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Using music to reduce anxiety and stress in patients undergoing coronary angioplasty: A randomized clinical trial protocol☆

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ABSTRACT

In the current health context, there is a widespread increase in chronic non-communicable diseases that predominantly affect the cardiovascular system. Recent epidemiological data in Brazil indicate a rise in these diseases, which can result in severe harm to patients, including death. This study aims to present a study protocol to evaluate the effect of music in reducing anxiety and stress in patients undergoing coronary angioplasty. A randomized, controlled, double-blind clinical trial will be conducted with 52 patients undergoing coronary angioplasty. The patients will be randomly assigned to one of two groups: a Control Group or an Experimental Group, to assess the effect of music on anxiety and stress. Two key points will be considered to evaluate the intervention's impact: data on patients' anxiety and stress, collected through structured forms, will be gathered both before and after the intervention, along with an assessment of vital signs. The primary expected outcome is a reduction in anxiety and stress, while the secondary expected outcome is stability in vital signs.

Specifications table

Subject area:	Medicine and Dentistry
More specific subject area:	Nursing, cardiology, complementary therapies to reduce anxiety and stress.
Name of your protocol:	Using music to reduce anxiety and stress in patients undergoing coronary angioplasty: a randomized clinical trial protocol.
Reagents/tools:	Not applicable.
Experimental design:	Fifty-two patients will be allocated to two groups: control and experimental. Headphones will be used in both groups; however, only in the experimental group will the individual's preferred music be played for 15 min before coronary angioplasty. The effectiveness of music in reducing anxiety and stress will then be assessed.

(*continued on next page*)

☆ **Related research article:** None.

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Trial registration:	Registrations: RBR-5jy7kzj - Brazilian Registry of Clinical Trials - REBEC (09/05/2024). This study was approved by the Research Ethics Committee of the Federal University of Rio Grande do Norte - UFRN, under CAAE - 74,989,823.6.0000.5537.
Ethics:	Individuals interested in participating in this study will receive a Free and Informed Consent Form, which they will read and sign to confirm their participation and inclusion in the sample.
Value of the Protocol:	• This protocol tests the effectiveness of a low-cost, non-pharmacological strategy for reducing anxiety and stress during an invasive arterial and coronary procedure. • This intervention could be incorporated into the Systematization of Nursing Care, enhancing the nursing team's autonomy and promoting more humanized care. • The therapy will be applied as a complementary treatment and will not replace the standard care recommended by the health service. Therefore, no individual involved in the study will be deprived of the gold-standard care for their clinical condition.

Background

In the current health context, there has been a significant rise in chronic non-communicable diseases, which primarily affect the cardiovascular system [1]. Acute myocardial infarction (AMI) is the leading cause of death in Brazil [2], and cardiovascular disease (CVD) is one of the top causes of mortality worldwide [3]. In 2017, AMI accounted for 10.2 % of hospitalizations within the Brazilian Unified Health System (SUS), according to DATASUS [2,4].

The high prevalence of cardiovascular illnesses necessitates both non-invasive and invasive techniques for diagnosis and treatment. These approaches include pharmacological interventions to maintain cardiovascular health, as well as surgical and hemodynamic procedures, such as transluminal coronary angioplasty or percutaneous coronary intervention [5].

Hemodynamic units are specialized centers for these procedures, which involve venipuncture or arterial puncture using radiopaque catheters to visualize and/or treat arteries, vessels, the heart, and the brain [5,6]. The hemodynamics unit, as a closed environment, can amplify feelings of insecurity, heightening patients' fear, stress, and anxiety, which may result in risks to procedure success due to potential hemodynamic instability related to psychosomatic responses [6,7].

A study of patients undergoing cardiac catheterization while awake and unsedated revealed that these patients experience intense stress, including anxiety and fear, as they are exposed to sounds from monitors, able to communicate with the healthcare team, and observe the progress of the procedure [8]. Thus, there is a need to develop strategies beyond pharmacological practices to reduce the stress and anxiety of patients undergoing hemodynamic procedures [9].

Music is currently used across various healthcare fields to address the physiological, psychological, and spiritual needs of patients. Its effectiveness as a non-pharmacological intervention to reduce anxiety and pain, while enhancing feelings of control and well-being, has been widely tested and discussed in the specialized literature, which consistently reports positive outcomes [10–21].

This protocol is relevant and well-justified for its contribution to science and academia, offering a systematic, detailed method that allows for replication by other researchers, adapted to diverse contexts and cultures, to assess the effectiveness of a non-pharmacological intervention in reducing anxiety and stress during coronary angioplasty. Furthermore, it can support health services and clinical practice by promoting the development and implementation of standardized operating procedures and protocols, thereby guiding nursing care toward evidence-based practice. Also noteworthy is the use of a low-cost intervention, with minimal risk and high user acceptability, which may reduce the need for high doses of anxiolytics and improve user satisfaction with the multidisciplinary team, the procedure, and overall healthcare experience.

This study aims to evaluate the effect of music on reducing anxiety and stress in patients undergoing coronary angioplasty.

Description of protocol

This study is registered on the Brazilian Clinical Trials Registry Platform (REBEC) under the number RBR-5jy7kzj (09/05/2024). It was approved by the Research Ethics Committee of the Federal University of Rio Grande do Norte (UFRN) under CAAE 74,989,823.6.0000.5537 (31/10/2023). The protocol follows the Standard Protocol Items for Randomized Trials (SPIRIT) guidelines [22].

Trial design

This protocol outlines a Randomized Controlled Trial (RCT) with 2 p.m. and a double-blind intervention design, comparing the effects of music therapy on reducing anxiety and stress in patients scheduled for elective transluminal coronary angioplasty.

Based on this design, the key question is: Is music therapy effective in reducing anxiety and stress in patients undergoing coronary angioplasty?.

Population

The study population will consist of individuals undergoing transluminal coronary angioplasty at the reference hemodynamics service in the state of Rio Grande do Norte, Brazil. The sample will be selected using simple random probability, with a total of 52 patients divided into two groups: the Control Group (CG) and the Experimental Group (EG).

Eligibility and recruitment criteria

The study will include patients over the age of 18 who are scheduled for their first coronary angioplasty. The inclusion criteria are as follows: (1) patients must be scheduled as outpatients; (2) patients must not be sedated prior to the procedure; (3) patients must have the cognitive ability to answer the questionnaire; and (4) patients must be capable of being assessed using anxiety scales, specifically the Beck Anxiety Inventory (BAI) and Lipp's Inventory of Stress Symptoms for Adults (ISSL). Both scales will be administered by the Auxiliary Researcher-2 (AR2) before and after the intervention. Exclusion criteria include patients with neurological disorders, hearing loss, those taking anxiolytics or antidepressants, and individuals who do not enjoy music.

Recruitment

Recruitment will take place in the hemodynamics unit of a university hospital in Natal, the capital of Rio Grande do Norte. This hospital serves as a reference center for SUS patients undergoing transluminal coronary angioplasty. Potential participants will be recruited by Assistant Researcher-1 (AR1) upon their admission to the preparation and recovery room of the hemodynamics unit (Fig. 1).

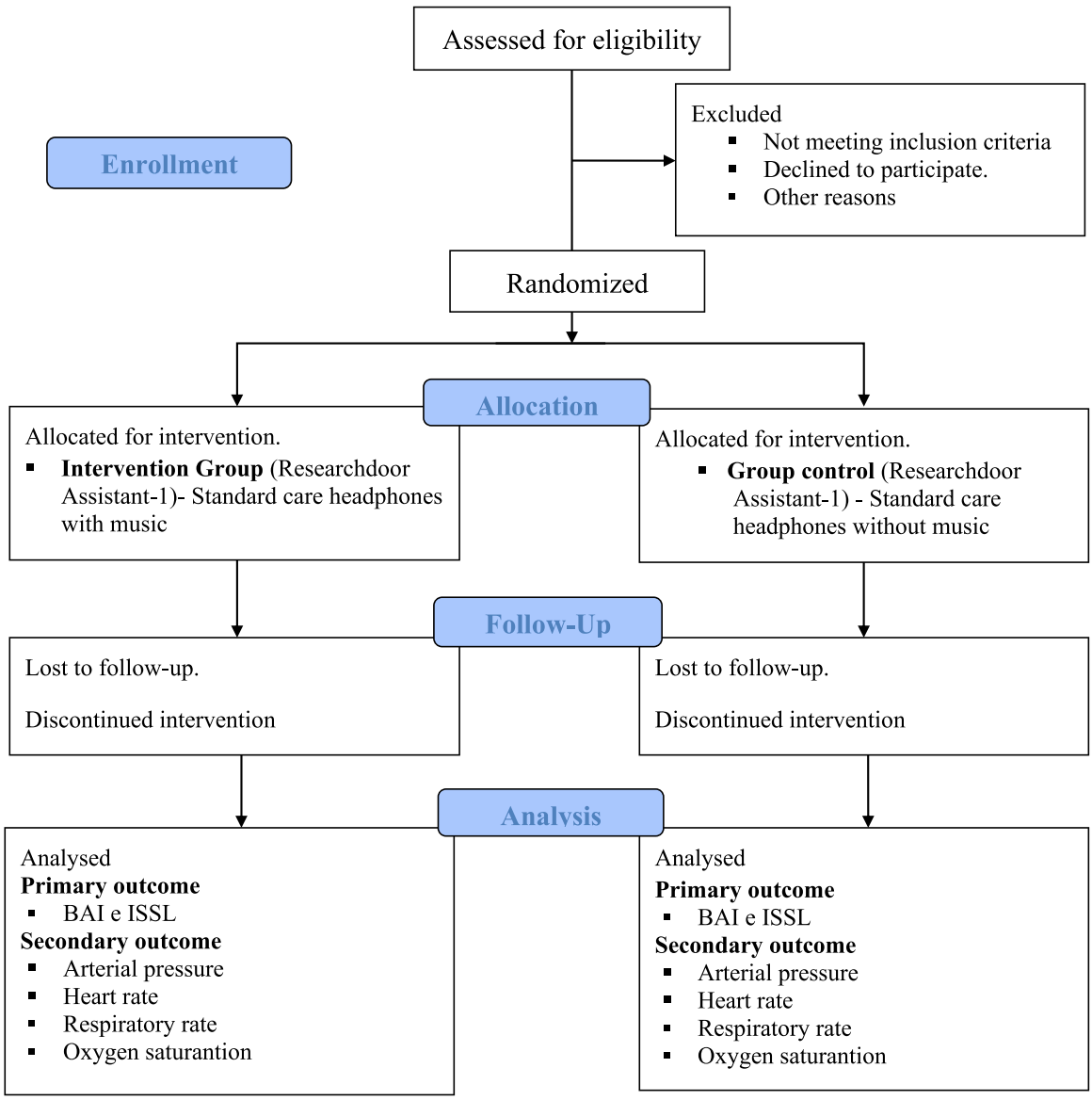

Fig. 1. Flow diagram of survey participants, adapted from CONSORT (2010) [23].

Interventions

The CG will consist of 26 patients, randomly allocated, who have a clinical indication to undergo the transluminal coronary angioplasty procedure. These patients will receive the standard care already adopted by the service, in addition to wearing headphones without musical transmission for approximately 15 min before the angioplasty procedure.

The EG will also consist of 26 patients, randomly allocated, who will receive the same care as the control group, with the addition of headphones that will transmit the patient's musical preference before the transluminal coronary angioplasty procedure. It is important to note that the use of headphones will be complementary and will not interfere with the standard care already provided by the service.

Questionnaire

To minimize the risk of bias, the researchers will be blinded. The project will involve two assistant researchers. AR1 will be responsible for the recruitment and initial selection of participants, obtaining and signing the Informed Consent Forms (ICF), and the randomization and allocation of patients to the CG and EG.

AR2 will be responsible for administering the three data collection instruments/questionnaires to patients in both groups, before and after the use of the headphones, as coordinated by AR1:

(a) AR2 will first administer a pre-prepared form to participants in both groups. This form will collect sociodemographic data, including date of birth, age, gender, ethnicity, marital status, education, occupation, family income, and musical preference. The second section of the form will gather clinical information such as comorbidities, the indication for the transluminal coronary angioplasty procedure, and current medications. Following this, vital signs (heart rate, respiratory rate, blood pressure) and oxygen saturation will be measured.
(b) AR2 will then administer the BAI to assess the patient's anxiety level. The BAI consists of 21 questions, with scores interpreted as follows: 0–21 indicates low anxiety, 22–35 indicates moderate anxiety, and scores above 36 indicate a concerning level of anxiety [24].
(c) AR2 will also administer the third instrument, the ISSL, which diagnoses the presence of stress symptoms and identifies the phase of stress: alertness, resistance/almost exhaustion, and exhaustion [25].

To ensure consistency, all researchers involved will undergo prior training to address any questions related to completing the data collection instruments.

Protocol validation

Primary outcome

The primary outcomes include the reduction of anxiety levels and stress symptoms following the music therapy intervention in patients undergoing the transluminal coronary angioplasty procedure. Data collected using the BAI and ISSL before and after the use of the headphones will provide information on the anxiety and stress levels in both the CG and EG.

Secondary outcome

The secondary outcomes include determining whether the use of music induces changes in vital signs (heart rate, respiratory rate, and blood pressure), as well as oxygen saturation.

Initial assessment

A few minutes before the procedure, the first researcher will recruit potential participants, explaining the main objective of the study, the possible risks and benefits, and emphasizing that they can withdraw at any stage.

Patients who meet the inclusion criteria and agree to participate by signing the ICF will be introduced to the study and instructed on the stages of the research during data collection. Any questions or concerns about the study will be addressed and clarified for the participants before the intervention (Table 1).

Sample size

The sample will be probabilistically selected using simple random sampling. This experimental study involves two groups: a control group (CG) and an intervention group (EG). The sample size, calculated using G*Power software version 3.1.9.2 (available at: http://www.gpower.hhu.de/), is based on a Cohen's effect size of 0.80, a test power of 0.80, and a significance level of 5 %. This results in a sample size of 26 participants per group, for a total of 52 patients across both groups (CG and EG).

Table 1
shows the detailed stages of the study, including the SPIRIT enrollment schedule, interventions, and assessments.

STUDY PERIOD						
	Enrolment	Baseline	Post-allocation: Allocation, Interventions, Follow-up			
TIMEPOINT			Allocation	P1	P2	Follow-up (F1)
ENROLMENT:						
Eligibility criteria	X					
Recruitment	X					
Initial assessment	X					
Informed consent	X					
Allocation			X			
INTERVENTIONS:						
Headphones with no musical transmission (Control group)					X	X
Headphones with the patient's musical preference (Experimental group)					X	X
ASSESSMENTS:						
Sociodemographic data		X		X		
Clinical data		X		X		X
BAI				X		X
ISSL				X		X

Source: Research data
Note:
P1: Immediately before the headphones are placed (30 min before the procedure).
P2: While the headphones are being worn (up to 10 min).
F1: After the headphones are removed, the questionnaires will be administered again, and a clinical assessment will be conducted.
BAI - Beck Anxiety Inventory
ISSL - Lipp's Inventory of Stress Symptoms for Adults.

Allocation randomization and blinding

After randomization, participants will be assigned to the two groups (CG and EG) using the website www.randomizer.org. This website will perform simple randomization, selecting participants for each group without researcher influence, ensuring the blinding of the study. The website will generate a list with the sequence of participants divided equally between the two groups. It is important to note that randomization will help prevent bias in participant selection and enable a fair comparison of the groups with respect to both known and unknown risk factors [23].

Blinding

Researcher-1 (AR1) will approach patients scheduled for coronary angioplasty upon their admission to the hemodynamics preparation/recovery room. AR1 will recruit patients, explain the study, and facilitate the signing of the informed consent form. After randomization into the two groups (CG and EG), AR1 will proceed to administer the headphones and offer the option of music to the EG patients. Researcher-2 (AR2) will be responsible for administering the data collection instruments, including sociodemographic and clinical information questionnaires, as well as the BAI and ISSL inventories. AR2 will conduct these assessments both before and after the use of the headphones, in addition to monitoring vital signs.

Data management

Initially, the research assistants (AR1 and AR2) will undergo training to ensure adherence to the study protocol during data collection. Data will be gathered in the patient admission/recovery room of the hemodynamics unit and stored in a pre-established database using Microsoft Office Excel software. The data will then be exported to Statistical Package for the Social Sciences (SPSS) software, version 20.0, for both descriptive and inferential analysis.

Losses and withdrawals will be meticulously documented to maintain the reliability of the study. Therefore, all instances of participant withdrawal will be carefully recorded. Any participant who withdraws will be replaced by the next eligible participant meeting the inclusion and exclusion criteria, ensuring that the initially calculated sample size is maintained.

All collected information will be securely stored by the responsible researcher for a period of five years and will only be used for scientific publications, safeguarding participant anonymity. Additionally, a dedicated spreadsheet will track the number of patient dropouts and other pertinent study-related information.

Data extraction and statistical analysis

Initially, data will be entered into a pre-established Microsoft Excel database and subsequently exported to Statistical Package for the Social Sciences (SPSS) software, version 20.0, for comprehensive descriptive and inferential analyses. A descriptive analysis of patients' sociodemographic and clinical profiles will be conducted using frequency and percentage distributions. Data collected

from the two inventories will be assessed using Likert scales. Descriptive statistics, including measures of central tendency (mean, median) and dispersion (range, standard deviation), will be employed to analyze data trends. All statistical tests in this study will be conducted at a significance level of 5 % ($p = 0.05$).

Discussion

In the Brazilian context, changes in the population's habits and lifestyle have underscored the growing and concerning prevalence of cardiovascular diseases in the country. It is therefore essential to develop strategies to reduce the stress and anxiety of patients undergoing hemodynamic procedures, alongside more conventional approaches, such as pharmacological interventions [9].

Psychiatric disorders appear to act as risk factors for cardiovascular morbidity and mortality. These disorders may also have a negative impact on disease stability, treatment adherence, and quality of life for patients with heart disease [26].

Anxiety disorders are often present in patients with cardiovascular diseases. Most available data focus on ischemic heart disease and heart failure. However, emotional distress in patients with carotid atherosclerosis has received comparatively less attention, especially when contrasted with the well-studied population with coronary atherosclerosis [27].

A systematic review with meta-analysis aimed at assessing anxiety, fear, and other emotional experiences commonly experienced by patients before and after cardiovascular interventions found that higher levels of anxiety could negatively impact patients' prognosis and recovery following the procedure [28].

Chronic psychosocial anxiety is associated with key outcomes in coronary artery disease (CAD), yet it is frequently overlooked by clinicians. The progression of CAD is thought to be influenced by factors such as heart rate variability, endothelial inflammation, and impaired myocardial perfusion, all of which are exacerbated by mental stress, including anxiety and other psychological stressors [29].

Therefore, it is crucial to consider strategies that reduce the anxiety levels of patients to improve both their physical and mental prognosis. While sedatives and opioids are commonly used, non-pharmacological approaches such as aromatherapy and music therapy have also been shown to be effective [30].

The effectiveness of music as a non-pharmacological intervention to reduce anxiety and pain, as well as to improve feelings of control and well-being, has been extensively researched and documented in the specialized literature [10]. Music has a significant impact on human emotions, serving as an inspiring, relaxing, soothing, and energizing tool. It has been shown to reduce anxiety levels and hemodynamic indices in patients undergoing cardiac catheterization [31].

Furthermore, a randomized clinical trial conducted in South Korea in 2022, which aimed to evaluate the effects of music on anxiety and stress responses in patients undergoing interventional cardiac catheterization, found that musical intervention effectively reduced anxiety and stress before the procedure. This study underscores the importance of considering music therapy as part of clinical management [8].

Thus, it is evident that musical intervention has beneficial effects in enhancing patient treatment and healthcare. Music exerts physiological effects by increasing parasympathetic activity, regulating respiratory and heart rates, improving attention and concentration, reducing stress and agitation, and promoting relaxation. As a non-pharmacological therapy, music contributes to enhancing overall well-being and quality of life, supporting the conclusions drawn from this study [32].

Additionally, music therapy aligns with a current trend advocated by the Brazilian Unified Health System (SUS), which promotes integrative health practices. These practices counter an approach to care and treatment based solely on curative, biomedical, and pharmacological methods. SUS incorporates integrative practices to complement traditional care models and improve health outcomes [33].

Limitations

Not applicable.

CRediT author statement

FCOM participated in the design of the study. FCOM, KVGS, TTMS, VSLP have drafted the work. KDD, KRBR, DVD, RAND participated in the critical revision of the manuscript. All authors read and approved the final manuscript.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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