

Zazen Meditation in Patients with Acute Myocardial Infarction: A Randomized Clinical Trial – Intervention Protocol

Meditação Zazen em Pacientes com Infarto Agudo do Miocárdio: Ensaio Clínico Randomizado – Protocolo de Intervenção
Meditación Zazen en Pacientes con Infarto Agudo de Miocardio: Ensayo Clínico Aleatorizado – Protocolo de Intervención

RESUMO

Objetivo: Verificar os efeitos da prática de meditação Zazen sobre a variabilidade da frequência cardíaca em pacientes com infarto agudo do miocárdio recente, de forma aguda e crônica. **Método:** Ensaio clínico randomizado, controlado e paralelo, com avaliação cega dos desfechos. Serão avaliadas variabilidade da frequência cardíaca, qualidade de vida, espiritualidade, parâmetros bioquímicos, fração de ejeção ventricular esquerda e capacidade funcional antes e após vinte e quatro sessões de meditação. Os efeitos agudos serão avaliados antes e após uma única sessão. A amostra será composta por quarenta e quatro participantes, vinte e dois em cada grupo. **Resultado:** Espera-se que a meditação Zazen promova melhora na modulação autonômica e nos parâmetros psicofisiológicos avaliados. **Conclusão:** A meditação Zazen pode representar uma prática complementar promissora na reabilitação cardíaca de pacientes após infarto agudo do miocárdio.

DESCRIPTORES: Infarto agudo do miocárdio; Variabilidade da frequência cardíaca; Meditação.

ABSTRACT

Objective: To evaluate the effects of Zazen meditation on heart rate variability in patients with recent acute myocardial infarction, both acutely and chronically. **Method:** Randomized, controlled, parallel clinical trial with blinded outcome assessment. Heart rate variability, quality of life, spirituality, biochemical parameters, left ventricular ejection fraction, and functional capacity will be evaluated before and after twenty-four meditation sessions. Acute effects will be assessed before and after a single session. The sample will consist of forty-four participants, twenty-two in each group. **Result:** Zazen meditation is expected to improve autonomic modulation and the psychophysiological parameters evaluated. **Conclusion:** Zazen meditation may represent a promising complementary practice in the cardiac rehabilitation of patients after acute myocardial infarction.

DESCRIPTORS: Acute myocardial infarction; Heart rate variability; Meditation.

RESUMEN

Objetivo: Evaluar los efectos de la meditación Zazen sobre la variabilidad de la frecuencia cardíaca en pacientes con infarto agudo de miocardio reciente, de forma aguda y crónica. **Método:** Ensayo clínico aleatorizado, controlado y paralelo, con evaluación ciega de los resultados. Se evaluarán variabilidad de la frecuencia cardíaca, calidad de vida, espiritualidad, parámetros bioquímicos, fracción de eyección ventricular izquierda y capacidad funcional antes y después de veinticuatro sesiones de meditación. Los efectos agudos se medirán antes y después de una sola sesión. La muestra estará compuesta por cuarenta y cuatro participantes, veintidós en cada grupo. **Resultado:** Se espera que la meditación Zazen mejore la modulación autonómica y los parámetros psicofisiológicos evaluados. **Conclusión:** La meditación Zazen puede representar una práctica complementaria prometedora en la rehabilitación cardíaca de pacientes tras un infarto agudo de miocardio.

DESCRIPTORES: Infarto agudo de miocardio; Variabilidad de la frecuencia cardíaca; Meditación.

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INTRODUCTION

Coronary artery disease (CAD) remains the leading cause of death in Brazil, manifesting as angina pectoris, acute myocardial infarction (AMI), and sudden death¹. Despite therapeutic advances, mortality and the incidence of post-AMI heart failure remain high, highlighting the need for preventive strategies and educational programs focused on modifiable risk factors¹.

The autonomic nervous system (ANS) plays an essential role in cardiovascular control through the sympathetic and parasympathetic pathways, modulating heart rate (HR) and baroreceptor activity³. Physiological variations in HR, known as Heart Rate Variability (HRV), reflect the heart's ability to respond to internal and external stimuli³. Low HRV is associated with autonomic dysfunction and worse prognosis in cardiovascular diseases⁵.

The literature shows that reduced

HRV is a risk marker for fatal arrhythmias and heart failure, and is recognized as an adverse prognostic factor in post-AMI patients^{5,6}. In addition to physical exercise, complementary practices such as meditation have been investigated for their effects on stress-related physiological parameters, including respiratory rate, oxygen consumption, and systolic blood pressure⁶.

Studies show that meditation increases HRV and improves autonomic balance. Nesvold et al.^{7,8} observed an increase in the high and low frequency bands of HRV and in the spectral power of RR intervals during meditation. Steinhubl et al.⁹ identified improvements in HRV and blood pressure in meditating individuals, while Phongsuphap¹⁰ reported that Samadhi meditation can increase vagal tone and optimize baroreflex.

Zazen meditation, originating in Japan, is a practice of mindfulness and open monitoring, performed in a sitting posture, which seeks awareness of

the present moment and body-mind balance. Despite its potentially beneficial characteristics, there are no previous studies on Zazen in post-AMI patients.

Due to its low cost, safety, and possible benefit on autonomic modulation, meditation is considered a promising strategy for cardiovascular rehabilitation^{16,18}. The American Heart Association (AHA) reinforces the need for randomized and methodologically robust clinical trials to evaluate its effects on cardiovascular risk¹⁹.

Given the barriers to access to cardiac rehabilitation, such as cost and distance, Zazen meditation emerges as an accessible and complementary alternative to conventional treatment. Thus, the present study proposes to evaluate the effects of Zazen practice on HRV in post-AMI patients, both acutely (after one session) and chronically (after 24 sessions), in addition to investigating impacts on quality of life, spirituality, biochemical param-

ters, ejection fraction, and functional capacity.

METHOD

This is a randomized, controlled, parallel clinical trial with blinded outcome assessment, conducted according to updated guidelines. The analysis will be by protocol. The effects of Zazen meditation on HRV will be evaluated acutely (after one session) and chronically (after 24 sessions). Participants will be recruited from the Cardiology Care Unit and the emergency room of the Hospital de Clínicas de Porto Alegre (HCPA).

Inclusion and Exclusion Criteria

Inclusion: Patients of both sexes with recent AMI, up to 30 days after discharge, confirmed by troponin elevation and evidence of ischemia (clinical, electrocardiographic, or imaging)²⁰. They must be available to attend the hospital twice a week and sign the informed consent form.

Exclusion: Patients with unstable angina, extensive residual ischemia, class III–IV heart failure, severe lung disease, pacemaker, limited mobility, cognitive difficulties, or participation in other clinical trials, due to the potential for interference with HRV results.

INTERVENTION

Participants will be randomized into two groups: Zazen meditation and control. The meditation group will perform guided Zazen sessions according to a pre-established protocol, with progressive duration (5, 10, and 15 minutes), twice a week, totaling 24 sessions. The practice will be adapted to a seated position in chairs, aiming at comfort and adherence, and will guide the cultivation of self-care and gratitude, without judgment of thoughts or external stimuli.

The control group will watch a neutral 30-minute documentary, following

the same schedule.

Acute effects will be assessed in the third session and chronic effects after 24 sessions, using HRV recorded with the Polar H10 before and after the interventions. All participants will arrive 40 minutes early for preparation, rest, and standardization of physiological measurements.

RESULTS

The primary outcome will be HRV, assessed by the RMSSD and SDNN parameters obtained by a validated heart monitor. The analysis will consider the change between baseline and post-intervention, using mean and standard deviation or median and interquartile range, depending on the data distribution. An increase in HRV will indicate improved autonomic modulation and potential post-infarction prognostic benefit.

Secondary endpoints will include: a) Quality of life (SF-36), analyzed by the variation in mean scores; b) Spirituality, religiosity, and personal beliefs (WHOQOL-SRPB), assessed by the change in scores; c) Inflammatory and hormonal markers (ultrasensitive C-reactive protein and cortisol), compared pre- and post-intervention; d) Functional capacity, measured by the distance of the 6-Minute Walk Test; e) Cardiac function, assessed by left ventricular ejection fraction obtained by echocardiography.

Statistical analyses will compare the meditation and control groups, with adjustments for covariates when necessary. The clinical relevance of the results is based on the association between autonomic balance, psychosocial aspects, and physiological markers, reinforcing the potential of Zazen meditation as a complementary practice in cardiovascular rehabilitation.

SAMPLE SIZE

The sample size was determined based on the study by Chang et al.⁸, in which a standard deviation of 13.04

was found in the experimental group and 7.67 in the control group for the SDNN variable after the intervention. To detect a minimum difference of 10 points in this variable, a statistical power of 80% and a significance level of 5% were considered. With these parameters, the calculation resulted in the need for 18 participants in each group ($n = 36$). To compensate for possible follow-up losses, a margin of 20% was added to the total number of participants, resulting in a final sample of 44 participants (22 per group). The sample size was calculated using WINPEPI V11.43 statistical software.

RECRUITMENT

Participants will be recruited during hospitalization in three stages: presentation of the study to the patient, post-discharge telephone contact for clarification, and in-person scheduling to sign the Informed Consent Form (ICF) and begin assessments. This process aims to ensure clarity of information, conscious adherence, and reduction of losses during recruitment.

ALLOCATION

Randomization will be performed using a table of random numbers with uniform distribution, generated by the REDCap platform,²⁹ used for the construction and management of databases and research.

BLINDING

Outcome assessors: Researchers responsible for collecting and analyzing study variable data (HRV, SF-36, WHOQOL-SR, PCR-us, cortisol, TC6M, echocardiography) will be blinded to participant allocation. **Data analysts:** Professionals responsible for statistical analysis of results will not have access to group identi-

cation. Participants and intervention administrators will not be blinded, as the nature of meditation prevents masking of the intervention.

INSTRUMENTS

HRV Analysis

HRV describes the oscillations of the intervals between consecutive heartbeats (R-R intervals), which are related to the influences of the ANS on the sinus node¹⁶. Cardiac HRV analysis is performed in two ways: using linear methods (time and frequency domain) and nonlinear methods. Linear methods in the time domain measure each normal RR interval (sinus beats) in a given time interval, examining various statistical measures or histograms of the RR interval. The statistical indices obtained by determining the R-R intervals are respectively: SDNN: standard deviation of all normal RR intervals recorded in a time interval (m/s). SDANN: represents the standard deviation of the RR interval means, every 5 min, in a given time interval (m/s). SDNNi: mean standard deviation of RR intervals every 5 min. RMSSD: square root of the mean square of the differences between adjacent normal RR intervals in a time interval (m/s). NN50: number of adjacent RRs that differ by more than 50 (m/s). pNN50: represents the percentage of adjacent RR intervals that differ by more than 50 (m/s).

The SDNN, SDANN, and SDNNi indices, which represent sympathetic and parasympathetic activity, are obtained from long-term recordings, while the rMSSD and pNN50 indices represent parasympathetic activity and are found from the analysis of adjacent RR intervals.

The time domain includes other ways of processing RR intervals, such as the triangular index and the Pointcaré plot, which present RR intervals in geometric patterns and use various

approximations to derive HRV measurements from them.

The second linear method mentioned above evaluates the cyclical nature of the RR interval series with spectral power analysis. Frequency analysis decomposes HRV into fundamental components, which are:

- High Frequency (HF): high-frequency component, indicator of the vagus nerve's action on the heart, corresponding to respiratory modulation - ranges from 0.15 to 0.4Hz.
- Low Frequency (LF): demonstrates the action of the vagal component in conjunction with the sympathetic component on the heart, with a predominance of the sympathetic component - ranges from 0.4 to 0.15Hz.
- Very Low Frequency (VLF) and Ultra Low Frequency (ULF): these indices are believed to be related to the renin-angiotensin-aldosterone system, thermoregulation, and peripheral vasomotor tone.

The HF/LF ratio (ratio between LF and HF powers) characterizes the sympathetic-vagal balance in the heart, showing relative and absolute changes between the parasympathetic and sympathetic components.

For the analysis of nonlinear methods, a number of 1000 consecutive RR intervals is recommended, including: power law scale (1/f) of Fourier spectra, H scaling exponent, coarse grain spectral analysis, and approximate entropy, which take into account complex interactions such as humoral variables, hemodynamics, among others²⁰.

In the present study, to perform HRV analysis, data will be collected by Polar H10,²¹ and paired via Bluetooth with the Elite HRV mobile app²². The data will be downloaded to a notebook and processed using Kubios HRV 4.1.0 software²³. The aforementioned devices are widely used in clinical research and have been validated in previous studies.

Stroop Test

The Stroop Test (ST) will be used to assess HRV with an emphasis on sympathetic stimulation. It consists of identifying the color of the ink of words that designate different colors, generating cognitive interference that increases the difficulty of the task and response time^{24,25}.

Quality of Life and Health – SHORT FORM-36

The SF-36 is a multidimensional questionnaire consisting of 36 items distributed across eight domains of quality of life: functional capacity, physical aspects, pain, general health status, vitality, social aspects, emotional aspects, and mental health. Easy to apply and understand, it has a validated version in Portuguese, adapted to the Brazilian sociocultural context, which ensures its reliability and usefulness as an outcome instrument in research²⁶.

Spirituality, religiosity, and personal beliefs (WHOQOL-SR)

The WHOQOL-SRPB is an extension of the WHOQOL-100 and WHOQOL-Bref instruments, created to more specifically address the spiritual and religious aspects of quality of life. It assesses eight dimensions related to spirituality and personal beliefs, including connection with a higher power, inner peace, purpose in life, awe, integration, spiritual strength, faith, and hope/optimism²⁷.

Biochemical markers

Analyses of the biochemical markers cortisol and ultrasensitive CRP will be performed using blood samples collected.

6-Minute Walk Test

The 6-Minute Walk Test (6MWT) assesses functional capacity by measuring the distance walked in six minutes. Performed on a flat 30-meter course, with monitoring of blood

pressure, heart rate, and oxygen saturation before and after the test, it allows participants to adjust their pace or rest, making it an accessible and safe submaximal assessment²⁸.

Transthoracic Echocardiography

The Left Ventricular Ejection Fraction will be assessed by Transthoracic Echocardiography.

PROTOCOL FOR THE PRACTICE OF ZAZEN MEDITATION

The practice of Zazen involves three fundamental postures:

1. Gassho (initial posture): hands joined palm to palm at nose level, with forearms aligned. It is used for a bow before starting and at the end of the practice.

2. Shashu (transitional posture): left hand closed with thumb tucked into fist, covered by right hand, both positioned at abdomen height with forearms straight. In this position, the practitioner sits.

3. Cosmic Mudra (meditative posture): once seated, the right hand is placed on the thighs, with the left hand on top of the right, thumbs lightly touching, forming a circle below the navel.

In this study, meditation will be performed sitting in a chair, with an upright posture, feet parallel on the floor, and body aligned. Before starting, a gentle side-to-side sway is performed to find the body's axis, followed by three inhalations through the nose and exhalations through the mouth, then moving on to exclusively nasal breathing.

During meditation, the back remains straight but relaxed, with the nose aligned with the navel and the ears with the shoulders. The eyes remain half-open at an angle of approximately 45°, with silent and natural breathing.

The first bell marks the beginning of the 15 minutes of Zazen, and the second bell signals the end. To con-

clude, return to Gassho, bow, and repeat the side-to-side sway, this time more actively, to reactivate the body and mind.

Each session will last up to 40 minutes, consisting of: 10 minutes for initial instructions, 15 minutes for meditative practice, and 15 minutes at the end for informal feedback among participants.

PROTOCOL FOR COLLECTING HRV RELATED TO SYMPATHETIC STIMULATION

HRV will be recorded for 15 minutes, analyzing 5-minute segments in the time and frequency domains, as recommended by the European Society of Cardiology and the North American Society of Pacing and Electrophysiology³⁰. The following will be calculated: mean RR interval, rMSSD, low frequency (LF) and high frequency (HF) components, expressed in normalized units (nu), in addition to the LF/HF ratio.

Samples will always be collected at the same time, with participants instructed to avoid caffeine, alcohol, stimulants, and intense exercise in the previous 24 hours, in addition to fasting for 2 hours.

To assess vagal modulation and sympathetic response, individuals will remain at rest in a supine position for 10 minutes in a quiet, semi-dark environment, followed by the Stroop Test for 5 minutes, which induces mental stress through cognitive interference between words and colors^{24,25}. HRV will be analyzed in the last 5 minutes of the test.

PROTOCOL FOR PRE- AND POST-INTERVENTION HRV COLLECTION

Participants will arrive 40 minutes before the intervention for placement of the Polar H10 chest sensor and preliminary instructions. After 10 minutes of monitored rest, the HRV signal will be recorded for 5 minutes before and 5 minutes after the intervention.

Participants will be instructed to avoid caffeine, alcoholic beverages, stimulants, and intense exercise in the previous 24 hours, in addition to fasting for 2 hours. Collections will take place in a quiet environment with controlled temperature ($\approx 23^{\circ}\text{C}$) and reduced lighting, ensuring standardized conditions and physiological stability for HRV measurement.

STATISTICAL METHODS

Sociodemographic variables will be described according to their nature: means and standard deviations or medians and interquartile ranges for continuous variables, and frequencies and percentages for categorical variables. Data normality will be verified using the Shapiro-Wilk test. Intra- and intergroup comparisons will be performed by ANOVA for repeated measures or, when necessary, by the Friedman test, with the Chi-square test applied to proportions. The level of significance adopted will be 5%, and all analyses will be conducted using IBM SPSS Statistics® software, version 23.0 or higher.

DISCUSSION

The study presents logistical and operational challenges that require careful planning to ensure its proper execution. Evaluators will receive standardized training on the use of instruments and application of questionnaires, ensuring consistency of measurements. Data management and quality will be monitored through double entry, consistency checks, and appropriate statistical treatment for missing data. Confidentiality will be strictly maintained, in accordance with ethical standards. If unforeseen difficulties arise, the protocol may be adapted, provided that the methodological and scientific integrity of the research is preserved.

CONCLUSION

This protocol describes a random-

ized, controlled, parallel clinical trial that will investigate, for the first time, the effects of Zazen meditation on HRV and other physiological and psychological outcomes in post-AMI patients. Based on evidence that HRV is an important prognostic marker of cardiac autonomic function, the study seeks to assess whether regular

practice of Zazen can promote sympatho-vagal rebalancing, improve psychosocial aspects, and contribute to cardiovascular rehabilitation in a safe, accessible, and low-cost manner.

Methodological standardization, the use of validated instruments, and rigorous design ensure the scientific robustness of the study. It is hoped

that the results will support new complementary care strategies, promoting a more comprehensive and humanized approach to the treatment of post-AMI patients and strengthening the role of Zazen meditation as an adjunctive tool in cardiac rehabilitation.

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