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## PROTOCOLO DE ESTUDO

# Hemodynamic effect of handgrip during cyclic exercise a randomized crossover clinical trial: Study protocol

***Efeito hemodinâmico do handgrip durante o exercício cíclico: Protocolo de ensaio clínico randomizado cruzado***

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## Abstract

*Introduction:* The combination of dynamic and isometric exercises, such as cyclic exercise with Handgrip contraction, may influence hemodynamic responses, improving cardiovascular regulation and offering new insights into exercise-based interventions. *Objective:* To test the hypothesis that

isometric contraction with the Handgrip device modulates the response of heart rate, systolic and diastolic blood pressure, double product, and subjective perception of exertion (Borg) during cyclic exercise. *Methods:* This randomized crossover clinical trial consists of three intervention arms. Forty male volunteers aged between 20 and 30 will be recruited. After screening, the volunteers will be randomized to treatment protocols (I: without HG; II: with HG at 30% of Handgrip Strength - HGS and III: with HG at 50% of HGS) which involve performing cyclic exercise on a treadmill, with four sprints at moderate intensity. The data will be presented by the variation (∆) of the sprint-rest and post-exercise-rest moments. The one-way Analysis of Variance (ANOVA) test will be performed in the case of symmetrical distribution and Kruskal-Wallys for non-parametric distribution, to analyze the three protocols during the same phases and then the same test to evaluate the individual responses over time. A p≤0.05 will be considered statistically significant. *Impact of the project:* This study will provide answers to the hemodynamic effects of isometric activity with handgrip associated with cyclic exercise and, if the hypotheses of this study are confirmed, we will have robust mechanistic evidence to broaden the field of scientific exploration in different clinical contexts.
**Keywords:** Hemodynamics; Vascular Resistance; Arterial Pressure.

## Resumo

*Introdução:* A combinação de exercícios dinâmicos e isométricos, como o exercício cíclico com contração do Handgrip, pode influenciar as respostas hemodinâmicas, melhorando a regulação cardiovascular e oferecendo novos insights sobre intervenções baseadas em exercícios. *Objetivo:* Testar a hipótese de que a contração isométrica com o dispositivo Handgrip modula a resposta da frequência cardíaca, pressão arterial sistólica e diastólica, duplo produto e percepção subjetiva de esforço (Borg) durante o exercício cíclico. *Métodos:* Este ensaio clínico randomizado e cruzado consiste em três braços de intervenção. Quarenta voluntários do sexo masculino com idade entre 20 e 30 anos serão recrutados. Após a triagem, os voluntários serão randomizados para protocolos de tratamento (I: sem força de preensão manual; II: com força de preensão manual a 30% da força de preensão manual - FPM e III: com força de preensão manual a 50% da FPM) que envolvem a realização de exercício cíclico em esteira, com quatro sprints em intensidade moderada. Os dados serão apresentados pela variação (∆) dos momentos sprint-repouso e pós-exercício-repouso. O teste de Análise de Variância (ANOVA) unidirecional será realizado no caso de distribuição simétrica e o teste de Kruskal-Wallys para distribuição não paramétrica, para analisar os três protocolos durante as mesmas fases e, em seguida, o mesmo teste para avaliar as respostas individuais ao longo do tempo. Um p≤0,05 será considerado estatisticamente significativo. *Impacto do projeto:* Este estudo fornecerá respostas aos efeitos hemodinâmicos da atividade isométrica com preensão manual associada ao exercício cíclico e, se as hipóteses deste estudo forem confirmadas, teremos evidências mecanísticas robustas para ampliar o campo de exploração científica em diferentes contextos clínicos.
**Palavras-chave:** Hemodinâmica; Resistência Vascular; Pressão Arterial.

## Introduction

Hemodynamic modulation during exercise is fundamental for maintaining cardiac output and this condition has already been widely explored in classic studies [1-3]. Recognizing these adjustments and the expected behavior for each exercise is fundamental for the construction of careful assessments with correct diagnoses of impaired cardiorespiratory capacity and the choice of therapeutic proposals based on physical exercise [4, 5].

Among physical exercise modalities, Cyclic Exercise (CE) on a treadmill is the most widely studied [4]. Under physiological conditions, performing CE results in an increase in heart rate, making it possible to find the maximum HR in an incremental test, an increase in systolic ejection volume and Systolic Blood Pressure (SBP), with maintenance or decrease in peripheral vascular resistance, as inferred by Diastolic Blood Pressure (DBP) [6]. Other modalities, such as isometric exercise with handgrips (HG), have been studied and applied in the health/disease binomial [7], however, their hemodynamic responses differ from CE in that they do not influence the behavior of HR and raise DBP [8]. This characteristic of HG opens the door to important therapeutic applications that would not be achieved with SBP, such as its use in the immediate reversal of syncopal events, which occurs by increasing peripheral vascular resistance to increase central blood flow towards the brain [9].

Even though CE and HG modalities are highly recognized and recommended as important forms of intervention to be used at different times during the training session [5], a gap still remains unresolved. There are no studies to date that elucidate the acute hemodynamic responses caused by the combination of CE associated with the use of HG. Therefore, to solve this problem we designed an intervention program capable of comparing the hemodynamic responses (heart rate - HR; SBP; DBP; and double product - DP) and subjective perception of exertion (Borg 6-20) during CE alone and in association with HG. We used a randomized crossover clinical trial as the research design and built this study protocol according to the guidelines of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [10].

## Methods

### *Design and hypotheses*

This is a three-arm randomized crossover clinical trial. The study will involve 40 male volunteers aged between 20 and 30 who will be assessed in 3 meetings at one-week intervals to see if HG modifies the acute response of heart rate, systolic and diastolic blood pressure, and the double product. We hypothesize that HG will be able to attenuate the fall in DBP during CE by at least 5mmHg, raise HR values by 10bpm, SBP by 10mmHg and SD by 1,000 units. We also hypothesize that there will be an increase of at least two units on the Borg scale (6-20).

The protocols will be carried out in an air-conditioned room at 23ºC in the school clinic of the Adventist College of Bahia. The collection period began in November 2023 and is expected to be completed by December 2024.

### *Recruitment*

The sample will be made up of university students from the Adventist College of Bahia and will be recruited through digital and printed posters on social networks and on the institution's premises. Screening meetings will be held on Mondays and Wednesdays, as scheduled, throughout the research period. All volunteers will be informed about the study proposal, risks, benefits, and the necessary precautions for participation. Volunteers will be made aware of the possibility of discontinuing their participation in the study at any time, without charge to the participant. In addition, the researchers will contact the participants by telephone to let them know when the research meetings will take place and if they have any questions.

### *Eligibility Criteria*

Young adults aged between 18 and 30, classified as active or irregularly active by the International Physical Activity Questionnaire (IPAQ) - Short Version [11], will be included. Individuals will be excluded if, based on the preliminary health assessment, they have limiting conditions reported in the medical history questionnaire or if they are classified as being at high risk of cardiovascular disease, with two or more risk factors, according to the guidelines for stress tests and their prescription of the American college of sports medicine [4]. Individuals who report pre-existing musculoskeletal disorders that make it impossible to perform the exercise protocol will also be excluded.

Those who meet the eligibility criteria will receive verbal and written information about the study protocol and will be invited to take part in the next stages of the research by signing the Free and Informed Consent Term (FICT).

### *Instruments used*

The following equipment will be used during the study:

- Welmy digital scale, with a maximum capacity of 200 kg and a stadiometer with an accuracy of 0.1 cm, certified by the National Metrology Institute (INMETRO);
- Polar H10 cardiofrequency meter (Polar Electro Oy, Kempele, Finland) [12];
- 3M™ Littimann® classic III™ stethoscope (3M do Brasil Ltda, Sumaré, SP, Brazil);
- Welch Allyn DS44-11BR Durashock sphygmomanometer (Welch Allyn, Barueri, SP, Brazil);
- EKO CORE MD™ auscultation amplifier (Eko Devices, Inc - Berkeley, California, USA), capable of amplifying sound up to 40 times, real-time transmission, and audio recording via Bluetooth;
- Jamar® hydraulic handheld dynamometer (Model J00105, Lafayette Instrument Company, Lafayette, Indiana, USA) [13];
- Handgrip device (Brother Medical, China) with a load of 5 to 40 kg;
- Athletic Extreme 3260T 18km/h treadmill (Athletic Comercio LTDA, São Paulo - SP).

### *Physical and clinical assessment*

Immediately after screening, a physical-clinical assessment will be carried out, with sociodemographic data being filled in, followed by a physical examination. The physical examination will include an assessment of height and weight, which will determine the body mass index (BMI - weight/height²). In addition, resting heart rate (HR) will be recorded using a Polar® H10 cardio-frequency meter [12] and Blood Pressure (BP), which will follow the recommendations of the American Heart Association [14].

### *Determination of Handgrip Strength (HGS)*

To determine the HGS, the recommendations of the American Society of Hand Therapists [13] will

be followed, using the Jamar® hydraulic dynamometer. The volunteer will be instructed to remain in a supine position and perform a maximum palmar contraction with the elbow flexed to 90º and the forearm in a neutral position. Three attempts will be made on each hand, with a one-minute rest between attempts. The highest values on each side will be recorded, and the measurement of the weaker arm will be selected to calculate the load used in the interventions.

***Treadmill stress test***

We will carry out an incremental exercise test on a treadmill to determine the speed required for the volunteer to reach the light and moderate training zones, at 30% and 50% of the reserve HR, respectively. The test will start at a speed of 2 km/h, with a gradual increase in speed to 4 km/h during the first 3 minutes of the test. Subsequently, the speed will be increased by 1km/h every minute. The target heart rate zones will be determined using the Karvonen equation: resting heart rate + (maximum predicted heart rate - resting heart rate) x % intensity. The maximum predicted heart rate for the calculation will be determined by the equation 220 - age, which in the chosen age group is the most accurate equation [15]. During the test, heart rate will be monitored using a cardiac transmitter combined with a Polar H10 cardiac sensor [12]. The speed for the protocol's target zone will be considered to be when the volunteer reaches and sustains, for at least 10 seconds, an HR 5bpm above or below the value stipulated by the equations.

***Sample randomization***

Randomization will be carried out simply and randomly by drawing numbered balls from 1 to 3, taken from a black bag by the volunteers. Each number will represent an exercise protocol to be carried out. The volunteer will draw the first ball to represent the protocol to be carried out in the first week, a second ball to represent the protocol for the second week, and the remaining ball to determine the protocol for the third week. The protocols will be carried out one week apart. Figure 1 shows the selection and randomization process for the three study arms.

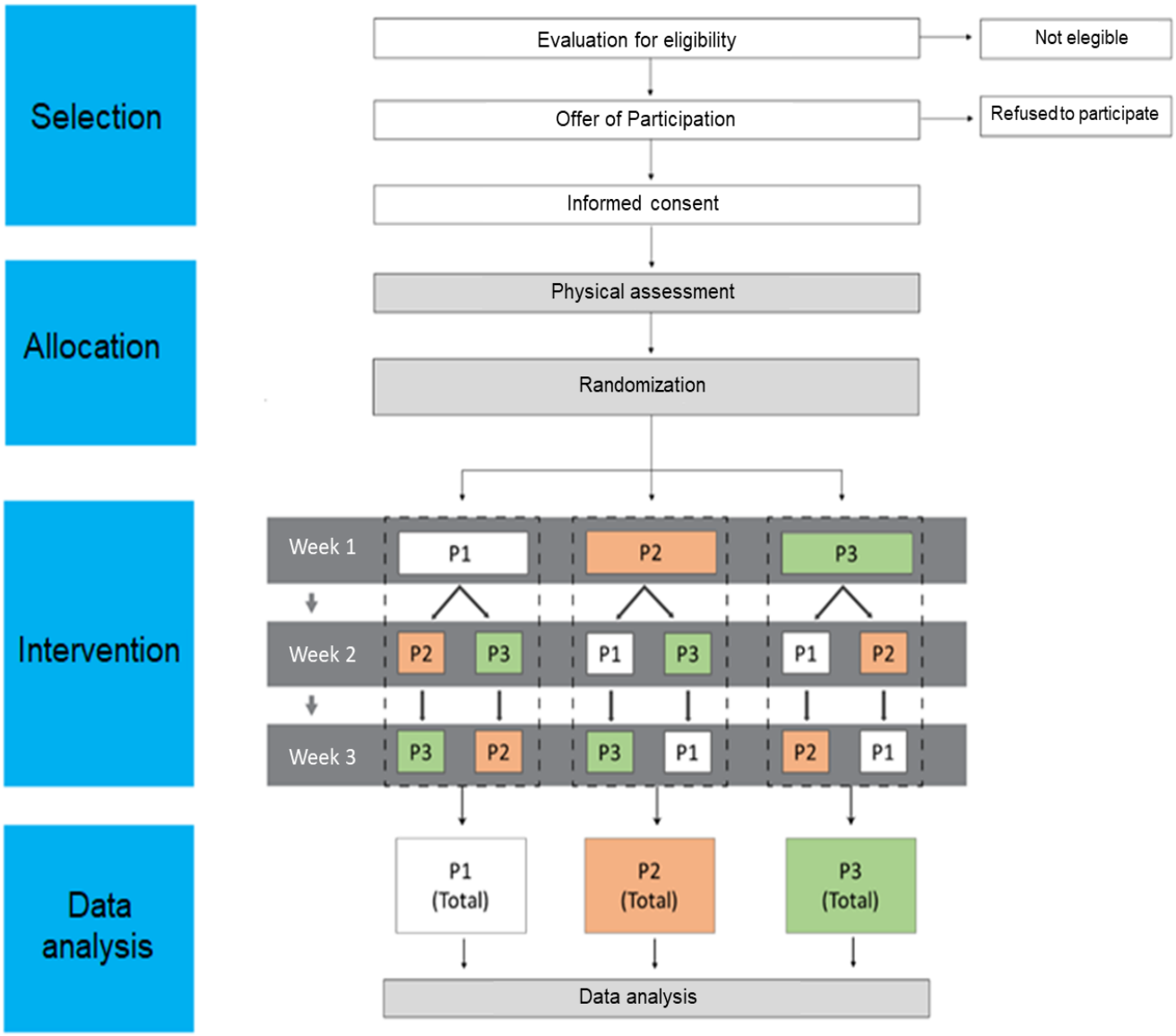



**Figure 1 -** *Flow diagram of sample selection and internal randomization throughout the study*

P1: protocol I (without handgrip); P2: protocol II (with handgrip with a load of 30% of handgrip strength); P3: protocol III (handgrip with a load of 60% of handgrip strength).

### *Blinding*

Due to the nature of the exercise intervention and the instrument used in the interventions, it will not be possible to completely blind the sample and the evaluators. The volunteers will be identified by groups that will alternate between the interventions, thus minimizing confounding bias. In addition, volunteers will be identified by number, two researchers will be responsible for allocation control, data recording, and general conduct of the study, while a single evaluator will be responsible for the hemodynamic assessments. The latter will not be informed about the group or protocol followed by the participant.

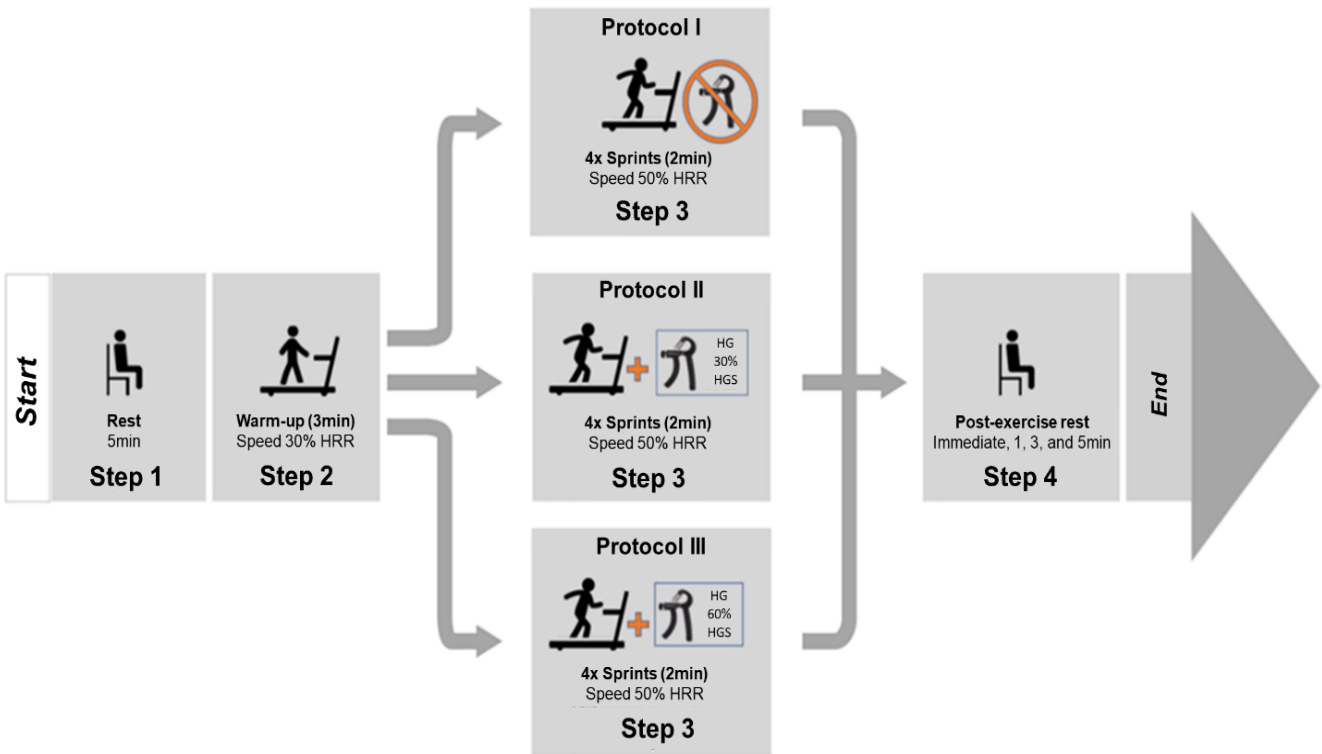
### *Intervention*

The protocols will be divided as follows: five minutes at rest to assess resting HR and BP, then the volunteer will be taken to the treadmill where they will warm up for three minutes at a speed of 30% of reserve HR. Subsequently, the participant will be subjected to four 2-minute sprints at a speed of 50% of reserve HR, separated by one-minute intervals at the same speed as the warm-up. Systemic blood pressure and HR will be measured in the final 20 seconds of each sprint, and during the active intervals of the sprints, the participants will be asked about their subjective perception of effort using the Borg scale (6-20).

At the end of the 4th sprint, we will start the two-minute warm-up phase, the first minute at the warm-up speed and the next with a progressive reduction to the minimum speed of the treadmill. The BP, HR, and Borg variables will also be collected immediately after the effort, in the first, third, and fifth minutes of rest.

### *Differentiation of protocols*

While Protocol I will follow the coordinates described above, Protocols II and III will add bilateral isometric contraction with an HG device during the sprints, at loads of 30% and HG 60% of the MPF obtained in the test, respectively. Figure 2 shows the stages of the interventions.




HRR: Heart Rate Reserve; HGS: Handgrip strength; HG: Handgrip;
Heart rate, systolic blood pressure, diastolic blood pressure, and perceived exertion (BORG 6-20) will be measured during stages 1, 3, and 4, in stage 3 at the end of each sprint and in stage 4 immediately, 1, 3 and 5 min after the effort.

**Figure 2 -** *Stages of the intervention protocols*

### *Hemodynamic monitoring during the intervention*

HR measurements will be recorded using a Polar H10 cardiofrequency meter [12] every minute and blood pressure measurements will follow the recommendations of the American Heart Association [14]. To increase safety when assessing blood pressure-related outcomes, a stethoscope will be used with an auscultation amplifier attached to the stethoscope.

During SBP monitoring, the assessor will be positioned on the left side of the treadmill. The sphygmomanometer will be kept on the volunteer's left arm throughout the protocol. The sphygmomanometer's clock will be supported by a metal bracket in order to avoid mechanical oscillations. At the time of measurement, the volunteer will be asked to maintain running speed and rest their left arm on the evaluator's shoulder, thus remaining with the limb extended and relaxed in a position of approximately 90º for shoulder flexion, with the forearm and hand supine. In addition, for the protocols using the HG, the volunteers will be instructed to stop the isometric contraction on their left side, handing over the device when the SBP is measured.

To determine SBP values, the evaluator will inflate the sphygmomanometer cuff while performing the auscultation. The device will be inflated by an average of 20mmHg/s until no sound is heard. From this point on, the assessor will inflate another 20mmHg and then open the valve, allowing the air to escape and reducing the pressure by 10mmHg/s. During the assessment, SBP and DBP will be determined by the first and fifth phases of the Korotkoff sounds, respectively [15].

### *Predictor variables*

Isometric contraction with HG: the presence of HG during the cyclic exercise protocol and the established load will be factors that differentiate the protocols, thus separating the 3 research groups.

Time of exposure to exercise: During the protocol, there may be a difference between the moments of evaluation due to the action of time on hemodynamic function and perception of effort. The data will be processed to differentiate between changes caused by HG and those resulting from exposure to exercise time.

Level of physical activity: It will be investigated whether the level of physical activity causes changes in the research outcomes.

### *Outcomes*

### *Primary outcomes*

The primary outcomes for this study will be the deltas (Δ = time - rest) of the variables HR, SBP, DBP, and the double product (DP = HR * SBP). The analysis will be made between the same moment of the 3 protocols and by the pattern of behavior of the variables throughout the sprints and post-exercise rest.

### *Secondary outcomes*

Subjective perception of exertion: the original Borg scale with a score of 6 to 20 will be used to assess the response of the perception of exertion between the protocols and throughout the interventions.

Adverse events: Adverse events will be recorded as a secondary outcome. The research team will report to the ethics committee all events during the interventions and up to one day after the completion of each protocol. Any adverse events related to training will be followed up immediately to check whether they are preventable, such as incorrect running technique or unsuitable running shoes. A prior checklist will be made available for monitoring signs and symptoms such as chest pain,

dizziness, nausea, muscle and/or joint pain, and prolonged fatigue (hours) after exertion.

### *Sample calculation*

A pilot study [16] with 7 volunteers was conducted to serve as a basis for sample calculation. DBP was the main variable selected for this study and had an average standard deviation of 15.6. A change of at least 5 mmHg in DBP was considered to be the minimum relevant clinical difference [17]. The sample size was calculated using three treatment arms, with a power of 0.80 and alpha of 0.05, resulting in 38 volunteers needed for each group. BioEstat software version 5.3 (Belém, SBP, Brazil) was used to calculate the sample size [18].

### *Statistical planning*

Initially, a descriptive analysis of the data will be carried out to characterize the sample. To identify the normality of the data distribution, symmetry and kurtosis will be checked and the Shapiro-Wilk test will be performed. Parametric data will be presented as mean and standard deviation, while non-parametric data will be presented as median and quartile range. Categorical variables will be presented as proportion and absolute frequency.

A simple linear regression will be carried out to identify whether the level of physical activity influences the outcome variables. If the linear regression confirms this influence, the outcome variables will be analyzed by subgroups: active and irregularly active. In addition, the variables HR, SBP, DP, and DBP will be reported according to variation (Δ = sprint or post-exercise values - initial resting value on the day of the protocol). Only Borg values (6-20) will be expressed as the absolute value obtained at the time of collection.

Hemodynamic variables and subjective perception of exertion will be assessed using one-way analysis of variance (ANOVA) for parametric distribution with Tukey's post-hoc test or Kruskal-Wallys with Dwass-Steel-Critchlow-Fligner post-hoc test for non-parametric distribution. Initially, a cross-sectional analysis of the behavior of the variables will be established, comparing the three protocols during the same moment of the intervention (sprints or post-exercise). Subsequently, the longitudinal response of each protocol will be analyzed during the sprints (1-4) and post-exercise phases (immediate, 1, 3, and 5 min). During the analyses, a $p \leq 0.05$ will be considered statistically significant.

### *Data management*

#### *Data entry*

Data will be double-entered to ensure data quality and accuracy. Data entry will be carried out separately by two independent researchers in a blinded manner. The personal information and identity of the participants will be strictly protected. Each participant will be assigned a unique study number, which corresponds to the data collected.

### *Data monitoring*

The data management team will continuously monitor the data collected on a weekly basis and report the progress of the study to the investigators. The results will be fully disseminated in peer-reviewed scientific journals and conferences. We expect that any possible adverse events related to the exercise interventions in this study will be minor. However, if any unexpected serious adverse events occur several times during the study, our investigators will discuss the situation to consider terminating the study.

### *Data security and backup*

All study data will be stored separately from participants' personal information. The participant's identity will be stored on encrypted hard disks kept

in a locked cabinet. Only the research staff of this project will be able to access the locked cabinet and the encrypted hard disks. The data will be stored for 7 years.

### *Ethics and disclosure*

Ethical approval: The study is conducted in accordance with the ethical principles of the Declaration of Helsinki and Resolution 466/12 of the National Health Council, which are consistent with Good Clinical Practice and the applicable regulatory requirements. The study was approved by the Ethics and Research Committee of the Faculdade Adventista da Bahia, Cachoeira, with CAAE: 44262121.2.0000.0042 and was registered in the Brazilian Registry of Clinical Trials (REBEC) with code RBR-78fhyrf, registered on November 17, 2023.

Dissemination: The results of the study will be published in local and international journals. In addition, the results will be presented at scientific conferences.

## Discussion

The randomized clinical trial proposed in this protocol seeks to analyze the hemodynamic responses of HG during cyclic exercise. The answer to this objective will determine important points in understanding the acute effects of palmar isometric contraction on the cardiovascular system and will broaden the field of scientific research into combined activities in specific populations.

Previous studies [8] have already shown that isometric contraction with HG promotes an increase in SBP and DBP. The mechanoconstriction generated by isometric contraction with HG exerts a direct force on the vessel wall, which triggers a transient increase in Peripheral Vascular Resistance (PVR) [19]. Faced with an increase in PVR and, consequently, afterload, the ventricle uses some strategies to ensure the necessary blood supply to the periphery, such as increased myocardial contractility, which triggers an increase in SBP [20]. One of the determinants of SBP elevation is increased HR, however, during isometric exercise with HG, HR does not seem to change [8], especially in traditional protocols, with up to 2 minutes of isometric contraction. In this scenario, there is an increase in cardiac work coordinated primarily by SBP elevation.

When we think about CE, the hemodynamic response differs considerably from isometric exercise. As the intensity and duration of the effort increase, there is a reduction in cardiac parasympathetic activity and an increase in sympathetic nervous activity, which acts by increasing HR and myocardial contractility, resulting in an increase in Cardiac Output (CO), which is essential to meet the demands of the target tissues. The sympathetic discharge acts on the peripheral arterial vessels, promoting vasoconstriction; however, during CO, the turbulent flow of blood favors the release of nitric oxide, which balances this balance with vasodilation [21]. An increase in SBP is observed when CO is raised while Peripheral Vascular Resistance (PVR) is maintained. Together, high SBP and HR exponentially increase cardiac work during exercise. Here we can already see a crucial difference between the interventions in terms of the response of DBP and DP.

Unlike isometric exercise, the intensity of the effort in CE can be modulated through HR, which even makes it possible to identify the appropriate training zones for each purpose [4]. Another way of monitoring intensity during exertion is through the Borg

subjective perception of exertion scale [5]. The Borg scale is an important tool for monitoring perceived exertion, recommended by the Brazilian Cardiovascular Rehabilitation Guidelines [5] and its graduation allows values to be anchored to HR. Despite its popularity in cyclical activities, we did not identify any studies with HG that used the scale for the same purpose, a choice that may be justified by the fact that no changes in HR were observed during this modality.

Aware of the characteristics of each isolated intervention, the present clinical trial will answer some mechanistic questions, such as: is the isometric contraction with HG during CE able to attenuate the fall of DBP? Is this response modulated by the HG load? Within this proposal, we can compare if the HG exerts a sum effect on SBP and if, different from what occurs in isometric exercise with HG, peripheral muscle contraction will require increased HR to meet the increased energy demand or increase the perception of effort.

Because it is a crossover study, with volunteers serving as their own comparators, we will avoid inherent flaws in the baseline comparison and individual characteristics that could determine the behavior of the result [22]. In this way, we will ensure a fair evaluation and treat possible confounding factors, such as the level of physical activity [23], which will receive appropriate statistical analysis. Finally, as an exploratory study, let us take care to select a sample composed of young volunteers without cardiovascular diseases, which configure low risk for complications related to the hemodynamic outcomes of this study. In addition, the team of researchers will be previously guided to identify adverse effects that may be related to the protocols, register, and offer the necessary care. This care will allow us to recognize the adverse events of this intervention strategy, and the feasibility of the strategy and formulate ideas that further protect volunteers from the next research that will be carried out in a clinical context.

Our protocol is timely in considering a mechanistic approach to exercise combinations not previously experienced in the literature. Conducting this research will provide a solid evidence base for future therapeutic investigations.

## Conclusion

This study will provide answers to the hemodynamic effects of isometric activity with handgrip associated with cyclic exercise. If the hypotheses of this study, we will have robust mechanistic evidence to guide new insights into exercise prescription, capable of expanding the field of scientific exploration in different clinical contexts.

**Conflict of interest**

The authors assert that they have no conflicts of interest.

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**Academic Affiliation**

This protocol is part of the Master's project of author Marvyn de Santana do Sacramento in Medicine and Human Health by the Bahian School of Medicine and Public Health, under the supervision of Dr. Jefferson Petto.

**Authors' contribution**

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