

Prevention of depression and anxiety in community-dwelling older adults: the role of physical activity

CLÓVIS ALEXANDRINO-SILVA¹, SALMA ROSE RIBEIZ¹, MARIA BEATRIZ FRIGERIO², LUCAS BASSOLLI³, TÂNIA FERRAZ ALVES¹, GERALDO BUSATTO¹, CÁSSIO BOTTINO^{1†}

¹Old Age Research Group (PROTER), Department of Psychiatry, University of São Paulo, São Paulo, SP, Brazil.

²NGO Envelhecer Sorrindo, São Paulo, SP, Brazil.

³Heart Institute (InCor) – Clinics Hospital of the University of São Paulo Medical School, São Paulo, SP, Brazil; †Deceased.

Institution where the study was conducted: Old Age Research Group (PROTER), Department of Psychiatry, University of São Paulo.

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Abstract

Background: With the growth of the elderly population in Brazil and the increasing impact of depression and anxiety, the importance of preventing these disorders has been highlighted. Studies have shown an inverse relationship between rates of depression/anxiety and physical activity, pointing out its role as a possible protective factor. **Objectives:** To conduct a randomized study with elderly adults in the community, who present with subsyndromal depression and anxiety, that will evaluate the effectiveness of physical activity with a collaborative stepped-care strategy; and to compare the effectiveness of physical activity in preventing subsyndromal depression and anxiety, with regard to the usual care group. **Methods:** The article contains the methodological description of an arm of a large study entitled “Prevention and Treatment of Depression in Elderly”, in which 2,566 Brazilian older adults were screened to identify clinically significant depressive and anxiety symptoms. Those with clinically significant depressive or anxiety symptoms, not meeting criteria for depressive or anxiety disorder, will be invited to participate in a randomized clinical trial with 2 intervention groups: a step-by-step preventive care programme using physical activity, and usual care. The effectiveness of physical activity in the prevention of depressive and anxiety disorders will be evaluated. **Discussion:** New health policies could be implemented, aiming to reduce the number of elderly people with depression and anxiety in primary care. In addition, training may be implemented for family health teams so that screening tools could be used to make an early identification of individuals with (or at risk of developing) mental disorders.

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Introduction

The significant increase in individuals aged 60 and over in the Brazilian population pyramid points to an unprecedented and inevitable reality. The ageing index of the population grew from 21.0 in 1991 to 44.7 in 2012¹, while life expectancy at birth rose from 66.9 years in 1991 to 74.5 years in 2012². Considering that a Brazilian's life expectancy was 33.7 years at the beginning of last century³, it has more than doubled in this timeframe.

With the growing number of Brazilian older adults, the relevance of diseases that affect a significant portion of this population also increases. Depression and anxiety are among the major mental disorders in the elderly, and both are frequent causes of emotional suffering and lost quality of life^{4,5}. These disorders in the elderly are associated with functional impairment, high costs of health care, and increased mortality⁶⁻⁸. Furthermore, it is known that depression can complicate the course and prognosis of cardiovascular diseases, stroke and other diseases^{9,10}.

Regarding the occurrence of depression in individuals aged 55 or more living in the community, the literature reports diverging prevalence rates, ranging from 0.4% to 35%¹¹. However, when clinical manifestations of depression are investigated separately, it is observed that cases of major depression are infrequent (weighted average prevalence of 1.8%), while episodes of minor depression prevail (9.8%). When all depressive syndromes with clinically significant symptoms are grouped, the average prevalence reaches 26%¹². These results suggest that, in the elderly, episodes of minor depression and depressive syndromes are particularly relevant, as opposed to the higher frequency of severe depressions that is observed in other age groups.

Epidemiological studies have shown that anxiety disorders are among the most common psychiatric disorders among people aged 60 or over, with a lifetime prevalence estimated over 15.3%, higher even

than the estimate for mood disorders (11.9%)¹³. In another population survey¹⁴, the prevalence of anxiety disorders in the elderly was 10.2%, with generalized anxiety disorder (GAD) being the most common (7.3%), followed by phobic disorder (3.1%), panic disorder (1.0%) and obsessive compulsive disorder (0.6%). In Brazil, there are few community studies investigating the occurrence of anxiety disorders in the elderly¹⁵⁻¹⁷.

The prevention of mental disorders has been considered one of the most viable alternatives available to reduce the impact that the emergence of new cases would have both on the quality of life of patients and on the healthcare system. Studies have shown that prevention is possible, reducing the risk of occurrence of new cases of mental disorders, especially regarding interventions for patients with subclinical symptoms¹⁸.

The effectiveness of an indicated preventive-intervention stepped-care programme focused on depressive and anxiety disorders in the elderly in primary care in the Netherlands was evaluated in a clinical trial with 170 subjects over 75 years old with subsyndromal symptoms of depression or anxiety¹⁹. Subjects were randomly assigned to a preventive stepped-care programme with therapy or to usual care. This intervention halved the cumulative incidence of major depressive disorders or anxiety disorders after 12 months (from 0.24 in usual care to 0.12 in the stepped-care group). The results of this study provided evidence that the risk of the occurrence of depression and anxiety in the elderly can be reduced through the implementation of structured interventions in a group of people at high risk of developing these disorders. As interventions with low cost were offered first – and only when they failed to keep the symptoms of depression and anxiety at acceptable levels were more intensive interventions were offered – this programme proved to be effective, both clinically and in terms of cost²⁰.

One low cost intervention not assessed in the Dutch study described above relates to the use of physical activity programmes.



In a literature review in which the dose-response effect of physical activity on depression and anxiety was evaluated, the authors concluded that the cross-sectional studies indicate that physical activity is associated with reduced depressive symptoms, having less evidence on the reduction of anxiety symptoms²¹. Data on the prospective studies are inconsistent, especially with respect to prevention. Evidence from randomized controlled trials showed a reduction in symptoms of depression, which can be attributed to the practice of resistance and aerobic exercises; there was limited evidence regarding anxiety disorders²¹.

The relationship between the role of physical activity in the prevention of depression suggests two strands: depression decreases the practice of physical activity, and physical activity may be useful in preventing depression. Given the physical and psychological benefits from physical activity, in general, and from physical exercise, in particular, its practice by depressed elderly adults without comorbidities may promote the prevention and reduction of depressive symptoms²².

Evidence suggests that physical activity can be used as an adjunct in the prevention of depression in the elderly. However, there are few studies in relation to anxiety, and the 'dose' of physical activity needed to assist in the reduction of depressive and anxiety symptoms has not been sufficiently investigated. We also note that the effectiveness of physical activity to prevent the onset of depression and anxiety in the elderly has also not been adequately evaluated in clinical trials, mainly through a survey of population coverage and characteristics.

Aims of the study

- To conduct a randomized study with elderly adults in the community, who are users of the Basic Health Units of the Butantã region and who present with subsyndromal depression and anxiety, that will evaluate the effectiveness of physical activity with a collaborative stepped-care strategy.
- To compare the effectiveness of physical activity in preventing subsyndromal depression and anxiety, with regard to the usual care group.

Methods

Study design

This is a naturalistic randomized parallel clinical trial, comprised of two arms: an intervention group (stepped-care programme with physical activity) and a control group (usual care).

Participants

Eligible subjects are aged 60 or more, with subsyndromal symptoms of depression or anxiety, who are enrolled in one of the selected Basic Health Units of the Butantã Region, and who are capable of giving informed consent and have sufficient knowledge of the Portuguese language. Participants will be defined as having subsyndromal symptoms of depression and/or anxiety, when he/she gets a score greater than or equal to 13 in the Center for Epidemiologic Studies Depression Scale (CES-D) but does not meet criteria for a depressive or anxiety disorder, according to Mini International Neuropsychiatric Interview (MINI)²³. Individuals who meet the criteria for major depression, dysthymia, bipolar disorder, mild cognitive impairment or dementia, use of substances, and/or anxiety disorder, or who are unable to consent to participate in the study, or who do not have mastery of the Portuguese language will be excluded. Elderly adults will be interviewed in their homes.

Ethics approval and consent to participate

The Ethics Committee for Research Project Analysis of the University of São Paulo approved this study (CAAE-14693013.4.0000.0068), and written consent forms were obtained for all participating subjects.

Confidentiality of the information was warranted. ClinicalTrials.gov Identifier: NCT03538873.

Sample size

The main study was designed with power to detect a 25% difference in the cumulative incidence rates of depressive and anxiety disorders, according to MINI/DSM-IV, in the physical activity group compared to the usual care group. It is expected that the incidence rates of depressive and anxiety disorders will be 35% for the usual care group, based on previous longitudinal studies¹⁴. In the group that will participate in the physical activity intervention, we estimated that the incidence rate of subsyndromal depressive and anxiety will be 10%. Using the formula below²⁴, we calculated that 32 participants will be required in each group, assuming $\alpha = 0.05$ and power $(1 - \beta) = 0.80$.

$$n = \frac{(\alpha + \beta)^2 [(p1/p2 \pm 1) - p2 ((p1/p2)^2 \pm 1)]}{p2 (1 - p1/p2)^2}$$

$$p1 = 0,35$$

$$p2 = 0,10$$

To ensure that the groups end the 12-month follow-up with an "n" greater than or equal to 32 participants per group, we added 10% due to possible losses, ending with an "n" equal to 35 participants per group.

Recruitment

Eligible subjects for this study will be selected from a pool of participants of a larger study entitled "Prevention and Treatment of Depression in Elderly", conducted in São Paulo, Brazil. When the main study was readied in 2009, the population of São Paulo, according to projections of SEADE, was 10,998,813 inhabitants, with 11.53% of people aged 60 years or older. The council was composed of 96 districts, from which Raposo Tavares and Rio Pequeno were chosen because their Basic Health Units (BHU) and the teams of the Family Health Program (FHP) were managed by the Faculty of Medicine Foundation, with the coordination of a board of directors composed of professors of the faculty of medicine of the University of São Paulo. The West Region Project, as it was called, included the units of the Raposo Tavares and Rio Pequeno districts, with 5 BHU and 29 FHP teams integrated into the design and 98,716 people registered since the end of 2009.

Interviews were conducted with 2,673 elderly people in their homes by lay interviewers, who applied a structured psychiatric interview, after receiving specialized training from professionals involved in the research. Of the total number of interviewees, 153 subjects had failed screening: 17 subjects were less than 60 years old, and 136 elderly people had at least one item absent in the Center for Epidemiological Studies-Depression (CES-D) or in the Mini Mental State Examination (MMSE), the two core questionnaires for screening the individuals in the study. However, 46 subjects from those who had at least one item absent for one of these two scales received further medical evaluation, with reapplication of the questionnaires; in these cases, the elderly were included in the valid sample of the study, and the 17 subjects who were younger than 60 years and the 90 individuals who had incomplete data on at least one of the two scales and did not receive further medical evaluation were excluded. This left a valid sample of 2,566 elderly participants.

The main objective of this first phase of the larger study was to calculate the prevalence of clinically significant depressive symptoms. Older adults with clinically significant depressive symptoms and who do not fulfil criteria for depressive and/or anxiety disorders will be invited to participate in a randomized clinical trial with 2 intervention groups, with 35 older adults in each one. Figure 1 presents the flowchart of study participants.

Outcome measures of the present study

The primary outcome will be the cumulative incidence of major depressive disorder or anxiety disorders, after 12 months, assessed

with the Mini International Neuropsychiatric Interview (MINI). Secondary outcomes will be the reduction of depressive and/or anxiety symptoms, evaluated with the Center for Epidemiologic Studies Depression Scale (CES-D) and improvement in quality of life, assessed with the 36-Item Short Form Health Survey (SF-36).

Instruments

CES-D

The Brazilian version of the CES-D²⁵ will be used for screening for clinically significant depressive and anxiety symptoms. This scale contains 20 items (scores range from 0 to 60) and evaluates behaviours and feelings that occurred in the last two weeks. The cut-off point used in most of the studies to identify individuals at risk of depression is greater than or equal to 16, and higher values suggest a direct relationship with depression severity²⁶. However, this cut-off point is not a rule, and other studies have used (or have found) higher or lower cut-off points for screening of depressive symptoms, depending on the characteristics of the samples evaluated²⁷⁻²⁹. One study that evaluated the effectiveness of the CES-D in screening for clinical depression in a sample of 1,005 subjects aged 50 or more found that the cut-off point that maximized both sensitivity and specificity for the total sample was 12 – the area under the ROC

curve (AUC) was 0.86, with 76% sensitivity and 77% specificity²⁹. Different factors (including socioeconomic issues) may contribute to the identification of the most appropriate CES-D cut-off point for each study³⁰. Since we investigated a population living under adverse socioeconomic conditions, we predicted that there would be a large proportion of elderly people with depression or presenting mild cognitive impairment/dementia. Considering this specificity of our studied population, we reduced the cut-off point of the CES-D scale to greater or equal to 13, rather than using the standard cut-off of ≥ 16 .

Correlations between GAI and CES-D

Anxiety symptoms will be assessed through the following four CES-D questions: 1. I was bothered by things that don't usually bother me; 2. I did not feel like eating; my appetite was poor; 3. I had trouble keeping my mind on what I was doing; and 4. My sleep was restless. To establish the correlations between the two scales, we have traced linear correlations according to the Pearson method between the CES-D score and the Geriatric Anxiety Inventory (GAI) score, in addition to the four selected questions (described above). We found statistically significant correlations of "strong" intensity ($r = 0,714$; $p < 0.001$ Pearson correlation).

D-10

D-10 is a screening scale for depressive symptoms with 10 issues (scores range from 0 to 10), which was developed by our group to be used in a community prevalence of dementia study, evaluating the presence of symptoms in the last two weeks. Six of the items are based on the "Geriatric Depression Scale" (GDS)³¹, one item is from the CES-D, and three additional items were chosen through a consensus of researchers. In a previous community study, the D-10 showed internal consistency, measured by Cronbach's alpha of 0.72, and high agreement with the GDS-5 ($r_s = 0.85$; $p < 0.001$). Considering the GDS-5 as the gold standard, the D-10 had a sensitivity of 78.8%, a specificity of 95.5%, a positive predictive value of 60.3%, and a negative predictive value of 98.1%³².

MINI diagnostic interview

The MINI is a short, structured diagnostic instrument (15 to 30 minutes) used to identify psychiatric disorders according to the DSM-IV and ICD-10³³. It has been used in several epidemiological studies and in clinical psychopharmacology¹⁹; it was translated and validated for the Portuguese language and administered by medical residents in a family medicine programme²³. The following MINI modules will be administered by trained physicians: depressive disorder, dysthymia, suicide risk, (hypo)manic episode, panic disorder, agoraphobia, social phobia, alcohol abuse/dependence, and generalized anxiety disorder.

Cognitive assessment

Cognitive assessments will be made with the CAMCOG brief neuropsychological battery, which is part of the Cambridge Mental Disorders of the Elderly Examination structured interview (CAMDEX)³⁴. CAMCOG (scores range from 0 to 107) was translated and adapted to the Portuguese language³⁵; it takes 20 to 30 minutes to be administered and has 67 items – including the Mini Mental State Examination (MMSE) and Verbal Fluency – which assess orientation, language, memory, praxis, attention, abstract thinking, perception and calculation. The MMSE³⁶ is the cognitive screening test most widely used worldwide, and it evaluates five areas of cognition: orientation, registration, attention and calculation, recovery, and language, with scores ranging from 0 to 30 points. In the initial screening of this study, MMSE ≥ 13 will be used as the cut-off point³⁷, considering the low level of education and the large number of illiterates in the studied population. However, as the subjects become

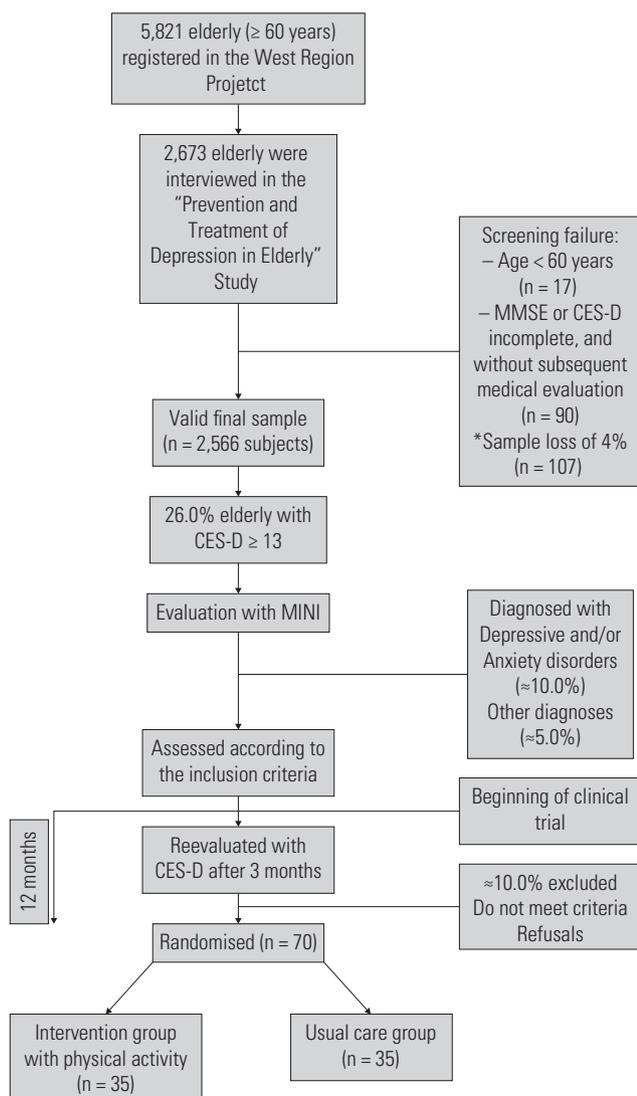


Figure 1. Flowchart of study participants.

candidates for randomization, the MMSE will be evaluated according to schooling. In these cases, the following cut points will be used^{38,39}: illiterates < 18; 1 to 4 years of schooling < 23; 5 to 8 years of schooling < 25, and more than 9 years of schooling < 26.

Another instrument of cognitive evaluation that will be used in the study is the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE), which contains 26 questions (scores from 1 to 5 points), in which the informant evaluates the patient's current performance in different life situations compared to the performance observed 10 years ago. IQCODE is valid for dementia screening in the general population⁴⁰, as well as in clinical practice⁴¹. The application of the long (26 items) and short (16 items) IQCODE by our group suggests that the two versions can be used for the screening of mild-to-moderate cases of dementia in Brazil⁴². The short version of the IQCODE will be applied to the relatives/informants of the elderly, using a cut-off point ≥ 3.53 to identify possible cases.

B-ADL

Functional assessment of patients will be done using the Bayer Activities of Daily Living Scale (B-ADL). The B-ADL has 25 questions comprising 13 areas of daily living, and it is applied to a relative or informant. The B-ADL is a brief instrument and can be used by general practitioners and in primary care, both for tracing and evaluating the effects of treatment and the progression of dementia⁴³. The Portuguese version was validated by our group, showing high internal consistency (Cronbach's alpha = 0.981) and the ability to differentiate elderly patients with mild-to-moderate dementia⁴⁴.

36-Item Short Form Health Survey (SF-36)

SF-36 measures the quality of life related to health⁴⁵. The thirty-six items assess the events in the last four weeks and are classified into eight separate areas: functional capacity, physical functioning, pain, general health, vitality, social role, emotional role and mental health. This scale has been translated, validated, and adapted to Brazil⁴⁶ and has been widely used in clinical studies of patients with cancer and other chronic diseases⁴⁷.

Assessments

The evaluation of physical activity to prevent depression and/or anxiety in the elderly in primary care has not been properly investigated. The intervention programme to be applied in this study consists of four steps (described below), lasting three months each:

Step 1 – Watchful Waiting

Participants with scores on the CES-D scale ≥ 13 who have a negative MINI score for depression and/or anxiety and are not suspected of having mild cognitive impairment or dementia will wait 3 months after medical evaluation to be re-evaluated. This period of “watchful waiting” is indicated to observe if the individual does not present spontaneous remission of depressive and/or anxiety symptoms. In the reassessment, the following questionnaires will be applied: the CES-D, SF-36, MMSE, and Verbal Fluency. If the subject continues to present subsyndromal depressive symptoms (with CES-D ≥ 13), he/she will be randomized into one of the arms of the study (physical activity or usual care).

Step 2 – Physical Activity Intervention 1

This step is taught by a physical educator and takes place in the home, with a duration of 50 minutes for each session, over a 3-month period. Twice a week, participants will be taught to practice physical exercises for strength and stretching (elongation); planned goals for this intervention include the practice of aerobic physical activity

(walking) at least 3 times a week. The evaluation of frequency and duration of physical activity will be assessed with a pedometer.

Step 3 – Physical Activity Intervention 2

After these 3 months of intervention, the CES-D and the MINI will be re-administered. The participant who continues to present scores on the CES-D ≥ 13 and have a negative MINI score for depression and/or anxiety will receive a new period of 3 months of assisted physical activity, with 24 more meetings at home, lasting 50 minutes each.

Step 4 – Referral to Primary Care

After that, if there is still a CES-D score ≥ 13 , a further period of 3 months will begin, but the elderly will not receive any intervention, as in step 1, when “watchful waiting” is performed. At the end of this period the following questionnaires will be reapplied: the CES-D, SF-36, MMSE, and Verbal Fluency. If the CES-D scores remain high, participants will receive guidance about the need to receive a specific medication that they can discuss with their doctors.

In the first contact with the subject, physical educators will conduct an assessment to verify if he/she is able to perform scheduled activities. Strength tests and the short version of the International Physical Activity Questionnaire Short Form (IPAQ-SF) will be applied⁴⁸. This latter instrument consists of seven open questions that will allow for estimating the time spent by the elderly in different physical activities (hiking and physical efforts of different intensities) the week before starting the proposed interventions; physical inactivity will also be assessed.

At each meeting with physical educators, standardized exercises (contained in the protocol drawn up for this purpose) will be performed, lasting approximately one hour.

Subjects will be instructed to walk at least 3 times a week for a period of 30 minutes, and they should write down on a weekly record if scheduled activities were completed.

The elderly participants will receive a pedometer, which is a mechanical counter that registers movements performed in response to vertical acceleration of the body, and he/she will be informed about its purpose. They will also be instructed to place the unit at the waist and to use it all day, removing it only at bedtime. The pedometer measures the daily steps of the individual and the daily caloric loss and covered distance; data will be downloaded once a week by responsible staff.

Regarding the usual care arm, subjects in this group will have unrestricted access to usual care for depressive and/or anxiety symptoms. Their use of health services and use of prescribed medications will be recorded. Assessments in this arm will be done with the same questionnaires and in the same timeframe that will be used for the physical activity group.

The randomization process

In this study, we will adopt a stratified randomization process according to sex and age. The random distribution list of the subjects will be generated by the online software “Randomization” (<http://www.randomization.com>).

To guarantee a balance between the two groups (physical activity and usual care) in relation to sex and age, we will use stratified randomization at the time of inclusion in the study. Therefore, a random distribution list of these two covariates will be generated for allocation into the two groups of the study.

Control of the concealment of the sequence of randomization and stratification will be guaranteed by the use of REDCap software⁴⁹. Initially, the allocation list previously developed in “randomization.com” software will be imported into REDCap; then, stratification according to sex and age will be enabled in REDCap; finally, to add a new patient into the study, he/she will automatically be allocated to the study treatment group in accordance with the characteristics

defined in the model of stratified randomization. The advantage of using the REDCap randomization module lies in four aspects: 1) It is not possible to have knowledge of the random distribution list; 2) you cannot change the sequence of randomization; 3) all user actions can be monitored, thereby enabling the data security control and confidentiality of randomization; and 4) the database manager (REDCap) can define the hierarchy levels for access to the randomization module, thereby avoiding the access by data collectors and researchers to the randomization control tools. Thus, we can say that the method chosen for randomization is in accordance with the CONSORT standards⁵⁰.

Data analysis

All data will be collected using specially designed questionnaires and uploaded to a Web-based data programme, "REDCap", which was developed at Vanderbilt University⁴⁹. Data will be stored on a central server, enabling automatic periodic reports that will be created to check the quality and consistency of data. The data collection questionnaires will be designed to be compatible with international standards, which will allow our data to be combined in the future with similar databases of researchers in Brazil and abroad. Statistical analyses will be performed using SPSS 22.0 software for Windows and STATA 9.0.

To test the hypothesis that the intervention with physical activity will be more successful than usual care in reducing the risk of depressive and anxiety disorders, logistic regressions of the outcome will be held (1 = disorder and 0 = no disorder) in the treatment indicators (0 = usual care and 1 = intervention) to estimate the odds ratio (OR) and relative risks (RR), which will describe the reduction of the risk to present a depressive or anxiety disorder in the intervention group compared to the control group. The 95% confidence interval will be reported.

Characterization of the sample

The valid final sample (n = 2,566 elderly participants) presents the following sociodemographic characteristics: it is mostly composed of white individuals (46.2%; n = 1,181), followed by subjects who declared themselves to be brown (40.4%; n = 1,034), with a mean age of 69.79 years (standard deviation of 7.14). The final sample is predominantly female (63.1%; n = 1,620), married (52.1%; n = 1,333), Catholic (63.2%; n = 1,611), and retired (73.0%; n = 1,826). Although 81.8% (n = 2,058) of the individuals have attended school, they have a low educational level: 63.5% of them (n = 1,309) have attended primary school, and only 2.5% (n = 52) have attended university.

The valid final sample was classified, into different strata of average household income, according to a classic Brazilian approach. This criterion takes into account the purchasing power of the subjects and their families, who live in urban areas, and present four strata of average household income⁵¹. Most of the participants (55.5%) were classified in an economic stratum of household income between US\$ 543 and US\$ 793 (the third level of the criterion). The second criteria level was represented by almost a quarter of the sample (26.7%), who presented household income between US\$ 930 and US\$ 1,792. Almost 8.7% of families (n = 225) were classified in lowest criteria level, with an average household income equal to or less than US\$ 380. The highest level of household income (≥ US\$ 3,295) was represented only by 0.8% of sample (n = 21) (Figure 2). It is interesting to note that two-thirds of the elderly sample declared themselves as the main providers of household income (69.5%).

Scales of depressive symptoms and cognitive and functional tests

In Table 1, we present the results of the evaluation scales of depressive symptoms and cognitive tests. Figure 3 shows the relative frequency of depressive symptoms (CES-D, D-10), general cognitive status

(MMSE) and functional impairment (IQCODE) for the total sample (n = 2,566).

The high percentage of subjects with clinically significant depressive symptoms (> 40.0%) deserves special mention. Compared with the results of a meta-analysis conducted by our group in elderly Brazilian adults living in the community¹² that found a prevalence of 26.0% for clinically significant depressive symptoms, the above data are astonishing.

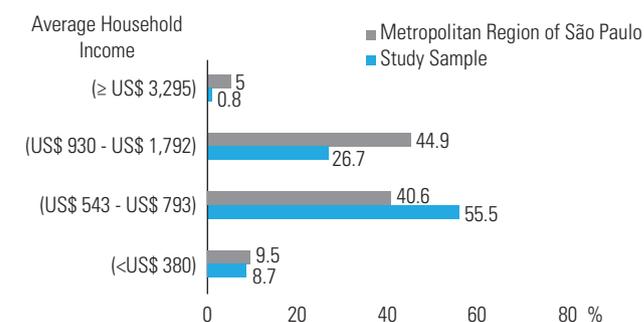


Figure 2. Comparison between the results of our sample and the results of a population sample from the metropolitan region of São Paulo.

Table 1. Results of depressive symptom scales and cognitive tests (n = 2,566)

Scales	Mean ± SD	Median (Min – Max)	Missing (%)
CES-D	13,81 ± 10,8	11,0 (0 – 57)	0 (–)
D-10	3,90 ± 2,5	4,0 (0 – 0)	1 (0,04)
MMSE	23,60 ± 4,78	25,0 (0 – 30)	0 (–)
IQCODE (n = 1,770)	3,07 ± 0,51	3,0 (0 – 5)	---

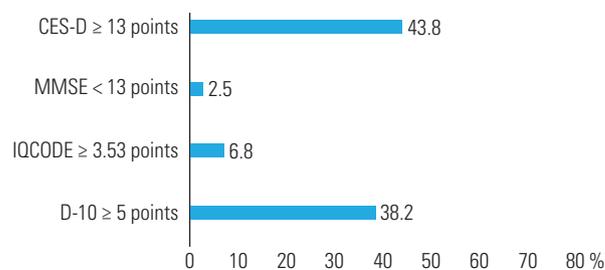


Figure 3. Relative frequency of depressive symptoms, general cognitive status and functional impairment (n = 2,566)

Discussion

It is known that clinically significant depressive symptoms can increase the risk of developing depressive disorder by almost 40%⁵². Such symptoms are more frequent than major depression in elderly people living in the community (7.0 x 26.0%); are associated with significant psychosocial impairment; can increase the risk of physical incapacity, clinical diseases, and use of health services; and are not usually recognized by health professionals^{12,18,53}.

Nonpharmacological interventions may be effective in preventing the development of depressive disorders in the elderly and may be quite useful in primary care. A recent review of the literature has demonstrated that different therapy techniques (such as cognitive behaviour therapy, competitive memory training, reminiscence group therapy, problem-adaptation therapy, and problem-solving therapy) have been able to reduce depressive symptoms in individuals who 65 years old; this highlights their usefulness in clinical practice and the benefit of this type of interventions, which offers minimal risks of side effects, especially in the elderly, who constitute a group in which

comorbidities are more frequent and pharmacological treatments increase the chances of drug interactions⁵⁴. Consistent with these findings, a meta-analysis on brief psychotherapeutic interventions for elderly people with subsyndromic depressive symptoms has shown that they can reduce the incidence of depression by 30%⁵³.

Another type of non-pharmacological intervention, one practically not evaluated in representative population studies, is physical activity. Physical activity reduces the occurrence of problems of balance, coordination and agility; decreases bone mass loss; increases cardiorespiratory function; promotes muscle strengthening; and reduces the risk of falls and fractures in the elderly^{55,56}. Another benefit that deserves to be highlighted is its role in forming social bonds, expanding contact networks and emotional support⁵⁷. To the best of our knowledge, this is the first community-dwelling study, with the methodology described, aimed at the elderly population with subsyndromic depressive symptoms.

In our randomized clinical trial, we may find that the elderly participants are resistant to perform physical activity with the necessary regularity. However, the presence of the physical educator in the participant's residence, the instructions provided and the benefits of the practice of the physical activity will be constantly reinforced; this will likely guarantee the minimum accomplishment of the exercises at least twice per week. In addition, the elderly participants will use a pedometer that will record their movements and caloric losses during the study period, allowing the team to monitor whether the exercises are being practised or not.

Another problem that we need to consider is the drop-out rate for the study, both for those who are in the intervention arm with physical activity and for those in the control group. If this occurs, in addition to having a trained professional visit the residence of the individual to learn what happened and see if we can help to solve the problem, the medical team will also contact the elderly participants to solve any doubts, as well as to encourage him/her to continue in the study. We believe that with these initiatives we will reduce the number of participant losses during the period, strengthening the bond with the subject of the research.

Regarding the socioeconomic characteristics of the sample studied, it is interesting to note that although most of the elderly are retired, approximately 70% of the sample declared themselves as the main providers of family income. This situation is commonly reported in times of economic crisis⁵⁸. The frequency of classified subjects among the four categories of family income was relatively similar to the results reported for the metropolitan region of São Paulo⁵¹. Most of the subjects were classified as having an intermediate family income (US\$ 543 – 793 and US\$ 930 – 1,792), although it was possible to perceive a higher proportion of elderly people in the category (US\$ 543 – 793) when compared to the results reported for São Paulo. The frequency of subjects in the sample, classified into the highest category of the criterion, was also different from the results reported for São Paulo, with approximately five times less frequency of subjects/families classified in this category. Nevertheless, for the lowest category of family income, the frequency of the elderly was similar to the results reported for São Paulo. The less favoured socioeconomic characteristics of our sample reinforce the possible value of the study if it demonstrates the effectiveness of a cheap and scalable intervention in this type of setting in the prevention of depression in the elderly.

Depending on the results that will be obtained in this study, new health policies could be implemented, aiming to reduce the number of elderly people with depression seen in primary care. In addition, training may be implemented for family health teams so that screening tools could be used to make an early identification of individuals with (or at risk of developing) mental disorders.

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