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The Effect of Music on The Level of Anxiety in Patients
Undergoing Cardiac Angiography: Randomized Controlled Trial
Hussam Alwan Jaber AL- Zourphi 1, Sabah Abbas Ahmed 2
1 Adult Nursing Department, Collage of Nursing, University of Baghdad,
Al- Diwaniya, Iraq.

2Prof. Dr., Adult Nursing Department, College of Nursing, University of Baghdad, Baghdad, Iraq.

Corresponding Authors: 1Email: hossam.nahu2202m@conursing.uobaghdad.edu.iq 2Email: dr.sabah@conursing.uobaghdad.edu.iq

الخااصة

الخلفية: أمراض القلب والأوعية الدموية تسبب ١٨٠٦ مليون حالة وفاة في جميع أنحاء العالم. وفي عام ٢٠١٩ كان هنالك ١٨٢ مليون حالة من أمراض القلب الإقفارية و ٢٠١٤ مليون حالة وفاة على مستوى العالم. الطريقة الأكثر فعالية لتشخيص أمراض القلب الإقفارية هي تصوير الاوعية التاجية. وهذا التداخل يسبب القلق لـ ٨٥٠% من المرضى الذين يخضعون له. الهدف من الدراسة: هو تقييم تأثير الموسيقى على مستوى القلق لدى المرضى الخاضعين لتصوير الاوعية التاجية. المنهجية: استخدام التصميم التجريبي في مركز قسطرة وجراحة القلب في مدينة الديوانية، العواق. لتعيين المرضى في الدراسة اخذت العينات بشكل نظامي، وبعد ذلك تم استخدام أخذ العينات بطريقه عشوائية بسيطة لتخصيص المشارك في أحد المجموعتين. اجريت الدراسة على ٨٨ مريضاً يخضعون لتصوير الاوعية التاجية الاختياري و/أو التدخل التاجي عن طريق الجلد. تم قبل وبعد تدخل القسطاري للأوعية التاجية.النتائج: أظهرت نتائج اختبار مقياس جرد حالة—سمة القلق بين الاختبار القبلي والاختبار البعدي فروق ألدت دلالة احصائية عند (١٠,٠ . .(٩> انخفض مستوى القلق لمجموعات الدراسة في الاختبار البعدي بشكل ذو دلالة إحصائية (المجموعة الضابطة عند (١٠,٠ . والي الموسيقى أثناء تصوير الاوعية التاجية و/أو التدخل التاجي عن طريق الجلا، قلل بشكل كبير من مستوى القلق في الاختبار البعدي أقل من المجموعة الضابطة عند (١٠,٠٠).الاستنتاج: الاستماع إلى الموسيقى أثناء تصوير الاوعية التاجية و/أو التدخل التاجي عن طريق الجلا، قلل بشكل كبير من مستوى القلق في الاختبار البعدي.

Abstract

Background: Cardiovascular disease cause 18.6 million mortality worldwide. In 2019 there were 182 million cases of ischemic heart disease and 9.14 million deaths globally. The most effective method for diagnosis ischemic heart disease is coronary angiography (CAG). That cause anxiety for 82% of patients who undergo this invasive procedure. The aim of study: was to evaluate the effect of music on anxiety level of patients undergoing CAG. Materials and methods: An experimental design was done at the Cardiac Catheterization and Surgery Center, in the Al-Diwaniyah city, Iraq. A systematic sampling was used to recruited patients in the study then simple random sampling used to allocate the participant in one of the two groups. Conducted on 78 patients undergoing elective CAG and/or percutaneous coronary intervention (PCI). They were assigned as music group, and control group. The anxiety level of patients in two groups was measured by state-trait anxiety inventory (STAI) before and after CAG intervention. Results: The results of STAI between the pre-test and post-test showed that high significant mean different at p < 0.01. The anxiety level of study groups post-test had reduced significantly (control, p = .001; Music, p = .000). Post-test mean score of music group was lower than control group at $p \le 0.0$. Conclusion: Listening to music during CAG and/or PCI, significantly reduced anxiety level post-test. Keywords: anxiety, cardiovascular disease, coronary angiography, music

Introduction

Cardiovascular disease (CVD) is one of the most frequent noncommunicable diseases worldwide, usually associated with a build-up of fatty deposits inside the arteries (atherosclerosis) and an increased risk of blood clots (Al-Rubayie et al., 2011; Kassar & Ali, 2021). Due to changes in human lifestyles, the prevalence of CVD is rising quickly worldwide (Al-Ganmi et al., 2018). The vast majority of CVD deaths occurred in developing nations, with a mortality rate of 220.8 cases per 100,000 persons (Update, 2017). In 2019, there were 182 million cases of ischemic heart disease (IHD) globally, and 9.14 million people died as a result of IHD (Roth et al., 2020). Coronary angiography (CAG) is a qualified approach for diagnosing CVD (Mustafa & Hassan, 2020). Keshvari et al. (2021) reported that it is also a gold standard technique for determining the best effective treatment method.CAG is an invasive procedure that uses X-ray imaging and opaque material to visualize the blood arteries of the heart and determined whether a plaque buildup in the coronary arteries is requires a balloon or stent implementation for treatment to improve myocardial blood supply (Aikgoz & Cick, 2021). Haddad et al. (2017) according to National Institute for Cardiovascular Outcomes Research report that every year, more than 1 million Americans have a CAG, while according to the Iraqi Ministry of Health's (2022) report on its official website, the number of catheter interventions for coronary arteries in Iraq reached more than 54,475 in 2020. CAG has several problems, as any invasive procedure and patients might suffer from psychological and physiological issues (Karimi et al., 2014; Stein &Sareen, 2015). CAG induce-anxiety is one of the most psychological problems, about 82% of the patient undergoing CAG suffering from anxiety before catheter intervention (Habibzadeh et al., 2018). Anxiety is defined as "an emotion state which involves sensations of tension, worried thoughts, and physical changes (American Psychological Association, 2022)." anxiety is one of the most prevalent problems before and during coronary angiography, which is a natural reaction of the body to stress and it's characterized by an increase in heart rate (HR), respiratory rate (RR), and blood pressure (BP) as a result increase releasing of adrenaline and noradrenaline hormones (Chair et al., 2004; Gaspersz et al., 2018; Ibrahim & ALI, 2021; Kassar & Ali, 2021). Consequently, there are number of techniques have been developed, including non-pharmacological methods, that reduce anxiety and discomfort prior to percutaneous coronary intervention (PCI) and/or CAG (Forooghy et al., 2015; Rejeh et al., 2016). Music therapy had received a lot of attention in recent years due to the fact that pharmacological medicines typically have varied adverse effects (Mozaffari et al., 2020). The Nursing Interventions Classification has accepted the use of music as an intervention, which is described as "using music to help achieve a specific change in behavior, feeling, or physiology (Bulechek et al., 2012)." Due to its safety, non-invasiveness, and simplicity, music intervention is acknowledged as the most popular non-pharmaceutical anxiety therapy technique (Lee et al., 2017). Study Objective: This study was conducted to reduce anxiety level in patients undergoing elective CAG and/or PCI by listening to nonverbal music during this invasive procedure. The study aimed to evaluate the effect of music on anxiety level of patients undergoing CAG and/or PCI.

2. Materials and Methods

2.1. Study Design

An experimental design was done with application of pre-test and post-test for both two groups. The period of this study started from 20th of November, 2023 to 1th of June, 2024 at Cardiac Catheterization and Surgery Center in Al-Diwaniyah city, Iraq.

2.2 Sample and Sampling of the Study

Study groups approach for 78 patients undergoing for elective CAG and/or PCI, by systematic sampling method was used to recruited patients in the study then participants assigned into two groups with simple random sampling in order to allocate the participant either in: Music group or control group by sealed envelope that contained two numbers: 1 was in music group, and 2 was in control group to achieve the study aim. From total of 78 patients undergoing elective CAG and/or PCI assigned into (music group n=40, and control group n=38), calculated based on level of confidence (80%), and a 5% margin of error (Cohen et al., 2013), participants were excluded from the study based on exclusion criteria was (29) participants, so the final sample size was (49) participants were randomly assigned in to music group (n=26) and control group (n=23).

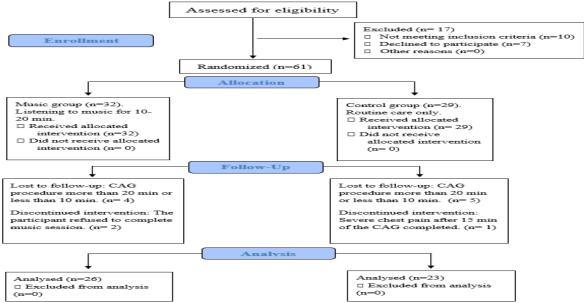


Figure 1: CONSORT Flow Diagram

. Y, "Inclusion and Exclusion Criteria

Patients met the eligibility criteria if they were above the age of eighteen, had an elective CAG or PCI booked and admitted, did not have visual impairment, had not had sedatives or antipsychotics prior to the procedure, and gave their consent to participate in the study. While Patient is excluded if who is suffering from acute pain, having a history of previous CAG and/or PCI, admitted for urgent CAG and/or PCI, and those who are refuse to engage in the study. Furthermore, the withdrawal exclusion criteria were refused to continue participating in the study, headphone removed during procedure, total CAG and/or PCI period more than 20 min or less than 10 min.

. Y, EIntervention and Data Collection Method

The first section of the data collection instruments contains socio-demographic information such as gender, age, level of education, occupation, marital status, and economic standing. Clinical data (hypertension, diabetes mellitus, and other chronic diseases) is included in section two. The third section used the State-Trait Anxiety Inventory (STAI) scale, which Spielberger et al. (1971) established to assess anxiety levels (pretest and posttest). A number of investigations have assessed individuals' anxiety levels using the self-report STAI scale (Amiri et al., 2020; Bozkurt et al., 2023; Ferede et al., 2022; Fenzke et al., 2023; Verma et al., 2021; Wondmieneh et al., 2020; Yazicioglu et al., 2022;). The STAI scale, which has internal consistency coefficients ranging from 0.86-0.95, is a viable and reliable tool (Spielberger et al., 1971). There are 40 items in two parts to this tool: Twenty items make up Form Y-1, which measures state anxiety, and twenty items make up Form Y-2, which measures trait anxiety. The weighted scores for each STAI item vary from 1 to 4 (1 = not at all, 2 = not at all) somewhat, 3 = moderately so, 4 = very much so), The STAI score is 40–160. A high number denotes a high degree of anxiousness (Al- jubouri et al., 2021). The current study measured the anxiety levels of participants prior to the onset of CAG and/or PCI (15 minutes), and following the completion of CAG and/or PCI (20 minutes), the posttest anxiety levels were evaluated. Given that the study sample speaks Arabic, the questionnaire was also written in Arabic. The STAI's Arabic version has the same number of items and rating scale as the original. Each participant spent between 8 to 13 minutes to complete the study's questionnaire. MP3 devices were given to experimental group members during CAG and/or PCI procedures (HYF- Design MP3 player, made in China) and a headphone (KAKU KSC-842, made in China) each participant will have one to use for listening to (60-80 bpm) nonverbal music (Ultimate stress relief- Smoothing music for relaxation, meditation, and anxiety reduction by Ultra Oceans) for 10-20 min, while routine care was provided to the control group. There was a 50–60 min interval between the pre- and post-tests.

- . You validity and Reliability of Scale Bahammam (2016) evaluated the STAI's Arabic version's validity and reliability for use in the Arabic-speaking community. The study found that the Arabic version of the STAI is reliable, with a Cronbach's alpha value of 0.989, and has acceptable convergent and criterion validity. Via email, researcher was received permission to use the tool.
- .Y, Tethics After obtaining the approval of the Council of the College of Nursing / University of Baghdad and the Ethical Research Committee on the study. Each participant provided written, informed consent to the researcher. The participants were informed by the researcher that their involvement in the study is optional. He

also gave them the assurance that the data would be securely maintained both during and after the study, in accordance with the subject's agreement sheet. This study was listed in the Iranian Registry of Clinical Trials Center (IRCT20240411061467N1).

.Y, Data Analysis Data analysis was done using SPSS version 25, the Statistical Package for Social Sciences. Utilizing the frequency, percentage, mean, and standard deviation, the descriptive data was analyzed. The study groups' overall anxiety levels were compared between the pre- and post-periods using the Paired-Samples t-Test. One-Way ANOVA to assess multiple comparisons, post hoc tests were used (Tukey HSD, Turkey's honestly significant difference test). The study variables were tested for association using the chi-square test and the Spearman Correlation Coefficient. For the current study, the significance threshold is < 0.05, meaning it is regarded significant, and ≤ 0.01 means it is highly significant.

. Results

Results showed that 14(53.8%), 17(73.9%) of studied participants for music group and control group respectively were male. With more than half of them approximately for groups were within (48-60) age group as 12(46.4%) of music group and 11(47.8%) of control group. In terms of educational level, the majority of the study's groups fell into the "read and write" category: The music group and the control group, respectively, were 6 (23.1%) and 4 (17.4%). In regards to occupation, the majority of the study's groups fell into the category of free jobs. However, those in the music group did quite well, scoring a percentage of 7 (26.9%) in the category of government employees. Additionally, the results revealed that a significant proportion of the investigation participants were married, with details as follows music group 19 (73.1%), control group 21 (91.3%). Lastly, the majority of group members' monthly income fell into the insufficient range, 16(61.5%) of music group and 11(47.8%) of control group as shown in table .(\)

Table (1): Distribution of The Socio-Demographic Characteristics of The Studied Samples.

Demographic Variables	Groups			usic roup		ntrol roup
			F.*	%	F.	%
1. Gender		Male	14	53.8	17	73.9
		Female			6	26.1
		Total	26	100.0	23	100.0
		35-47	4	15.3	3	13.0
2. Age		48-60	12	46.4	11	47.8
Groups		≥ 60	10	38.3	9	39.1
		Total	26	100.0	23	100.0
		M.± SD			5	7 ±8
			5	7±9		
	Read and write			23.1	4	17.4
3. Educational level	Primary school			15.4	4	17.4
	Inte	rmediate school	4	15.4	4	17.4
	Preparatory school			11.5	3	13.0
	Diploma			11.5	2	8.7
	Bachelor			15.4	4	17.4
	Post	graduate studies	2	7.7	2	8.7
		Total	26	100.0	23	100.0
4. Occupation		Free job	5	19.2	8	34.8
		Retired	4	15.4	6	26.1
	Emplo yee	Governmental	7	26.9	6	26.1
	유 현 Private		2	7.7	0	0.0
	Mixed		8	0.0	0	0.0
	Housewife Total			30.8	3	13.0
		26	100.0	23	100.0	
5. Social status	Single Married		0	0.0	0	0.0
		19	73.1	21	91.3	
		1	3.8	0	0.0	
		Widow	6	23.1	2	8.7
		Separated	0	0.0	0	0.0

	Total	26	100.0	23	100.0
6. Monthly income	Sufficient	5	19.2	5	21.7
	Insufficient	16	61.5	11	47.8
	Barely sufficient	5	19.2	7	30.5
	Total	26	100.0	23	100.0

F= frequency,

%= percent,

M. = Mean, SD= standard deviation

Table (2) presents the study's findings, which indicate that throughout the pre-test period, all study groups showed a moderate level of anxiety. Additionally, results indicated that the study's overall mean score was 113.45, Table (2): Descriptive Analysis of Total Anxiety Level at Pre-Test Period for Groups of The Study.

Groups		Pre-test period									
	No anxiety		xiety Mild Moderate Se		vere	Total Mean Score					
										T	
	F.	%	F.	%	F.	%	F.	%			
Music	0	0.0	1	3.8	17	65.4	8	30.8	113.30±14.93		
Control	0	0.0	0	0.0	16	69.6	7	30.4	113.60±11.97		
Grand Mean Score 113.45±13.45 (Moderate)											

F= frequency, %= percent

and that there were no statistically significant mean differences between the study's groups prior to the intervention, as indicated by table .(*)

Table (3): Comparison of Level of Total Anxiety for The Study Groups at Pre-Test Period.

Comparison	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	345.894	3	115.298	.574	
Within Groups	18089.521	90	200.995		.634
Total	18435.415	93			

Df= degree of freedom, Sig= significance level

The post-test results, displayed in Table (4), demonstrated that the music group's overall STAI score following the intervention was mild (67.34), whereas the control group's score was moderate (102.47). Furthermore, the STAI score's overall mean score was $.(^{\Lambda\xi}, ^{q})$ Table (4): Descriptive Analysis of Total Anxiety Level at Post-Test Period for Groups of The Study.

Groups		Post -test period							
	No anxiety		Mild		Moderate		Severe		Total Mean Score
	F.	%	F.	%	F.	%	F.	%	
Music Group	0	0.0	23	88.5	3	11.5	0	0.0	67.34±9.67
Control Group	0	0.0	3	13.0	19	82.6	1	4.3	102.47±16.06
Grand Mean Score	(Moderate) 84.90±12.86								

F= frequency, %= percent

Table (5): Effect of Interventions on Level of Total Anxiety at Post-Test Period.

Comparison	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	23090.366	3	7696.789	37.315	.000
Within Groups	18563.687	90	206.263		
Total	41654.053	93			

Df=degree of freedom, sig.= significance level

In fact, as table (5) illustrates, there were extremely significant mean differences between the study's experimental and control groups at p (0.000). Furthermore, the results show that there were significant mean

differences between the pre- and post-test periods for both study groups (the music group and the control group) at p < 0.01. Table (6): Comparison of Total Anxiety Level between Pre and Post Periods for The Study Groups.

	Paired Samples Test								
Group		Pair	ed Differe	nces		T	D	Sig.	
S	Mean	Std.	Std.	95% Co		f	(2-		
	differen	Deviatio	Error	Interval of the				taile	
	ce (pre-	n	Mean	Difference				d)	
	test vs.			Lower Upper					
	post-test								
	period)								
Contr	11.13	14.1912	2.9590	4.99368	17.2671	3.761	2	.001	
ol		4	8		9		2		
Group									
Music	45.96	20.4146	4.0036	37.7158	54.2072	11.48	2	.000	
Group		6	4	8	0	0	5		

Std= standard Df=degree of freedom, sig. =level of significance, HS= highly significant, NS= non-significant The music group also showed a higher mean difference (45.96) than the control group (11.13), indicating that the music group was more effective than routine care in terms of its effect on anxiety levels alone, as indicated in table .(7) Table (7): Association of The Demographic and Clinical Characteristics of The Studied Samples with Total Anxiety Level at Post-Test Period.

Demographic Variables	Music Group					
	Test value	Sig.				
1. Gender	X^2 2.907	0.088				
2. Age	c.c. .315	.118				
3. Educational level	c.c. 036	.862				
4. Occupation	X ² 6.896	.075				
5. Social status	X ² .304	.859				
6. Monthly income	c.c. .286	.157				
7. Hypertension	X ² 1.539	.215				
8. Diabetes mellitus	X ² 1.507	.220				
9. Other chronic disease	<i>X</i> ² .442	.506				

X2= A Chi-square test, C.C. = Spearman Correlation Coefficient, Sig. = significance level.

Moreover, table (7) shows that, for the experimental group of the study, the results show no significant association at p < 0.05 between any of the sociodemographic and clinical characteristics and the level of anxiety following intervention.

. ¿Discussion

According to the study's findings shown that, 14(53.8%), 17(73.9%) of the patients in the music group and control group, respectively, were male. The study's findings are explained by the researcher, who notes that

men are more likely than women to get heart attacks. Both Gao et al. (2019) and Isam and Hassan (2023) found that the majority of study sample patients with coronary artery disease were male. These findings suggest that men are more likely than women to have CVD. The study groups comprised nearly half of the participants, with mean ages of (57±9, 57±8) for the music group and the control group, respectively, falling within the 48-60 age range. In study on patients with coronary heart disease in Baghdad, Iraq, Athbi and Hassan (2019) found that the patients' ages ranged from 50 to 60 years old on average. The present study's groups were classified as "read and write" based on their various levels of education: music group 6(23.1%) and control group 4(17.4%). The authors of the study thought that this resulted from the previous decades' lack of interest in education. Regarding occupation, the study's control group fell into free job category 8 (34.8%), whereas participants in the music group scored highly, making up percent 7 (26.9%) of the governmental employee category. According to Mansour et al. (2019) the majority of patients in Baghdad City undergoing angiography were employed in free jobs. The results indicated that the vast majority of research participants were married based on their social standing, as follows: Music group 19(73.1%), 21(91.3%), and control group. According to Iraqi studies, 70% of the study sample was married when it came to heart disease patients (Atiea & Kadhum, 2018; Isam & Hassan, 2023). As indicated by table (1), the majority of the participants in the music group 16(61.5%), control group 11(47.8%), and other groups fell below the minimum monthly income threshold. As indicated by table (2), the study's grand mean score was moderate (113.45±13.45), with over half of the participants in the control and music groups had moderate levels of total anxiety pre-test 113.60±11.97 and 113.30±14.93, respectively. Additionally, the study's findings, as indicated in table (3), indicate that there were non-significant mean differences in the study groups' anxiety levels prior to the intervention at p (.634). In light of the fact that this was their first experience with an invasive procedure that directly involved the coronary arteries, the majority of patients undergoing coronary catheter intervention were anxious about the procedure's outcome, according to the researcher's explanation of the study's findings. Esfandiari et al. (2022) corroborate this result, demonstrating that patients receiving CAG intervention prior to entering the Cath lab room had a modest grand mean score of STAI (109.5±12.39). Indeed, these results are consistent with an Iranian study that looked at patients' anxiety levels prior to coronary angiography. The study's findings indicated that most participants (86%) had moderate levels of anxiety, while only 14% had severe levels (Shohani et al., 2018). According to Mozaffari et al. (2022), there was no statistically significant difference (P = 0.152) between the control and study groups' mean anxiety scores at baseline, which was moderate for patients receiving CAG. The music group and control group had total anxiety levels of 67.34±9.67 and 102.47±16.06 during the post-test period, respectively, with the majority of study participants (23, or 88.5%) in the music group having mild anxiety and the control group having moderate anxiety. Furthermore, the results revealed that the grand mean score, as indicated in table (3), was (84.90±12.86). As table (5) illustrates, there are, in fact, highly significant mean differences between the research groups following the intervention at p (0.000). The reason may be that the patient listens to music and does not listen to the sounds of the equipment and medical staff, which can increase anxiety level. This highlighted that listening to music is more sufficient in reducing level of anxiety than routine care only. Additionally, when the study groups' total anxiety levels are compared between the pretest and posttest periods, the results show that there are an experimental extremely significant mean differences between the two times for the study groups at p < 0.01. Furthermore, a larger mean difference (45.96) was seen between the music group and the control group (11.13), indicating that the music group outperformed the control group in terms of its impact on anxiety levels, as indicated by table (6). The study's findings are consistent with a meta-analysis by Jayakar and Altere (2017), which assessed the effect of music intervention on patients' anxiety levels during CAG procedures. Their study's findings showed a statistically significant decrease in mean STAI scores with music intervention (p value less than 0.005). Indeed, the results of this study agree with a study done in Zarqa, Jordan, which found that patients who listened to music throughout their PCI treatment had considerably lower anxiety levels after the procedure P = .001 (Ashour et al., 2023). Comparably, a study by Esfandiari et al. (2022) that assessed the influence of particular music and an eye mask on patients undergoing CAG found that the experimental groups' mean total anxiety scores pre and post the intervention were statistically significant in lowering the level of anxiety at p value .(•• •).) Additionally, the results demonstrated that the music group had the lowest anxiety level, with a mean STAI score of 70.26, in comparison with the following music-eye mask group, control group, and eye mask group, respectively. For other hand, Cetinkaya et al. (2018) investigated whether music listening during coronary angiography affected the patient's anxiety level. The study's findings indicated that there was no statistically significant difference in the mean STAI during the intervention (p > 0.05). Additionally, Forooghy et al. (2015) indicated that the experimental group's

anxiety level rose when they listened to music throughout the CAG procedure. Regarding the association between clinical information and demographic traits with anxious level, the findings show that, at $p \le 0.05$, there was no statistically significant correlation between any clinical or sociodemographic variable and anxiety level following music exposure as shown in table (7). The study's findings revealed that, compared to their preintervention levels, all groups' levels of anxiety decreased following the intervention. When comparing groups, the music group was significantly more effective in lowering anxiety level than routine therapy (p < 0.01). As a result, because listening to music allows the patient to avoid hearing the voices of the medical staff and their conversations about his health condition, as well as the external noise of the sounds of medical devices and equipment, their total anxiety level drops significantly post-test in the experimental group.

The present study showed that listening to music was more beneficial than daily routine care in decreasing total anxiety in patients undergoing elective CAG and/or PCI. As a result, music can be utilized clinically to lessen anxiety during CAG. On the other hand, no significant association appeared among the level of anxiety of interventional group (post-test) and socio-demographic and clinical characteristics, including their age, gender, education level, marital status, occupation, and monthly income, as well as HTN and DM. Nurses can use "listening to music" as a preventative and soothing intervention to accelerate recovery and improve the well-being of patients because it is risk-free.

Conflicts of interest: There is no conflict of interest.

Acknowledgements

Conclusions

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