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Effect of Benson relaxation technique on the preoperative anxiety and hemodynamic status: A single blind randomized clinical trial



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KEYWORDS

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Abstract *Background:* Preoperative anxiety is a challenge in most surgical interventions that needs to be taken into consideration. This trial assessed the effect of relaxation technique on the anxiety and hemodynamic response in patients undergoing surgical procedures.

Methods: This single blind, randomized clinical trial was conducted on patients who were candidates for coronary artery bypass graft, coronary angiography, percutaneous intervention, or general surgery at Ekbatan and Besat Hospitals, Hamadan University of Medical Sciences, from March to August 2014. Patients were randomly assigned to intervention and control groups. The intervention group received Benson's relaxation technique, a half an hour before surgical procedures. The preoperative anxiety and hemodynamic status (systolic and diastolic blood pressure, pulse pressure, heart rate, and respiratory rate) were evaluated before and after intervention.

Results: Of 166 patients identified, 144 patients enrolled into the study. No patient declined follow-up. The baseline clinical characteristics of the patients in the intervention and control groups were nearly the same. The mean systolic and diastolic blood pressure, pulse pressure, the average number of heart rates and respiratory rates declined significantly in the intervention group compared to the control group ($P < 0.001$). The mean score of hospital anxiety was significantly lower in the intervention group than in the control group ($P < 0.001$). The intervention was effective in both males and female patients.

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Conclusion: This trial indicated that Benson's relaxation technique is a safe method with no adverse effects with significant beneficial effect on preoperative anxiety and hemodynamic responses in patients who were candidates for surgical procedures.

Trial registration: Iranian Registry of Clinical Trials registration number: IRCT201312249014N19. <http://www.irct.ir/searchresult.php?id=9014&number=19>.

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Introduction

Most patients experience anxiety before any kind of surgical procedure. It is reported that 24%–72% of patients has some degree of anxiety before percutaneous intervention (PCI).¹ Anxiety is a common emotional distress among patients undergoing coronary artery bypass graft (CABG).² About 25%–80% of patients experience anxiety before heart surgery.³

Anxiety can exacerbate the symptoms of the disease and may have an undesirable effect on the physiological status.⁴ Anxiety can trigger stress response and stimulate releasing epinephrine and norepinephrine. Activation of the neuroendocrine response to stress may be associated with several physiologic changes such as an increase in blood pressure, heart rate, and cardiac output.⁵ Poor management of anxiety may be life-threatening in patients with coronary artery disease and may increase the likelihood of myocardial infarction or stroke.^{1,3}

Apart from conventional medical treatment, other approaches, such as the relaxation response, education, and music therapy, can be used to manage the preoperative distress and anxiety in patients who are candidates for surgical procedures.^{3,6} Relaxation is one of non-pharmaceutical techniques that may be useful in reducing anxiety and increase self-esteem by effecting on the mental and emotional status.⁷ Benson's relaxation technique is one of the most popular methods of relaxation which was first introduced in 1975 by Herbert Benson, a Harvard physician. He denoted that the technique could bring about the relaxation response by reducing the activity of the autonomic nervous system.⁸ It is indicated that Benson's relaxation technique can reduce the severity of pain and improve the quality of life in patients with hemodialysis.⁹ It can efficiently decrease the emotional distress during the period of diagnostic uncertainty in women who underwent percutaneous breast biopsy.¹⁰ In addition to its simplicity, this technique is an inexpensive, efficacious, and practical method to reduce pain, anxiety, and medication during invasive procedures such as femoral angiography.¹¹

It is posited that Benson's relaxation technique can counteract the stress response before and during invasive procedures and might be associated with better patient outcomes, however, no study has been conducted that examines and compares the effect of this relaxation technique on different types of surgeries. This clinical trial was conducted to examine the effect of Benson's relaxation technique on the anxiety and hemodynamic response in patients undergoing various kinds of surgical procedures

including coronary artery bypass graft (CABG), coronary angiography (CAG), percutaneous intervention (PCI), or general surgeries.

Materials and methods

This single blind, randomized clinical trial was conducted in Ekbatan and Besat Hospitals, affiliated with Hamadan University of Medical Sciences, in the west of Iran, from March to August 2014. The patients were enrolled voluntarily into the trial and gave written informed consent. The Ethics Committee of the university approved the consent procedure and the whole trial. The protocol was registered with the Iranian Registry of Clinical Trials on January 6, 2014 (IRCT201312249014N19).

The study population included patients aged 18 to 65 who were candidates for CABG, CAG, PCI, or general surgery. Patients with any of the following problems were excluded from the trial: (a) hearing loss; (b) muscle paralysis; (c) known psychiatric disease; (e) substance or alcohol abused dependent.

According to the results of a clinical trial conducted by Zakerimoghadam et al.,¹² the mean (SD) level of anxiety on the first hour after angiography was 3.96 (2.17) and 6.58 (2.18) in the intervention receiving relaxation technique and the control groups, respectively, on a scale of 0–10. On the basis of these results, we arrived at a sample size of 18 for each group and a total sample size of 36 at 95% significance level and 95% statistical power. Since we used the intervention for four different groups of patients undergoing CABG, CAG, PCI, and general surgeries, we quadrupled the sample size to a maximum of 144, of which 36 were allocated to the CABG group, 36 to the CAG group, 36 to the PCI group, and 36 to the general surgery.

The eligible patients were randomly assigned to the intervention and control groups using the balance block randomization method. The allocations remained concealed during the study. For this purpose, we prepared four sheets of paper, writing on two sheets "I" for "intervention" and on two "C" for control". The paper sheets were pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets were drawn. The four paper sheets were then placed back into the container and this action repeated until the sample size was reached.

The trial was carried out as single blind so that the examiner who evaluated the preoperative anxiety and hemodynamic responses was not aware of the allocated intervention. Furthermore, the statistical analyst was unaware of

the trial groups until the data were analyzed and the labels were decoded.

The intervention of interest was listening to an audio file for 20 min through a headphone about a half an hour before surgical intervention. In addition, the intervention group received routine preoperative medications. The control group received routine preoperative medications alone.

Among several quiet and relaxing music, six music were selected of which two music were finally used for relaxation technique. The audio file included the following recommendations broadcasted for the patients during listening to music through a headphone.^{5,7,9,13}

- (a) Lie down quietly in a comfortable position.
- (b) Close your eyes slowly.
- (c) Relax all your muscles deeply from the feet to the face.
- (d) Meanwhile, inhale deeply through the nose. Be aware of your breathing and pay attention to it. Then, exhale quietly through your mouth while repeating a word on the lips.
- (e) Repeat these actions several times for 15–20 min. Then, open your eyes for a few moments while you are lying down.
- (f) Do not worry whether or not you are at a deep level of relaxation. Let the relaxation happens itself. When annoying thoughts occur, try to ignore them.

The primary outcome of interest was preoperative anxiety, which was evaluated before and immediately after intervention using the Hospital Anxiety and Depression Scale (HADS) including subscales for anxiety (7 items), which was used in this trial, and depression (7 items). Each item was rated from 0 to 3, where higher scores indicated more anxiety. The maximum score was 21 on the anxiety

subscale. The range of scores for cases was as follows: 0–7 normal, 8–10 mild disorder, 11–14 moderate disorder, and 15–21 severe disorder.^{14,15} The Cronbach's alpha coefficient was used to measure the reliability of the anxiety questionnaire. The coefficient was 0.86 for before and 0.90 for after intervention based on our results.

The secondary outcomes of interest were: (a) systolic and diastolic blood pressure in mmHg; (b) heart rate per minute; and (c) respiratory rate per minute. The secondary outcomes were measured before and immediately after intervention using a heart monitoring device.

We used the independent t-test for comparison mean difference between intervention and control groups before and after intervention. We also used ANOVA and multivariate analysis for comparing the mean difference between the two groups adjusting on baseline values. All statistical analyses were performed at a significance level of 0.05 using Stata software, version 11 (StataCorp).

Results

Of 166 patients identified, 18 were ineligible and 4 declined to participate. The randomization was based on the remaining 144 patients, of whom 72 patients were allocated to the intervention and 72 to the control groups. No patient declined follow-up (Fig. 1). The analysis was based on data from 144 patients (male/female ratio was 42/30 and 41/31 in the control and intervention groups, respectively, $P = 0.866$) including 36 in the CABG group, 36 in the CAG group, 36 in the PCI group, and 36 in the general surgery group. The mean (SD) age of the patients was 51.3 (10.9) years ranged from 17 to 65 years.

The baseline characteristics of the participants in the two groups are given in Table 1. The results show that there

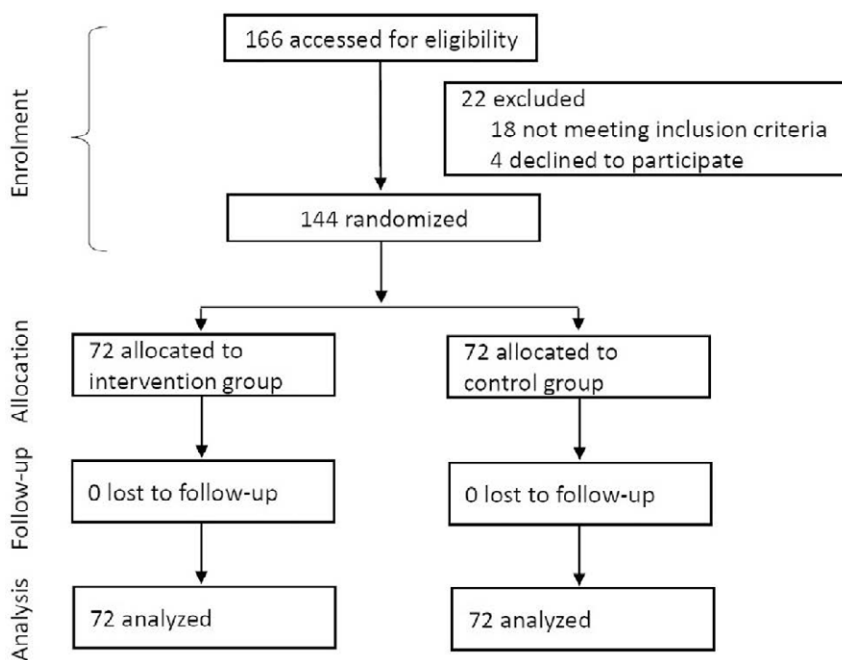


Figure 1 Flowchart of progress through the trial.

Table 1 Baseline clinical characteristics of the intervention and control groups.

Variables	Control		Intervention		P value
	Mean	SD	Mean	SD	
Age (yr)	51.41	11.25	51.31	10.70	0.957
Systolic blood pressure (mmHg)	124.09	13.38	124.90	12.64	0.711
Diastolic blood pressure (mmHg)	76.59	7.99	78.25	8.90	0.243
Pulse pressure (mmHg)	47.50	9.96	46.65	10.22	0.615
Respiratory rate (/min)	17.65	2.07	17.88	2.24	0.512
Heart rate (/min)	77.12	9.04	80.55	7.73	0.015
Anxiety score	10.73	4.45	10.56	4.02	0.814

was no statistically significant difference between the patients' hemodynamic status, including systolic and diastolic blood pressure, pulse pressure, respiratory rate, and preoperative anxiety score except heart rate, in the intervention and control groups at baseline.

The effect of the Benson's relaxation technique versus no intervention on the preoperative anxiety and hemodynamic responses are given in Table 2. The mean level of systolic and diastolic blood pressure, pulse pressure, the average number of heart rates and respiratory rates declined significantly in the intervention group compared to the control group ($P < 0.001$). In addition, the mean

score of preoperative anxiety was significantly lower in the intervention group than the control group ($P < 0.001$). The results indicated that the intervention was effective in both male and female patients. After adjusting on baseline values, the mean differences between the intervention and control groups became more significant for all hemodynamic variables and anxiety score.

The effect of the Benson's relaxation technique on the preoperative anxiety and hemodynamic response are given in Table 3 by type of surgical procedures including CABG, CAG, PCI, general surgery. Regardless of the type of surgical procedures, the mean score of preoperative anxiety was significantly lower in the intervention group than in the control group. Furthermore, the hemodynamic responses were improved significantly in the intervention group than control group except the diastolic blood pressure in patients undergoing CAG, the systolic blood pressure, pulse pressure, and the heart rate in patients undergoing PCI, and pulse pressure and the heart rate in patients undergoing general surgery. Although, some hemodynamic responses were not statistically different between the intervention and control groups, however, the averages of hemodynamic responses were lower in the intervention group than in the control group.

Discussion

The use of Benson's relaxation technique is a safe and inexpensive method that is associated with a beneficial

Table 2 Comparison of the effect of Benson's relaxation technique versus no intervention on the hemodynamic status and hospital anxiety by gender.

Variables	Control		Intervention		P value ^a	P value ^b
	Mean	SD	Mean	SD		
Total						
Systolic blood pressure (mmHg)	125.72	13.66	115.41	12.93	0.001	0.001
Diastolic blood pressure (mmHg)	77.91	7.67	72.68	8.24	0.001	0.001
Pulse pressure (mmHg)	47.80	10.58	42.73	10.31	0.004	0.001
Respiratory rate (/min)	18.05	1.70	15.97	1.82	0.001	0.001
Heart rate (/min)	78.58	8.15	71.95	11.48	0.001	0.001
Anxiety score	10.83	4.33	5.54	2.94	0.001	0.001
Female						
Systolic blood pressure (mmHg)	129.06	14.33	116.29	13.47	0.001	0.001
Diastolic blood pressure (mmHg)	78.00	9.15	73.38	8.88	0.050	0.016
Pulse pressure (mmHg)	51.06	8.94	42.90	9.19	0.001	0.134
Respiratory rate (/min)	17.90	1.60	15.87	1.91	0.001	0.001
Heart rate (/min)	78.26	8.74	73.54	7.95	0.031	0.001
Anxiety score	11.06	3.84	6.41	2.90	0.001	0.001
Male						
Systolic blood pressure (mmHg)	123.33	12.81	114.75	12.63	0.002	0.001
Diastolic blood pressure (mmHg)	77.85	6.54	72.14	7.78	0.001	0.003
Pulse pressure (mmHg)	45.47	11.14	42.60	11.18	0.245	0.091
Respiratory rate (/min)	18.16	1.77	16.04	1.77	0.001	0.001
Heart rate (/min)	78.80	7.80	70.75	13.54	0.001	0.069
Anxiety score	10.66	4.66	4.87	2.82	0.001	0.001

^a Comparing intervention and control groups using independent t-test.

^b Multivariate analysis using ANOVA comparing hemodynamic variables between intervention and control groups adjusted on baseline values and the anxiety score and comparing anxiety score between the two groups adjusted on the baseline value and hemodynamic variables.

Table 3 Comparison of the effect of Benson's relaxation technique versus no intervention on the hemodynamic status and hospital anxiety by surgical procedures.

Variables	Control		Intervention		P value
	Mean	SD	Mean	SD	
Coronary artery bypass graft (CABG)					
Systolic blood pressure (mmHg)	126.94	13.18	114.16	13.17	0.006
Diastolic blood pressure (mmHg)	78.61	8.18	72.66	8.35	0.038
Pulse pressure (mmHg)	48.33	8.22	41.50	7.26	0.012
Respiratory rate (/min)	18.66	1.32	16.05	1.05	0.001
Heart rate (/min)	82.88	6.20	74.05	6.11	0.001
Anxiety score	13.50	2.95	7.05	2.77	0.001
Coronary angiography (CAG)					
Systolic blood pressure (mmHg)	124.55	11.24	112.77	11.27	0.003
Diastolic blood pressure (mmHg)	75.00	5.42	72.77	7.90	0.332
Pulse pressure (mmHg)	49.55	11.50	40.00	11.73	0.012
Respiratory rate (/min)	18.44	1.19	16.55	1.19	0.001
Heart rate (/min)	78.27	7.53	73.11	6.97	0.040
Anxiety score	11.11	2.21	5.16	1.79	0.001
Percutaneous intervention (PCI)					
Systolic blood pressure (mmHg)	127.77	12.27	124.72	11.69	0.449
Diastolic blood pressure (mmHg)	79.44	5.91	74.72	7.37	0.041
Pulse pressure (mmHg)	48.33	10.71	50.00	12.60	0.671
Respiratory rate (/min)	18.27	1.40	16.83	1.15	0.001
Heart rate (/min)	79.94	7.56	72.16	19.10	0.117
Anxiety score	9.61	2.00	6.50	1.61	0.001
General surgery					
Systolic blood pressure (mmHg)	123.61	17.80	110.00	11.37	0.009
Diastolic blood pressure (mmHg)	78.61	10.11	70.55	9.37	0.018
Pulse pressure (mmHg)	45.00	11.88	39.44	7.25	0.099
Respiratory rate (/min)	16.83	2.17	14.44	2.52	0.004
Heart rate (/min)	73.22	8.53	68.50	9.02	0.116
Anxiety score	9.11	6.96	3.44	3.79	0.004

effect on preoperative anxiety and the hemodynamic status in patients who are candidates for undergoing a various kinds of surgical procedures such as CABG, CAG, PCI, and general surgery. The investigations have shown that relaxing music can significantly reduce heart rate, respiratory rate, and myocardial oxygen demand.¹⁶ In addition, listening to music in a quiet and restful environment may reduce anxiety in persons with coronary heart disease, especially those patients recovering from acute myocardial infarction.^{16,17}

Apart from anti-anxiety effect of music therapy, it has a beneficial effect on pain relief. Using music can decrease opioid administration and improve satisfaction in patients undergoing hysterectomy.¹⁸ Music can reduce the dose of sedative medication required for colonoscopy.¹⁹ Listening to music during labor has a beneficial effect on labor pain and anxiety, maternal–fetal parameters and may reduce postpartum analgesic requirement.²⁰

The investigations suggest that music can modify the physiological function through several mechanisms, including the autonomic nervous system, plasma cytokine, and catecholamine levels. The evidence has shown that music can induce parasympathetic activities and reduce plasma cytokine and catecholamine levels.^{21–24}

The main limitation of the present study was that the blinding of the intervention to the patients was impossible.

This might raise the possibility of the information bias. Despite its limitation, this trial was carried out several groups of patients undergoing various kinds of surgical procedures in two separate hospitals. This increases the generalizability of the intervention effect.

We performed music therapy through a headphone which has its own limitation when this method of relation is to be used for a large number of patients. Therefore, we suggest the effect of this technique is examined on preoperative anxiety and hemodynamic responses broadcasting music through speakers in the ward for all patients rather than individually through a headphone.

Conclusion

The results of this trial indicated that music therapy is a safe and less expensive method with beneficial effects on preoperative anxiety and hemodynamic responses in patients undergoing coronary artery bypass graft, coronary angiography, percutaneous intervention, or general surgeries.

Conflict of interest

The authors declare that they have no conflicts of interest.

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