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STUDY PROTOCOL

Acute blood pressure responses of hypertensive patients after multimodal training session: Protocol study

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Abstract:

Background: Systemic arterial hypertension (SAH), as well as other chronic degenerative diseases, has been growing around the world. In this context, physical exercise is presented as a non-pharmacological strategy both in the treatment and in the prevention of this disease. Although pressure responses to strength and aerobic exercise are vast in the literature, in high-intensity multimodal exercises they are very scarce. **Objectives:** To develop a study protocol on the acute effects of blood pressure after a high-intensity multimodal training session in adult hypertensive individuals through a randomized crossover clinical trial. **Methods:** This is a controlled crossover clinical trial to evaluate the acute responses of blood pressure after a multimodal training session in hypertensive patients. 20 hypertensive adults will be recruited, who, after inclusion in the study, will perform 02 protocols with an interval of 07 days, one session of high-intensity multimodal exercises, and a control session (without exercises). Blood pressure (BP) will be measured before, immediately after, and for 60 minutes after carrying out the protocols. **Results:** The designed intervention is expected to provide additional information on the behavior of (BP) hypertensive individuals in the practice of multimodal exercises.

Keywords: Multimodal training; blood pressure; hypertension; high-intensity exercise.

BACKGROUND

Systemic arterial hypertension (SAH), as well as other chronic degenerative diseases, has been growing around the world[1, 2]. It is a multifactorial clinical condition characterized by high and sustained levels of blood pressure (BP). BP is often associated with functional and/or structural changes in target organs (heart, brain, kidneys, and blood vessels) and also with metabolic changes, with a consequent increase in the risk of fatal and non-fatal cardiovascular events[3, 4]. Because SAH is present in the organism in a multifactorial and polygenic form, its etiology is difficult to diagnose. The risk factors that lead to SAH and the actions to deal with these also deserve to be highlighted[5].

As it is a chronic disease, the control of SAH requires monitoring and treatment throughout life, involving pharmacological measures, with the use of antihypertensive medication, and non-pharmacological measures with lifestyle changes: eating habits, behavior, and exercise. physicist. Important about physical activity stand out due to its action both in the control and gains in the treatment of SAH.

Several studies have pointed out the beneficial effects of physical exercise[6-8], and its positive effects occur both acutely after performing a single exercise session[9, 10], and chronically, after performing several exercise sessions[11, 12]. Post-exercise hypotension (PEH) is an expected and beneficial acute effect for this public, which is characterized by a decrease in BP after exercising, mediated by an increase in vasodilator substances[13], a decrease in cardiac output[6], and peripheral vascular resistance[14], in addition to improving sympathetic nerve activity[15], which will chronically ensure a decrease in BP in hypertensive patients, often allowing the physician to reduce or even abolish antihypertensive drugs, due to the patient's blood pressure control[8, 16].

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In addition to the direct benefits of the disease, physical exercises are related to functional improvement[17] and quality of life[18], reduction in the percentage of fat[19], increase in strength and muscle mass[20], metabolic control with improvement in glycemia[21], lipemia[22], and several other related parameters to health.

The prescription of aerobic and strength exercises for the treatment of SAH is widely studied and is even well established by the main global guidelines in the area[23-25]. On the other hand, studies with multimodal exercises, which are composed in their prescription by different types of exercises and modalities in a single session, such as Cross training[26], performed at high intensity, are extremely scarce when related to the hypertensive public. Thus, the objective of this research is to develop a study protocol with the acute effects of BP after a high-intensity multimodal training session in hypertensive individuals through a randomized crossover clinical trial.

METHODS

This is a randomized, controlled, and crossover study to be carried out with patients with systemic arterial hypertension (SAH) living in the city of Rio Verde (Goiás, Brazil). The sample will consist of 20 participants, men and women according to the order of recruitment, based on the inclusion/exclusion criteria mentioned below. The sample calculation was performed according to data from the study by Cunha et al[27], where a minimum systolic BP of 5 mmHg was considered, with a standard deviation of 10 mmHg, to be detected by t-test for dependent samples (training or control) power statistical value of 80% and the accepted error $P<0.05$.

Participants with SAH will be selected from advertisements in print and digital media in the city of Rio Verde (GO), Brazil. The participants will perform two protocols in cross methodology, where a list will be generated after the inclusion of the participants, establishing who will start in the Experimental Protocol (EP), executing after 1 Week, the Control Protocol (PC), and the individuals will start in the PC and after 1 week they will perform the PE.

Inclusion criteria

Will be included in the study volunteers of both sexes, aged between 25 and 55 years old, diagnosed with SAH23, with BP controlled for at least 3 months, not exercising for at least 3 months, Systolic blood pressure (SBP) between 140 mmHg and 160 mmHg and Diastolic blood pressure (DBP) between 90 mmHg and 100 mmHg; sign an informed consent form.

Exclusion criteria

Patients with a febrile state and/or with an infectious disease, class II obesity or more – BMI (body mass index) ≥ 35 kg/m2, class III or IV heart failure, recent cardiovascular event (last 3 months), will be excluded from the study. Chronic renal failure, severe liver disease self-reported or detected in laboratory tests, active smoking, or any physical or mental limitation that prevents the performance of the exercises.

Method of randomization and confidentiality of the allocation list

The randomization technique will be performed using a computer program (https://measuringu.com/randomization-test/) containing the coded distribution. Allocation secrecy will be guaranteed by a randomization list that will be in a remote place, 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 "blinded" to the study, after selecting the 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 of the beginning of the experiments[28].

Experimental draw

After signing the TCLE and clinical evaluation to analyze the inclusion/exclusion criteria, the included patients will be randomized into 2 protocols, with an equal number of participants: PE and PC. Then, they will perform the test of 10 maximum repetitions (10RM) to define the load to be used in the PE. After 72 hours, they will carry out the study protocols. In the PC, the patients will not perform the exercise, and in the EP, they will perform a multimodal exercise session. Clinical BP measurements will be performed before each protocol, immediately after, and at intervals of 15 minutes up to 60 minutes after the end. After a 1-week washout, the participants will perform the cross-protocol protocol, where the individuals who performed the CP will be allocated to the PE and vice versa, characterizing the cross-sectional design.

All participants will receive nutritional and physical information before the start of protocol assessments, such as not drinking alcohol at least 48 hours before; do not drink coffee on the day of the study; not performing exercises that are not prescribed in the study protocols.

Study protocol

All study protocols will be performed at a gym in the city. The multimodal exercise consists of an adaptation of High-intensity resistance training (HIRT)[29]. The proposal to be used in this study consists of performing an exercise session composed of exercises of different modalities in the same session, being performed at high intensity.

In the experimental protocol (EP) a multimodal training session will be performed with predominantly anaerobic characteristics, lasting 30 minutes, consisting of a warm-up period with light movements (5 minutes). The main part of 25 minutes, with high-intensity exercises, and pre-established loads (65-70% 1RM).

The exercise session will be divided into 3 circuited sets: SET 1, SET 2, and SET 3. Each set will consist of 3 exercises, which will be performed in a circuit without rest, 3 times (totaling 9 series performed without rest). After finishing the first SET, there will be a 1-minute rest interval, and the same circuit of 9 series will be performed 2 more times, which will total 27 series performed at the end of each SET. Between SETS, there will be a 1.5-minute break. SET 2 and 3, which will have different exercises, will follow the same pattern.

SETS will have the following characteristics:

- SET 1: Machine Bench Press – 10 reps or 20 seconds / Jumping Jacks – 20 seconds / Stationary Run – 20 seconds.
- SET 2: Leg press 45 – 10 reps or 20 seconds / squat lunge with body weight – 20 seconds/plank – 20 seconds.
- SET 3: Rowing – 10 reps or 20 seconds / Jump Rope – 20 seconds / Sit Up – 20 seconds.
- control protocol

In the control protocol (PC), the individuals will not perform any type of physical activity during the 25 minutes of the session but will have all blood pressure measurements taken in periods similar to the PE. The control protocol group will be allowed to stand, sit, talk, and drink water, and physical activity and food intake will be prohibited for up to 60 minutes after.

Study evaluations

Anthropometric assessment

The BMI assessment will be carried out from the identification of height, using a stadiometer graduated in centimeters with and precision of 1 mm, (brand Sanny ES2060, São Paulo, Brazil), and body mass, from an electronic scale, the precision of 0,05kg, (Welmy brand - W200A, São Paulo, Brazil). The BMI classification will be according to the World Health Organization (1995). Abdominal circumference will be performed us-

ing a 1 mm precision measuring tape (Sanny TR4013, São Paulo Brazil), at the point of greatest abdominal circumference, parallel to the ground[30].

Blood pressure

BP measurements will be performed by the regulations of The primary outcome (blood pressure) will be evaluated using 1 (one) technique: clinical evaluation. The clinical evaluation consists of blood pressure measurements as an acute response to physical exercise, and will be carried out by the regulations of the Seventh Report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure[31], with the individual sitting down, using a semiautomatic blood pressure device (ONROM HEM-7122, São Paulo, Brazil), validated by international organizations. BP will be measured initially in the pre-study assessments in both arms, adopting the side with the highest value for research purposes.

BP measurements in the protocols will occur at the following times; before the start of each protocol (Pre); immediately after the end (0 min), and for 60 minutes after the session, with intervals of 15 minutes (15 min, 30 min, 45 min and 60 min). The measurements will be repeated with intervals of 2 minutes between them and the measurement of the two will be adopted for analysis.

Statistical analysis

The collected data will be tabulated in the Microsoft Excel program and analyzed in the software (Statistical Package of Social Science - version 19.0, Chicago, IL, USA). The Shapiro-Willk test will be used to verify if the numerical data presented normal distribution. Student's t-test will be used for paired samples in the intragroup evaluations, comparing the pre and post-training moments, for the pressure behavior variables, since the study is a randomized crossed clinical study, in which the samples are related to each other. For intergroup evaluations of the moments before, immediately after, 15', 30', 45', and 60' min post, the normality of the data will be tested using the Shapiro-Wilk test. The comparison of MAP, SAP, and DAP will be performed using the Friedman test [2x6, session (EG and GC) x time (pre, post, 15 min, 30 min, 45 min, and 60 min)] followed by the post-test hoc de Bonferroni. Statistical analyzes will be performed using the SPSS program (Statistical Package for the Social Sciences) (version 26.0, IBM, USA). The significance level $p < 0.05$ will be adopted.

Place of research and data collection

The pre-and post-intervention assessments will be carried out at the same location along with the physical exercise sessions taking place at the city's Gym, which it has all the structure for carrying out the study.

Ethical aspects

The selection of patients with SAH, as well as the evaluation and performance of the experiments, will begin after the approval of the project by the Ethics Committee. All data collected will be confidential, seeking to help participants in this and other experimental research in the health area, ensuring that the benefit is greater, or at least equal to the alternatives already established for prevention, diagnosis, and treatment . Therefore, all information will be confidential, the name of the participant will be kept confidential and the data obtained will only have academic purposes. All data will be archived for five years and after that period, they will be incinerated, by CNS Resolution 466/12.

Risks and benefits of the study

The present research poses the risk of constraints about the questionnaire, which may contain some questions interpreted as invasive, but necessary for the progress of the research; Risks of dizziness, nausea, and discomfort caused by possible hypotension; and finally risks of minor injuries caused by the practice of exercise, as well as discomfort and in some people feeling dizzy. However, these risks decrease with the monitoring and

support of experienced researchers throughout the research. However, the study may contribute to a better understanding of blood pressure responses after a multimodal session.

Individuals will have all the results of their tests and exams during the development of the tests. Therefore, seek the benefits of better access to promising treatments, which in general would not yet be available in clinical practice; More frequent monitoring of the progress of the disease, through consultations and examinations according to the clinical protocol; Voluntary collaboration for the advancement of therapies to better offer future treatments with more effective and safer drugs.

RESULTS

We hope that the intervention designed by the experimental protocol can contribute information that will help health professionals to indicate or contraindicate high-intensity multimodal exercise for patients with Arterial Hypertension.

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