



Research Protocol

Effectiveness of multimodal circuit exercises for chronic musculoskeletal pain in older adults: A randomized controlled trial protocol

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Abstract

Studies have shown that musculoskeletal pain is one of the most prevalent health conditions that affects many individuals worldwide. In older adults, persistent pain is a widely prevalent and a disabling condition of multiple contributing factors: physical, mental, and social. Consequently, their quality of life is hampered. We aimed to analyze the effectiveness of a multimodal circuit exercise program on chronic musculoskeletal pain and disabling in older adults. This is a randomized parallel study (two arms) with blinded outcome assessments. The participants' recruitment will be done by a non-probabilistic sampling resulting from invitations to Basic Health Units (BHU). The sample size estimation indicated 164 participants. Participants will be allocated, by means of a randomization process, to one of two groups (82 for each group): Experimental Group (multimodal circuit exercise) or Control Group (cycle of multidisciplinary lectures on pain and stretching exercise). All analyses will be processed using the RStudio software, with significance when a p-value of 2 tails is less than 5% ($p < 0.05$). Statistical analysis will follow the intention to treat.

Trial registration: ClinicalTrials.gov NCT04719130, January 20, 2021.

Keywords: Aged, Exercise, Musculoskeletal Pain, Chronic Pain

Introduction

Chronic musculoskeletal pain can be defined as persistent or recurrent pain resulting from multiple physical, mental, social and age-related factors that directly affect bones, joints, muscles and soft tissues¹. It is one of the main causes of disabling in the elderly, leading to relevant impacts on the level of physical activity, functional mobility, mood, risk of falls and sleep quality^{2,3}. Much has been discussed about the importance of promoting an approach in pain management with its patients. Pain neuroscience education contributes to greater understanding, facilitating the process in which the patient deals with his/her pain, since each person has an individual experience about pain^{4,5}.

Recently, multimodal circuit exercises have been

recommended for older adults to increase physical-function and to prevent the risk of falls⁶. Multimodal exercises combine neuromotor skills and physical skills in the same physical training⁷⁻¹¹.

The authors have no conflict of interest.

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Edited by: Dawn Skelton

Accepted 20 February 2022

	Weeks							
	Selection	Allocation	Procedures					Conclusion
			B	I	PI	FU	FUP	
	8	0	1	12	1	12	2	4
Eligibility criteria	X							
Informed consent	X							
Allocation		X						
Intervention								
Multimodal workout circuit				X				
Stretching exercise program				X				
Assessment								
Numeric Rate Scale (NRS)			X		X	X		
Mini-Mental State Examination			X		X	X		
Geriatric Anxiety Inventory (GAI)			X		X	X		
Geriatric Depression Scale			X		X	X		
Short Physical Performance Battery (SPPB)			X		X	X		
The International Physical Activity Questionnaire (IPAQ)			X		X	X		
The Brief Pain Inventory (BPI)			X		X	X		
Independence Index in Activities of Daily Living (Katz Index - KI)			X		X	X		
6- minute walk test			X		X	X		
Time up and go test (TUG)			X		X	X		
Sitting and Standing on the Chair Test (30 seconds)			X		X	X		
Data Analysis							X	

Legends: B - Baseline; I – Intervention; PI - Post Intervention; FU- Follow up; FUP- Follow up post.

Table 1. Study timeline.

There is strong evidence of the use of exercises for adults with chronic low back pain demonstrating clinical improvement and reduction of functional limitations of practitioners^{12,13}. Exercise can contribute to decreased disability, improve symptoms and quality of life in a variety of chronic musculoskeletal pain conditions¹⁴, in addition, due to the lack of studies on the efficacy of exercise interventions in pain and disabling outcomes, there is inconsistent evidence regarding the description of which types of exercises could reduce these outcomes in older populations^{3,15-18}.

Thus, there is a gap in the literature regarding the association between the practice of multimodal circuit exercises and its effects on chronic pain and disability in the elderly.

The present study aims to analyse the multimodal circuit exercise program's effectiveness in chronic musculoskeletal pain and disabling in the older adults.

Methods

Study design

We designed a randomized controlled trial with two parallel groups (control group and experimental group) with a blinded outcome assessment. Table 1 shows the study timeline. This project will be carried out in Basic Health Units (BHU) in the city of Palmas (Tocantins, Brazil).

Participants

All Basic Health Units - BHU in the city of Palmas will be invited to participate in this study.

The inclusion criteria are participants from both sexes, aged 60 or higher, who had a history of chronic pain in at least one synovial joint for more than three months. The existence of one or more sites of chronic pain on the day of the interview will be investigated through the following

question: "Have you had pain in any areas of your body in a persistent or recurring way for over three months?" After an affirmative response, participants will be asked about the presence of one or more sites of pain. To facilitate identifying the exact sites of pain, an illustration of the human body, with anterior and posterior perspectives, will be used.

The participants will be excluded if they present: some types of comorbidities that may interfere with the research parameters, such as a history of stroke, stenosis of the spinal canal, severe heart disease, fibromyalgia (because it does not present a localized specific joint chronic pain), rheumatoid arthritis; present a level of pain between 7 and 10 points on the Numeric Rate Scale (NRS) in any body location (pain above 7 points, presents itself as severe, disabling; unable to perform activities of daily living, requiring specialized individual care); being under psychiatric treatment; with sensory deficits (visual, auditory and intellectual) and if they were performing any supervised and structured exercise at the moment of study enrollment or six months before (participants with supervised physical activity who already receive some type of therapy).

Participants will be randomized into two groups: Experimental Group (EG): multimodal circuit exercise developed by the researcher in the Basic Health Units (BHU) or Control Group (CG): cycle of multiprofessional lectures on pain and stretching exercises developed in the Basic Health Units (BHU).

For this process, we will use a random sequence generation and randomization block of 4, 6, 8 participants to ensure a balanced number of participants in each group. Randomization will be performed by a researcher not involved in the recruitment, evaluation or treatment of participants. The allocation will be hidden and performed by an independent researcher using opaque and sealed envelopes containing the descriptions of the groups. The groups will not know of each other's existence, because each group is being the group concentrated in different UBS so that it has no influence on the research, ensuring the blindness of the research. As baseline collections, the primary and secondary results will be performed by independent researchers according to the criteria of the PEDro (Physical Therapy Evidence Bank), maintaining the blindness of evaluators and statisticians, being the responsibility of the responsible researcher, only the interventions of the post-allocation groups.

The sample size analysis estimated a total of 164 participants (82 in each group), based on the following parameters: two-way analysis of variance (repeated measures; within-between interaction) effect size: 0.10; type 1 error=5%; Type 2 error=20%; group number=2; measure number=3. The software used was the G*power (version 3.1.9.6). A small effect size (0.10) determined a priori is considered important at this stage of the project to eliminate the possibility of underpowered results. This decision was made considering the absence of studies with a similar design to provide a real based effect size.

Hypothesis and Justification

The study is justified by the intention to use field collection to measure and compare the pre- and post-intervention results of the research participants who attend the Basic Health Units-BHU and their variables through statistical treatment and discussions comparing two groups: Experimental Group (EG) and Control Group (CG). We start with the question of the following research problem: Can physical exercise performed in a multisensory way (working functional balance, strength, postural control, among others) provide control and reduction of chronic pain and, consequently, improve the quality of life of the elderly participants in the research when compared to the control group? Considering that multimodal exercises have been strongly recommended to improve physical and functional components, in the present study, we hypothesize that this type of exercise could also reduce the pain and disabling of the elderly, that is, that the EG group will present more satisfactory results in relation to the CG. Based on these considerations, this study becomes relevant in order to investigate the effect of physical exercise performed with a multisensory circuit in the treatment of chronic pain and, consequently, improvement in the quality of life of the elderly participants who attend Basic Health Units – BHU in the municipality of Palmas-TO, considering the relevance, accessibility and efficacy of the training proposal to be applied.

Assessment procedures

Baseline assessments

Participants will be evaluated at their BHU for eligibility through the following protocols:

Numeric Rate Scale (NRS) - The Numeric Rating Scale (NRS)¹⁹, will be used to measure pain intensity in adults in a single dimension. Participants who present a pain level between 7 and 10 points on the NRS in any part of the body will be excluded from the research.

Anamnesis – Simplified questionnaire used to identify if there were recurrent falls (two or more in the last 12 months), and if the participants performed any supervised and structured exercise at the time of enrollment in the study or six months before, as well as any pathologies.

Mini-Mental State Examination²⁰ - Neuropsychological test, which superficially addresses the cognitive function of the elderly, such as questions related to recent memory and immediate memory recording, temporal and spatial orientation, attention and calculation and language - aphasia, apraxia and constructional ability .

Short Physical Performance Battery (SPPB)²¹⁻²⁴ - Test used to verify the level of functional independence of the lower limbs in the elderly.

Participants included will be invited to participate and sign the Informed Consent Form. On the same day, the included participants will answer a questionnaire to verify sociodemographic, economic, anthropometric parameters, physical activity level.

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE (IPAQ)	
Very Active: the one who followed the recommendations for duration and frequency:	
a) VIGOROUS	5 days/week and =30 minutes per session
b) VIGOROUS	3 days / week and = 20 minutes per session + MODERATE and /or WALK: = 5 days / week e = 30 minutes per session.
Active: the one who followed the recommendations of:	
a) Vigorous	3 days / week and = 20 minutes per session.
b) Moderate or Walk	5 days / week e = 30 minutes per session) Any activity added: = 5 days / week e = 150 minutes / week (walking + moderate + vigorous).
Irregularly Active: one who performs physical activity but is insufficient to be classified as active because it does not meet the recommendations regarding frequency or duration:	
Irregularly Active A	One who meets at least one recommendation criteria regarding frequency or duration of activity: a) Frequency: 5 days week or b) Duration: 150 min/week.
Irregularly Active B	One who has not met any of the recommended criteria for frequency or duration.
Sedentary	One who has not performed any physical activity for at least 10 continuous minutes during the week.

Table 2. International Physical Activity Questionnaire (IPAQ).

In addition to the above questionnaire, the Geriatric Anxiety Inventory (GAI)²⁵ and the Geriatric Depression Scale^{26,27} will also be applied.

The International Physical Activity Questionnaire (IPAQ)^{28,29} will be used to assess physical activity. This questionnaire allows estimating the weekly time spent in moderate and vigorous physical activities in different contexts of daily life, classified as shown in Table 2.

Presence of Chronic Pain

At the baseline, the existence of chronic pain in one or more sites at the time of the interview will be investigated with the following question: - "Do you have pain in any body region persistently or recurrently for more than three months?" In the case of an affirmative response, participants will be asked about its presence in one or more sites. To discriminate the site(s) of musculoskeletal pain, a picture of a person in the supine/prone and standing position will be presented to the participants.

Outcomes investigated

The first meeting with the study participants will be finished with primary outcomes evaluation. The collection will be carried out in a room inside the BHU with privacy and comfort so that the participant is not embarrassed during data collection. Secondary outcomes will take place on a second day according to the participants' schedule. For this second meeting, participants will receive instructions on the best clothes and shoes to perform the tests.

Primary outcomes

Pain intensity

To assess the pain intensity, two evaluation protocols will be used, according to the recommendations of the Initiative

on Methods, Measurement, and Evaluation of Pain in Clinical Trials (IMMPACT)³⁰. The Brief Pain Inventory (BPI)^{31,32} a multidimensional, easily used questionnaire, aiming to diagnose a patient's chronic pain during the last 24 hours.

The Numeric Rating Scale (NRS)¹⁹ will be used to measure pain intensity in adults in a single dimension.

Disabling

To assess functional disabling in the elderly, we will use the Independence Index in Activities of Daily Living (Katz Index - KI)^{33,34}. This Index has two versions: the original version with seven items and the new modified version with six items. The new version, which will be used in this study, contains six basic functional tasks: bathing, dressing, going to the bathroom, transfer, bowel and bladder control, and feeding.

Secondary outcomes

Cardiorespiratory capacity

We will use the 6-minute walk test^{35,36} will be applied to assess an individual's response to exercise. The participants try to cover the longest possible distance in five minutes. They are authorized to stop walking in case of extreme fatigue or another limiting symptom, enabling the patient to determine the rhythm of walking

Functional mobility

Scaled through the time up and go (TUG) test³⁷⁻³⁹ will assess how long the subject takes to stand up from a chair, at 43 to 46 cm from the floor, walk 3 meters, go around a marker, return to their seat and sit down. The longer that period, the lower their performance. The time score for performing the test in seconds is considered: 10 s (normal for healthy adults); 11 to 20s (important predictor of functional disabling); 12s (Normal for community older adults).

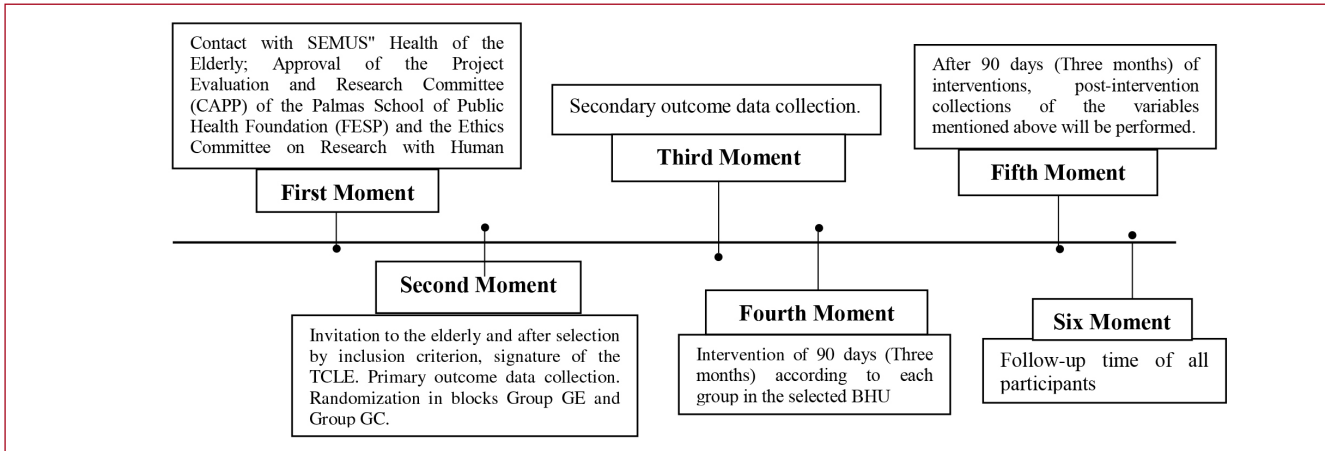


Figure 1. 6 (six) project steps.

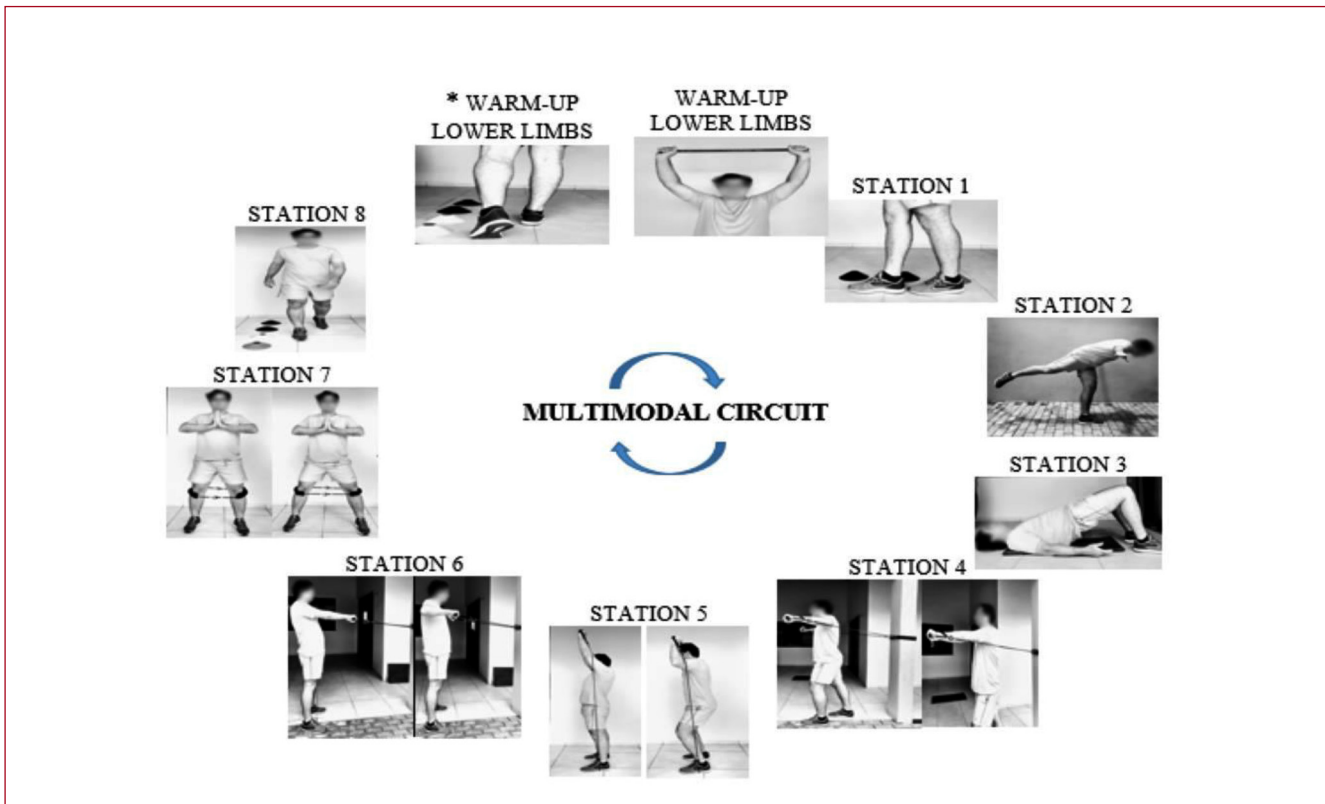


Figure 2. Multimodal Circuit. * Indicate the first exercise program.

Physical and Functional Fitness

Sitting and Standing on the Chair Test (30 seconds)^{40,41}, used to assess the strength and resistance of the lower limbs (number of executions in 30" without the use of the upper limbs).

Figure 1 describes in the timeline the six steps of the project.

Description of the interventions

Experimental group - The experimental group performs a circuit of structured and supervised multimodal exercises

Exercises/stations	Aim	Materials	Volume/Intensity
Light walk	Lower limb warm-up	-	5'
Shoulder flexion	Upper limb warm-up	Wooden or plastic stick	2 series of 12 repetitions (30" to 120" of RI)
1- Tandem gait	Motor coordination	Mini cones	180"
2- Single leg ("airplane")	Balance	-	180"
3- Hip bridge exercise	Strength training	Mat	2 series of 12 repetitions (interval of 30" to 120" between series)
4- Bench press	Strength training	Elastic bands	2 series of 12 repetitions (interval of 30" to 120" between series)
5- Squat	Strength training	Elastic bands	2 series of 12 repetitions (interval of 30" to 120" between series)
6- Rowing	Strength training	Elastic bands	2 series of 12 repetitions (interval of 30" to 120" between series)
7- Lateral steps	Strength training	Elastic bands	2 series of 12 repetitions (interval of 30" to 120" between series)
8- Walking	Aerobic resistance	Mini cones	180"
Global body stretching cool-down.	Stretching	Mat	10'

Legends: RI: rest interval.

Table 3. Multimodal Circuit Workout Program.

Professional	Theme/Lecture	Local
Medicine	The role of medication in chronic pain	BHU
Physical education	Exercise, stress reduction and quality of life	BHU
Nursing	Prevention of chronic-degenerative diseases	BHU
Social work	Physical and mental well-being	BHU
Psychology	Relationships between pain, emotion and depression	BHU
Physiotherapist	Movement and fear of movement	BHU

Table 4. Table of forecasts of meetings and lectures on pain and health education.

twice a week, during 12 weeks of execution in the order described in Table 3. To provide gradual adaptations on postural and neuromotor responses, in the first week of familiarization, the intensity level will be "low perceived" by participants (1 to 4 in scale) by the use of the OMNI Resistance Exercise Scale (OMNI-RES)^{42,43}. The multimodal exercise sections will have a total duration of 50 minutes, being divided by execution time or series according to each station, as described in Table 3, totaling 1 lap per circuit per training section. The circuit was organized alternating the order of balance exercises, upper limbs, lower limbs and aerobics, with no recovery intervals between exercises, only 30 to 120 seconds interval between sets. The volume and intensity progressions will be controlled and adjusted according to the need and development of each participant.

Figure 2 corresponds to the images of the multimodal circuit proposed for this study with the exercises and series mentioned in Table 3.

Control group - The stretching exercise program will be performed twice (2) per week for 90 days, in a placeholder within the Basic Health Units - BHU. A cycle of multidisciplinary lectures on pain will be offered by professionals of Physical Education, Nursing, Physiotherapy, Medicine, Psychology and Social Work. The lectures will take place in the Basic Health Units every 15 days. In total, six lectures will be held lasting around 45 minutes each as described in Table 4.

Statistical Analysis

The characteristics of the participants will be presented using descriptive statistic tests. The Kolmogorov-Smirnov

test will confirm the data normality assumptions, and appropriate measures will be adopted, such as median and interquartile range or mean and standard deviation.

The between-group differences will be verified by an Analysis of Variance considering three time points (pre-intervention, post-intervention, and follow-up) and two groups (experimental and control). The intervention effects will be adjusted for the baseline characteristics. The Bonferroni Post-hoc method will be used if a statistically significant difference was found between groups. Levene's tests will confirm homogeneity. The analysis will follow the intention to treat principle⁴⁴. 41 Multiple imputations will be carried out using predictive values from regression analysis for dealing with missing data.

All analyses will be carried out using RStudio Software (version 1.1.463 – RStudio, Inc.) with a significance level $p \leq 0.05$ was adopted to all variables.

Ethics approval

Approved by the Project Evaluation and Research Committee (CAPP) of the Palmas School of Public Health Foundation (FESP), Protocol: 28013.56Xov6b*zq45k and by the Ethics Committee on Research with Human Beings (Plataforma Brasil), CAAE: 26526119.0000.5519. Research Ethics Committee, CAAE: 26526119.0.0000.5519, protocol n. 3.986.922.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

This work is funded by the Decanato de Pós-graduação (DPG) of University of Brasília (UnB), process nº 11/2019, and by the Master and PhD Program in Physical Education (PPGEF/UnB; Public Call Notice PPGEF 01/2020).

Acknowledgments

The authors would like to thank the University of Brasília, and the employees of SEMUS (Elderly Health – Palmas, TO) and FESP (Palmas-TO School of Public Health Foundation) for the apio and guidance for the UBS and access to volunteers participating in the study.

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