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ORIGINAL ARTICLE

# Effectiveness of educational intervention with manual for anxiety and stress reduction: controlled clinical trial

*Efetividade da intervenção educativa com manual para redução da ansiedade e estresse: ensaio clínico controlado*

*Efectividad de la intervención educativa con manual para reducción de la ansiedad y estrés: ensayo clínico controlado*

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## ABSTRACT

**Objective**: To evaluate the effectiveness of the educational intervention through an informative manual in reducing anxiety, stress, and changes in vital signs in patients awaiting cardiac catheterization. **Methods**: Parallel, randomized, controlled, blind clinical trial. The study excluded patients waiting for cardiac catheterization; those who received the information manual were randomized to the intervention group, and those who received routine information from the unit went to the control group. The study used the State Anxiety Inventory and Perceived Stress Scale and the ANOVA test to analyze the outcomes between the groups. Clinical Trials NCT03369873. **Results**: There was no change concerning time, first and second moment (anxiety, P=0.225; and stress, P=0.696), interaction (anxiety, P=0.183; and stress, P=0.444), or groups, control, and intervention (anxiety, P=0.341; and stress, p=0.624). **Conclusion**: Although the educational intervention performed did not have an impact on the reduction of anxiety and stress, this type of intervention should be maintained for greater comfort and safety of patients and family members.

**Descriptors**: Cardiac Catheterization; Anxiety; Psychological Stress; Controlled Clinical Trial; Prospect for Patient Education.

## RESUMO

**Objetivo:** Avaliar a efetividade da intervenção educativa mediante manual informativo na redução da ansiedade, estresse e alterações dos sinais vitais em pacientes que aguardavam o cateterismo cardíaco. **Métodos:** Ensaio clínico paralelo, randômico, controlado, cego. Incluíram-se pacientes que aguardavam o cateterismo cardíaco; os que receberam o manual informativo foram randomizados para o grupo-intervenção; e os que receberam informações rotineiras da unidade, para o grupo-controle. Utilizaram-se Inventário de Ansiedade-Estado e Escala de Estresse Percebido. Realizou-se teste ANOVA para análise dos desfechos entre os grupos. Clinical Trials NCT03369873. **Resultados:** Não houve alteração em relação ao tempo, primeiro e segundo momento (ansiedade, p=0,225; e estresse, p=0,696), interação (ansiedade, p=0,183; e estresse, p=0,444) ou grupos, controle e intervenção (ansiedade, p=0,341; e estresse, p=0,624). **Conclusão:** Embora a intervenção educativa realizada não tenha apresentado impacto na redução da ansiedade e estresse, esse tipo de intervenção deve ser mantido, para maior conforto e segurança dos pacientes e familiares.

**Descritores:** Cateterismo Cardíaco; Ansiedade; Estresse Psicológico; Ensaio Clínico Controlado; Prospecto para Educação de Pacientes.

## RESUMEN

**Objetivo**: Evaluar efectividad de intervención educativa mediante manual informativo en la reducción de ansiedad, estrés y alteraciones de signos vitales en pacientes que aguardaban cateterismo cardíaco. **Métodos**: Ensayo clínico paralelo, aleatorio, controlado, ciego. Incluidos pacientes que aguardaban cateterismo cardíaco; los que recibieron el manual informativo fueron randomizados al grupo intervención; y los que recibieron informaciones rutinarias de la unidad, al grupo control. Utilizados Inventario de Ansiedad-Estado y Escala de Estrés Percibido. Realizada prueba ANOVA para análisis de desfechos entre los grupos. Clinical Trials NCT03369873. **Resultados**: No hubo alteración en relación al tiempo, primer y segundo momento (ansiedad, p=0,225; y estrés, p=0,696), interacción (ansiedad, p=0,183; y estrés, p=0,444) o grupos, control e intervención (ansiedad, p=0,341; y estrés, p=0,624). **Conclusión**: Aunque la intervención educativa realizada no tenga presentado impacto en la reducción de ansiedad y estrés, ese tipo de intervención debe ser mantenido, para mayor comodidad y seguridad de pacientes y familias.

**Descriptores**: Cateterismo Cardíaco; Ansiedad; Estrés Psicológico; Ensayo Clínico Controlado; Folleto Informativo para Pacientes.

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## INTRODUCTION

Cardiovascular disease (CVD) remains the leading cause of death worldwide in recent years[1]. Among its various forms, coronary artery disease (CAD) is one of the most prevalent. CAD is characterized by the imbalance between the supply and consumption of oxygen in the myocardium. It can be caused by a reduction in blood flow due to chronic atherosclerotic obstruction of the coronary artery, setting up the "chronic coronary syndrome,"[2] or be triggered by a rupture of an atherosclerotic plaque, termed "acute coronary syndrome"[3]. The diagnosis of CAD is constructed by assessing signs and symptoms, electrocardiogram, necrosis markers, and coronary angiography or cardiac catheterization (CATH). CATH is an invasive method that shows obstructions of the coronary arteries and can cause several negative feelings to the patient, such as anxiety and stress[3-4].

Anxiety is characterized by symptoms such as tension, restlessness, difficulty concentrating due to some concern, fear that something terrible may happen, and a feeling of loss of control over oneself[5]. Stress is a transient disorder that occurs in an individual exposed to a stressful event, which triggers an acute reaction with unpleasant and lasting consequences and leads to a state of post-traumatic stress or adaptation disorder[6].

It is observed that anxiety and stress associated with CATH arise from the threat of change in health status, concerns, and expectations regarding the outcome of the procedure, and due to the possibility of performing percutaneous coronary intervention or coronary artery bypass grafting[4]. These feelings can cause activation of the sympathetic nervous system, increasing contractility and heart rate, blood pressure, and oxygen consumption, worsening the evolution of the disease[7].

Different strategies may reduce anxiety and stress. Studies have shown that massage therapy[8], aromatherapy[9], therapy[10], and the educational intervention of nursing[11-12] help these patients develop greater self-control of these feelings. The nursing educational intervention about the treatment, conduct, and procedures necessary for its therapy provides greater interaction with the multidisciplinary team and greater control of the disease, with benefit to patients as they can understand what happens to their health[11-12].

The nursing educational intervention can be done verbally using oral explanations; or in a written form, using a standardized script, such as an informative manual containing texts and images. The informative manual, as an educational nursing strategy, favors the nursing orientation to patients in a standardized and dynamic way, facilitating the processing and retention of information to effect nursing interventions and expand patient learning[13].

A previous study[13] developed a guide manual for patients who would be referred to CATH, which was validated by experts and patients, obtaining adequate evidence of content and face validity. However, this educational material was not evaluated for its effectiveness in reducing or stabilizing anxiety and stress levels in patients awaiting CATH. Therefore, the following question was asked to verify its effectiveness: does the educational intervention performed through an informative manual in patients waiting for CATH reduce anxiety and stress levels when compared to the oral educational intervention?

For this study, given the questioning formulated, the hypothesis was that patients waiting for CATH and who were guided through a previously validated information manual would have lower levels of anxiety and stress when compared to patients who were oriented verbally.

## OBJECTIVE

To evaluate the effectiveness of the educational intervention through an informative manual in reducing anxiety and stress levels, and changes in vital signs in patients waiting for CATH.

## METHODS

### Ethical aspects

This study followed the recommendations of Consolidated Standards of Reporting Trials (CONSORT). It was approved by the Research Ethics Committee of the hospital and university and registered in the Clinical Trials database (NCT03369873).

### Design, period, and place of study

It is a parallel, randomized, controlled and blind clinical trial, guided by the CONSORT tool, conducted from April to December 2017, in the inpatient and critical units of a hospital in São Paulo specialized in cardiology.

### Population, criteria of inclusion and exclusion

This study included patients who were waiting for CATH; aged between 18 and 79 years; literate, as the instruments for the evaluation of the main outcome are self-applied; hospitalized for any manifestation of coronary artery disease (acute[3] or chronic[2] coronary syndrome) in Killip I (without signs of pulmonary congestion) and Killip II (Rales in the pulmonary bases, jugular stasis or third bulge), because they are patients without signs of respiratory distress. These clinical data were extracted from the evaluation of the patient's medical record.

The study did not include subjects who underwent emergency CATH; with a visual deficit that made reading impossible and/or with some alteration in the level of consciousness; patients using benzodiazepines, anxiolytics, and/or any herbal medicine that could influence mood, anxiety, and stress, and patients who experienced situations in which they received guidance on CATH before the beginning of the research in the current hospitalization and/or who expressed the desire not to receive information. It also excluded subjects who presented situations of hemodynamic instability and/or precordial pain that could influence anxiety, stress, and vital signs during the collection period.

As in the previous study, this study stipulated that the participant should have a difference of 7 points in the score between the evaluations to obtain a significant reduction in state anxiety, considering that the control group would not present differences in the level of anxiety and stress before and after the intervention ($\Delta control = 0$)[14]. Therefore, for a significance level of 5%, text power of 90%, and considering the possibility of losses of 10%, a

minimum sample of 122 participants was required, with sixty-one patients randomized for each group (control and intervention).

### Study protocol

This research had three collaborators. The first researcher performed the simple randomization of the participants in the intervention group (IG) and control group (CG) through the Random® program and had no contact with the participants. The principal researcher evaluated the participants who met the inclusion criteria, applied the Informed Consent Form, and implemented the intervention in the IG. A third researcher, who was graduated in Nursing and Psychology, did not have access to randomization and allocation of participants, remaining blind, collected sociodemographic and clinical variables only once; evaluated anxiety and stress through validated and self-applied instruments before and after the IG and CG interventions, and measured the vital signs of patients. Researchers instructed participants not to reveal which intervention they received.

The IG had participants who received the educational intervention, conducted through the informative manual on CATH, previously prepared and validated[13]. This manual consisted of seven topics on where and how the CATH was performed, the time needed for the examination, and the care before, during, and after the procedure. After its elaboration, this manual was submitted to content validation by the Delphi technique by a group of eight cardiologist nurses, and it took four rounds to have its content considered valid. Subsequently, thirty-five patients who underwent CATH evaluated this manual for its understanding, using a five-point Likert scale, in which the average score presented was 4.83 to 4.91, which was considered valid by patients[13].

Participants randomized to the IG read the informative manual and were questioned if they had doubt left. If so, the principal researcher provided the clarifications according to the information contained in the manual. If they had no questions, they would finish the intervention.

The CG had participants who received only oral information according to the institutional routine. The information was related to the procedure technique, possible arterial puncture sites, and preparation of the patient for the procedure, such as fasting, trichotomy, placement of venous access, and rest after the procedure. The nurse who attended them in the units where they were hospitalized provided this information.

The nursing orientations of both groups were performed after the first measurement of vital signs as well as evaluation of anxiety and stress, which lasted a maximum of 20 minutes in a single time. After this time, the auxiliary researcher measured vital signs again, and reapplied the anxiety and stress instruments.

The primary outcome of this study consisted of the anxiety and stress of the participants waiting for the CATH, evaluated through the State Anxiety Inventory (A-State) and the Perceived Stress Scale 10 items (PSS-10), respectively. Both instruments are self-administered, and the secondary outcomes were vital signs. The study evaluated outcomes before (first moment – M1) and after interventions (second moment – M2).

Anxiety was assessed by the subscale of the State-Trait Anxiety Inventory (IDATE), the A-State, in which the participant answered how he felt at a given moment. These scales were translated and validated into Brazilian Portuguese[15-16]. The following categorization was used for the analysis of the results: low anxiety (20-34 points), moderate anxiety (35-49 points), high anxiety (50-64 points), and very high anxiety (65-80 points). The PSS-10 was translated and validated in adults and the elderly in Brazil[17], and it assesses life experiences and how unpredictable, uncontrollable, and burdensome they can be in a month. The study used the cutoff point established in a previous study in patients with ACS: unstressed (less than or equal to 21 points); moderate stress (22 to 27 points); stressed (28 to 31 points), and high stress (greater than or equal to 32 points)[17]. The vital signs measured were heart rate (HR), respiratory rate (RR), systolic blood pressure (SBP), and diastolic blood pressure (DBP), and the evaluation occurred with the patient lying down, at bed rest for at least five minutes. HR was verified using the apical pulse for 60 seconds; HR was checked by counting thoracic incursions for 60 seconds; and SBP and DBP were obtained through a manual Aneroid sphygmomanometer, validated by INMETRO and calibrated.

The study collected the antecedent variables through an instrument previously developed and used in a previous study(18): age; gender; race or skin color; marital status; schooling; cardiovascular risk factors (systemic arterial hypertension [SAH], diabetes *mellitus* [DM], sedentary lifestyle, obesity, dyslipidemia [DLP], smoking, alcoholism and family history of cardiovascular diseases); use of beta-blocker, vasodilator and angiotensin-converting enzyme (ACE) inhibitors; previous medical diagnosis and/or symptoms of depression; hospitalization and/or previous experience of percutaneous intervention[18].

### Analysis of results and statistics

The study presented measures of centrality and dispersion for the description of quantitative variables; and, for qualitative variables, it used percentage and absolute frequencies. It also used the non-parametric ANOVA test for longitudinal data to evaluate the change in stress and anxiety levels about time (first and second moment) and groups (control and intervention).

## RESULTS

A hundred and twenty-eight patients were evaluated for eligibility, among whom five did not meet the inclusion criteria because they were not literate, and one refused to participate in the study; thus, the study included 122 patients, sixty-one of whom were randomized to the CG, and sixty-one to the IG, as shown in Figure 1.

Table 1 shows the sociodemographic and clinical characteristics of the CG and IG participants, presenting that most of them were male, white, and married and had systemic arterial hypertension, sedentary lifestyle, dyslipidemia, and family history of cardiovascular diseases. The groups (control and intervention) were homogeneous, except for the variable "race," in which the number of whites was more prevalent in the IG, as seen in Table 1.

Regarding the drugs used on the day of evaluation, more than half of the participants used beta-blockers (n = 95; 78%), angiotensin-converting enzyme inhibitors (n = 94; 77%), and vasodilators, with no statistical difference in the comparison between the groups.

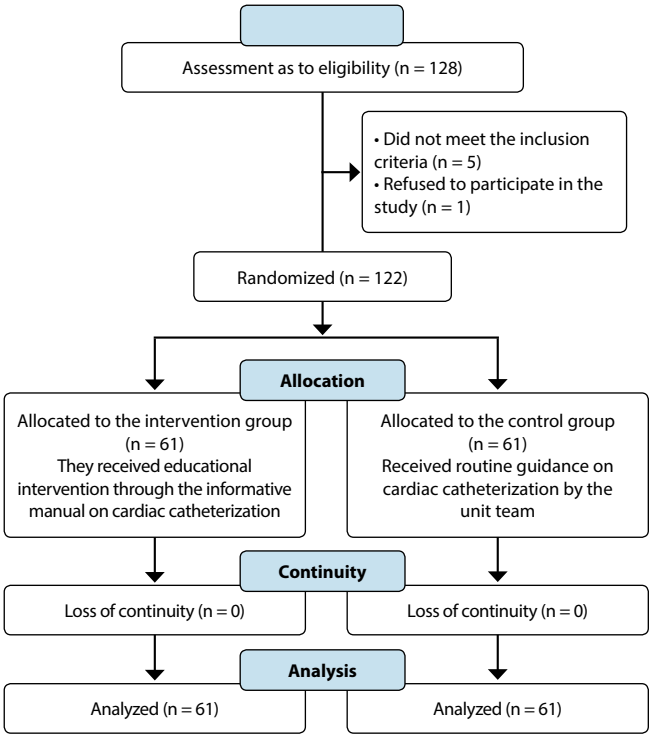


**Figure 1** - Diagram of inclusion of participants in the study, São Paulo, São Paulo, Brazil, 2017

There was no relevant difference when comparing anxiety and stress before and after the intervention between the groups. The same happens when the study relates the level of anxiety and stress in each group and the interaction between the groups, and the moment of evaluation of these outcomes, according to the data in Table 2.

The study did not observe any significant changes in the measured values of SBP and HR when comparing vital signs before and after the educational intervention between the groups. DBP had a relevant increase after the educational intervention in both groups; and verified that the RR value in the IG was lower after the educational intervention and higher in the CG, as shown in Table 3.

## DISCUSSION

The sociodemographic and clinical characteristics of the participants in this study showed similarity with the national and international literature[1-2]. Except for the variable "color," in which there was a predominance of white participants in the IG, the groups were homogeneous.

The study did not support the hypothesis that the informational manual educational intervention would more significantly reduce the anxiety and stress levels of patients waiting for the CATH. This result may have been influenced by the method used during the intervention, in which the guidelines were given through the reading of the informative manual by the participant himself, with the clarification of doubts only when requested; and the patients' level of understanding of CATE was also not assessed after the implemented educational interventions.

Although the study did not prove the hypothesis, other studies have demonstrated the importance of educational nursing intervention and the use of the informative manual. A review article, which analyzed nineteen studies, showed that the information offered to the patient in written form may impact knowledge, increase patient satisfaction, and improve adherence to treatment, diet, and lifestyle changes, especially in the short term and in acute conditions when well delineated and applied at the appropriate

**Table 1 –** Comparison of sociodemographic variables between the control group and the group-intervention, São Paulo, São Paulo, Brazil, 2017

| | Control Group | Intervention Group | Total | *p* value |
|---|---|---|---|---|
| Average age (years) (SD) | 59.4 (8.3) | 61.9 (9.7) | 60.7 (9.0) | 0.12* |
| Gender | | | | |
| Male | 50 (82) | 44 (72.1) | 94 (77) | 0.28† |
| Female | 11 (18) | 147 (27.9) | 28 (33) | |
| Race | | | | |
| White | 38 (62.3) | 49 (80.3) | 87 (71.3) | 0.04† |
| Not white | 23 (37.7) | 12 (19.7) | 35 (28.7) | |
| Marital status | | | | |
| Married | 49 (80.3) | 41 (67.2) | 90 (73.8) | 0.40† |
| Single | 3 (4.9) | 5 (8.2) | 8 (6.6) | |
| Widow | 4 (6.6) | 8 (13.1) | 12 (9.8) | |
| Divorce | 5 (8.2) | 7 (11.5) | 12 (9.8) | |
| Education (years) Median (Q25/Q75) | 8 (4/12) | 9 (5/14) | 8 (5/13) | 0.33‡ |
| Comorbidities n (%) | | | | |
| High blood pressure | 45 (73.8) | 52 (85.2) | 97 (79.5) | 0.17† |
| Diabetes *mellitus* | 25 (41) | 29 (47.5) | 54 944.3) | 0.58† |
| Dyslipidemia | 37 (60.7) | 39 (63.9) | 76 (62.3) | 0.85† |
| Self-reported stress | 33 (54.1) | 29 (47.5) | 62 (50.8) | 0.58† |
| Depression | 9 (14.8) | 10 (16.4) | 19 (15.6) | 1.00† |
| Obesity | 21 (34.4) | 21 (34.4) | 42 (34.4) | 1.00† |
| Family history | 46 (75.4) | 44 (72.1) | 90 (73.8) | 0.83† |
| Sedentary lifestyle | 45 (73.8) | 43 (70.5) | 88 (72.1) | 0.84† |
| Smoking | 15 (24.6) | 9 (14.8) | 24 (19.7) | 0.25† |
| Daily drinking | 3 (4.9) | 1 (1.6) | 4 (3.3) | 0.32 |
| Previous experience of percutaneous intervention | 31 (50.8) | 32 (52.5) | 63 (51.6) | 1.00 |

*Note: SD – standard deviation; Q25 – first interquartile range; Q75 – third interquartile range; * test t of Student; Fisher's exact test; ‡ Mann-Whitney.*

**Table 2 –** Mean and median of anxiety and stress at both moments by group, São Paulo, São Paulo, Brazil, 2017

| | | Group-control | Group-intervention | Total | *p* value* |
|---|---|---|---|---|---|
| Anxiety | | | | | |
| M1 | Mean (SD) | 43.0 (±9.2) | 41.1 (±9.1) | 42.0 (±9.2) | Group: 0.34 |
| | Median (Q25 / Q75) | 43.0 (37/48) | 41.0 (34/46) | 42.0 (35/47) | Time: 0.22 |
| M2 | Mean (SD) | 42.2 (±11.1) | 41.3 (±9.2) | 41.8 (±10.2) | Interaction: 0.18 |
| | Median (Q25 / Q75) | 41.0 (35/49) | 40.0 (35/46) | 40.5 (35/47) | |
| Stress | | | | | |
| M1 | Mean (SD) | 19.5 (±5.6) | 18.8 (±7.2) | 19.1 (±6.4) | Group: 0.62 |
| | Median (Q25 / Q75) | 19.0 (16/23) | 18.0 (15/22) | 19.0 (15/23) | Time: 0.69 |
| M2 | Mean (SD) | 19.1(±5.6) | 18.6 (±7.3) | 18.8 (±6.5) | Interaction: 0.44 |
| | Median (Q25 / Q75) | 20.0 (16/21) | 20.0 (12/22) | 20.0 (13/22) | |

*Note: *Value of p – ANOVA test; SD – standard deviation; Q25 – first interquartile range; Q75 – third interquartile range; A-State – Anxiety Inventory-State; M1 – first moment of assessment; M2 – second moment of assessment; PSS-10 – Perceived Stress Scale-10.*

**Table 3 –** Descriptive measures for vital signs (systolic blood pressure, diastolic blood pressure, heart rate and respiratory rate) segmented by moments and groups, São Paulo, São Paulo, Brazil, 2017

| | Intervention group | | | | Control group | | | | *p* value* |
|---|---|---|---|---|---|---|---|---|---|
| | Mean (SD) | Median | Q25 | Q75 | Mean (SD) | Median | Q25 | Q75 | |
| PAS (M1) | 123.5 (±18.4) | 122.0 | 110.0 | 138.0 | 122.0 (±18.8) | 122.0 | 106.0 | 136.0 | Group: 0.82 |
| PAS (M2) | 124.1 (±18.1) | 124.0 | 112.0 | 136.0 | 124.7 (±21.3) | 122.0 | 108.0 | 140.0 | Time:0.28 |
| | | | | | | | | | Interaction: 0.49 |
| PAD (M1) | 73.1 (±13.2) | 72.0 | 64.0 | 80.0 | 71.4 (±11.5) | 72.0 | 62.0 | 78.0 | Set: 0.250 |
| PAD (M2) | 75.1 (±12.2) | 78.0 | 68.0 | 80.0 | 73.2 (±11.5) | 72.0 | 66.0 | 80.0 | Time: 0.01 |
| | | | | | | | | | Interaction: 0.96 |
| FC (M1) | 68.7 (±14.7) | 66.0 | 60.0 | 76.0 | 67.3 (±11.6) | 65.0 | 60.0 | 71.0 | Group: 0.42 |
| FC (M2) | 68.5 (±14.3) | 66.0 | 60.0 | 76.0 | 67.0 (±12.3) | 65.0 | 60.0 | 68.0 | Time:0.46 |
| | | | | | | | | | Interaction: 0.54 |
| FR (M1) | 18.6 (±2.5) | 18.0 | 16.0 | 20.0 | 18.3 (±3.1) | 18.0 | 16.0 | 20.0 | Group: 0.381 |
| FR (M2) | 18.3 (±2.7) | 18.0 | 16.0 | 20.0 | 19.1 (±3.1) | 19.0 | 16.0 | 20.0 | Time:0.725 |
| | | | | | | | | | Interaction: 0.04 |

*Note: *Value of p - ANOVA test; SD – standard deviation; Q25 – first interquartile range; Q75 – third interquartile range; SBP – systolic blood pressure; M1 – first moment of evaluation; M2 – second moment of evaluation; DBP – diastolic blood pressure; HR – heart rate; RR – respiratory rate.*

time[19]. Another research that validated an informative manual on care in the postoperative period of myocardial revascularization demonstrated that this type of educational intervention may reduce complications and ensure more safety for patients[20].

In contrast, studies also showed similar data: the group that received verbal instructions briefly and routinely presented, although not significant, slightly higher levels of anxiety[21-23]. These results may be related to the lack of practices that individualize the needs of patients and the passive participation of patients in self-care[23].

A study suggests that the educational intervention should be done promptly about what the participant wants to know, what are their expectations regarding the procedure, what their disease means to them, their treatment and being hospitalized; and, subsequently, the study must consider their ability to assimilate the information provided by health professionals[24].

Another possible justification for the results identified in the present study is that some participants already had a moderate anxiety score at the first moment of evaluation (mean 42 points), as well as a low-stress score (mean 19 points) - scores considered normal for adults. The results will possibly support future studies that investigate the applicability and effectiveness of educational methodologies used by nursing in patients with higher levels of anxiety and stress and can demonstrate relevant clinical outcomes.

These data corroborate the findings of other studies that show that the level of anxiety in the majority of this population is moderate[4,8,12,21-22,25]. Studies that evaluated the effect of educational video on CATH and used the IDATE scale to assess anxiety indicated that patients had a score ranging from 38 to 49 points[12,22]. Another study, showed the effects of massage on the anxiety generated by percutaneous intervention, attested that the scores ranged from 40 to 41 points before the proposed intervention[8]. A Brazilian study, which evaluated the use of multimedia in anxiety generated by CATH and used Beck's anxiety inventory, pointed out that patients had mild to moderate anxiety[21]. Another study, which assessed the level of anxiety by the Visual Analogue Scale for Anxiety of 2,604 patients submitted to CATH or angioplasty, revealed that the average anxiety score was 40.6±25.7 (mild to moderate anxiety) at hospital admission[4]. Batista et al. also identified moderate levels of anxiety (mean score of 40.2±10.4) in this population[25].

Regarding stress, the low scores found in this study did not coincide with the data found in the literature. A study that related the stress to food consumption in patients with ACS and used PSS-10 found that patients had a variation in the score of 8 to 40

points, with an average of 27.03±6.57, which can be considered as a moderate level of perceived stress[18]. Another study, using the instrument Depression, Anxiety and Stress Scales (DASS-21), assessed the aromatherapy effect on the anxiety and stress of patients awaiting percutaneous coronary intervention: it showed that patients had a score of moderate emotional disorder[9].

The results regarding stress identified in this study can be attributed to the fact that being admitted to a reference hospital in cardiology and with the guarantee of treatment and follow-up can increase coping mechanisms, minimizing the perception of stress. Another factor that may have contributed to non-significant changes in anxiety and stress scores after the educational intervention with the manual and verbally was that more than half of the participants in both groups had already experienced previous hospitalizations, which may have brought them more security in performing the CATH[21,26-27].

Regarding the CATH experiences and previous hospitalizations with stress and anxiety, a study that qualitatively analyzed the immediate repercussions of the nurse's educational action on patients waiting for the cardiovascular intervention procedure showed that those with prior knowledge or previous hospitalizations felt safer when talking about the procedure[26]. Previous experiences of hospitalizations and invasive procedures can contribute to a better clarification of the process and care needed, even in the face of the possibility of unexpected outcomes[21,26-27].

Anxiety and stress, when present, present psychological effects, such as mental fatigue, tension, anguish, insomnia, difficulties in interpersonal relationships, excessive worry, inability to relax, and emotional hypersensitivity. The physical effects are increased sweating, muscle tension, tachycardia, increased blood pressure, and nausea-symptoms, which can worsen the evolution of the disease[21].

This study observed that most vital signs, and anxiety and stress, did not change with the interventions. The only parameters that changed were DBP, in which there was an increase in the second moment of evaluation in both groups; and RR, which was higher in the second moment in the CG. Despite the increased values of these vital signs, they were still within the normal parameters, as well as anxiety and stress, which makes us reflect that such a difference identified in these variables of vital signs were statistical differences and not clinically relevant.

In the literature, different results are observed regarding changes in vital signs. Research that evaluated the effects of massage on the anxiety of patients undergoing percutaneous coronary intervention showed that the values of SBP, DBP, and HR of the IG, evaluated one hour before the procedure, were significantly lower when compared with the values of the CG ($p < 0.05$)[8]. Another study, which evaluated individuals who received guidance on CATH through the educational video, found that the values of SBP, DBP, HR, and RR, measured before and after CATH, did not show significant differences in any of the two measures between the two groups ($p > 0.05$)[22]. In these studies, vital sign values were also within normal limits.

The evaluation of the impact of the use of a multimodal guidance package (written information, informative video, and clarification of doubts by professionals) on vital signs in patients undergoing CATH indicated that there was no significant difference in SBP ($p = 0.820$) and DBP ($p = 0.930$) between the intervention and control groups one day before the CATH[11]. However, half an hour before and half an hour after the procedure, there was a significant difference between the groups: the SBP and DBP means were higher in the CG both before the procedure ($p = 0.030$, $P = 0.015$, respectively), and after ($p = 0.031$, $p = 0.023$, respectively); and there was no statistical difference between the groups concerning RR changes at any[11]. Another study that compared the impact of music therapy in 70 patients who underwent percutaneous interventions showed a difference in SBP of -3.3±17.3 mmHg in the IG with music therapy and of -2.3±19.4 mmHg in CG, but no statistical difference ($p = 0.83$)[10]. There was also a difference in DBP -1.9±12.2 mmHg in the group with e music therapy of 2.0±13.4 mmHg in the CG, also without statistical difference ($p=0.23$)[10].

The results obtained in this clinical trial did not identify any changes in the anxiety and stress levels and SBP and HR values when comparing the groups and when comparing the two evaluated moments, that is, before and after the educational intervention was performed.

### Study limitations

The results of the present research may be related to some limitations of the study, such as the understanding of the participants that was not evaluated regarding the information about the CATH offered to the members of the control and intervention groups; participants were not asked what information they would like to receive since they might not be willing to listen to all those passed on; the study did not include only patients with high levels of anxiety and very high levels of anxiety and stress, and did not exclude participants who had previously performed the CATH.

### Contributions to the fields of Nursing and Health

These results may stimulate novel studies that explore the use of the informative manual in larger populations, in other centers and even using additional strategies of educational nursing intervention. In addition, the expectation is that future research will be conducted to identify whether the educational intervention with the use of the informative manual reduces fear and improves both knowledge and patient satisfaction.

## CONCLUSION

The educational intervention, conducted through the informative manual, did not reduce the anxiety or stress of patients waiting for CATH. DBP was higher in the second evaluation in both groups, and RR was lower in the intervention group and higher in the control group in the second evaluation. Despite the results found, the educational intervention favors the knowledge of the patient, the family, and society, positively impacting the quality of care and effective communication between team and patient.

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