

STUDY PROTOCOL

Title: Effects of Traditional Concurrent Training and Concurrent Training Composed by Strength Training and Dance Classes in Functional Performance, Cognitive Function and Quality of Life of Older Adults: a Randomized Controlled Clinical Trial

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Abstract: The aging is a natural, progressive and multifactorial process that affects all the organism. Whereas, generally (but not necessarily) the aging process is associated with chronic diseases, the health aging premise is not the absence of disease, but the opportunities to continue experiencing situations that are considered valuable over the years. Thus, independence becomes one of the most important outcomes for maintaining a great quality of life throughout the aging process. Functional independence is influenced by several factors and an active lifestyle can act directly in this aspect. In this sense, the World Health Organization recommends, in addition to the practice of physical activities, the regular practice of structured physical exercise for older people. In this logic, the combination of strength training and aerobic training (i.e., concurrent training) has been a widely used intervention for health outcomes. In addition, dance has been a physical practice well described in the literature as an aerobic activity that can bring several health benefits, especially for older people. Thus, dance with strength training seems to be an interesting option for a complete physical training program. Thus, the aim of the present study is to identify and compare the impacts of traditional concurrent training and concurrent training consisting of strength training combined with dance classes on functional performance, cognitive function and quality of life of older people.

Key-words: aging, functional capacity, physical activities.

INTRODUCTION

The world population aging is a reality. The World Health Organization (WHO, 2022b) affirm that until 2050, 2.1 billion people will be considered old individuals. The aging is a natural, progressive and multifactorial process that affects the organism entirely (LITVOC & BRITO, 2004). This process provoked muscle alterations that could decrease the functional performance (NETTO, 1999).

Whereas, generally, but not necessarily, the aging process is associated with chronic diseases, the healthy aging premise is not the absence of diseases, but is the opportunities to continue experiencing situations that are considered valuable over the years (WHO, 2020a). Thus, functional independence becomes one of the most important outcomes for the quality of life maintenance throughout the aging process.

Functional independence can be affected by different factors, such as the presence of diseases, injuries and alterations related to aging (WHO, 2020a). In that regard, active lifestyle can attenuate functional independence, whereas physical activity can prevent and attenuate chronic diseases, increase the mobility, decrease depressive symptoms and decelerate cognitive declines (IZQUIERDO *et al.*, 2021).

About functional performance, muscle strength is one of the most important factors, whereas it is strongly related to sarcopenia and, consequently, to functional independence. Though strength training alone can not be beneficial for balance related outcomes (CADOORE *et al.*, 2013), besides having minimal effects on cardiorespiratory capacity compared to aerobic training (CADOORE *et al.*, 2011). Balance and cardiorespiratory capacity are, respectively, important to prevent falls and to maintain functional independence in old people (BLANCO-RAMBO *et al.*, 2022; SHEPHARD, 2009). Therefore, it is necessary to include others training modalities in the routine of old individuals.

In that regard, the combination of strength and aerobic training (i.e., concurrent training) has been widely used. This modality unifies aerobic and strength training in one session, and can promote the same benefits as both training performed separately in addition to optimizing the time in training (CADORE & IZQUIERDO, 2013). Nonetheless, traditional concurrent training does not include exercises for other physical components recommended by WHO (2020b) for old individuals, like balance exercises.

Though, dance has been a physical activity well described in the literature as an activity that can bring many health benefits, especially for the old people. Dance can increase cardiorespiratory capacity (RODRIGUES-KRAUSE *et al.*, 2016), improve dynamic and static balance (BLANCO-RAMBO *et al.*, 2022), gait ability, mobility and physical performance (FERNÁNDEZ-ARGÜELLES *et al.*, 2015), in addition to decrease motor symptoms of Parkinson's disease, improve cognition (CARAPELLOTTI *et al.*, 2020), in addition to being a fun, pleasurable and common activity among the elderly (VERGHESE, 2006).

However, despite the many benefits that dancing can provide to the older population, it causes little or no improvement in muscle strength.(SERRA *et al.*, 2016).Thus, using dance together with strength training seems to be an interesting option for a complete physical training program for old peoples, following the WHO recommendations. However, to our knowledge, studies using the combination of these two modalities (i.e., strength training and dance) as an alternative for improving neuromuscular, cardiorespiratory and cognitive performance of old individuals have not yet been carried out.

OBJECTIVES

The general objective of this randomized controlled clinical trial is to identify and compare the impacts of traditional concurrent training and concurrent training consisting of strength training combined with dance classes on functional performance, cognitive function and quality of life in older people.

The specific objectives of of this randomized controlled clinical trial is to identify and compare the impacts of traditional concurrent training and concurrent training consisting of strength training combined with dance classes on:

- Dynamic balance
- Static balance
- Seat and stand capacity
- Climb stairs capacity
- Lower limb strength
- Hand grip strength
- Muscle thickness of quadriceps
- Specific tension of quadriceps
- Cardiorespiratory capacity
- Quality of life
- Cognitive performance
- Affectivity with the intervention
- Lipid profile
- Depressive symptoms

METHODS

Study type

This study is characterized as a Randomized Controlled Clinical Trial, with three arms in parallel and will follow the recommendations of CONSORT 2010 Statement (SCHULZ *et al.*, 2010).

Population and sample

The study will be carried out with the elderly population, who do not have disease or neuromuscular disorders. The sample will be voluntary, composed of men and women aged between 65 and 75 years, residents of the city of Porto Alegre-RS, who have not performed regular physical training for at least three months.

Eligibility criteria

Inclusion criteria: Be male or female aged between 65 and 75 years old; Do not practice regular physical exercises for at least three months; No history of competitive sports throughout life; Not having musculoskeletal and neurological diseases or disorders that may influence the performance of the exercises or affect the test results; Not having health conditions in which physical exercise is contraindicated; Achieve a score of no less than 24 on the Mini Mental State Exam; Achieve a score of up to 9.11 on the Baecke Physical Activity Questionnaire.

Exclusion criteria: Miss more than 20% of training sessions; Miss more than three workouts in a row; Failure to attend any of the evaluations will be excluded from the study.

Sample size

The sample calculation was performed based on the study by Rodrigues-Krause *et al.*, (2018) for the gait ability variable (TUG) (total $n = 27$, i.e. $n = 9$ individuals per group). The calculation was performed using the GPOWER version 3.1.9.4 program, in which $\alpha = 0.05$ and power of 95% were adopted. Anticipating possible sample losses, three more individuals will be added to each group (total $n = 36$).

Recruitment

Participants will be recruited through publicity using posters that will be posted at University, as well as published on the researchers' social media with the email and their personal phone. The responsible researchers will evaluate the eligibility criteria and verify if the individual has the necessary characteristics to participate in the project.

Randomization

Participants will be randomized into groups through <https://www.random.org/>. The person who will carry out the randomization will not be one of the researchers responsible for the evaluations. Participants will be informed of their group before starting training. Individuals who are randomly assigned to the control group, after the 12-week period, will be able to choose to participate in one of the physical exercise groups according to their preference.

Experimental design

Initially, an interview will be carried out via telephone (or in person for volunteers who do not have access to this means of communication), in which clarifications about the study will be carried out, as well as scheduling of the first visit. The first face-to-face visit will take place at the University, in which the participants will be introduced to the responsible research subjects, will receive the informed consent form and, if they agree with all the study procedures, will be invited to sign the term in two copies. In case of acceptance, the tests referring to the inclusion criteria will be applied (Baecke's Physical Activity Questionnaire, Mini Mental State Examination and Geriatric Depression Scale), as well the socioeconomic and quality of life questionnaires. If the volunteers reach the required score, respectively below 9.11 and above 24, the second visit will be scheduled. On the second visit, blood collection will be performed to assess the lipid profile.

Afterwards, the subjects will be scheduled for the third visit, in which the quadriceps muscle thickness and quality assessment, anthropometric assessments, as well as familiarization with the lower limb strength test will be performed. Physical tests will be performed on the fourth visit. After the evaluations, the participants will be randomly allocated to one of the two interventions or the control group. After 8 weeks,

a fifth visit will be held, where the physical tests will be reassessed, as well as the application of the questionnaire on affectivity with the intervention. At the end of the 12 weeks of training, participants will be reassessed on all tests.

Arms and Interventions

Traditional concurrent training: The subjects will perform two sessions per week of traditional concurrent training, consisting of strength training followed by aerobic exercise over 12 weeks, with progressive intensities and training volumes. Each traditional concurrent training session will consist of specific warm-up performed on equipment for upper and lower limbs with a load of less than 30% of the training load. Then the bench press, low row, leg press, extension and knee flexion exercises will be performed. Participants will be instructed to perform the concentric phase of the movement in one second and the eccentric phase in two seconds. After strength training, aerobic training (walking outdoors or on a treadmill) will be performed with intensity based on the adapted BORG effort perception scale (ranged to 0 = minimum effort, to 10 = maximal effort).

Concurrent training consisting of strength training combined with dance classes: Each concurrent training session associated with dance classes will consist of the same strength training as the traditional concurrent training group, but the traditional aerobic training will be replaced by a dance class. Each dance class will consist of a 5-minute general warm-up with joint mobility exercises and dynamic stretching. Then the main part will be performed with the elaboration of choreography, lasting approximately 20 minutes. Finally, there will be a 5-minute cool-down with stretching exercises. Classes will be held in four different dance modalities, divided into four modules.

Control group: Subjects will be instructed to maintain their usual routine during the study period. After the end of the 12 weeks, the participants in the control group will be able to participate in one of the exercise groups according to their preference. The Control Group is necessary in this study, since some of the variables analyzed still have little evidence of the effects of physical exercise. For this reason, in addition to comparing protocols, it is also interesting to compare the results with a group that will not perform physical exercise.

OUTCOME MEASURES

Cognitive performance: will be assessed through the Mini Mental State Examination (MMSE) which will be carried out following the recommendations of Lourenço & Veras (2006). The MMSE consists of answering a questionnaire with 11 open questions grouped into six categories: temporal and spatial orientation, processing, attention, calculation, evocation, language and constructive ability. The participant will be instructed to answer the 11 questions without asking for help.

Physical activity level: will be assessed using the questionnaire proposed by Simões (2009) which refers to the last 12 months of the elderly person's life and is divided into 3 domains. The first domain refers to daily life, the second to sports activities and the third to free time activities. The first domain will be evaluated according to frequency: 0= never, 1= sometimes, 2= almost always, 3= always, in this domain the sum of the answers is divided by the number of questions (10). Domains 2 and 3 will be evaluated according to codes: for intensity, weekly and annual duration. The product of the item codes for each activity is added across all activities, the sum of the different domains classifies individuals according to the level of physical activity: sedentary (< 9); active ($\geq 9 \leq 16$); and athletes (≥ 17) (SIMÕES, 2009). The cutoff point will be adopted in which individuals who reach a score ≤ 9.11 have a low level of physical activity; between 9.12 and 16.17 will be moderately active and ≥ 16.18 will be considered very active.

Depressive symptoms: will be measured using the Geriatric Depression Scale, that consists of 15 questions with binary answers (yes/no) and easy to understand. It ranges from zero (absence of depressive symptoms) to fifteen points (maximum score of depressive symptoms).

Socioeconomic Characterization: For sample characterization data, the elderly must answer the questionnaire from the Brazilian Association of Research Companies (ABEP, 2022) (Annex 6), which contains 15 socioeconomic indicators. The sum of answers generates a classification for the Brazilian population in strata from 0 to 100, being classes A, B1, B2, C1, C2, D and E).

Quality of life: will be assessed using the WHOQOL Questionnaire - ABRIDGED Version in Portuguese, following WHO recommendations (2011), which

consists of answering a questionnaire with 26 questions about your perception of quality of life. The participant will be guided to answer the questions with reference to the last two weeks. To complete the questionnaire, the individual will be instructed to circle the number that best represents their answer to each question, with 1 being the most negative answer and 5 being the most positive.

Anthropometric measurements: Body mass and height will be measured using a stadiometer and scale (0.1 kg resolution) (Urano, Canoas, Brazil). Waist circumference will be measured using a measuring tape (1 mm resolution).

Dynamic balance: will be measured using the Timed Up & Go test, according to the instructions by Podsiadlo & Richardson (1991), which consists of getting up from a standard chair (approximate seat height of 43 cm), walking a distance of 3 meters, go around a cone, walk back to the chair and sit down again.

Static balance: will be evaluated through the Single-Leg Stance Test performed according to the indications of Michikawa et al., (2009), which consists of remaining standing, with unipodal support as long as possible (with a limit of 60 seconds). The participant will be instructed to perform the test with the preferred leg.

Ability to sit and stand: will be evaluated through the 30s chair-stand test performed according to the indications of Rikli & Jones (1999), which consists of standing up and sitting on a chair as many times as possible during 30 seconds.

Ability to climb stairs: will be assessed using the Stair Climbing test performed according to the guidelines by Müller et al., (2021), which consists of climbing a ladder with 10 steps (approximate step height of 16 cm).

Muscle thickness: will be assessed by ultrasonography (Nemio XG, Toshiba, Japan) of the quadriceps. A transducer will be placed on the skin of the thigh of the individual's right leg, perpendicular to the tissue interface, after mapping the measurement site. The measurements will be performed with the participants lying down, after 10 minutes of rest and after 48 hours without vigorous physical activity. A water-based gel will be used to promote acoustic contact between the skin and the transducer. Three images of the rectus femoris, vastus medialis, vastus intermedius and vastus lateralis will be digitized and analyzed using Image-J software (National Institute of Health, USA). Measurements of the rectus femoris and vastus intermedius

will be taken at the midpoint between the greater trochanter and the lateral epicondyle of the femur, while the vastus lateralis will be at 30% of the distance from the lateral epicondyle of the femur to the greater trochanter. The subcutaneous adipose tissue-muscle interface and the muscle-bone interface will be identified, with the distance from the adipose tissue-muscle interface defined as muscle thickness. The thickness of the quadriceps femoris muscle of each leg will be considered as the sum of the four muscles mentioned.

Specific tension (TE): will be expressed as force per unit of muscle thickness and will be calculated by dividing the value of 1RM of knee extension by muscle thickness. Therefore, TE will be evaluated according to the following equation: $[TE = 1RM \text{ (kg) of knee extension} / \text{muscle thickness (mm)}]$

Lower limb strength: will be evaluated through the 1RM test for the knee extension exercise, following the recommendations of Cadore et al., (2013), which consists of performing the knee extension exercise with the highest possible load for one repetition complete.

Handgrip strength: will be assessed through the handgrip strength test in a Palmar Dynamometer (Jamar Hydraulic Hand Dynamometer), following the recommendations of the American Society of Hand Therapists (MACDERMID et al., 2015), which consists of squeezing the handle of the dynamometer as hard as possible for 3 seconds.

Cardiorespiratory capacity: will be evaluated through the 6-minute walk test according to the indications of Rikli & Jones (1999), which consists of walking the maximum possible distance in six minutes.

Affectivity through the intervention: will be measured through the Affective Valence Scale, proposed by Rejeski et al., (1987), which consists of answering a quantified scale from +5 to -5. The participant will be instructed to respond to the scale with reference to their feelings throughout the training session and dance class. The scale has values from +5 to -5 that correspond, respectively, to the feelings "very good" and "very bad".

Lower limb power output: will be evaluated in the knee extension exercise at 30 and 70% of 1 RM. For this, the individuals will perform 5 repetitions at the

maximum possible speed in the concentric phase at each intensity (30 and 70%) of the exercise. The interval between each execution will be 2 minutes. The maximum and average power values will be determined through a linear displacement sensor (ChronoJump, Barcelona, Spain), coupled to the equipment.

Lipid profile: plasma concentrations of total cholesterol, HDL and triglycerides will be determined by the colorimetric method with specific kits in an automatic analyzer (Cobas C111, Roche Diagnostics, Basel, Switzerland). In addition, LDL lipoprotein levels will be estimated using the Friedewald equation (1972).

ETHICAL CONSIDERATIONS

The present work was submitted to the Ethics Committee for Research with Human Beings of the Local University (CAAE: 5570222.0.0000.5347). It is noteworthy that the study will offer a greater than minimal risk to participants in compliance with Resolution N°466 of December 12, 2012 of the National Health Council. Finally, all study participants will sign the Free and Informed Consent Form (Annex 2) having the autonomy to withdraw their participation at any time. Confidential research data will be kept in a safe place, at the Exercise Research Laboratory, which the researcher is part of, for a period of 5 years.

Risks and benefits

The study presents a greater than minimal risk. During the performance of the evaluations and/or training, the participant may feel discomfort or late muscle pain and tiredness due to the intensity of the training. In addition, there is the possibility of some muscle injury occurring during assessments or training. As a way to minimize this risk, all participants will be familiarized with the exercises, will warm up beforehand, have a place to rest and water available throughout their participation and will be accompanied by qualified researchers. During the application of the questionnaires, there may be some embarrassment, since they will be carried out in the form of an interview. To minimize this risk, these assessments will be carried out in a private location. In addition, blood collections may cause small skin lesions,

however, it will be performed by a trained professional seeking to minimize this factor. All procedures may cause physical and mental fatigue due to the large number of questionnaires and evaluations performed. In this sense, to minimize this risk in any of the procedures, the elderly will be questioned periodically during the evaluations about their physical and mental state and if they report any symptoms of discomfort, a break will be held whenever necessary in an appropriate place. If any event occurs during the performance of the procedures, the responsible researcher will be responsible for any and all assistance deemed necessary, with the latter presenting a commitment to provide assistance for any material and immaterial damages resulting from participation in the research. Any type of major damage foreseen or not, resulting from participation in the study, in addition to the right to immediate, full and free assistance, participants will be entitled to compensation, according to items III.2.0, IV.4.c, V.3, V .5 and V.6 of the National Health Council Resolution 466/12.

As a benefit, participants will have feedback on their pre and post intervention results through an individual report. These data can be used to support future physical training, in addition to serving as an indicator of health status. In addition, the participants will benefit from the physiological adaptations provided by the training of the groups with interventions, as well as the gain in relation to functional valences such as gait speed, balance, muscle strength and cardiorespiratory fitness. In order to provide the same gains to participants in the control group, after the 12-week period, they will have the opportunity to carry out one of the proposed interventions according to their preference.

STATISTICAL TREATMENT

Results will be presented as mean \pm standard deviation. The distribution of normality and homogeneity parameters will be verified using the Shapiro-Wilk and Levene test respectively. Comparison of pre-training values between groups will be analyzed using one-way Analysis of Variance (ANOVA), regardless of data distribution, as ANOVA is robust enough for this (Sawyers, 2013). The effects of training will be evaluated using two-way ANOVA (time x group). If time x group interaction is observed, an analysis will be performed using one-way ANOVA with Tukey's post hoc test for group factor and repeated measures ANOVA for time factor. Significance will be accepted when $p \leq 0.05$. All statistical analyzes will be performed using SPSS software (version 25.0). The eta-square values will be used to analyze the effect size: small ($\eta^2 \geq 0.02$), medium ($\eta^2 \geq 0.13$) or large effect size ($\eta^2 \geq 0.26$) (COHEN, 1988). Individuals who do not complete the study will be analyzed using intention to treat. All assessments and data analysis will be performed by researchers blinded to the group of participants.

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