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The effect of music intervention in relation to gender during coronary angiographic procedures: A randomized clinical trial

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Abstract

Several studies have evaluated music interventions prior and after coronary angiography and percutaneous coronary intervention (PCI), but there is no clear evidence showing that music has an effect on patients during these procedures. The purpose was to investigate the effects of music on anxiety, angina, pain, relaxation, and comfort in patients during angiographic procedures and to evaluate gender differences. The study was a four-armed, prospective randomized controlled trial included 240 patients undergoing coronary angiography and/or PCI. Patients were allocated to receive relaxing music, MusiCure® or standard care during the procedure. Outcome measures were; puncture pain and the discomfort related to it, angina and the discomfort related to it, anxiety, experience of the sound environment, discomfort of lying still, and the doses of anxiolytics and analgesics during the procedure. No differences were found between the music and control groups regarding any of the trial endpoints or gender-related differences. The overall rating of the sound environment and feeling of relaxation was high. In conclusion, music intervention in patients undergoing angiographic procedures was highly feasible, but not effective in this study though the delivery of music went smoothly and did not disturb the examination and patients and staff alike looked favorably on it.

Keywords: Music; Gender; PCI; Angiography; Pain; Anxiety

1. Introduction

Coronary angiography and percutaneous coronary intervention (PCI) are routine procedures in cardiology. Undergoing these procedures can be associated with feelings of stress and anxiety that accompany experiencing the unknown, a strange environment, and uncertainty about the findings and outcome of the procedure [1]. Spielberger [2] defined *state anxiety* as a transient experience of an unpleasant sensation that arouses worry and discomfort and is caused by intrinsic and extrinsic stimulation. Anxiety is also defined as a symptom, representing the reaction to stress and psychological distress that results from threat and danger [3]. These physiologic and psychological responses to stress may increase the duration of the coronary angiography procedure and the amount of sedative the patient requires [4]. A cardiac catheterization laboratory can be a frightening environment, with high-tech equipment and staff in sterile clothing. The sound environment includes unfamiliar noise, e.g. from X-ray devices [5], and noise has been reported to cause stress [6]. Healthcare personnel have the responsibility to establish a healing environment for the patient, an environment that reduces stress. A healing environment helps patients refocus from negative stimuli to something pleasant and familiar, allowing them to escape into "their own world". One feature of such an environment can be soothing music, an intervention that can help patients focus their awareness on the music, to promote

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relaxation. Music intervention is an interdisciplinary tool to facilitate healing through pre-recorded music, defined as "a supportive source of environmental sound that stimulates and maintains relaxation and reduces or controls distress by a self-management technique" [7]. The use of listening to pre-recorded music has also been defined as "Music medicine" in contradiction to "Music therapy" that includes an in-person music therapy treatment by a music therapist [8].

Music intervention has been reported to decrease anxiety and stress associated with surgery [7,9] and to increase relaxation following open heart surgery [10]. Several previous studies have evaluated music interventions during coronary angiography and PCI [11,12,4,13,14,5,15,16]. Buffum et al. [4] reported that patients who listened to music prior to vascular angiography reduced their anxiety and heart rate. Two other studies found no effect of music prior to cardiac catheterization with respect to anxiety, heart rate, and respiratory rate [15,16] or uncertainty and mood [16]. A study by Bally et al. [12], where patients listened to music prior to, during, and after coronary angiography, reported no effect of music on postprocedural pain and anxiety.

A study by Argstatter et al. [11] on music interventions during coronary angiography found a reduction in subjective anxiety in a subgroup of patients with higher-than-average psychological strain, but no effects on physiological variables or medication. Using specially selected music seems to have positive effects on wellbeing and patients' experience of environmental sound during coronary angiographic procedures [5]. Reduced pain, heart rate, respiratory rate, and blood pressure have been reported in patients listening to music while undergoing a C-clamp[1] procedure after PCI. However, the researchers also found a negative effect from music intervention by an observed deleterious effect on oxygen saturation [13,14]. To summarize, there is no clear evidence showing that soothing music has a positive effect on patients during coronary angiographic procedures.

Four of the studies mentioned above include small samples, ranging from 45 to 83 subjects [11,14,13,16].

To improve the quality of research evidence, we designed a large randomized controlled trial to investigate the effects of music intervention in comparison to no music in patients during coronary angiography and/or PCI. Furthermore, previous studies have not evaluated gender differences in response to music intervention in perioperative settings [7] or during angiographic procedures. Hence, our study has two aims:

- to test the hypothesis that patients will use less anxiolytics and analgesics, experience less anxiety, angina, and puncture-related pain, and a higher degree of relaxation and comfort if they listen to music during coronary angiographic procedures
- to evaluate whether the response to music intervention differs by gender.

2. Method

2.1. Sample and setting

Our four-armed, prospective randomized controlled trial included a sample of 240 patients undergoing coronary angiography and/or percutaneous coronary intervention (PCI). We conducted the study at the PCI unit of a university hospital, and patients were consecutively and prospectively enrolled between May and December 2007. Inclusion criteria were: 18 years or older and could read and understand Swedish. Exclusion criteria were; ST-elevation myocardial infarction or other critical illness; participating in other studies; and hearing impairment or difficulties in cooperating participating in during measurements.

2.2. Intervention

Patients were stratified into gender and thereafter randomly allocated to music intervention or control groups, based on a computer-generated randomization list. Hence, the study encompassed four groups: a female music group, a male music group, a female control group, and a male control group. Nurses at the PCI unit selected the next available number for female and male participants respectively for entry into the trial and conducted all interventions and outcome assessments. The patients became aware of their assigned group after they had signed the participant consent form.

Patients randomized to the control group received standard care, while patients in the music group received standard care and music intervention. Music was delivered to the patient via a Maysound® Music Player, a dual-loudspeaker system designed for health care [17]. The music, MusiCure®, [18] Gefion Records, Copenhagen, Denmark was soft, relaxing, and included different melodies of 60 to 80 beats per minute (bpm). Niels Eje specially composed the music for relaxation, drawing on studies of the sound environment in hospitals and its impact on hospitalized patients [19]. The music began as soon as the patient was lying on the operating table, continued during the entire procedure, and ended just before the patient left the operating table. A nurse controlled the volume (60–70 dB) to ensure a sound level that was satisfactory to the patient yet allowed the patient to easily follow verbal instructions from the cardiologist and nurses during the procedure.

2.3. Outcome assessment

Before the procedure, nurses at the PCI unit documented patient-related demographic variables and asked patients to rate their angina and anxiety level on a numeric rating scale (NRS), scoring from 0=*no angina* to 10=*severe angina* and 0=*no anxiety* to 10=*severe anxiety*. After the procedure, using the same scale, the participants rated their pain from

[1] A method to achieve hemostasis of the punctured femoral artery.

the arterial puncture, their discomfort related to the puncture pain, angina during the procedure, and their discomfort related to the angina. Patients also rated the discomfort of lying still and their feeling of relaxation using the same type of NRS, but from 0=*not at all* to 10=*very much*. Environmental sound during the procedure was also assessed with an NRS from 0=*not at all good* to 10=*very good*.

The NRS for pain has been tested for reliability and validity in a Swedish population, $r=0.80$ [20] and the NRS for anxiety has been psychometrically tested and found reliable, $r=0.64$ [21]. The NRS has been used frequently as an outcome assessment for pain and anxiety in studies testing music [7]. The NRS used to rate angina and the discomfort of lying still has not been psychometric tested as thoroughly as for measuring relaxation. However, the NRS for relaxation has been used in a study testing music intervention in patients who had undergone open heart surgery. The study found that the changes over time in relaxation levels were equal to the changes in s-oxytocin release, suggesting that the NRS scale measured relaxation [10].

After the procedure, participants were also given the short version of the State-Trait Anxiety Inventory (STAI) [22] to rate their anxiety. The short STAI is a 6-item questionnaire [2] developed from the 20-item STAI. The short STAI has been psychometrically tested and found to be reliable in comparison with the 20-item STAI, $r=0.95$ [22,23]. State anxiety questions ask about the intensity of the negative feeling (e.g. 1 to 4, where 1 indicates *not at all* and 4 indicates *very much so*). The total score is the weighted sum of all 6 responses, and ranges from 6 to 24: low anxiety (6 to 11), moderate anxiety (12 to 17), and high anxiety (18 to 24) [22]. Scores are reported to be considerably higher under stress than under normal conditions [2].

The accumulated doses of anxiolytics (diazepam) and analgesics (morphine) administered during the procedure were also recorded in the study protocol.

3. Ethical considerations

The study followed common ethical principles in clinical research and was approved by the local ethics committee in Uppsala. All patients gave their informed oral and written consent after they had been provided with written notification that any individual was permitted to discontinue participation in the study after receiving the information. The participants were also entitled to make individual decisions on how long they wished to participate and under what conditions. They were able to break off their participation without facing any

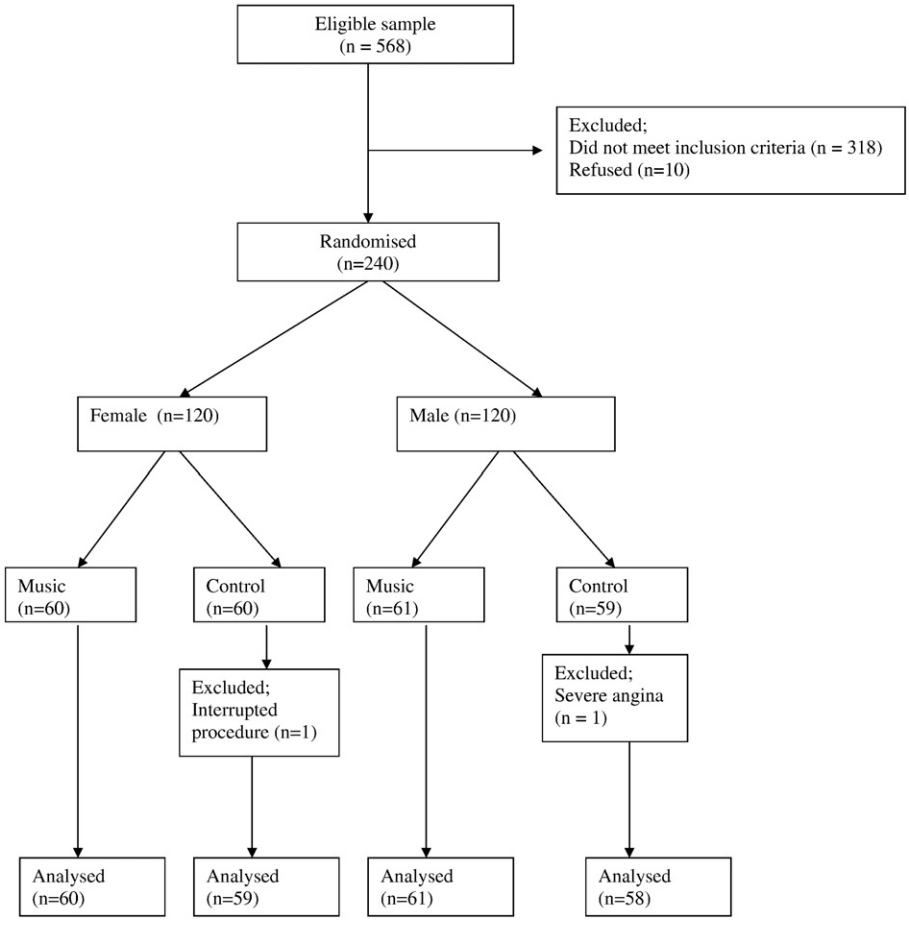

Fig. 1. Study flow chart of the trial.

Table 1
Comparison of patients' characteristics, duration of the intervention and pre procedural anxiety and angina levels between the control group and music group.

		Control group (n=117)	Music group (n=121)	p-value
Age (year)	Mean (±SD)	64 (9.3)	67 (9.7)	0.040
Gender;				1.000
Male	n (%)	58 (50%)	61 (50%)	
Female		59 (50%)	60 (50%)	
Diagnosis;	n (%)			0.313
Angina		86 (73%)	80 (66%)	
Investigation		28 (24%)	31 (25%)	
MI		1 (1%)	5 (5%)	
No information		2 (2%)	5 (4%)	
Diabetes	n (%)	21 (18%)	20 (17%)	0.978
Smoker	n (%)	21 (18%)	14 (12%)	0.193
Antianginal drugs (n)	mean (range)	1.0 (0–4)	1.1 (0–5)	0.228
Previous MI	n (%)	27 (23%)	27 (22%)	1.000
Previous undergone coronary angiographic procedures	n (%)	34 (29%)	39(32%)	0.540
Type of procedure;				0.234
Angiography	n (%)	71 (61%)	79 (65%)	
PCI		1 (1%)	5 (4%)	
Angiography and PCI		45 (38%)	36 (30%)	
Access;				0.736
A. Radialis	n (%)	92 (77%)	95 (79%)	
A. Femoralis		14 (12%)	18 (15)	
A. Radialis and *femoralis*		11 (9%)	8 (7%)	
Duration of the procedure (min)	Mean (±SD)	45.4 (32.5)	44.6 (37.6)	0.859
Duration of the music (min)	Mean (±SD)		61.0 (37.9)	
Angina (0–10)	Median (quartiles*)	0 (0–0)	0 (0–0)	0.741
Anxiety (0–10)	Median (quartiles*)	2 (0–5)	2 (0–4)	0.479

Abbreviations; PCI, percutaneous coronary intervention; MI, myocardial infarction.
*25th–75th percentiles.

negative consequences. Participants were not subjected to any form of persuasion, or efforts to retain them in the study. Those who refrained from taking part or did not participate in the entire study were not given a lower level of care.

4. Statistics

Calculation of sample size was based on the following assumptions concerning a one-way analysis (4 groups) for STAI to detect an estimated medium effect size of 0.19 with a standard deviation of 5.2, power of 80% and a significance level of 1%. These assumptions suggested a sample size of 60 in each of the 4 groups. Statistics are presented as means, standard deviation, median, and interquartile range. Student's t-test and the Mann–Whitney U-test were used to compare differences between the 2 groups (music and control), and the Kruskal Wallis test with a Mann–Whitney U-test and a Bonferroni correction were used to compare differences between the 4 groups (female music group, male music group, female control group, and male control group). A p-value less than 0.01 was considered statistically significant. SPSS (SPSS Inc., Chicago, Illinois; USA) for Windows was used in all statistical analyses.

5. Results

Patients were enrolled from April 8, 2007 to January 15, 2008. Among 568 eligible patients undergoing coronary angiography and/or PCI, 240 fulfilled the inclusion criteria and were randomized. One patient in the female control group was excluded due to an interrupted procedure, and one in the male control group due to severe angina. Consequently, 121 participants in the music group and 117 participants in the control group were included in the analysis (Fig. 1). Patients in the music group were significantly older, aged 67 years versus 64 years in the control group (Table 1). The two groups were otherwise comparable with respect to medical and demographic

Table 2
Comparison of patients' characteristics, duration of the intervention and pre procedural anxiety and angina levels between genders.

		Males (n=118)	Females (n=119)	p-value
Age (year)	Mean (±SD)	64 (9.1)	67 (9.8)	0.007
Diagnosis;	n			0.060
Angina		88	78	
Investigation		23	35	
MI		3	3	
No information		4	3	
Diabetes	n	13	28	0.014
Smoker	n	24	11	0.019
Antianginal drugs	mean (range)	1.0 (0–4)	1.2 (0–5)	0.098
Previous MI	n	25	29	0.493
Previous undergone coronary angiographic procedures	n	40	32	0.238
Type of procedure;				0.009
Angiography	n	64	85	
PCI		4	2	
Angiography and PCI		50	32	
Access;				0.394
A. Radialis	n	94	92	
A. Femoralis		17	15	
A. Radialis and femoralis		7	12	
Duration of the procedure (min)	Mean (±SD)	51.1 (39.4)	38.9 (29.2)	0.008
Angina (0–10)	Median (quartiles*)	0 (0–0)	0 (0–1)	0.216
Anxiety (0–10)	Median (quartiles*)	1 (3)	3 (5)	0.001

Abbreviations; PCI, percutaneous coronary intervention; MI, myocardial infarction.
*25th–75th percentiles.

Table 3
Results from the outcome measures between the music and the control group.

		Control group, (n=117)	Music group, (n=121)	p-value
Diazepam (mg)	Mean (±SD)	4.4 (1.9)	4.0 (1.7)	0.071
Morphine (mg)	Mean (±SD)	0.1 (0–7)	0.3 (0–5)	0.182
Short STAI (6–24)	Median (quartiles*)	15 (13–15)	15 (14–15)	0.932
Puncture pain (0–10)	Median (quartiles*)	3 (2–5)	3 (1–5)	0.487
Discomfort related to the puncture pain (0–10)	Median (quartiles*)	3 (1–4)	2 (1–4)	0.260
Angina (0–10)	Median (quartiles*)	0 (0–3)	0 (0–3)	0.732
Angina discomfort (0–10)	Median (quartiles*)	0 (0–2)	0 (0–2)	0.864
Discomfort of lying still (0–10)	Median (quartiles*)	1 (0–3)	0.5 (0–2)	0.193
Feeling of relaxation (0–10)	Median (quartiles*)	8 (4–9)	8 (5–9)	0.218
Sound environment (0–10)	Median (quartiles*)	10 (8–10)	10 (8–10)	0.764

*25th–75th percentiles.

characteristics and preprocedural levels of angina and anxiety.

In the gender comparison, we found the following differences in baseline characteristics: the female group was significantly older (67 versus 64 years); included more patients with diabetes (28 versus 13); and scored higher in preprocedural median anxiety level (3 versus 1). The male population included significantly more smokers (24 versus 11) and was significantly more often subject to both angiography and PCI. Hence, they had a longer procedure time and longer exposure to music intervention (Table 2).

We found no differences regarding any of the trial endpoints between the music and control groups (Table 3). The overall ratings of the sound environment (rated 10) and a feeling of relaxation (rated 8) were high, and the ratings of discomfort related to the puncture pain, angina, and lying still were low. Almost no angina was observed in the population during the procedure, and puncture-related pain received a rating of 3 (Table 3).

We did not find any gender-related differences in the outcome of music intervention. However, compared to the male group, the female group gave a significantly higher rating to puncture-related pain (Table 4). We also analyzed subgroups of patients–patients with higher preprocedural anxiety scores, i.e. >4; patients undergoing PCI only; patients who received ≤2.5 mg diazepam–without finding any differences between the music group versus the control group.

6. Discussion

Our trial did not show any effect of soft and relaxing music on patients undergoing coronary angiography or PCI. We found only one randomized controlled trial with music intervention in patients during coronary angiographic procedures [11]. Contrary to our study, that trial showed decreased levels of subjective anxiety and improvement in physiological parameters among patients in a subgroup of patients with higher-than-average psychological strains. However, patients who listened to music in the Argstatter et al study [11] had a music therapist present during catheterization. Potentially, the therapist and not the music might have had the calming effect. The control group received only standard care, and therefore no music therapist was present. Moreover, only one [4] of three studies [4,15,16] with music intervention prior to cardiac catheterization reported a reduction in subjective anxiety levels. Hence, it appears that music has a minor effect on subjective levels of anxiety in patients during coronary angiographic procedures.

Previous studies have revealed a variety of responses to different kinds of soft and relaxing music (60–80 bpm), but

Table 4
Results from the outcome measures between the gender and intervention groups.

		Control group male (n=58)	Control group female (n=59)	Music group	Music group	p-value
				Male (n=61)	Female (n=60)	
Diazepam (mg)	Mean (±SD)	4.3 (1.8)	4.6 (2.1)	3.9 (1.6)	4.1 (1.8)	0.235
Morphine (mg)	Mean (min–max)	0.2 (0–5)	0.1 (0–2.5)	0.2 (0–5)	0.5 (0–10)	0.340
Short STAI (6–24)	Median (quartiles*)	15 (13–15)	15 (14–15)	15 (14–15)	14 (13–15)	0.187
Puncture pain (0–10)	Median (quartiles*)	2 (1–4)	3 (2–5)	3 (1–4)	4 (2–6)	0.021
Discomfort related to the puncture pain (0–10)	Median (quartiles*)	2 (1–3)	3 (1–5)	2 (0.5–3)	3 (1–5)	0.004[a]
Angina (0–10)	Median (quartiles*)	0 (0–3)	0 (0–2)	1 (0–2.5)	0 (0–2.5)	0.093
Angina discomfort (0–10)	Median (quartiles*)	0 (0–2)	0 (0–2)	0 (0–2)	0 (0–2)	0.966
Discomfort of lying still (0–10)	Median (quartiles*)	1 (0–3)	1 (0–3)	1 (0–3)	0 (0–1)	0.050
Feeling of relaxation (0–10)	Median (quartiles*)	8 (3–9)	7 (4–9)	8 (7–9)	8 (4–9)	0.365
Sound environment (0–10)	Median (quartiles*)	9 (8–10)	10 (8–10)	9 (8–10)	10 (9–10)	0.178

Abbreviation; STAI, State Trait Anxiety Inventory.
*25th–75th percentiles.
[a]control group male versus control group female, p=0.021.

no clear picture emerged regarding which genre is most beneficial [4,5,11–16] and it has been shown in a meta-analysis [8] and a systematic review [7] that there is no different results in its effects between research selected and patients selected music. The MusiCure® music chosen for our trial [18] might possibly be a less effective alternative. However two recent studies tested the MusiCure® [18] music on heart surgery patients and found no effect on pain or anxiety [9]. However, the studies reported some positive effects, e.g. decreased cortisol levels [9] and increased oxytocin levels and subjective relaxation levels [10]. The music was also evaluated among 267 patients in a post-operative care unit. The results showed that patients found the sound environment, i.e. MusiCure music played through ceiling-suspended loudspeakers, to be *pleasant* or *very pleasant*. However, the study did not compare the MusiCure® music with silence, i.e. no music, or another genre of music [19]. Perhaps their results would have been similar to ours had they conducted a randomized control trial (RCT). This is an important aspect as regards internal validity, causal effect, and results drawn from a study. The Consolidated Standard of Reporting Trials (CONSORT), which this manuscript follows, addresses the problem of internal validity and documents recommendations for reporting clinical trials that aim to improve quality and the evidence that supports it [24].

The volume used in our study was slightly higher than the 50 to 60 dB used for patients in perioperative settings [7], reflecting the higher environmental sound level in a cardiac radiology department [5]. We did not measure the environmental sound level in the present study. However, given the fact that patients rated the sound environment as *very good*, we could assume that our PCI unit was not perceived as noisy.

Racial and cultural differences may influence the effect of music interventions, but this remains speculative. Two studies from China reported reduced pain in patients listening to music while undergoing a C-clamp procedure after PCI [13,14]. C-clamp, however, is not a method used in our patients. Another possible explanation could be that the doses of anxiolytics (diazepam) in our trial might have been greater than the doses used in other studies. Diazepam is believed to reduce anxiety by affecting the limbic system [25], the same pathway music is thought to utilize for reducing anxiety [7]. Perhaps the effect of the music intervention could have been greater in our study if the patients had not received anxiolytics. This was a clinical trial to test music intervention in the standard care of patients undergoing coronary angiographic procedures, and our standard care includes diazepam.

Given the conditions of this study, the results show no gender differences in response to the intervention. Studies reporting gender differences in response to different music stimuli are rare [26]. We found no studies on gender differences in response to music interventions in clinical settings. Under experimental conditions, young men and women (mean age 27 years) were found to react the same to musical stimuli. The musical stimuli included slow, comforting, renaissance music and fast, arousing, heavy metal music. Renaissance music led to a significantly calmer state compared to heavy metal music [26]. Gender differences in response to music interventions need further study, particularly in clinical settings.

In respect to gender our study revealed some findings of interest, e.g. compared to male patients, female patients had significantly higher preprocedural anxiety and a higher degree of puncture-related pain. Bjerkeset reported women to be at greater risk for anxiety and depression in the first 2 years after myocardial infarction [27]. Han found subjective pain and unpleasantness from pain to be higher in females than in males [28].

7. Study limitations

The intervention was used only during the procedure, and only one type of music was offered to the participants. One could speculate on a positive effect had we used the music intervention both prior to and during the coronary angiographic procedure and had we given the patients the option to select their own music. Furthermore, anxiety and relaxation were measured only by subjective anxiety and relaxation levels without comparable pre and post values, i.e. anxiety was assessed with NRS as pre value and with short STAI as post value, and relaxation was measured only as post values. The outcomes were also assessed after the procedure was completed. Perhaps the results had been different if the patients had rated their pain, anxiety, relaxation and comfort levels during the procedure. Finally, the staff and participants were aware of the intervention, which may have affected the results.

8. Implications for further research

Future research should continue to test the effects of music interventions on stress and anxiety in patients undergoing coronary angiographic procedures by measuring respiratory rate, hemodynamic parameters, oxygen saturation, cortisol levels, and levels of relaxation measured by bispectral index scores, as well as pain, anxiety, relaxation and comfort during the procedure. To rule out a possible Hawthorne effect, it would be of interest to compare a music group and a control group with a third group, one that is unaware of the study. Further research is needed on gender differences in the effects of soothing music in cardiac patients. Also, studies are needed that measure the noise level in PCI units and its relation to stress and anxiety.

9. Conclusions

Music intervention in patients undergoing angiographic procedures was highly feasible, though not effective in this study. The delivery of music during the procedures went

smoothly and did not disturb the examination. Patients and staff alike looked favorably on the music. Music intervention is safe and inexpensive, and its role in cardiac care deserves to be clarified in further randomized controlled trials.

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