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Effect of nature-based sound therapy on agitation and anxiety in coronary artery bypass graft patients during the weaning of mechanical ventilation: A randomised clinical trial

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ABSTRACT

Background: Weaning from mechanical ventilation is a frequent nursing activity in critical care. Nature-based sound as a non-pharmacological and nursing intervention effective in other contexts may be an efficient approach to alleviating anxiety, agitation and adverse effects of sedative medication in patients undergoing weaning from mechanical ventilation.

Objectives: This study identified the effect of nature-based sound therapy on agitation and anxiety on coronary artery bypass graft patients during weaning from mechanical ventilation.

Methods: A randomised clinical trial design was used. 120 coronary artery bypass graft patients aged 45–65 years undergoing weaning from mechanical ventilation were randomly assigned to intervention and control groups. Patients in the intervention group listened to nature-based sounds through headphones; the control group had headphones with no sound. Haemodynamic variables, anxiety levels and agitation were assessed using the Faces Anxiety Scale and Richmond Agitation Sedation Scale, respectively. Patients in both groups had vital signs recorded after the first trigger, at 20 min intervals throughout the procedure, immediately after the procedure, 20 min after extubation, and 30 min after extubation. Data were collected over 5 months from December 2012 to April 2013.

Results: The intervention group had significantly lower anxiety and agitation levels than the control group. Regarding haemodynamic variables, a significant time trend and interaction was reported between time and group ($p < 0.001$). A significant difference was also found between the anxiety ($p < 0.002$) and agitation ($p < 0.001$) scores in two groups.

Conclusions: Nature-based sound can provide an effective method of decreasing potential adverse haemodynamic responses arising from anxiety and agitation in weaning from mechanical ventilation in coronary artery bypass graft patients. Nurses can incorporate this intervention as a non-pharmacological intervention into the daily care of patients undergoing weaning from mechanical ventilation in order to reduce their anxiety and agitation.

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What is already known about the topic?

- Anxiety and agitation is still poorly managed by critical care nurses during the process of weaning from mechanical ventilation.
- Weaning process is prolonged when pharmacological agents for the treatment of the patient's anxiety and agitation are used.

What this paper adds

- This study supported the effectiveness of the nature-based sounds listening intervention as a non-pharmacological therapy during provision of care to patients undergoing weaning from mechanical ventilation.
- Nature-based sounds listening intervention could be considered to be an effective approach for reducing potentially harmful physiological responses arising from anxiety and agitation during weaning from mechanical ventilation.
- Nature-based sound intervention as a complementary therapy nursing intervention alleviated patients' complaints of anxiety and agitation.

1. Introduction

Mechanical ventilation is one of the most common therapeutic modalities provided to patients in the intensive care unit. In the past two decades, great efforts have been devoted to define the most effective approach to weaning patients from mechanical ventilation in different intensive care unit designs and structures (Danckers et al., 2012). Mechanical ventilation is commonly used in critical care units to treat respiratory insufficiency derived from a variety of causes (Chlan, 2004; Lee et al., 2005). It is the most common technological intervention used in critical care and is often the primary reason for admission to these units (Eskandar and Apostolakos, 2007). Mechanical ventilation is associated with well-documented complications influencing patients' morbidity and mortality. Weaning from mechanical ventilation refers to the transition from mechanical ventilation support to spontaneous breathing or enabling the patient to assume a greater ventilation workload by reducing the support given by the ventilator (Rose and Nelson, 2006; Hess, 2002). Weaning covers the entire process of liberating the patient from both mechanical ventilation support and the endotracheal tube (Boles et al., 2007). While many patients are able to breathe independently immediately, others need extended mechanical ventilation. Patients may require a slow, graduated process of weaning, described as lengthening the time spent free from mechanical ventilator support until permanent liberation is achieved (Boles et al., 2007). Patients undergoing mechanical ventilation may experience fear, agitation, discomfort, thirst, immobility, dyspnoea, confusion, communication problems and inability to relax (Lee et al., 2005), with approximately 10–25% encountering difficulties during the weaning process (Hunter et al., 2010). While this creates adverse physiological and psychological experiences for the patient and their family members, a primary objective is to discontinue mechanical ventilation support as soon as the patient becomes able to sustain spontaneous and safe breathing (Dries, 2004). Reducing these effects may be enhanced by increasing patients' involvement in their care (Crocker and Scholes, 2009).

Patients demonstrating difficulty in the weaning process appear to have a longer than average hospitalization time with increased medical complications. Furthermore, longer periods of intubation are associated with higher rates of difficulties at weaning. Over time, the number of mechanically ventilated patients has increased together with the costs of healthcare and use of resources (Epstein et al., 2002). In addition, the longer a patient remains dependent upon mechanical ventilation, the higher the risk of complications and lengthened hospital stay (Lindgren and Ames, 2005).

Although mechanical ventilation is common, many patients experience stress and anxiety during the procedure (Ayalon, 2007; Lindgren and Ames, 2005; Thomas, 2003). Many patients also suffer higher anxiety during the process of weaning (Boles et al., 2007). Chlan's (1998) study in the US provided an overview of the experiences of patients undergoing mechanical ventilation, describing it as the worst experience in patients' lives. Patients describe their experiences using the following words: fear, thirst, sleeplessness, agitation, pain, frustration from being restrained, inability to speak, immobility, noise, confusion, inability to match breathing pattern with the ventilator, and suctioning of the endotracheal or tracheostomy tube (Thomas, 2003). Anxiety plays a major role in preventing patients from weaning, and can be compounded by difficulty in communication and the presence of delirium. If anxiety is not managed appropriately, it may interfere with patient recovery and impede liberation from mechanical ventilation. Anxiety may also trigger the sympathetic nervous system activation causing tachycardia, increased respiratory rate, increased blood pressure, and airway constriction, which interferes with breathing and causes fatigue. Consequently, the patient may fail to be liberated from the ventilator easily (Thomas, 2003; Wong et al., 2001).

Several strategies are reported to minimise agitation and anxiety during mechanical ventilation that can reduce the time spent to wean the patient (Boles et al., 2007). Pharmacological agents may have a profound effect on the process's outcome. For instance, weaning patients may require sedation during extubation and discharge from the intensive care unit (No authors listed, 2002). Meade et al. (2001) reviewed randomised controlled trials investigating interventions to assist the weaning process and concluded that further studies are required to explore strategies to reduce the complications accompanying the weaning process. Thomas (2003) suggested that multidisciplinary, patient-centred, holistic, and non-pulmonary approaches may be important in shortening the length of the weaning process. The effective use of hypnosis and relaxation, patient education and information sharing, music therapy, and supportive touch reduce common stressors of ventilation (Han et al., 2009). However, few studies have explored the effect of non-pharmacological interventions on the alleviation of patient-perceived stress and anxiety during the weaning process.

Critical care nurses have a pivotal role in the management of the weaning process, with their engagement being dependent on their experience, personal preferences and work place culture (Rose and Nelson, 2006; Blackwood et al., 2006) – they have been described as around-the-clock surveillance agents (Aiken et al., 2003). Nurses in the intensive care unit often explore alternative, less expensive and more efficient ways to alleviate anxiety by balancing the potential benefits of decreased anxiety and the adverse effects of sedative medications. Exploration of the utilisation of nature-based sound therapy (N-BS) may provide non-pharmacological approaches to the reduction of anxiety during the weaning process. Saadatmand et al. (2012) reported the application of N-BS, defined as listening to pleasant N-BS through headphones, as effective in reducing anxiety and agitation in patients receiving mechanical ventilation by reducing potentially harmful physiological responses. They discussed the importance of the patient's N-BS preference in the intensive care unit, where a patient undergoing mechanical ventilation has little control over the environment or treatment plan. Additionally, the N-BS as a complementary therapy may help with the facilitation of the weaning process, which has, so far, not been investigated.

N-BS has a positive emotional effect on different people (Maller et al., 2006), and has been shown in various studies to have more relaxing effects in comparison to other interventions (Lavandier and Defre'ville, 2006; Nilsson and Berglund, 2006). Pleasant N-BS has been used with patients after surgery (Ulrich, 1984), undergoing bronchoscopic procedures (Anon, 2003) and mechanical ventilation (Saadatmand et al., 2012). Few studies have focused on the effect of non-pharmacological interventions on the level of agitation and anxiety in patients who have undergone coronary artery bypass graft during weaning from mechanical ventilation. Therefore, the specific aim of this study was to investigate the effect of the N-BS intervention on the levels of (a) anxiety; (b) agitation; and (c) haemodynamic variables (systolic blood pressure [SBP], diastolic blood pressure [DBP], heart rate [HR], respiratory rate [RR], mean arterial pressure [MAP] and oxygen saturation [SpO_2]) during weaning from mechanical ventilation in this group of patients.

2. Methods

2.1. Study design

In this randomised placebo-controlled trial study, a convenience sample of 120 coronary artery bypass graft patients were randomly assigned to the intervention and control groups during the phase of weaning from mechanical ventilation. The patients in the intervention group listened to N-BS through headphones; those in the control group used headphones without N-BS. The research hypothesis for this study was as follows: there were significant differences between the intervention group and the control group in terms of agitation, anxiety, SBP, DBP, HR, RR, SpO_2, and MAP during weaning from mechanical ventilation.

2.2. Setting and participants

This study was conducted in a high turnover open heart surgery intensive care unit of a teaching hospital in Tehran, Iran from December 2012 to April 2013.

A convenience sample of patients who met inclusion criteria and were undergoing weaning from mechanical ventilation was chosen, with no patient declining to participate. The size of the sample was determined using a sampling formula ($\alpha = 0.05$, $\beta = 15\%$, power = 80%, Altman's Nomogram) and also based on the sample size of the study by Roohy et al. (2005).

The patients were:

- recovering from coronary artery bypass graft surgery;
- aged between 45 and 65 years;
- weaning from mechanical ventilation according to the programmed protocol;
- on adaptive support ventilation (ASV) mode;
- able to hear;
- haemodynamically stable during the process of weaning;
- had no psychiatric or neurological illnesses;
- not receiving inotropic support;
- not taking any neuromuscular blocker agent or anti-hypertensive drug;
- not drug addicted;
- not having active drainage;
- showing no facial signs of being scared;
- had no previous experience of the N-BS intervention; and
- had no previous experience of heart surgery.

2.3. Measures

2.3.1. Demographical descriptive data and clinical characteristics of subjects

Baseline data was collected using patients' medical records to compare patients in the intervention and control groups with respect to age, gender, educational level, job, marital status, ejection fraction (EF), co-morbidities (diabetes, hyperlipidaemia, and hypertension), fraction inspiratory oxygen (%FIO_2), drug taking (nitroglycerine (TNG)), and number of grafts.

2.3.2. Physiological measures

Physiological signs of anxiety measured were SBP, DBP, HR, RR and MAP, obtained by means of indwelling arterial lines. Oxygen saturation (SpO_2) in the blood was measured by pulse oxymetry calibrated before data gathering.

2.3.3. Anxiety level

During the N-BS intervention or rest periods, data on the level of anxiety was gathered using the Faces Anxiety Scale (FAS). This scale was chosen because it was easier for open heart surgery intensive care unit patients to respond to in comparison to other anxiety scales (Chlan, 2004). Unlike most studies, the FAS was used to assess anxiety because patients in the intensive care unit were often nonverbal, many of whom could not respond to existing validated signs of anxiety; making use of currently available anxiety measures difficult. The FAS appeared to

be a promising means of obtaining self-reports on anxiety status from ventilator-dependent patients for routine clinical purposes as well as for research purposes. The relationship between the FAS and patients' nonverbal responses to short questions from the Profile of Mood States Anxiety (FMSA) subscale had been reported to be 0.64 ($p < .001$), within the range of 0.4–0.8 for criterion validity, indicating that the FAS was a valid tool for the measurement of anxiety (McKinley et al., 2003; Gustad et al., 2005). The FAS is a single-item scale with 5 possible responses, ranging from a neutral face to a face showing extreme fear, and is scored from 1 to 5. It was believed that most intensive care unit patients were able to respond to this scale in comparison to a 6-item anxiety scale or a numeric analogue anxiety scale, and it has ordinal and interval properties of continuous measurement (McKinley et al., 2004).

2.3.4. Agitation level

The Richmond Agitation Sedation Scale (RASS) score was already a part of routine monitoring of patients in the intensive care unit in this hospital. RASS is a 10-point scale, with four levels of anxiety or agitation (+1 to +4 [combative]), one level to denote a calm and alert state (0), and 5 levels of sedation (−1 to −5) culminating in unarousable (−5). The validity of the RASS had been demonstrated by strong correlations between the RASS and the Sedation Agitation Scale (SAS) score ($r = 0.78$, $p < 0.0001$), the Ramsay Sedation Scale (RSS) score ($r = 0.78$, $p < 0.0001$), and Glasgow Coma Scale (GCS) score ($r = 0.79$, $p < 0.0001$). Excellent inter-rater reliability was also demonstrated for the RASS among the entire adult intensive care unit population (intraclass correlation = 0.956 [0.948]) ($k = 0.73$ [0.71, 0.75]). Correlations between the RASS, and the RSS ($r = 0.78$) and the SAS ($r = 0.78$) confirmed its validity (Sessler et al., 2002). The Persian version of the RASS had been shown to be valid and reliable for the measurement of patients' agitation in the intensive care unit (Tadrisi et al., 2009).

2.4. Procedure

Following ethical approval the nurse manager in the open heart surgery intensive care unit was informed of the study's purpose and selection criteria to identify eligible participants daily from patient records. The investigator explained the study in terms of its purpose, benefits and potential risks to patients who met the inclusion criteria. Patients were randomly assigned to either a control group who received only standard care or an intervention group who received the N-BS listening intervention in addition using sequentially numbered containers as the allocation concealment mechanism.

Participants and investigator (first author) were unaware of the groups assigned to them (blinding technique), therefore, to limit bias in the recording of variables and sedation scores. The patients were only informed about the true purpose of the study after the experiment (i.e., our interest in the effect of N-BS). They were asked to select a CD from a collection of N-BS consisting of: birds' song, soothing rain sounds, river streams, waterfall sounds, or a walk through the forest; using media player and headphones for listening. Baseline outcome signs, including the physiological signs, were obtained.

The environment for both groups was enhanced to promote rest by posting a 'Please Do Not Disturb' sign. Each participant was instructed to think of something pleasant. The N-BS was played using a MP3 media player through disposable foam-lined headphones. The volume of the MP3 player was adjusted to the participants' comfort by responding to their facial expression and holding up fingers responsive to researcher's questions. Participants were asked to close their eyes and follow the flow of sounds during the intervention. The participants' hearing thresholds were tested. The average sound pressure level was set to 25–50 dB.

The control group patients wore the foam-lined headphones and rested in silence for a similar time frame to the intervention group to minimise unpleasant environmental noises or stimuli. Following the intervention, post-test measures were conducted according to the study protocol (Fig. 1).

The investigator recorded the agitation and anxiety scores and physiological signs for all participants during the intervention. The physiological signs were monitored on the bedside monitors according to the intensive care unit protocol of weaning. Patients in both groups had signs recorded after the first trigger, at 20 min intervals throughout the procedure, immediately after the procedure, 20 and 30 min after extubation. As the outcomes, agitation and anxiety were assessed by using the RASS and the FAS, respectively at the same time intervals.

2.5. Ethical considerations

Ethical approval from the Ethics Committee of Shahed University was obtained. All patients were provided with a full explanation of the study and invited to participate. Confidentiality and anonymity were assured and signed informed consent obtained. Participants were told that they could withdraw at any time throughout the study and non-participation would not have any detrimental effects in terms of the essential or regular hospital treatments and services received.

2.6. Data analysis

SPSS-PC software (Version 15.0 for Windows, US Illinois) was used for all data analyses. Descriptive statistics were used to summarise demographic and clinical characteristics of participants in both groups. The Chi-square test was performed to detect any significant baseline differences between the two groups. The Mann–Whitney U test was used to detect any significant difference in the FAS and RASS scores. An independent t-test was used to detect any significant difference between the groups' mean values of physiological signs. Nonparametric statistics were performed to check for variables that were not normally distributed (Kolmogorov–Smirnov test: $p < 0.05$). As there were no

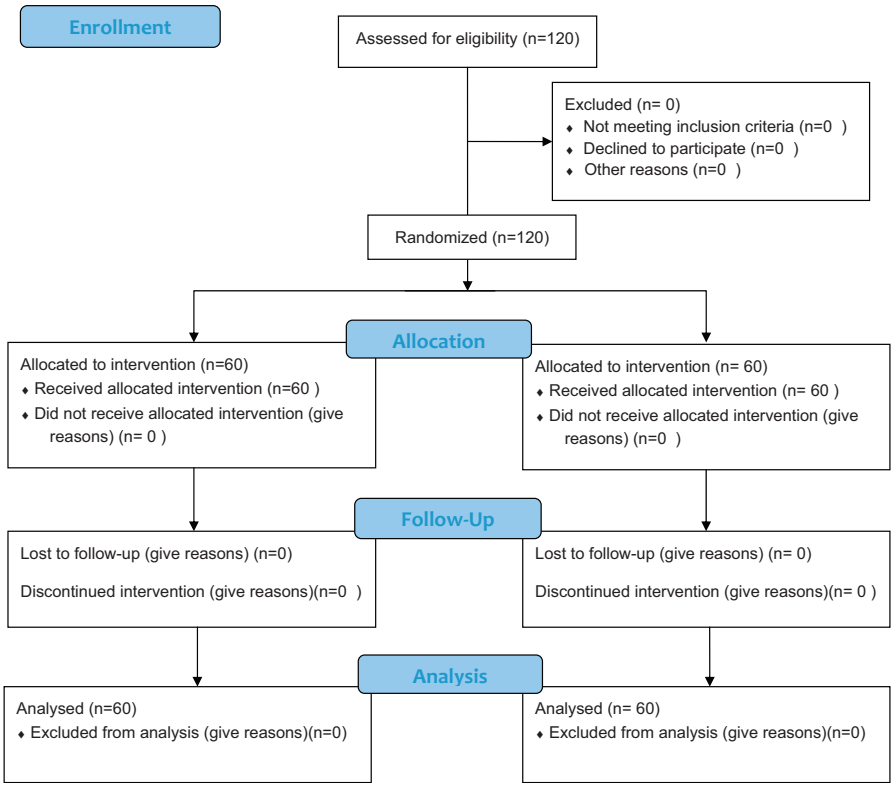

Fig. 1. The process of study design.

variables which deviated from normal distribution, repeated measures of analyses of variance (RANOVA) were used for each variable. RANOVA was also used to examine mean SBP, DBP, MAP, RR, HR, and SpO_2 across the intervention period.

3. Results

3.1. Demographical and baseline characteristics of the patients

120 patients were randomly assigned to the control ($n = 60$) and intervention ($n = 60$) groups. In the control group, 31 patients (51.70%) were male and 29 patients (48.30%) were female. In the intervention group, 35 patients (58.30%) were male and 25 patients (41.70%) were female ($p = 0.46$). The mean ± SD age of the patients was 56.66 ± 5.84 and 58.10 ± 6.05 in the control and intervention groups, respectively ($p = 0.19$). The rate of illiteracy was 45.0% (27 patients) in the control group and 43.3% (26 patients) in the intervention group ($p = 0.93$). 47 patients (78.30%) in the control group and 44 patients (73.30%) in the intervention group were married ($p = 0.18$). Clinical and baseline characteristics of participants in the intervention group and control group were compared. As shown in Tables 1 and 2, there was no significant difference between the two groups on baseline data and SBP, DBP, HR, RR, MAP, SpO_2 and at baseline before the intervention ($p > 0.05$).

3.2. The effects of nature-based sounds' intervention

3.2.1. Haemodynamic variables

The repeated measures ANOVA model was used to assess the concurrent effect of time trend, intervention (group variable) and interaction between time and group on different response variables (haemodynamic outcomes including SBP and DBP, HR, RR, SpO_2, and MAP). In these models, the impact of baseline values of these haemodynamic variables on response variables was adjusted by including the baseline values of the haemodynamic variables as a covariate.

3.2.1.1. Systolic blood pressure. The results of RANOVA for SBP showed a significant time trend ($p = 0.012$) and interaction between time and group ($p < 0.001$) (Fig. 2).

3.2.1.2. Diastolic blood pressure. The results of RANOVA for DBP showed a significant time trend ($p = 0.018$) and interaction between time and group ($p < 0.001$) (Fig. 3).

3.2.1.3. Heart rate. The results of RANOVA for HR showed a significant time trend ($p = 0.020$). The interaction between time and group was statistically significant ($p < 0.001$) (Fig. 4).

Table 1
Patients' demographic and clinical characteristics.

Characteristics	Total (n = 120)	Experiment group (n = 60)	Control group (n = 60)	Statistical test and p value
Age				
Mean ± SD	57.32 ± 5.94	58.10 ± 6.05	56.66 ± 5.84	t = 1.319, p = .19
Gender, n (%)				
Male	66(%100.00)	35(%53.00)	31(%47.00)	f = 0.53, df = 3, p = .58
Female	54(%100.00)	25(%46.30)	29(%53.70)	
Educational level, n (%)				
Illiterate	53(%100.00)	26(%49.10)	27(%50.90)	x^2 = 0.259, df = 3, p = 0.96
Primary	20(%100.00)	11(%55.00)	9(%45.00)	
Secondary	25(%100.00)	12(%48.00)	13(%52.00)	
High/undergraduate school	22(%100.00)	11(%50.00)	11(%50.00)	
Marital, n (%)				
Single	91(%100.00)	44(%48.40)	47(%51.60)	x^2 =4.139, df = 2, p = 0.12
Married	4(%100.00)	4(%100.00)	0(%0.00)	
Others	25(%100.00)	12(%48.00)	13(%52.00)	
Job n (%)				
Employer	18(%100.00)	10(%55.60)	8(%44.40)	x^2 =0.576, df = 3, p = 0.90
Retired	53(%100.00)	25(%47.20)	28(%52.80)	
Housewife	34(%100.00)	18(%52.90)	16(%47.10)	
Others	15(%100.00)	7(%46.70)	8(%53.30)	
Smoking, n (%)				
Yes	16(%100.00)	11(%73.30)	4(%26.70)	x^2 = 3.733, df = 1, p = 0.095
No	105(%100.00)	49(%46.70)	56(%53.30)	
Diabetes, n (%)				
Yes	61(%100.00)	30(%49.20)	31(%50.80)	x^2 =0.033, df = 1, p = 1
No	59(%100.00)	30(%50.80)	29(%49.20)	
Hypertension, n (%)				
Yes	68(%100.00)	37(%54.40)	31(%45.60)	x^2 =1.222, df = 1, p = 0.350
No	52(%100.00)	23(%44.20)	29(%55.80)	
Hyperlipidaemia, n (%)				
Yes	54(%100.00)	25(%46.30)	29 (%53.70)	x^2 = 0.539, df = 1, p = 0.582
No	66(%100.00)	35 (%53.00)	31(%47.00)	
Ejection fraction, n (%)				
Mean ± SD	48.39 ± 6.48	49.28 ± 6.22	47.50 ± 6.67	t = 1.514, df = 118, p = 0.13
Grafts (n)				
Mean ± SD	2.83 ± 0.84	2.93 ± 0.89	2.73 ± 0.77	t = 1.302, df = 118, p = 0.195
Fraction inspiratory oxygen (%FIO_2)				
Mean ± SD	42.73 ± 6.44	42.28 ± 4.39	43.18 ± 7.99	t = −0.764, df = 118, p = 0.447
Nitro-glycerine (cc/per hour)				
Mean ± SD	19.74 ± 16.24	19.18 ± 17.91	20.30 ± 14.51	t = −0.377, p = 0.707, df = 118

Table 2
Comparison of the patients' clinical characteristics in the groups.

Characteristics	Group	Mean ± SD	p^*
Baseline systolic blood pressure	Control	126.15 ± 16.38	0.62
	Intervention	124.55 ± 19.31	
Baseline diastolic blood pressure	Control	72.41 ± 9.27	0.66
	Intervention	73.16 ± 9.41	
Baseline heart rate	Control	103.70 ± 8.82	0.10
	Intervention	100.36 ± 13.07	
Baseline respiratory rate	Control	17.70 ± 3.50	0.92
	Intervention	17.63 ± 4. 42	
Mean arterial pressure	Control	90.83 ± 9.45	0.57
	Intervention	89.79 ± 10.72	
Oxygen saturation	Control	99.77 ± 2.00	0.73
	Intervention	96.90 ± 2. 33	

* p-Values were obtained from the independent t-test.

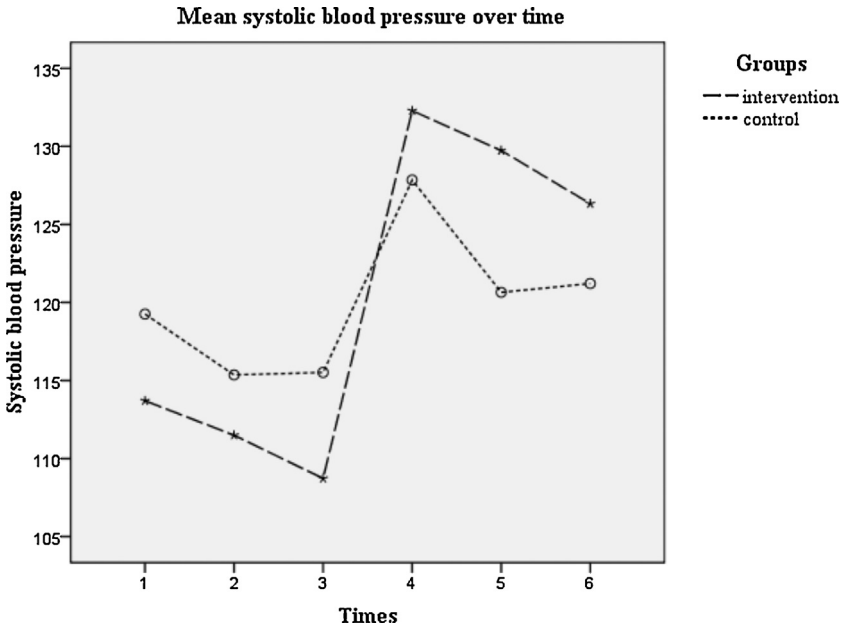

Fig. 2. Time trend of mean systolic blood pressure in the intervention and control groups.

3.2.1.4. Respiration rate. The results of RANOVA for respiration rate showed significant time trend ($p = 0.023$) and interaction between time and group was statistically significant ($p < 0.001$) (Fig. 5).

3.2.1.5. Oxygen saturation. The results of RANOVA for SpO_2 showed a significant time trend ($p = 0.037$). The interaction between time and group was statistically significant ($p < 0.001$) (Fig. 6).

3.2.1.6. Mean arterial pressure. The results of RANOVA for MAP showed a significant time trend ($p = 0.023$) and interaction between time and group was statistically significant ($p < 0.001$) (Fig. 7).

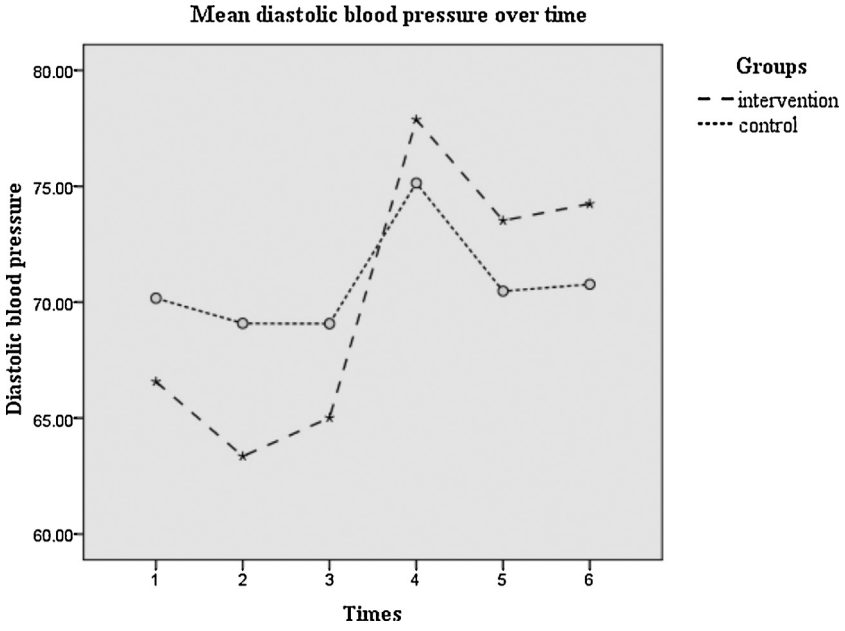

Fig. 3. Time trend of mean diastolic blood pressure in the intervention and control groups.

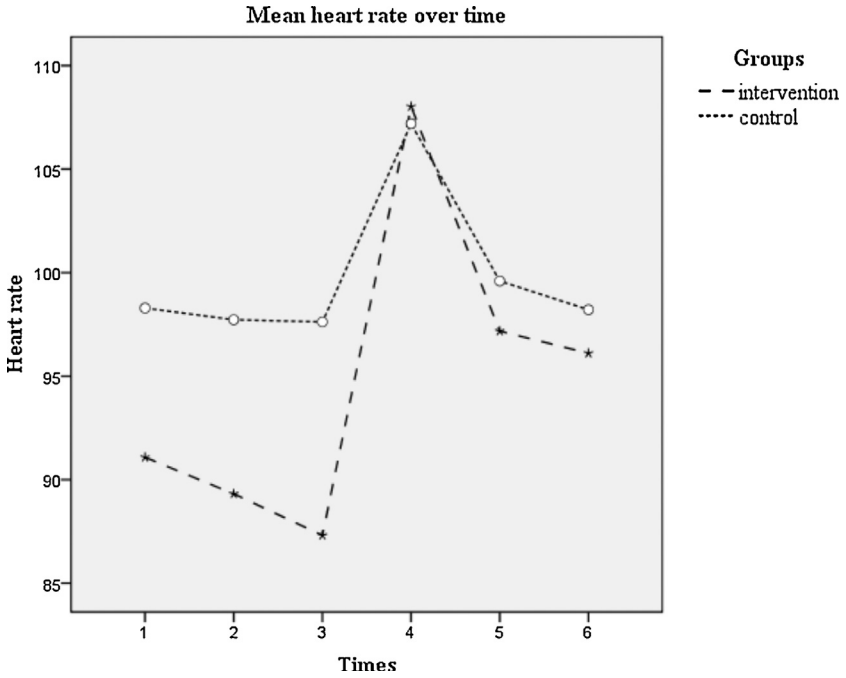

Fig. 4. Time trend of mean heart rate in the intervention and control groups.

3.2.2. Anxiety and agitation level

In the next step, because of the ordinal nature of anxiety and agitation scores, the marginal modelling approach (GEE analysis) was used to assess the concurrent effect of time, intervention (group variable) and interaction between time and group on anxiety and agitation scores (adjusted for the baseline scores of these variables) (Table 3).

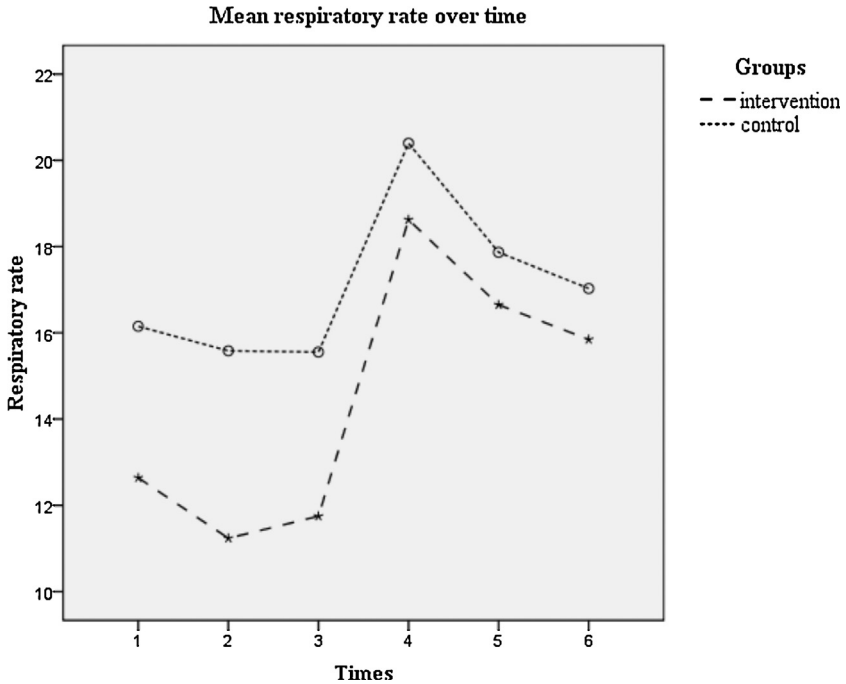

Fig. 5. Time trend of mean respiration rate in the intervention and control groups.

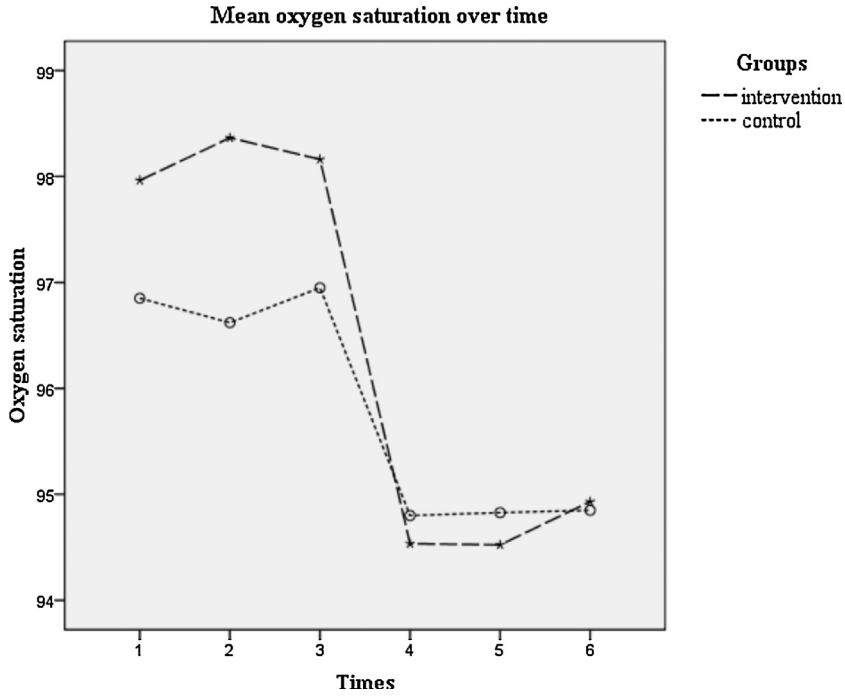

Fig. 6. Time trend of mean SpO_2 in the intervention and control groups.

3.2.2.1. Anxiety level. The results of marginal modelling for anxiety scores showed significant effect of time ($p = 0.890$) and interaction between group and time ($p = 0.001$). However, a significant difference was found between the anxiety scores of two groups ($p < 0.002$). The estimated regression parameter for the variable group was 1.33. This meant that the odds of having higher scores of anxiety in the control group was

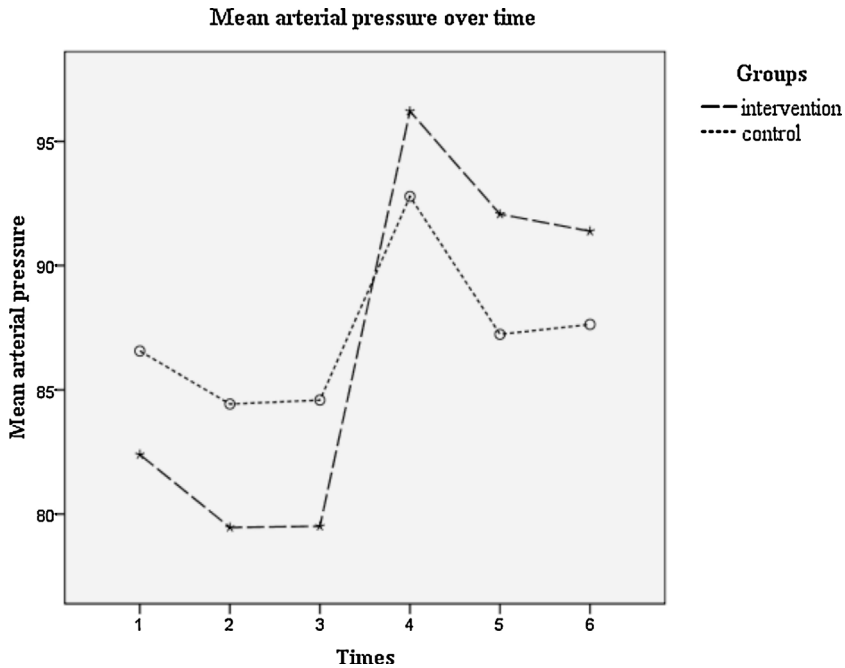

Fig. 7. Time trend of mean arterial pressure in the intervention and control groups.

Table 3
Comparison of baseline anxiety and agitation scores in the two groups.

Parameter	Score	Control group (%)	Intervention group (%)	p^a
Baseline anxiety	1	0 (0.0)	0 (0.0)	(0.171)
	2	1 (1.70)	0 (0.00)	
	3	6 (10.00)	5 (8.30)	
	4	20 (33.30)	32 (53.30)	
	5	33 (55.00)	23 (38.30)	
	6	0 (0.0)	0 (0.0)	
Baseline agitation	1	38 (63.30)	0 (0.0)	0.198
	2	22 (36.70)	31(51.70)	
	3	0 (70.0)	29 (48.30)	

[a] From Mann–Whitney test.

exp(1.33) ≈ 2.669 times of the same odds in the intervention group (Fig. 8).

3.2.2.2. Agitation level. The results of marginal modelling for agitation scores showed significant effect of time ($p = 0.740$) and interaction between group and time ($p = 0.269$). A significant difference was found between the agitation scores in the two groups ($p < 0.001$). The estimated regression parameter for the variable group was 2.927. This meant that the odds of having higher scores of agitation in the control group was exp(2.927) ≈ 11.295 times of the same odds in the intervention group (Fig. 9)

4. Discussion

This study was conducted to determine the effect of N-BS listening as a non-pharmacological nursing intervention to facilitate relaxation and alleviate anxiety in patients who had undergone coronary artery bypass graft during weaning from mechanical ventilation.

Findings from the post-test comparison indicated significantly lower levels of agitation and anxiety in the N-BS listening group compared to those in the control group. Interestingly, a lowered level of agitation and anxiety was also found in the control group, which was possibly related to the elimination of background noise during the weaning process. The results support the findings of Jaber et al's (2007) study that a single music therapy session is effective in decreasing anxiety and promoting relaxation indicated by decreases in heart rate, blood pressure, bi-spectral index and respiratory rate in intubated patients during the weaning process. Hunter et al. (2010) investigated the effect of music therapy as an adjunctive treatment modality on anxiety associated with weaning from mechanical ventilation. Likewise, greater

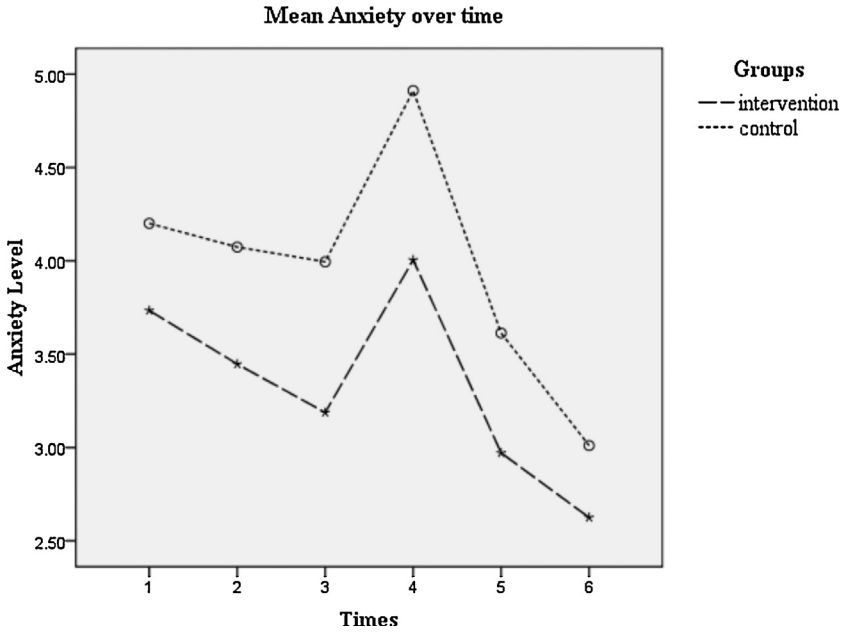

Fig. 8. Time trend of mean facial anxiety in the intervention and control groups.

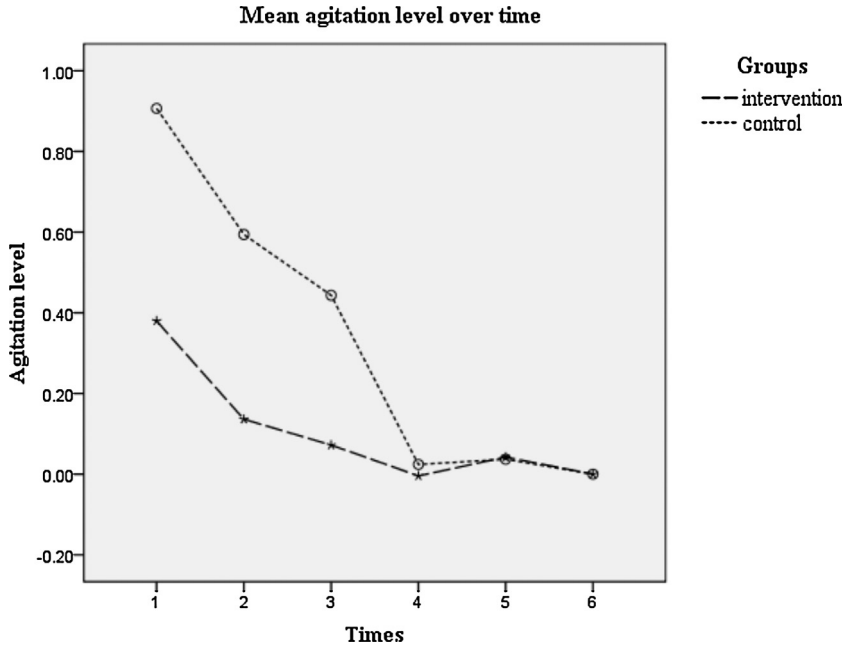

Fig. 9. Time trend of mean agitation level in the intervention and control groups.

mean differences in haemodynamic variables were found in the N-BS listening group.

Similarly, the patients in the control group showed a greater and significant reduction in their SBP implying that it might be due to the effect of the elimination of background noise.

In addition, the trend of changes in haemodynamic variables throughout the 20-min study period showed a significant reduction in anxiety and agitation of the N-BS listening group and a significant increase in the control group. Decreases in these physiological variables can indicate a relaxed response (Wong et al., 2001). However, the interpretation of the changes in vital signs needs to be viewed with caution due to between-group variations at baseline.

The findings of this study are consistent with the findings of previous studies (Wong et al., 2001; Lai and Feng, 2004; Lee et al., 2005). They provide systematic evidence supporting the notion that listening to N-BS music offers pleasant stimulus and an alternative perceptual focus for mechanical ventilation patients, which in turn is likely to reduce physiological stress responses during weaning. According to Saadatmand et al.'s (2012) study, the application of N-BS significantly reduced anxiety and agitation in patients undergoing mechanical ventilation. As mentioned in the Lim and Locsin's (2006) review of therapeutic use of music in the Asian population, cultural preferences in music selection is extremely important. A person's preferences are affected by differences in culture, age and peer group. In this study, attention was paid to the personal preferences of patients in N-BS selections and what was deemed to be relaxing prior to the intervention. In terms of N-BS selection, there were over 36 choices in the researcher's collection, and a diverse variety of N-BS preferences were reported. However, it was difficult to compare the effects of self-selected and researcher-selected N-BS listening, or the comparative benefits of different types of N-BS selections, largely because of the variation in the duration of N-BS interventions, ranging from 20 to 30 min per session reported in previous studies.

4.1. Limitations and suggestions for future studies

The interpretation of the findings needs to be treated with caution due to the following limitations: the study was conducted with adult patients between the ages of 45 and 65 years during weaning from mechanical ventilation support following coronary artery bypass graft. This could be a threat to the generalisability of the findings to other similar settings or samples undergoing weaning from mechanical ventilation. It is suggested that similar studies are conducted in other settings and in different age groups to test the applicability of the findings.

Though 36 N-BS choices were available, the six broad categories might be seen as a limitation. The presence or absence of any long-term effects was not examined as we focused on a single 20 min N-BS listening session on weaning from mechanical ventilation. It is suggested that this intervention is conducted with more groups of patients. Additional groups could use the intervention without wearing headphones or other non-pharmacological interventions such as music. Continuous applications of the N-BS intervention during weaning from mechanical ventilation in the intensive care unit are suggested to investigate the hypothesis concerning patients' sedation levels. We also cannot claim to know the therapeutic

dosage (duration and number of sessions) of N-BS listening.

5. Conclusion

With increasing emphasis on providing non-pharmacological interventions, this randomised controlled trial study builds on the existing evidence of physiological and psychological benefits of self-selected N-BS listening for weaning from mechanical ventilation in the intensive care unit. Our findings confirm that short-term therapeutic effects of N-BS listening results in the substantial reduction of physiological responses arising from anxiety and agitation in weaning from mechanical ventilation in this group of patients.

N-BS listening is a non-pharmacological intervention in high-tech critical care settings where the noisy and stressful aspects of environments may stimulate nervous tensions. Therefore, nurses are in a prime position to make appropriate therapeutic use of N-BS listening in the provision of care to patients undergoing weaning from mechanical ventilation. Given its inexpensive and non-invasive nature, nurses can use N-BS listening as a relieving intervention to provide a simple application to facilitate healing and ensure a degree of well-being among patients undergoing weaning from mechanical ventilation in the intensive care unit. It is used in order to reduce the consumption of anxiolytics and analgesics and reduce their associated morbidities.

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

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