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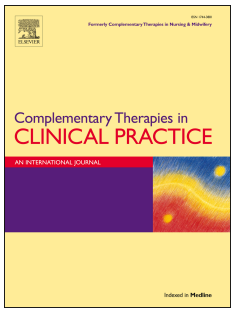

The impact of listening to pleasant natural sounds on anxiety and physiologic parameters in patients undergoing coronary angiography: A pragmatic quasi-randomized-controlled trial

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The impact of listening to pleasant natural sounds on anxiety and physiologic parameters in patients undergoing coronary angiography: a pragmatic quasi-randomized-controlled trial

Running title: Pleasant natural sounds therapy and anxiety

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Conflicts of interest

None of the authors have any conflicts of interests with regards to this research.

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Contributions

Study design: NR, MHK;

Data collection: NR, AJ;

Data analysis: SJ, SDT;

Manuscript preparation: NR, MV, SJ.

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The impact of listening to pleasant natural sounds on anxiety and physiologic parameters in patients undergoing coronary angiography: a pragmatic quasi-randomized-controlled trial

Abstract

Objective: This study aimed to investigate the impact of listening to pleasant natural sounds on anxiety and physiological parameters in patients undergoing coronary angiography.

Methods: The present pragmatic quasi-randomized controlled clinical trial was conducted on 130 patients undergone elective angiography. The participants were randomly divided into two groups, including a pleasant natural sounds group, and a control group (n½ 65 per group). Spielberger's state/ trait anxiety inventory was used to assess levels of anxiety. The patients' anxiety level and physiological parameters were measured at baseline, before, during, immediately after, and twenty minutes after coronary angiography.

Results*:* The mean level of anxiety was similar in both arms at baseline (t=1.317, df=128, p= 0.190). The intervention arm displayed significantly lower anxiety levels than the control arm during the intervention (Wilks' lambda 0.11, Pillai's trace 0.89, P 0.001, F 2.05). The physiological parameters (systolic and diastolic blood pressure, mean arterial pressure, heart rate, and oxygen saturation) of both groups showed statistically significant differences (p<0.05) over time and in group-by time interactions.

Conclusion: As an effective nursing intervention presenting no side-effects, listening to pleasant natural sounds can be helpful in the management of anxiety.

Key words: Anxiety, Coronary Angiography, Music Therapy, Physiologic Parameters

1. Introduction

The prevalence of cardiovascular and circulatory diseases and associated mortality are increasing worldwide [1]. The highest ischemic heart disease (IHD) mortality rates are in Eastern Europe and Central Asia, and for working-age populations, IHD mortality rates are mostly higher in transitional and developing countries than in developed countries [2]. Coronary angiography is one of the most common invasive procedures to locate blocked coronary arteries, and plays an important role in determining treatment [3]. Although it is essential for the detection of cardiovascular disease, it can cause fear, anxiety, and emotional stress [4]. The coronary angiography laboratory with highly technical equipment and unfamiliar sounds can create a stressful situation for patients. More than 80% of patients scheduled for coronary angiography experience a decreased sense of control over bodily functions and a high level of anxiety before the procedure is commenced [5- 6]. Anxiety is highest whilst waiting for the procedure and immediately prior to the procedure, and lowest after the procedure [7]. An elevated level of anxiety may negatively influence patients' psychological and physiological wellbeing and may interfere with nursing care [8]. Patients may feel more anxious before coronary angiography than heart surgery [9].

to prolongation or cancellation of the procedure, or impair cardiac functioning. Patients may interpret their symptoms as an impending heart attack [10]. Stress-related tachycardia and hypertension may cause clinical deterioration, dysrhythmia and an increase in the area of infarction [11].

2. Background

Angiography is an invasive diagnostic procedure that may be perceived as threatening or a threat to health [8), nurses should establish an environment that minimises stress [12]. Nurses in critical

care settings such as the coronary angiography laboratory should balance the potential benefits of reduced anxiety with the possible adverse effects of sedatives, such as opioid and benzodiazepines, and explore alternative, less expensive and more efficient ways of alleviating patients' anxiety [13].

Various strategies have been used to reduce patients' anxiety before coronary angiography [14]. Administration of anxiolytics and nursing care do not always reduce patients' perceptions of anxiety [15-16], although they are likely to be useful for the most anxious. However, increasing the dose of anxiolytics until patients report no anxiety may reduce the level of patients' alertness and hinders the implementation of the procedure [6]. Despite the development and application of a range of educational and pharmacological interventions before the procedure, few approaches have significantly reduced anxiety [5], and additional non-pharmacological interventions are needed [6]. Although non-pharmacological interventions have not yet been incorporated into routine care [15], anxiety is one of the top five conditions for which alternative medicine is most frequently advised [17].

Complementary and alternative medicines are likely to become more popular if their effectiveness can be demonstrated [18].

Listening to pleasant natural sounds as a non-pharmacological approach to reducing anxiety has been reported to be effective in the reduction of patients' anxiety in other situations, such as mechanical ventilation in intensive care [13, 19]. However, to our knowledge, there are no reports of the effect of pleasant on post-procedural emotional disturbances, such as anxiety, and related physiological parameters in patients undergoing coronary angiography.

This study aimed to investigate the impact of listening to pleasant natural sounds on anxiety and physiological parameters (including systolic blood pressure [SBP], diastolic blood pressure

[DBP], mean arterial pressure [MAP], heart rate [HR], and respiratory rate [RR], and oxygen saturation [SPO2]) in patients undergoing coronary angiography.

3. Methods

3.1. Study design

This pragmatic parallel group quasi-randomized controlled trial with a pre-intervention–post-intervention design was conducted with an intervention (n = 65) and a control arm (n = 65) from 1st April 2014 to 31st December 2014.

3.2. Participants and setting

This trial was undertaken with patients scheduled for elective coronary angiography in a high turnover, referral teaching hospital in Tehran. The angiography unit treats over 2000 patients every year. The study's inclusion criteria were: scheduled to undergo coronary angiography for the first time, no planned cardiac catheterization, arriving at the hospital at least 1.5 hours before the procedure, score >20 on the Spielberger Trait Anxiety Inventory for Adults (STAI-AD), no previous invasive procedures prior to angiography, such as trans-esophageal echocardiography, no diagnosed heart valve lesions, alert and orientated, not diagnosed with a critical condition, no reported hearing loss, willing and able to consent to using headphones, no prior history of mental illness, as assessed by a psychiatrist.

We excluded patients: reporting ingestion of alcoholic beverages or narcotic analgesics within the last week or prescribed anti-hypertensive, antidepressants or anxiolytic drugs, as these might impact on assessments of psychometric or physiological variables.

Following permission from hospital authorities, nurse managers and the laboratory, the investigator (first author) approached potential participants meeting the inclusion criteria, and

informed them of the purpose, possible benefits and potential risks of the study. Patients gave informed, signed consent to participate.

3.3. Sample size

The sample size was determined using a standard formula [20] with alpha = 0.05, power = 90%. We were unable to identify publications using our anxiety scale; based on parameters in a similar trial [21], we calculated that we would require 130 patients, 65 in each arm.

3.4. Randomization

According to the patients' admission date, they were allocated to the intervention or control arm (n=65 in each arm). The toss of a coin decided that patients admitted on even dates would be allocated to the intervention arm. Patients who presented on even-numbered dates were allocated to the intervention arm and patients that presented on odd-numbered days were allocated to the control arm.

Administrators offered admissions throughout the days of the week with no particular criteria or pattern and also without any specific day allotting to certain patients. The patients booked procedures Saturday to Wednesday (working days in Iran) without specific criteria. Nursing work patterns and staff remained unchanged throughout the study period five to six patients were admitted each day and patients were discharged 24 hours after completion of the procedure. The procedure was:

1) Before the intervention and during admission, the main investigator (NR) sought consent from patients, extracted data from their documentation, and conducted the pretest evaluation. 2) The fourth researcher (AJ) randomly allocated the patients to the experimental and control groups and implemented the intervention for the experimental group. 3) The first researcher (NR) who was completely blinded to allocation of the patients conducted the posttest evaluations.

3.5. Data collection and measurements

1) The patients' medical records were the source of data for comparison of patients in the intervention and control arms with respect to age, gender, educational level, employment status, marital status, history of hospitalisations, and duration of any heart disease (Table 1).

2) Physiological measurements were extracted from observation charts: systolic blood pressure (SBP, diastolic blood pressure (DBP) , heart rate (HR) , respiratory rate (RR) and mean arterial pressure (MAP). Measurements were taken by standard electronic devices manufactured by SAIRAN®, including indwelling arterial lines, and pulse oximeters, all calibrated before data gathering. Measurements were taken at baseline, before, during (when the patients would be routinely monitored by clinicians for the side-effects of contrast media injected for angiography), immediately after, and twenty minutes after coronary angiography.

3) To measure anxiety we used the Spielberger State-Trait Anxiety Inventory for Adults (STAI-AD), which is widely used in multicenter, international clinical trials. This self-report measure indicates the intensity of feelings of anxiety; it distinguishes between trait anxiety (a general tendency to perceive situations as threatening) and state anxiety (a temporary condition experienced in specific situations). Spielberger referred to state anxiety as a temporal cross-section of a person's emotional stream-of-life [22]. Spielberger's standard questionnaire for the measurement of the level of anxiety consists of two sections measuring trait and state anxiety. Both sections comprise 20 questions and each scores between 1 and 4. The total score for each individual was between 20 and 80. The patients were classified into three groups with regard to trait scores for anxiety: mild (20-40 points), moderate (40-60), and severe (60-80). [23, 24, 25]. In this study, our measurements were based on state anxiety.

Mahram (1994) has translated the STAI into Farsi and evaluated its reliability and validity. The Farsi version of this scale has been repeatedly used and evaluated among various groups and its validity and reliability have been reported. Reliability of the Farsi version was assessed using Cronbach's alpha coefficient (0.94 for overall scores) [26].

The questions were read to the participants by a nurse, who completed the questionnaire accordingly. State anxiety levels were recorded; at baseline, before, during (when the patients would be approached to be checked about the side-effects of radiopaque drugs injected for angiography), immediately after, and twenty minutes after coronary angiography

3.6. Intervention

As in the studies of Aghaie et al. (2014) [13] and Saadatmand et al. (2013) [19] , all participants were seated in a private room, away from the laboratory waiting room to minimize noises and disruptions, and enhance relaxation. Patients assigned to the control arm received routine care and were exposed to the usual sound environment. Patients in the intervention arm were asked to sit on a comfortable bed and avoid reading, speaking on the phone, listening to the radio or watching television. Thirty minutes before angiography, patients in the intervention arm used headphones for 20-minutes to listen to pleasant natural sounds. Participants selected a CD from a collection of natural sounds: birds' song, soothing rain, river streams, waterfalls, or a walk through the forest, as prearranged by the researcher. They used MP3 media players plus disposable foam-lined headphones. The volume of the MP3 player was adjusted by the researcher to the participants' comfort by responding to their facial expressions and holding up fingers in response to researcher's questions. The average sound pressure level was set to 25–50 dB depending on the patients' hearing thresholds. Data were recorded: at baseline, before, during, immediately after, and twenty minutes after coronary angiography.

4. Ethical considerations

The institutional review board of Shahed University granted the ethical approval for the study (decree number: 41-198181). In Iran, public hospitals are run under the direct supervision of Universities. Therefore, the permission to enter the hospitals was granted by the ethics committees affiliated with Shahed University. Such permission to enter hospitals was approved by the hospital's directors and authorities. The research was registered in the Iranian Registry of Clinical Trials (IRCT) Center, number IRCT201412047529N5. All participants gave their informed consent prior to entering the study. For illiterate patients, the informed consent documentation was read aloud by their companions or relatives and they were asked to add their finger prints to the documentation if they agreed with the content. Verbal informed consent was also obtained. Numbers rather than names were used to de-identify participants to ensure confidentiality and anonymity. Participants were informed of the voluntary nature of the study, their right to withdraw at any time without any negative effects on their care. The study was conducted under the supervision and control of a cardiologist and psychologist.

5. Statistical analyses

SPSS for Windows version 21 was used for statistical analysis (IBM SPSS Inc., Chicago, IL, USA). Descriptive statistics were used to summarize demographic and clinical characteristics of participants. Independent sample t-tests and Chi square tests were used to determine any significant differences in the variables distributions between the arms. The concurrent effect of time trend, intervention (group variable) and interaction between time and group on different response variables (state anxiety, SBP, DBP, MAP, HR, RR, and SpO2) was assessed using multivariate analysis of variance (MANOVA). The model was checked for outliers, data distribution, and homogeneity of variance-covariance matrices. R^2 was calculated to check the

overlap of the variances of the dependent variable (the levels of anxiety) between the 2 trial arms. The data analyst was blinded as to trial arm allocation.

6. Results

Comparing trial arms

All 130 patients assessed were eligible for inclusion, and all were approached. All patients agreed to participate and fully collaborated throughout the study process. The CONSORT 2010 flow diagram is shown in Figure 1. Independent t-tests and χ^2 tests showed no significant differences between the two arms in terms of age, gender, marital status, level of education, employment status, health insurance status, and history of hospitalization (Table 1).

Pleasant natural sounds and anxiety

A statistically significant difference was reported between the state anxiety scores of the two arms. The time trend for mean state anxiety in the patients of the intervention and control arms is displayed (Fig. 2).

No significant difference was found between the two groups at baseline in state anxiety (Table 2). A statistically significant difference was visible in state anxiety between trial arms during the intervention ($F(2.05) = X$, $p<0.001$, Wilks $\Lambda = 0.11$). Before the intervention, R^2 was low, indicating that differences between subjects could not be explained by trial arm. However, after the intervention R^2 ranged between 34% and 76.3% indicating that the study variables accounted for much of the variation observed.

At baseline, the 2 arms were similar in all respects, when tested on the F distribution. However, during the intervention, the differences between trial arms were found statistically significant Wilk's lambda (Table 2).

Pleasant natural sounds and physiological parameters

The time trends for SBP, DBP, MAP, HR, RR and oxygen saturation are displayed in Figures 3-8.

No statistically significant differences were identified in SBP, DBP, MAP, HR, RR and oxygen saturation between the two groups at baseline.

The increase in R^2 values after baseline indicated trial arm explained some of the differences in the values between trial arms. At baseline, model parameters did not explain the variance between subjects (adjusted R2 0.001-0.007). After the intervention, the model parameters accounted for some of the variance observed between subjects (adjusted R2 0.20-0.37), indicating that trial arm was predicting physiological outcomes (Table 3).

During the study, no adverse events or complications related to angiography or headphone use were reported by the patients.

7. Discussion

Listening to pleasant natural sounds reduced the level of anxiety and tended to improve physiological parameters in patients undergoing coronary angiography. Focusing on pleasant sounds was an effective, non-pharmacological and unobtrusive comfort measure.

Anxiety is a common experience in hospitalised patients, particularly before invasive procedures such as coronary angiography [27].

Findings from the comparisons at the five time points indicated significantly lower levels of anxiety in the listening arm compared to those in the control arm (Fig 2).

Our findings are similar to those of previous studies on pleasant natural sounds interventions during invasive medical procedures (mechanical ventilation and the others lab studies) [13, 19] and similar results were reported with music therapy [28, 29].

Whilst the mechanism underlying the effectiveness of relaxing sounds has not been elucidated, listening to pleasant sounds is associated with comforting emotions [30]. Enhanced comfort improves perceptions of well-being and decreases perception of stress [31].

The patients in the control arm showed a significant change in anxiety implying that improvements might be due to the "Hawthorne effect". Decreases in physiological parameters can indicate relaxation [32, 33].

The findings of this study are in line with the findings of our previous studies supporting the notion that listening to natural sounds is a pleasant stimulus and an alternative perceptual focus for patients undergoing mechanical ventilation [13, 19]. Similarly, Gullick and Kwan (2015) also indicated that patient-controlled music therapy is a helpful and effective nursing intervention that reduces anxiety in patients undergoing mechanical ventilation [34]. According to the Nguyen et al.'s study, music reduced anxiety scores and some physiologic parameters in children with leukemia who underwent lumbar puncture procedure [35].

Lim and Locsin's (2006) review of therapeutic use of music in Asian populations reported that cultural preferences in music selection are extremely important [36]. Personal preferences are affected by differences in variables such as culture, age, and peer group. In this study, attention was paid to the patients' preferences prior to the procedure. Previous studies have used a variety of researcher- and patient-selected pleasant sounds and timeframes for listening [13,19]. Therefore, it is difficult to compare the effects of listening for 20 minutes with studies of different duration or different types of sounds.

Some of the differences in physiological parameters were clinically significant. For example, the mean values for oxygen saturation in the control arm were <96%, and would have scored on

National Early Warning Score in order to help with the early detection of clinical deterioration [37].

7.1 Limitations

Caution is needed when interpreting these results. As a limitation, this study was conducted with adult patients between the ages of 49-74 years who were undergoing angiography in one hospital in an urban area of Iran. This might be influence the generalizability of the findings to other settings. Environment and hospital equipment not under the control of the researchers can affect patients' anxiety.

Sometimes decrease of anxiety may be attributable to a Hawthorne effect. Since the patients were aware of the intervention and the study design, and observed the researcher's activities and felt that they were under supervision, we cannot exclude the possibility of a Hawthorne effect in our subjects. Also, researchers' presence or data collection instruments may exacerbate the Hawthorne effect. A lowered level of anxiety was also seen in the control arm, possibly related to the "Hawthorne effect" whilst waiting for coronary angiography [32, 33]. It is estimated that the Hawthorne effect plus participants' awareness of their allocation can overestimate treatment effects by about 17% [16]. The impact of the Hawthorne effect cannot be estimated due to the ethical requirements for informed consent. All those approached participated, removing volunteer bias, which can affect trial outcomes. The high participation rate reflects the cultural context, where patients feel enfranchised into the care system and the production of clinically important knowledge, and are keen to co-operate with clinicians and gain their approval. We have observed similar altruistic attitudes amongst those who are retained in clinical trials and donate blood samples [38].

We acknowledge that the difficulties of blinding participants and investigators and the quasi-randomised allocation increase the risk of bias in this trial [39].

8. Conclusions

Listening to pleasant natural sounds reduced the level of anxiety and physiological responses related to anxiety in patients undergoing coronary angiography. Pleasant natural sounds listening is a non-pharmacological intervention in high-tech critical care settings such as the coronary angiography laboratory where the noisy and stressful aspects of environments may stimulate nervous tensions. The pleasant natural sounds intervention provided a positive experience to patients. Given its cost-effective and noninvasive nature, nurses can use pleasant natural sounds listening as a relieving intervention to provide a simple application to ensure a degree of well-being in patients. It is used in order to reduce the consumption of anxiolytics and analgesics and reduce their associated morbidities.

With an increasing emphasis on provision of non-pharmacologic interventions based on research evidence, this trial builds on existing knowledge of physiological and psychological advantages of self-selected listening for patients undergoing angiography. More studies are required to assess reductions in the consumption of anxiolytics and analgesics and the associated complications such as emesis.

Given that it is minimal risk, nurses can use “listening to pleasant natural sounds” as a preventative and relieving intervention to accelerate healing and improve patients’ well-being. Listening might be considered a low-risk non-pharmacologic intervention of choice in high-tech laboratories where stressful environments can generate nervous tensions. The therapeutic effects of listening to pleasant natural sounds may reduce anxiety-related physiological responses in patients undergoing coronary angiography [40- 41].

Moreover, using listening as an intervention for patients undergoing coronary angiography increases nurses' autonomy and the perspective that nurses are able to influence the care environment. The application of pleasant natural sounds intervention as a treatment modality is novel and, as yet, under-developed. Further work is needed to compare pleasant natural sounds interventions with pharmacological and other non-pharmacological interventions for both immediate and longer-term benefit.

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Table 1. Demographic characteristics of the patients in the intervention and control groups

Characteristics	**Total (n = 130)**	**Intervention arm (n = 65)**	**Control arm (n = 65)**	**Statistical test and *p* Value**
Age Mean ± SD	61.68 ± 12.05	61.84 ± 11.52	61.52 ± 12.65	t=015 *p* =0. 88 df=128
Gender, n (%)				x^2 =3.07
Male	64(%100)	27(42.2%)	37(%57.8)	*p* = 0.11
Female	66(%100)	38(%57.6%)	28(%42.4)	
Level of Education, n (%)				
Illiterate	37(100%)	20(54.1%)	17(45.9%)	x^2 = 1.07
Primary	21(100%)	11(52.4%)	10(47.6%)	df=3
Secondary	39(100%)	20(%51.3)	19(48.7%)	*p* =0. 78
High/undergraduate school	33(100%)	14(%42.4)	19(57.6%)	
Marital status, n (%)				
Single	43(100%)	22(51.2%)	21(48.8%)	x^2 =0.03
Married	87(100%)	43(49.4%)	44(50.6%)	df=1 *p* =0.85
Employment, n (%)				
Employed	36(100%)	21(58.3%)	15(41.7%)	x^2 =1.47
Retired	27(100%)	12(44.4%)	15(55.6%)	df=3
Housewife	38(100%)	18(47.4%)	20(52.6%)	*p* =0. 688
Others	29(100%)	14(48.3%)	15(51.7%)	
Health Insurance, n (%)				x^2 =3.07
Yes	127(100%)	62(48.8%)	65(51.02))	df=1
No	3(100%)	3(100%)	0(%00.00)	*p* =0. 24
History of hospitalization, n (%)				x^2 =1.46 df=1
Yes	118(100%)	61(51.7%)	57(48.3%)	*p* =0. 36
No	12(100%)	4(33.3%)	8(66.7%)	
Duration of heart disease, (months) Mean ± SD	8. 93±3.81	9. 07±3.72	8.78 ± 3.93	t =0.43 df=128 *p* =0. 66

Table 2. State anxiety in intervention and control arms compared

Anxiety	Baseline	Before angiography	During angiography	Immediately after angiography	20 minutes after angiography
Variance	R^2 =0 .01 Adjusted R^2= 0.006	R^2 = 0.54 Adjusted R^2 = 0.54	R^2 = 0.76 Adjusted R^2 = 0.76	R^2 = 0.74 Adjusted R^2 =0 .73	R^2 = 0.34 Adjusted R^2 = .34
Intervention arm (Spielberg's state score)	63.47±8.96	47.06±8.169	36.26±4.40	37.93±7.33	46.30±8.29
Control arm (Spielberg's state score)	65.29±6.56	64.53±7.87	61.36±8.90	64.41±8.41	60.58±11.16
Statistics for comparisons at each step	df=1,F=1.73, p=0.19	df=1,f=154.20, p=0.001	df=1,f=415.22, p=0.001	df=1,f=325.65, p=0.001	df=1,f=68.430, p=0.001
MANOVA					
Pillai's Trace	Value=.892,F=2.0492 Sig.=.001, Observed Power=1.00				
Wilks' Lambda	Value=.108,F=2.0492 Sig.=.001, Observed Power=1.00				

Table 3. Hemodynamic parameters in the intervention and control arms compared

Physiological parameter	Baseline	Before angiography	During angiography	Immediately after angiography	20 minutes after angiography
SBP (variance)	R^2 = 0.001 Adjusted R^2 =- 0.007	R^2 = 0.152 Adjusted R^2 =0.145	R^2 =0 .037 Adjusted R^2 =0.030	R^2 = 0.215 Adjusted R^2 = 0.209	R^2 = 0.176 Adjusted R^2 =0.169
INTERVENTION (mmHg)	164.66±21.69	132.26±10.466	141.72±15.53	112.26±10.46	136.62±9.21
CONTROL (mmHg)	163.40±13.64	143.12±14.99	149.62±24.06	124.71±13.33	147.51±14.06
Statistics for comparisons at each step	df=1,f=0.157,p=0.692	df=1,f=22.925,p=0.001	df=1,f=4.935,p=0.028	df=1,f=35.038,p=0.001	df=1,f=27.281,p=.0.001
MANOVA					
Pillai's Trace	Value=.378,F=15.077 Sig.=.0001, Observed Power=1.00				
Wilks' Lambda	Value=.622,F=15.077 Sig.=0.001, Observed Power=1.00				
DBP	R^2 =0.016 Adjusted R^2 = 0.008	R^2 =0.080 Adjusted R^2 = 0.073	R^2 = 0.202 Adjusted R^2 = 0.196	R^2 =0.299 Adjusted R^2 = 0.203	R 2 =0 .079 Adjusted R^2 =0 .073
INTERVENTION (mmHg)	81.38±8.66	79.48±12.87	71.48±12.87	78.48±6.76	87.12±16.22
CONTROL (mmHg)	79.15±8.88	88.28±16.97	81.28±1.59	97.66±19.83	97.66±19.83
Statistics for comparisons at each step	df=1,f=2.100,p=0.150	df=1,f=11.091,p=0.001	df=1,f=13.441,p=0.001	df=1,f=54.466,p=0.001	df=1,f=10.994,p=0.001
MANOVA					
Pillai's Trace	Value=.370,F=14.588 Sig.=0.001, Observed Power=1.00				
Wilks' Lambda	Value=.630,F=14.588 Sig.=0.001, Observed Power=1.00				
MAP	R^2 = .013 Adjusted R^2 =0.006	R^2 = .143 Adjusted R^2 =0.137	R^2 = .122 Adjusted R^2 = 0.115	R^2 = .374 Adjusted R^2 =0.369	R^2 = .092 Adjusted R^2 =0 .085
Intervention (mmHg)	109.14±8.42	97.07±9.70	94.89±10.13	89.26±5.93	107.25±10.87
Control (mmHg)	107.24±8.08	106.56±13.37	104.06±14.33	104.43±12.66	113.90±10.16
Statistics for comparisons at each step	df=1,f=1.734,p=0.190	df=1,f=21.407,p=0.001	df=1,f=17.716,p=0.001	df=1,f=76.463,p=.0.001	df=1,f=12.957,p=0.001
MANOVA					
Pillai's Trace	Value=.403,F=16.708 Sig.=0.001, Observed Power=1.00				
Wilks' Lambda	Value=.597,F=16.708 Sig.=0.001, Observed Power=1.00				
HR	R^2 = 0.001 Adjusted R^2 = -0.007	R^2 = 0.098 Adjusted R^2 = 0.091	R^2 =0 .138 Adjusted R^2 = 0.131	R^2 = 0.338 Adjusted R^2 =0 .331	R^2 = 0.079 Adjusted R^2 =0 .072
Intervention beats per minute	87.23±18.53	93.15±10.68	72.43±13.10	72.97±10.06	71.68±11.37
Control beats per minute	88.00±20.92	103.08±18.64	86.35±21.05	94.45±15.10	78.94±13.55
Statistics for comparisons at each step	df=1,f=0.049,p=0.825	df=1,f=13.855,p=0.001	df=1,f=20.481,p=0.001	df=1,f=91.009,p=0.001	df=1,f=10.948,p=0.001
MANOVA					
Pillai's Trace	Value=.450,F=20.503 Sig.=0.001, Observed Power=1.00				
Wilks' Lambda	Value=.550,F=20.503 Sig.=.001, Observed Power=1.00				

SBP = systolic blood pressure, DBP = diastolic blood pressure, MAP = mean arterial pressure, HR = heart rate,

Table 4. Respiratory rate and oxygen saturation in the intervention and control arms

Physiological parameter	Baseline	Before angiography	During angiography	Immediately after angiography	20 minutes after angiography
RR	R 2 = .024 Adjusted R 2 = -.017	R 2 = .141 Adjusted R 2 = .135	R 2 = .302 Adjusted R 2 = .297	R 2 = .082 Adjusted R 2 = -.075	R 2 = .218 Adjusted R 2 = .211
Intervention breaths per minute	14.17±1.755	12.49±1.174	15.11±1.724	13.06±1.685	14.00±2.222
Control breaths per minute	14.68±1.470	13.74±1.848	12.89±1.669	14.03±1.571	16.18±1.944
Statistics for comparisons at each step	df=1,f=3.197,p=.076	df=1,f=21.056,p=.001	df=1,f=55.407,p=.001	df=1,f=11.504,p=.001	df=1,f=35.594,p=.001
MANOVA					
Pillai's Trace	Value=.450,F=20.269 Sig.=.001, Observed Power=1.00				
Wilks' Lambda	Value=.550,F=20.269 Sig.=.001, Observed Power=1.00				
Oxygen saturation	R^2 = .001 Adjusted R^2 = -.008	R^2 = .103 Adjusted R^2 =.096	R^2 = .158 Adjusted R^2 = .152	R^2 = .365 Adjusted R^2 = .360	R^2 = .113 Adjusted R^2 = .106
INTERVENTION (%)	93.08±4.09	95.62±3.31	97.15±2.26	97.55±1.86	95.15±3.25
CONTROL (%)	92.98±3.34	93.38±3.31	94.78±3.16	93.22±3.62	92.98±2.85
Statistics for comparisons at each step	df=1,f=.020,p=.888	df=1,f=14.737,p=.001	df=1,f=24.087,p=.001	df=1,f=73.518,p=.001	df=1,f=16.320,p=.001
MANOVA					
Pillai's Trace	Value=.497,F=24.515 Sig.=.001, Observed Power=1.00				
Wilks' Lambda	Value=.503,F=24.515 Sig.=.001, Observed Power=1.00				

RR = respiratory rate.

Figure 1. The process of study according to the Consort flow diagram (2010)

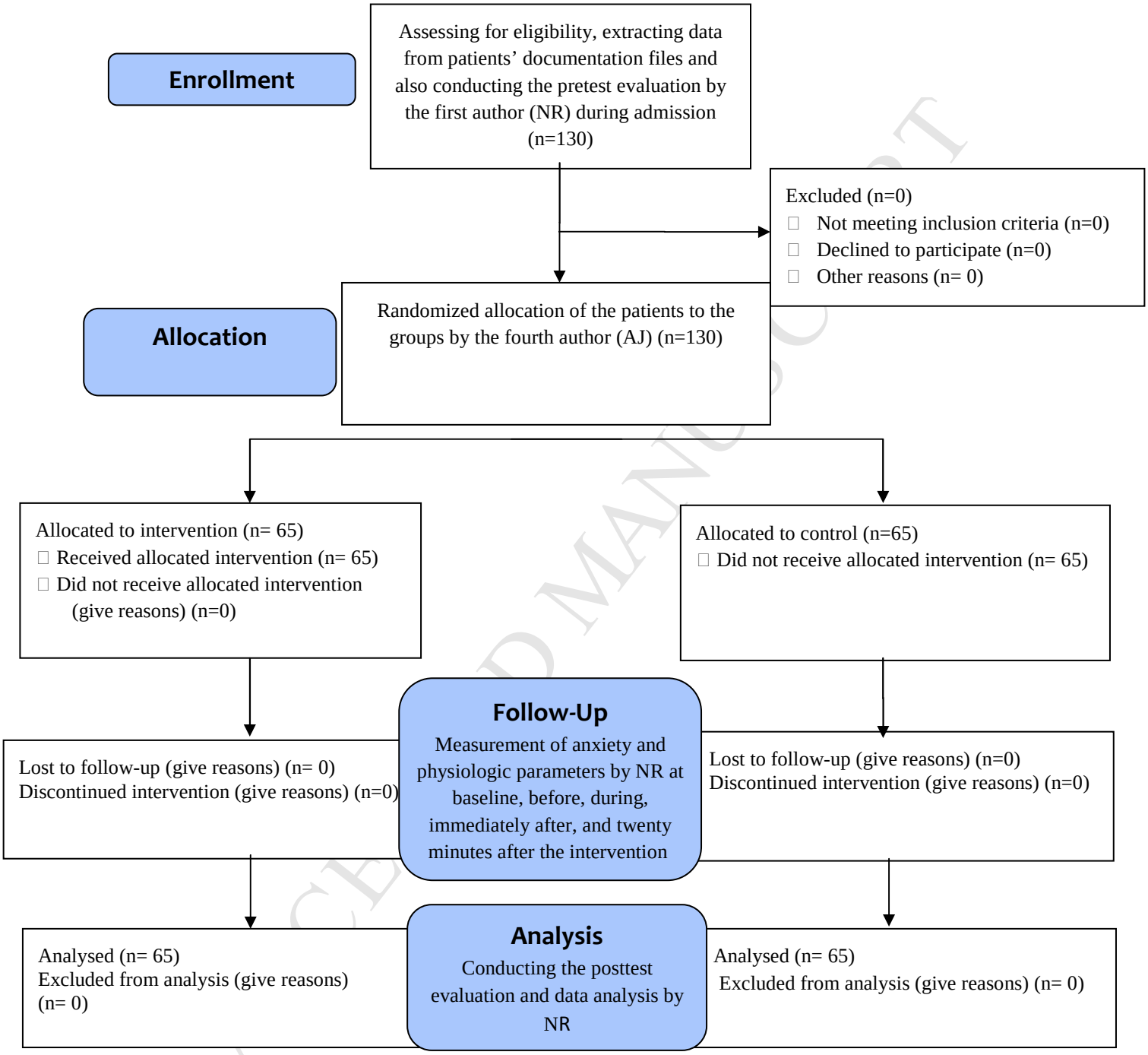


Figure 2. Time trend of mean of state anxiety in the patients of intervention and control groups

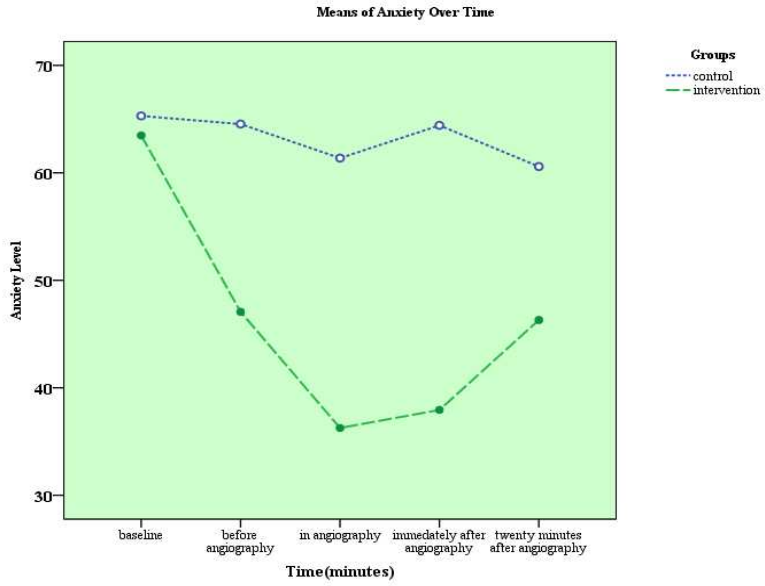


Figure 3. Time trend of mean systolic blood pressure in the patients of the intervention and control groups

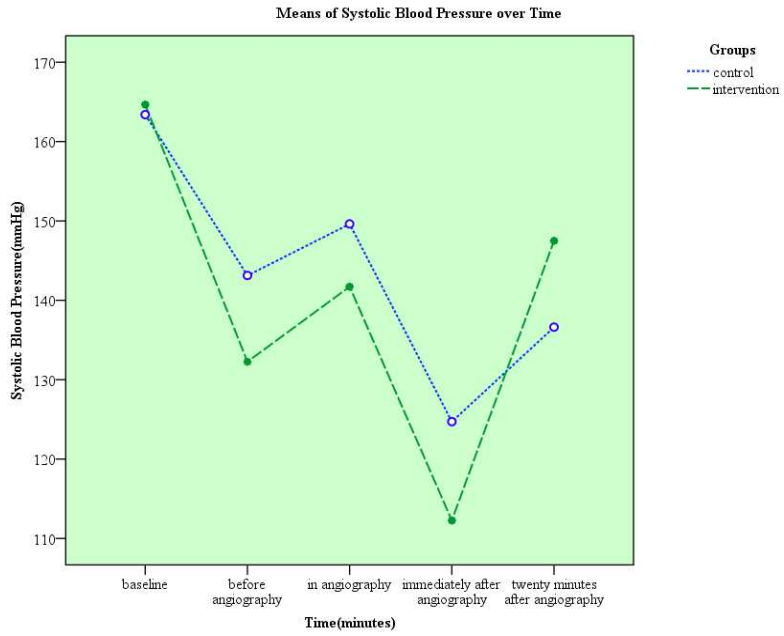


Figure 4. Time trend of mean diastolic blood pressure in the patients of the intervention and control groups

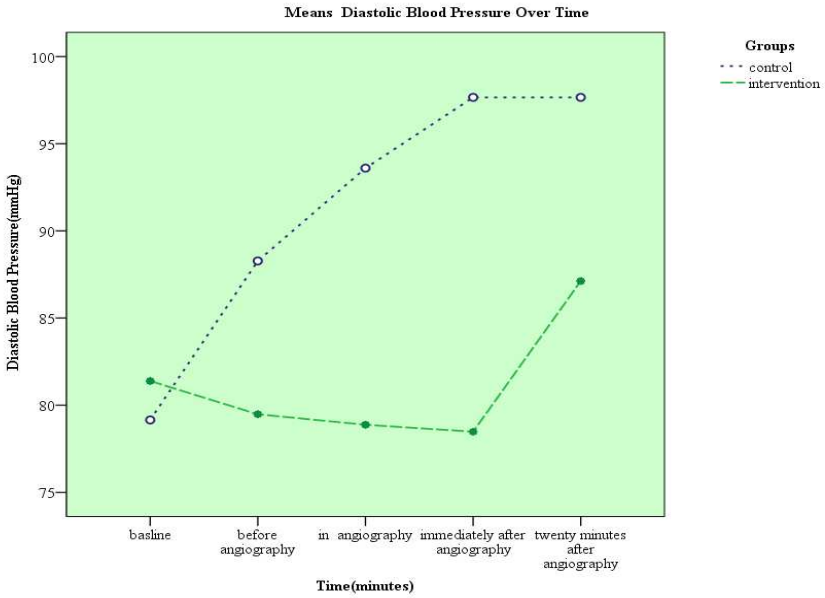


Figure 5. Time trend of mean blood pressure in the patients of the intervention and control groups

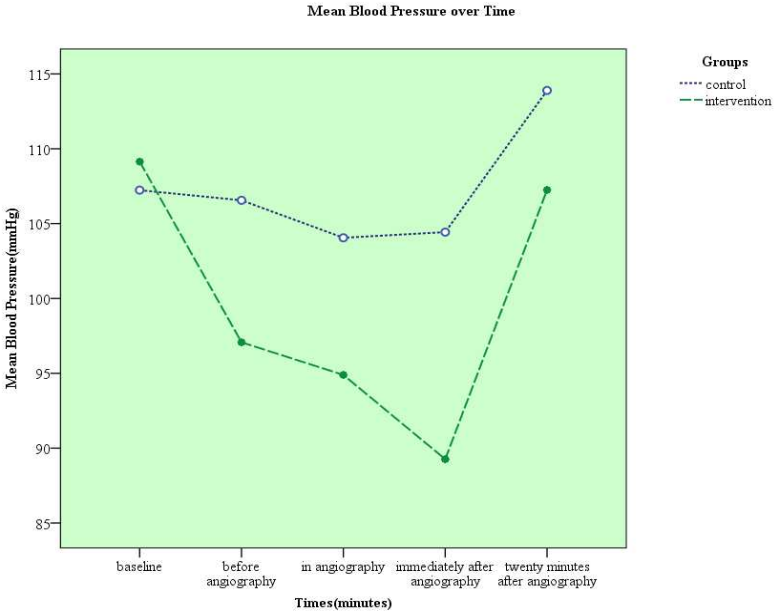


Figure 6. Time trend of mean heart rate in the patients of the intervention and control groups

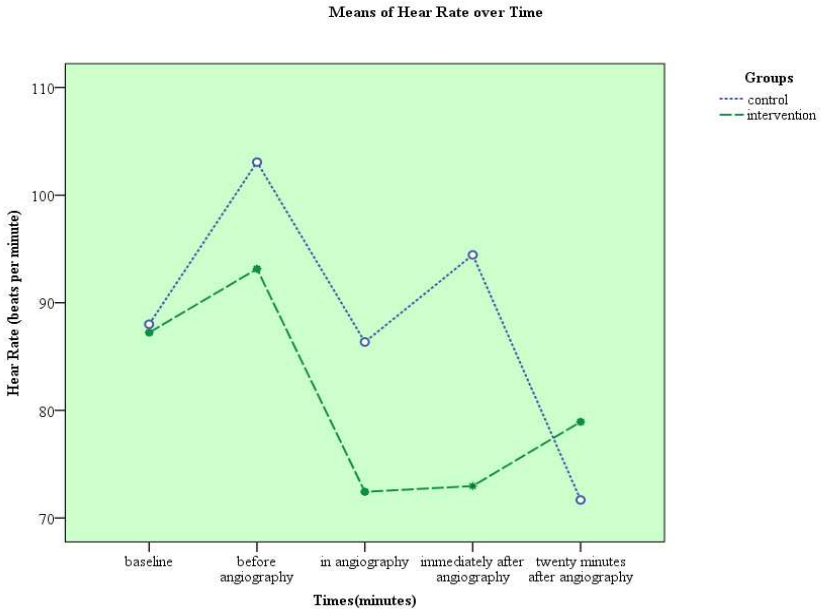


Figure 7. Time trend of mean respiration rate in the patients of the intervention and control groups

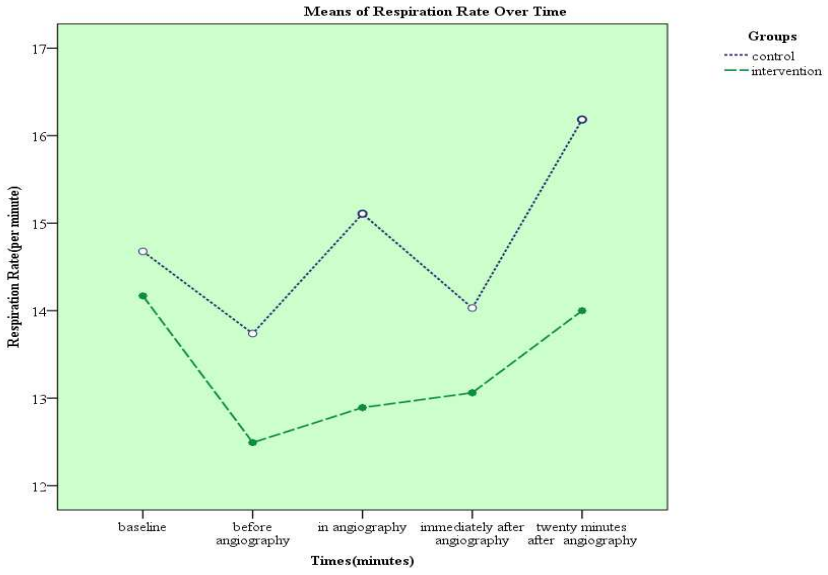
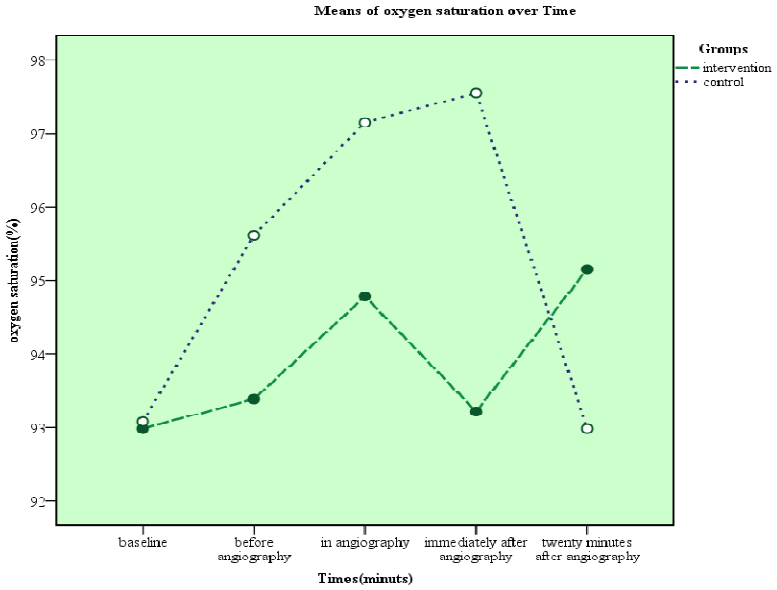


Figure 8. Time trend of mean oxygen saturation in the patients of the intervention and control groups



Highlights

- Reduction of anxiety and promotion of comfort in patients undergoing coronary angiography is an important challenge;
- Listening to nature-based sounds is a non-invasive and non-pharmacological strategy, which has potential to improve care for patients awaiting coronary angiography;
- After listening to pleasant natural sounds, the intervention arm displayed significantly lower anxiety levels than the control arm during the intervention;
- After listening to pleasant natural sounds, the physiological parameters of both groups showed statistically significant differences over time and in group-by time interactions;
- Listening to pleasant natural sounds as non-invasive and non-pharmacological therapy can reduce the level of anxiety reported by patients undergoing coronary angiography, and may improve physiological parameters;
- Application of pleasant natural sounds for patients undergoing coronary angiography promotes nursing autonomy and the notion that nurses can influence the patient's environment.