.

[5] Tinetti ME, Speechley M, Ginter SF. Risk factors for falls among elderly persons living in the community. The New England journal of medicine. 1988;319:1701-7.

[6] Gale CR, Cooper C, Aihie Sayer A. Prevalence and risk factors for falls in older men and women: The English Longitudinal Study of Ageing. Age and ageing. 2016.

[7] Craig J, Murray A, Mitchell S, Clark S, Saunders L, Burleigh L. The high cost to health and social care of managing falls in older adults living in the community in Scotland. Scottish medical journal. 2013;58:198-203.

[8] Hartholt KA, Polinder S, Van der Cammen TJ, Panneman MJ, Van der Velde N, Van Lieshout EM, et al. Costs of falls in an ageing population: a nationwide study from the Netherlands (2007-2009). Injury. 2012;43:1199-203.

[9] National Institute for Health and Clinical Excellence (NICE). Falls: Assessment and prevention of falls in older people (NICE clinical guideline 161). http://wwwniceorguk/guidance/cg161. 2013.

[10] Peel N, Bell RAR, Smith K. Queensland Stay On Your Feet® Community Good Practice Guidelines – preventing falls, harm from falls and promoting healthy active ageing in older Queenslanders. Brisbane: Queensland Health. 2008.

[11] Skelton D, Todd C. What are the main risk factors for falls among older people and what are the most effective interventions to prevent these falls? Copenhagen: WHO Regional Office for Europe. 2004.

[12] Vellas BJ, Wayne SJ, Romero L, Baumgartner RN, Rubenstein LZ, Garry PJ. One-leg balance is an important predictor of injurious falls in older persons. Journal of the American Geriatrics Society. 1997;45:735-8.

[13] Muir SW, Berg K, Chesworth B, Klar N, Speechley M. Balance impairment as a risk factor for falls in community-dwelling older adults who are high functioning: a prospective study. Physical therapy. 2010;90:338-47.

[14] Lord SR, Ward JA, Williams P, Anstey KJ. Physiological factors associated with falls in older community-dwelling women. Journal of the American Geriatrics Society. 1994;42:1110-7.

[15] Gale CR, Cooper C, Aihie Sayer A. Prevalence and risk factors for falls in older men and women: The English Longitudinal Study of Ageing. Age and ageing. 2016;45:789-94.

[16] Horak F. Clinical assessment of balance disorders. Gait & Posture. 1997;6:76-84.

[17] Woollacott MH, Shumway-Cook A, Nashner LM. Aging and posture control: changes in sensory organization and muscular coordination. International journal of aging & human development. 1986;23:97-114.

[18] Lord SR, Clark RD, Webster IW. Postural stability and associated physiological factors in a population of aged persons. Journal of gerontology. 1991;46:M69-76.

[19] Roemer K, Raisbeck L. Temporal dependency of sway during single leg stance changes with age. Clinical biomechanics. 2015;30:66-70.

[20] Onambele GL, Narici MV, Maganaris CN. Calf muscle-tendon properties and postural balance in old age. Journal of applied physiology. 2006;100:2048-56.

[21] Era P, Sainio P, Koskinen S, Haavisto P, Vaara M, Aromaa A. Postural balance in a random sample of 7,979 subjects aged 30 years and over. Gerontology. 2006;52:204-13.

[22] Abrahamova D, Hlavacka F. Age-related changes of human balance during quiet stance. Physiological research. 2008;57:957-64.

[23] Sherrington C, Michaleff ZA, Fairhall N, Paul SS, Tiedemann A, Whitney J, et al. Exercise to prevent falls in older adults: an updated systematic review and meta-analysis. British journal of sports medicine. 2016.

[24] Gillespie LD, Robertson MC, Gillespie WJ, Sherrington C, Gates S, Clemson LM, et al. Interventions for preventing falls in older people living in the community. The Cochrane database of systematic reviews. 2012;9:CD007146.

[25] Lesinski M, Hortobagyi T, Muehlbauer T, Gollhofer A, Granacher U. Effects of Balance Training on Balance Performance in Healthy Older Adults: A Systematic Review and Meta-analysis. Sports medicine. 2015;45:1721-38.

[26] McPhate L, Simek EM, Haines TP. Program-related factors are associated with adherence to group exercise interventions for the prevention of falls: a systematic review. Journal of physiotherapy. 2013;59:81-92.

[27] Simek EM, McPhate L, Haines TP. Adherence to and efficacy of home exercise programs to prevent falls: a systematic review and meta-analysis of the impact of exercise program characteristics. Preventive medicine. 2012;55:262-75.

[28] Merom D, Pye V, Macniven R, van der Ploeg H, Milat A, Sherrington C, et al. Prevalence and correlates of participation in fall prevention exercise/physical activity by older adults. Preventive medicine. 2012;55:613-7.

[29] World Health Organization (WHO). Adherence to long-term therapies - evidence for action. http://apps.who.int/medicinedocs/en/d/Js4883e/; 2003.

[30] Franco MR, Tong A, Howard K, Sherrington C, Ferreira PH, Pinto RZ, et al. Older people's perspectives on participation in physical activity: a systematic review and thematic synthesis of qualitative literature. British journal of sports medicine. 2015;49:1268-76.

[31] Franco MR, Howard K, Sherrington C, Ferreira PH, Rose J, Gomes JL, et al. Eliciting older people's preferences for exercise programs: a best-worst scaling choice experiment. Journal of physiotherapy. 2015;61:34-41.

[32] Nadasen K. Life without line dancing and the other activities would be too dreadful to imagine": an increase in social activity for older women. Journal of Women and Aging. 2008;20:329-42.

[33] Lima MMS, Vieira AP. Ballroom Dance as Therapy for the Elderly in Brazil. American Journal of Dance Therapy 2007;29:129-4.

[34] Fernandez-Arguelles EL, Rodriguez-Mansilla J, Antunez LE, Garrido-Ardila EM, Munoz RP. Effects of dancing on the risk of falling related factors of healthy older adults: a systematic review. Archives of gerontology and geriatrics. 2015;60:1-8.

[35] Keogh JW, Kilding A, Pidgeon P, Ashley L, Gillis D. Physical benefits of dancing for healthy older adults: a review. Journal of aging and physical activity. 2009;17:479-500.

[36] Merom D, Mathieu E, Cerin E, Morton RL, Simpson JM, Rissel C, et al. Social Dancing and Incidence of Falls in Older Adults: A Cluster Randomised Controlled Trial. PLoS medicine. 2016;13:e1002112.

[37] Silva AFG, Berbel AM. O benefício da dança sênior em relação ao equilíbrio e às atividades de vida diárias no idoso. Arquivos Brasileiros de Ciências da Saúde (ABCS). 2015;40:16-21.

[38] Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC medicine. 2010;8:18.

[39] Brucki SM, Nitrini R, Caramelli P, Bertolucci PH, Okamoto IH. [Suggestions for utilization of the mini-mental state examination in Brazil]. Arquivos de neuro-psiquiatria. 2003;61:777-81.

[40] Shigematsu R, Chang M, Yabushita N, Sakai T, Nakagaichi M, Nho H, et al. Dance-based aerobic exercise may improve indices of falling risk in older women. Age and ageing. 2002;31:261-6.

[41] Holmerova I, Machacova K, Vankova H, Veleta P, Juraskova B, Hrnciarikova D, et al. Effect of the Exercise Dance for Seniors (EXDASE) program on lower-body functioning among institutionalized older adults. Journal of aging and health. 2010;22:106-19.

[42] Springer BA, Marin R, Cyhan T, Roberts H, Gill NW. Normative values for the unipedal stance test with eyes open and closed. Journal of geriatric physical therapy. 2007;30:8-15.

[43] Guralnik JM, Simonsick EM, Ferrucci L, Glynn RJ, Berkman LF, Blazer DG, et al. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. Journal of gerontology. 1994;49:M85-94.

[44] Delbaere K, Close JC, Mikolaizak AS, Sachdev PS, Brodaty H, Lord SR. The Falls Efficacy Scale International (FES-I). A comprehensive longitudinal validation study. Age and ageing. 2010;39:210-6.

[45] Tombaugh TN. Trail Making Test A and B: normative data stratified by age and education. Archives of clinical neuropsychology : the official journal of the National Academy of Neuropsychologists. 2004;19:203-14.

[46] Nasreddine ZS, Phillips NA, Bedirian V, Charbonneau S, Whitehead V, Collin I, et al. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. Journal of the American Geriatrics Society. 2005;53:695-9.

[47] Sechrist KR, Walker SN, Pender NJ. Development and psychometric evaluation of the exercise benefits/barriers scale. Research in nursing & health. 1987;10:357-65.

[48] Picorelli AMA, Pereira DS, Felício DC, Gomes DA, Dias RC, Pereira LSM. Adhesion of older women to a home exercise program post ambulatory training. Fisioterapia & Pesquisa. 2015;22:291-308.

[49] Tiedemann A, O'Rourke S, Sesto R, Sherrington C. A 12-week Iyengar yoga program improved balance and mobility in older community-dwelling people: a pilot randomized controlled trial. The journals of gerontology Series A, Biological sciences and medical sciences. 2013;68:1068-75.

[50] Bollini P, Pampallona S, Tibaldi G, Kupelnick B, Munizza C. Effectiveness of antidepressants. Meta-analysis of dose-effect relationships in randomised clinical trials. The British journal of psychiatry : the journal of mental science. 1999;174:297-303.

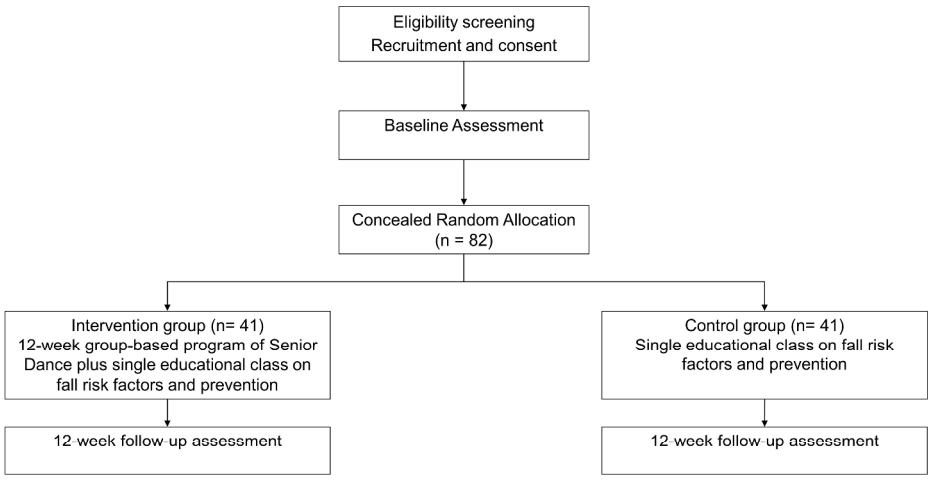
[51] Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. Jama. 1995;273:408-12.

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. 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.

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	
Administrative information			
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
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 5
	6b	Explanation for choice of comparators	Page 6
Objectives	7	Specific objectives or hypotheses	Page 7

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
Methods: Participants, interventions, and outcomes			
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
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
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 8 Page 9
	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
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 9
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
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
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
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			Page 8

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

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

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
	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			
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" license.