

Acute blood pressure behavior in hypertensive elderly people after a strength training session under the superserie method: Study protocol for a randomized clinical trial

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Abstract:

Background: Chronic degenerative diseases have increased significantly, among them, systemic arterial hypertension (AH) stands out. The treatment of hypertension includes, in addition to specific hypotensive drugs, regular physical exercise. However, even though it is strongly recommended in national and international guidelines, the acute and subacute effects of physical exercise on the regulation mechanisms of the blood pressure system in different types of exercises still require further studies, especially regarding strength training and its methods in elderly people, which at least to our knowledge, there are not many studies published to date on this topic. Strength training has metabolic characteristics related to moderate intensity, a safe factor when it is related to the elderly, and can be an important ally for controlling the blood pressure system in this group. **Objective:** To evaluate the effects of a strength training session on blood pressure behavior in elderly people with hypertension. **Methods:** This is a randomized crossover clinical trial protocol. The minimum sample size was determined based on a previous study published by our research group. The size of 30 individuals was estimated, using a significance level of 5%, power of 80%, and a difference of 5mmHg in systolic blood pressure, after being included in the study, they will undergo a battery of tests, in order to outline their physical-functional and metabolic profile, and will be allocated into two protocols: CP (control protocol) and EP (experimental protocol). Control session, without exercise, and the EP which consists of a strength training session, using a superserie method. The blood pressure will be measured before the protocols, immediately after (minute 0), and at minutes 15, 30, 45 and 60 after. Individuals will perform the other protocol, featuring the crossover design. Expected results: It is expected that by carrying out this study, we will obtain the hypotensive effect as well as contribute to the understanding of the effects of strength training under the superserie method on blood pressure levels in elderly people with hypertension, and its real practical applicability.

Keywords: Elderly; arterial hypertension; physical exercises; strength exercises.

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Received: 05 Dec, 2023.

Accepted: 03 Feb, 2024.

Published: 20 Feb, 2024.

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BACKGROUND

According to the World Health Organization (WHO), the aging of the population is directly linked to the country's development, and it is understood that elderly people in developing countries are 60 years old or older, whereas in developed countries they are considered elderly at 65 years old^(1,2).

According to the National Household Sample Survey (PNAD) carried out by the Brazilian Institute of Geography and Statistics (IBGE), in 2019 the total Brazilian population was 210,1 million, and among this population 34 million are elderly, representing 16,2% of the national population of the total of 210.1 million Brazilians, 34 million were elderly in the 4th quarter of 2019⁽³⁾. In line with Dieese⁽³⁾, Bomfim et. al 2022, make a projection at a global level, estimating the increase in the elderly population, going from 1 billion in 2019 to 1.4 billion in 2050, while on a national level, the projection estimates an increase of 38,7% in 2060⁽⁴⁾.

The old age is a stage of life, considered an integral part of the natural and biological cycle and constitutes a unique and differentiated experience, where this event is a physiological process that occurs in a degenerative way characterized as natural processes in which morphological, functional changes, biochemical and psychological represent a relationship between the organism's autonomy and adaptation to the external environment. This induces greater susceptibility in individuals coupled with greater vulnerability to physical and physiological dysfunctions⁽⁵⁾.

The aging process is associated with significant changes in the immune system, compromising the functioning of all systems, including cellular dysfunctions, opening the door to possible chronic diseases that are associated with the age factor⁽⁶⁾. However, this same process can be maximized or minimized according to the lifestyle that the person adopts throughout their life. We are, therefore, faced with a group that, in many circumstances, finds itself in vulnerable conditions⁽⁴⁾, bad habits such as poor nutritional quality, smoking, high-stress levels, lack of sleep, physical inactivity along with aging also contribute to cellular and vascular dysfunctions, events that cause vascular remodeling, endothelial dysfunction and vascular stiffness, common events also in systemic arterial hypertension (AH), a pathology prone to the elderly, due to aging processes^(7,8).

AH is a chronic non-communicable disease, characterized by a persistent elevation in blood pressure (BP), that is, systolic BP (SBP) greater than or equal to 140 mmHg and/or diastolic BP (DBP) greater than or equal to 90 mmHg, measured with the correct technique, on at least two occasions⁽⁹⁾.

AH is an increasingly prevalent disease in our society, affecting all age groups, people aged 18 or over who were diagnosed with high blood pressure in Brazil were 23.9% in 2019, which corresponds to 38.1 million people. However, the increase in blood pressure levels has been more prominent in the elderly population, with people aged 60 to 64 being 46.9%, 56.6% among people aged 65 to 74, and 62.1% among the population aged 75 or older⁽¹⁰⁾.

Some factors are identified as additional risks for the development of hypertension, such as genetics, age, sex, ethnicity, overweight and obesity, sodium and potassium intake, physical inactivity, alcohol, smoking, socioeconomic factors, and in addition to these common factors prevalent in our society, factors such as the use of prescribed drugs and illicit drugs can contribute to the risk, as well as obstructive sleep apnea, thus increasing the likelihood of developing the disease^(9,11). These risks are closely linked to other factors that can be developed as a result of the complication of AH, such as cerebrovascular disease, coronary artery disease, heart failure, chronic renal failure, and vascular disease of the extremities⁽⁹⁾.

Among the measures that aim to reduce blood pressure levels in people with hypertension are pharmacological and non-pharmacological measures. Pharmacological measures are the use of antihypertensive medications, there are 7 classes of antihypertensives most used in clinical practice, which are: diuretics (IUDs), adrenergic antagonists, direct vasodilators, and channel blockers. calcium (CCB), angiotensin-converting enzyme inhibitors (ACEI), angiotensin receptor blockers (ARB), and direct renin inhibitors. The group of adrenergic antagonists can be divided into 3 classes: central α -2 agonists, β -adrenergic blockers (BB), and α -1 adrenergic blockers. And the non-pharmacological ones are weight control; dietary patterns; reducing salt consumption; Moderation in alcohol consumption and physical exercise (PE)^(9,12,13).

It is already known that the aging process causes, in a degenerative way, several physical, physiological, and psychological changes, naturally and progressively as age advances, leading to the involvement of several diseases, including AH^(14,15).

According to Barroso et. al⁽⁹⁾, around 65% of people over 60 years old have AH, and we must consider the epidemiological transformation that the country has been undergoing, with an even greater number of elderly people (≥ 60 years old) in the coming

decades, will result in a substantial increase in the prevalence of HA and its complications.

Although PE and physical activity are often used to designate the same action, they are not synonymous, disassociating them, physical activity can be defined as any activity that generates movement, contraction of skeletal muscles producing an increase in the need for energy expenditure above the basal state, PE is a systematized activity, that is; evaluated; organized and planned, with a sequence of movements to achieve a goal, generally linked to health, physical strengths or sports performance⁽¹⁶⁾.

Current evidence shows that physical exercise provides health benefits for the elderly, maintaining functional independence and improving their quality of life. In a systematic review, 110 articles published between 2011 and 2016 were selected, of which 12 were selected for their final analysis, considered in the inclusion and exclusion strategies, and the result of this research, raises and reinforces the idea of the positivity of physical exercise for with the elderly, especially those considered frail, and there were benefits in functional aspects, such as increased handgrip strength, lower limb strength, mobility, physical performance, muscle mass, balance, gait speed and increased step length; aspects related to quality of life, such as reducing the incidence of falls. The article also suggests an intervention, with multicomponent PE, considering it ideal to include resistance, balance, gait, and muscular strength exercises for this population⁽¹⁷⁾.

The benefits of PE on all physiological systems are already in the literature, as well as researchers' interest in analyzing its effects in pathological groups, including the hypertensive elderly, is growing even more like evidenced in a meta-analysis study that included 71 studies on strength exercise in adults and elderly people. MacDonald and colleagues (2016) investigated the effects of strength training (ST) on BP control, and the results were promising. The authors observed that SBP had a significant reduction, with a mean of 5.7 ± 9 mmHg for SBP and 5.2 ± 8.4 mmHg for DBP⁽¹⁸⁾.

Aiming to improve exercise prescription for hypertensive elderly people, given that, in the literature, there are greater blood pressure reductions in hypertensive patients after aerobic exercise and probably the same relationship is maintained in strength exercise, justifying this research^(19,20,21).

Therefore, we seek to validate this protocol, to carry out a controlled, randomized, and crossover clinical study, to verify the acute blood pressure of the hypertensive elderly after a strength training session (STF). For AH sufferers, this work may provide and reaffirm knowledge of yet another non-pharmacological tool, taking into consideration the superseries method – alternated by follow-up as a safe variant for treating the disease.

Goals

Argument and validate the protocol that we will use to evaluate the acute BP responses of hypertensive elderly people after STF in a crossover randomized clinical trial.

Specific objectives

Determine the clinical and physical profile of the sample.

Evaluate blood pressure effects before, immediately after, and up to 60 minutes after the experimental and control protocol.

Compare blood pressure responses between experimental and control protocols

METHODS

Materials and methods

This is a clinical study that follows the recommendations of CONSORT Statement⁽²²⁾.

Kind of study

The present study is a randomized, crossover-controlled clinical trial.

Sample

The minimum sample size was determined based on a previous study published by our research group. The size of 30 individuals was estimated, using a significance level of 5%, power of 80%, and a difference of 5mmGh in Systolic Blood Pressure⁽²¹⁾.

We will select hypertensive elderly people pre-registered at an exercise program of a university of the city, according to the inclusion and exclusion criteria proposed in the project. They will be contacted via telephone to schedule a formal visit to express the invitation to the study. Participants will perform 2 protocols: one experimental (EP), with strength exercises; and another control (CP), without performing exercises, in a crossed methodology, where a list will be generated after the inclusion of participants, and individuals numbered as pairs will start in the Experimental Protocol (EP), executing the Control Protocol (CP) after 72 hours, and individuals in odd numbers will start on the PC and after 72 hours they will perform the PE.

Study design

The study will be carried-out in gym of a sportive club of the city. After the invitation, patients will be informed about the study and, if they agree, they will sign the informed consent form. They will undergo a clinical and physical evaluation to define the inclusion and exclusion criteria for the study. A date will be scheduled for a familiarization session at the gym, where load test⁽²³⁾ will also be carried out to define the load to be used in the EP. They will then be randomized into 2 protocols: Experimental protocol (EP) and control protocol (CP).

EP consists of a STF, with 6 exercises involving large muscle groups of the lower and upper limbs, in addition to biceps and triceps under superserie method. The CP will be a non-exercise session. After 72 hours, individuals will perform the crossed protocol (those who performed the PE will perform the CP, and those who performed the CP will perform the EP), as shown in Figure 1, below.

Inclusion criteria

As inclusion criteria, all patients must sign the Free and Informed Consent Form, age between 65 and 80 years old, undergoing regular treatment and using antihypertensive medication, not be enrolled in no systematic physical training program for a period equal to or longer than 45 days, with stable blood pressure, without changing medications in the last 2 consultations. Systolic Blood Pressure (SBP) must be equal to or below 160 mmHg and Diastolic Blood Pressure (DBP) equal to or below 100 mmHg.

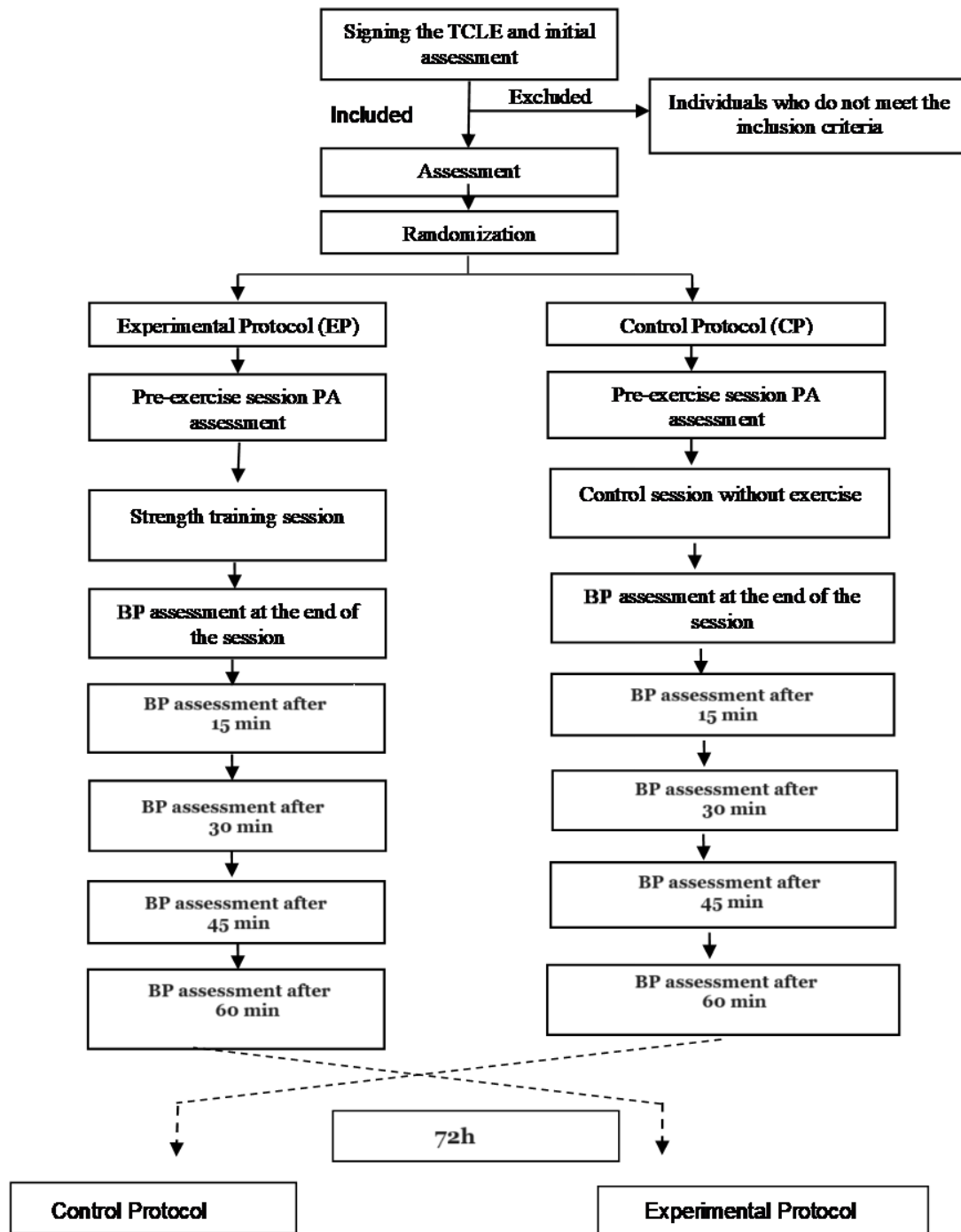


Figure 1: Study Protocol

Exclusion criteria

As exclusion criteria, body mass index $BMI \geq 35 \text{Kg/m}^2$ (WHO), decompensated diabetes mellitus, decompensated chronic heart failure (CHF), recent cardiovascular event (last 3 months), chronic renal failure (CRF), liver disease, limitations orthopedics or any physical or mental limitation that prevents the performance of the exercises.

Criteria for study suspension

The research will be suspended in case of non-compliance with the project, as well as lack of responsibility and serenity with the research. If there is no adherence on the part of the target population to participate in activities and others that make it impossi-

ble to create a statistically viable sample, it will be possible to re-discuss the project outline, suspend it or even close it.

Randomization method and maintaining confidentiality of the allocation list

The randomization technique will be carried out using a computer program (www.randomizer.org) containing the coded distribution. Allocation confidentiality will be guaranteed by a randomization list that will be located in a remote location, which will prevent the researcher from identifying which intervention will be initiated by each patient. The generation of the sequence of numbers will be done by a researcher "blind" to the study, after selecting patients according to the inclusion and exclusion criteria. The sequence of numbers to be used for randomization will be kept confidential until the exact moment the experiments begin.

STUDY PROTOCOLS

Experimental Protocol

The experimental protocol will consist of super series strength training, containing 6 exercises in accordance with the training prescription guidelines for the elderly and hypertensive patients, which will be adapted to the dimensions of the proposed work^(20,21). The following exercises will be used: Closed Anterior Pulley, Incline Bench Press, Seated Chair Flexor, Chair Extension, Dumbbell Curl, Triceps Pulley. The session will consist of 3 sets, of 10 repetitions, with a load of 75%1RM, 1 minute-interval between series and exercises using superserie method (combination of 2 related exercises for maximize the muscle work, where the exercises will be carried-out without pause). The valsalva maneuver will be discouraged throughout EP.

Control protocol

In the control protocol (CP), individuals will not perform any type of systematic physical exercise for a period similar to the EP session (around 45 minutes), but will have all blood pressure measurements taken in periods similar to the PE. Individuals will be allowed to stand, sit, talk and drink water.

Assessments

Anthropometric assessment

The BMI assessment will be carried out based on the identification of height, using a stadiometer graduated in centimeters and with an accuracy of 1 mm, Sanny brand, and body mass, using an electronic scale, with an accuracy of 0,05 kg, made by Welmy. The BMI classification will be by the World Health Organization (1995)⁽²⁴⁾. The abdominal circumference will be measured using a Sanny measuring tape, with a precision of 1 mm, at the point of greatest abdominal circumference, parallel to the ground.

Statistical analysis

The collected data will be tabulated in the Microsoft Excel program and analyzed using the SPSS software (StatisticalPackageof Social Science – version 22.0, Chicago, IL, USA). The Kolmogorov-Smirnov test will be used to verify whether the numerical data presented a normal distribution. The Student t-test for paired samples will be used in intragroup assessments, comparing pre-and post-training. For intergroup assessments with pre- and post-training, analysis of variance (ANOVA) followed by Bonferroni

post-hoc will be used. The Wilcoxon test will be used for data that do not present a normal distribution. Correlations will be made using Pearson, when applicable to a normal distribution, or Chi-square, in opposite cases. All analyses will be carried out by intention to treat and the significance level adopted will be $p < 0.05$.

Ethical aspects

The selection of patients with AH, as well as the evaluation and carrying out of the experiments, will begin after the project is approved by the Ethics Committee, mediated by Plataforma Brasil. All data collected will be confidential. All information will be confidential, the participant's name will be kept confidential and the data obtained will only be for academic purposes. All data will be archived for five years and after this period, it will be incinerated, as per guidance in CNS Resolution N 466/12.

Risks and benefits

This research presents the risk of constraints regarding the initial clinical assessment questionnaire, which may contain some questions interpreted as invasive, but necessary for the progress of the research. Therefore, the team will be trained to conduct such a moment; Risks of dizziness, nausea, and discomfort, as well as risks of small muscle injuries, can occur when practicing any type of exercise. However, these risks decrease with the monitoring and support of researchers throughout the research. The study will contribute to a better understanding of BP blood pressure responses in elderly people after strength training. Individuals will have all the results of their exams and monitoring during the development of the tests and research, and if they wish, they will be informed about the results of the study.

EXPECTED RESULTS

It is expected a positive BP effect regarding the hypotensive factor in hypertensive elderly people after undergoing an STF under the superserie method.

Author Contributions: Authors RMC and WGC contributed equally to the writing of this study protocol.

Financial Support: Authors RMC and WGC contributed equally to the writing of this study protocol.

Funding: The author WGC would like to thank the Fundação de Amparo a Pesquisa do Estado de Goiás (FAPEG) for the Master's Degree research grant process number FAPEG - 202110267000525.

Conflict of interest: The authors declare not conflict of interest.

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