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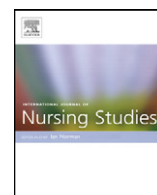
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# Effect of nature-based sounds' intervention on agitation, anxiety, and stress in patients under mechanical ventilator support: A randomised controlled trial

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### ABSTRACT

**Background:** Few studies have been conducted to investigate the effect of nature-based sounds (N-BS) on agitation, anxiety level and physiological signs of stress in patients under mechanical ventilator support. Non-pharmacological nursing interventions such as N-BS can be less expensive and efficient ways to alleviate anxiety and adverse effects of sedative medications in patients under mechanical ventilator support.

**Objectives:** This study was conducted to identify the effect of the nature-based sounds' intervention on agitation, anxiety level and physiological stress responses in patients under mechanical ventilation support.

**Methods:** A randomized placebo-controlled trial design was used to conduct this study. A total of 60 patients aged 18–65 years under mechanical ventilation support in an intensive care unit were randomly assigned to the control and experimental groups. The patients in the intervention group received 90 min of N-BS. Pleasant nature sounds were played to the patients using media players and headphones. Patients' physiological signs were taken immediately before the intervention and at the 30th, 60th, 90th minutes and 30 min after the procedure had finished. The physiological signs of stress assessed were heart rate, respiratory rate, and blood pressure. Data were collected over eight months from Oct 2011 to June 2012. Anxiety levels and agitation were assessed using the Faces Anxiety Scale and Richmond Agitation Sedation Scale, respectively.

**Results:** The experimental group had significantly lower systolic blood pressure, diastolic blood pressure, anxiety and agitation levels than the control group. These reductions increased progressively in the 30th, 60th, 90th minutes, and 30 min after the procedure had finished indicating a cumulative dose effect.

**Conclusions:** N-BS can provide an effective method of decreasing potentially harmful physiological responses arising from anxiety in mechanically ventilated patients. Nurses

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can incorporate N-BS intervention as a non-pharmacologic intervention into the daily care of patients under mechanical ventilation support in order to reduce their stress and anxiety.

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### What is already known about the topic?

- While mechanical ventilation in itself is a life-saving treatment, it induces a variety of experiences, which are physiologically and psychologically stressful for patients.
- To relieve anxiety and promote relaxation, nurses frequently administer a variety of sedative non-pharmacologic interventions to patients under mechanical ventilation.

### What this paper adds

- N-BS interventions can be considered to be an effective method of reducing potentially harmful physiological responses arising from anxiety.
- This study supports the effectiveness of the N-BS intervention as a complementary therapy to the care of patients under mechanical ventilation.
- N-BS intervention as a non-pharmacologic nursing intervention alleviated patients' anxiety and agitation.

## 1. Introduction

Mechanical ventilation (MV) is a common, lifesaving and frequently employed treatment modality for a variety of medical diagnoses in intensive care units (ICU) (Besel, 2006). While this intervention itself is a life saving treatment, patients who are mechanically ventilated often face a variety of distressing situations including anxiety and agitation due to emotional distress, fear of pain or dying, fear raised from family members' previous experiences of those who have died in similar situations, discomfort, thirst, immobility, dyspnoea, confusion, and inability to relax (Dijkstra et al., 2010), pain, lack of sleep, tenseness, lack of control and loneliness, which are typically common stress and anxious reactions even when patients are sedated (Yagan et al., 2000; Rotondi et al., 2002; Thomas, 2003).

Patients undergoing MV require endotracheal intubation and often have either intermittent or sustained periods of agitation because of the endotracheal tube itself. Intubated patients who are relatively alert mostly become frustrated by their inability to communicate verbally and then fall into a cycle of continued agitation. Finally, the ICU environment, with its high noise levels, lights, and continual other stimuli can significantly contribute to increasing distress and agitation (Heiderscheit et al., 2011; Khalaila et al., 2011).

Having a dependency on MV to breathe can result in sleep disturbances, increased myocardial oxygen consumption and increased sympathetic output (Tracy and Chlan, 2011). Poorly managed stress can result in the patient's inability to adjust to the disease and the use of

medical assistance or anti-anxiety agents (Wong et al., 2001). Thus, MV may be a distressing experience for the patient, and may result in an increase in anxiety and reduced comfort even when the patient is sedated (Besel, 2006).

Nurses in the ICU frequently administer sedative medication to ventilated patients to counteract the negative effects of treatment. However, sedative agents have a number of undesirable side effects, which may result in complications such as nausea and vomiting, decreased gut motility, urinary retention, mental status instability, respiratory depression, pruritus, venous stasis, hypotension, soft tissue damage, respiratory and extremity muscle weakness or atrophy, increased risk of infection, central nervous system changes and even death, and delayed weaning from MV (Chlan, 2002). These, in turn, prolong the length of dependency on the ventilator (Lee et al., 2005; Lindgren and Ames, 2005), increase length of stay in the ICU, increase the need for medication, and costs of hospital care (Seneff et al., 2000; Arroliga et al., 2005).

Drugs may be prescribed to preserve patient safety during periods of severe agitation and anxiety. However, use of complementary therapies in conjunction with sedative agents may potentiate the effects of both types of therapies and decrease the amount of sedative drugs needed to get the same outcome. Complementary therapies, if used on a routine basis, can help reduce anxiety (Pun and Dunn, 2007). Therefore, sedative drugs do not have to be the first choice in attempts to mitigate patients' distress associated with MV support (Chlan, 2002).

There is a need for additional research examining alternative non-pharmacological interventions for patients requiring MV. Non-pharmacological approaches consist of a variety of environmental adjustments that are frequently underutilized (Summer, 2002). Although music therapy has been shown to be an effective intervention in the care of patients under MV, not all patients welcome this intervention. Nurses caring for patients under MV support must have several non-pharmacological adjuncts, which can be implemented in order to provide a humanistic caring environment in which healing can occur (Chlan, 2002). In this respect, sound therapy can act as a non-pharmacological nursing intervention to allay the signs of anxiety in such patients. Sound therapy has been used to reduce anxiety and distress and improve physiological functioning in medical patients; however its effect on patients under mechanical ventilation support needs to be investigated.

### 1.1. Background

Ulrich (1984) demonstrated that patients whose windows faced a park recovered faster compared to

patients whose windows faced a brick wall. Since then, several studies have demonstrated restorative effects of natural environments in comparison with urban environments. These effects include increased well-being and decreased physiological stress responses (Grinde and Patil, 2009; Maller et al., 2006).

Ulrich suggested that natural environments have restorative effects by inducing positive emotional states, decreased physiological activity, and sustained attention (Ulrich, 1984). This is concurrent with Kaplan and Kaplan's theory (1995) that a natural environment facilitates recovery of directed attention capacity and thereby reduces mental fatigue (Kaplan, 1995). It has also been found that positive emotion improves physiological recovery after stress (Fredrickson et al., 2000). Soundscape research has shown that natural sounds are typically perceived to be pleasant (Lavandier and Defréville, 2006; Nilsson and Berglund, 2006).

Nature sounds have a positive emotional effect on all people (Maller et al., 2006), and are used in studies as they have the most relaxing effect in comparison to other interventions (Lavandier and Defréville, 2006; Nilsson and Berglund, 2006). Nature sounds are limited only by geographical boundaries and have the capacity to appeal to all cultures. Nature-based sounds (NB-S) in the pre-operative area can be considered culturally neutral (Cullum, 1997).

Investigators at Johns Hopkins Medical Centre (2003) have strong evidence that distracting patients during and after bronchoscopy with a colourful mural of a meadow and the gurgle of a babbling brook significantly enhances efforts to reduce pain (Anon., 2003). The Hopkins group tested the natural sights and sounds on 41 men and women during their 25-min bronchoscopies and three-hour recovery periods. They listened to nature sounds through headphones and a tape player. Thirty-nine similar patients underwent the procedures without distraction therapy, but with comparable levels of care and pain control. Both groups completed questionnaires rating their pain on a five-point scale, along with their anxiety, perceptions of privacy, difficulty in breathing, willingness to have the procedure done again and safety. Patients who listened to the nature sounds and looked at the mural during bronchoscopy were 43% more likely to report pain control as very good or excellent, even after controlling for such factors as pain medication, health, race and education (Anon., 2003).

No studies have focused on the effect of NB-S on physiological stress responses, agitation and anxiety level in patients receiving MV support. This study was conducted to identify the effect of nature-based sounds' intervention on agitation, anxiety level and physiological stress responses in patients under mechanical ventilation support.

## 2. Methods

### 2.1. Study design

A randomized placebo-controlled trial was used to conduct this study (Fig. 1) from Oct 2011 to June 2012. To

determine the sample size, a pilot study was conducted with five patients. The least amount of difference in each endpoint was related to agitation 30 and 60 min after the intervention in the experiment group ( $0.0 \pm 0.707$ ) and in the control group ( $0.6 \pm 0.548$ ). Using the statistical parameters of  $\alpha = 0.5$  and  $\beta = 0.5$ , the sample size was determined to be 30 patients in both the intervention and control groups. 60 patients under mechanical ventilation support were randomly assigned to either the intervention or control groups where both the investigator and patients were blinded to treatment allocation. Randomisation numbers were generated from the Randmiser website of the Social Psychology Network.

### 2.2. Setting and participants

The intensive care unit of a university teaching hospital in Tehran, Iran was the study's setting. A convenience sample of patients who met the study criteria and who were under mechanical ventilation support in an ICU was chosen, with no patient declining to participate. The patients were aged between 18 and 65 years; were on pressure support ventilation mode and SIMV/CPAP; were able to hear; had Glasgow Coma Scale Point 9 or above; were mentally competent and able to communicate by holding up fingers responsive to researcher's questions at the time of data collection; were haemodynamically stable; had no psychiatric or neurological illnesses; were not receiving inotropic support; were not taking any neuromuscular blocker agent and antihypertensive drug; had no previous experience of the N-BS intervention; were not drug-addicted, and had no facial signs of being scared.

### 2.3. Measures

#### 2.3.1. Clinical and demographical characteristics of the patients

Data was collected over eight months from Oct 2011 to June 2012 by one investigator. Baseline data was collected using patients' medical records to compare patients in the experimental and control groups with respect to age, gender, educational level, marital status, primary medical diagnosis, drug therapy in the past 24 h, ventilator settings, length of stay, length of stay in the ICU before the beginning of the intervention, number of days receiving MV and also their Glasgow Coma Scale (GCS) score.

#### 2.3.2. Physiological parameters

Physiological signs of anxiety measured were systolic blood pressure, diastolic blood pressure, heart rate, and respiratory rate obtained by means of bedside monitors, which were calibrated carefully before data gathering.

#### 2.3.3. Anxiety level

During the N-BS intervention or rest periods, data on the level of anxiety was recorded using the Faces Anxiety Scale (FAS). This scale was chosen because it has been demonstrated to be easier for ICU patients to respond to in comparison to other anxiety scales (Chlan, 2004). Unlike

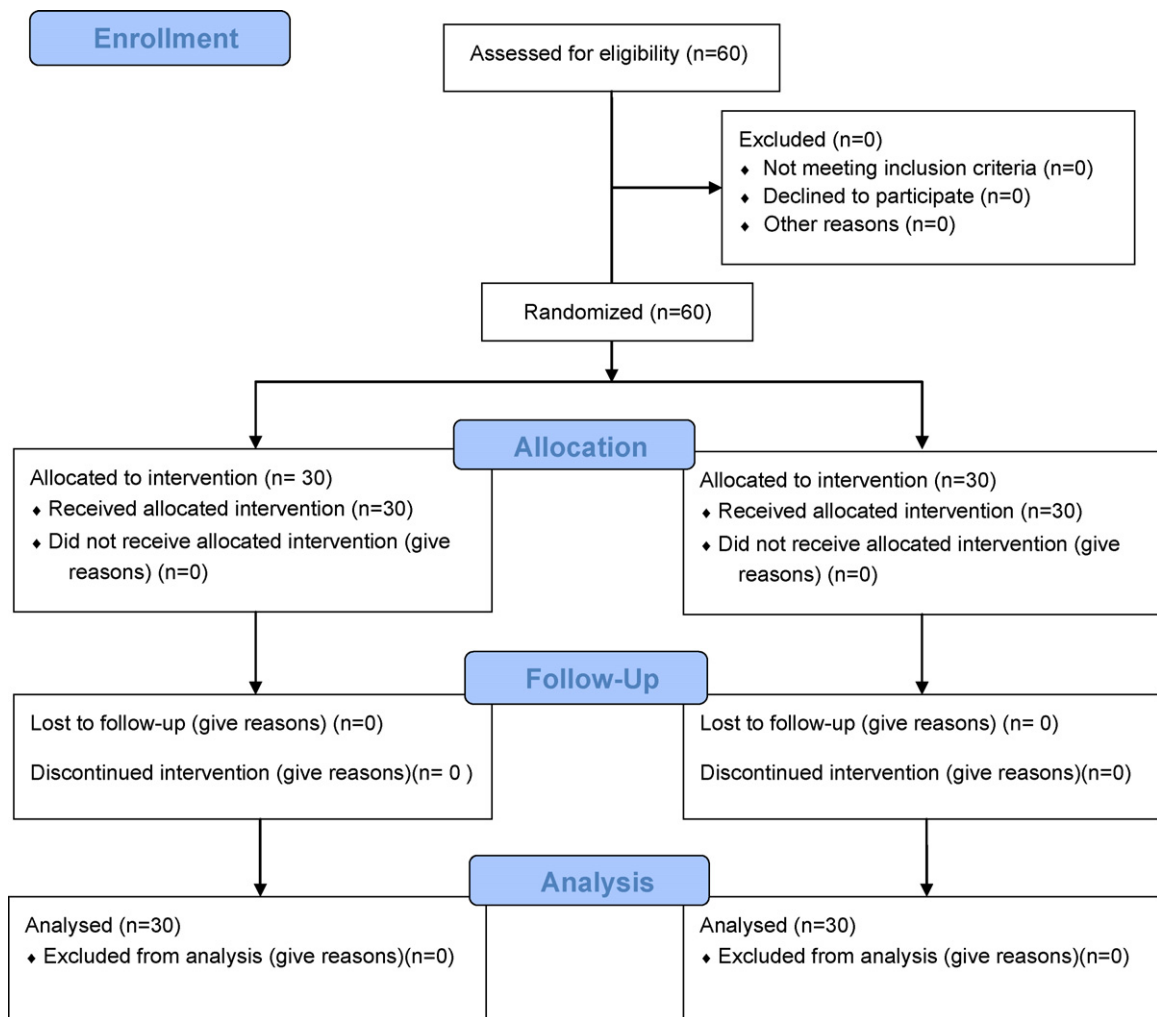


Fig. 1. The process of study design.

most studies, the FAS was used for assessing anxiety because critically ill ICU patients are often nonverbal, many of whom cannot respond to existing validated parameters of anxiety, therefore use of currently available anxiety measures is difficult. The FAS appears to be a promising means of obtaining self-reports on the status of anxiety from ventilator-dependent patients for routine clinical purposes as well as for research purposes. The relationship between FAS and patients' nonverbal responses to short questions from the Profile of Mood States Anxiety Subscale has been reported to be 0.64 ( $p < .001$ ), within the range of 0.4–0.8 for criterion validity, indicating the Faces Anxiety Scale is a valid measure of anxiety (McKinley et al., 2004). 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 is believed that most ICU patients are 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., 2003).

#### 2.3.4. Agitation level

The Richmond Agitation Sedation Scale (RASS) score was already a part of routine monitoring of patients in the ICUs 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 RASS after implementation in a medical ICU has been demonstrated by strong correlations between RASS and the Sedation–Agitation Scale score ( $r = 0.78$ ,  $p < 0.0001$ ), Ramsay sedation scale score ( $r = -0.78$ ,  $p < 0.0001$ ), and Glasgow Coma Scale score ( $r = 0.79$ ,  $p < 0.0001$ ). Excellent inter-rater reliability is also demonstrated for RASS among the entire adult ICU population (intraclass correlation = 0.956 [0.948]) ( $\kappa = 0.73$  [0.71, 0.75]). Correlations between RASS, and Ramsay Sedation Scale ( $r = -0.78$ ) and the Sedation Agitation Scale ( $r = 0.78$ ) confirm its validity (Sessler et al., 2002). The Persian version of RASS has been shown to be a valid and reliable for measuring patients' agitation in ICU units (Tadrisi et al., 2009).



#### 2.4. Intervention

Patients were randomised to a control group who received only standard care and an intervention group who received the N-BS intervention consisting of 90 min of listening to the N-BS and standard care using sequentially numbered containers as the allocation concealment mechanism.

To accommodate nursing activities and the unit's routine, the intervention was conducted during the afternoon or early evening. Unlike Korhan et al.'s study (2011), our study was conducted in the afternoon, because anxiety might be affected by the time of the day at which the data were collected. Moreover, patients' family members were asked not to visit the patients in the afternoon to prevent interference with the intervention's effect and they cooperated well.

The patients were only informed about the true purpose of the study after the experiment (*i.e.*, our interest in the effect of nature-based sounds). They were asked to select a CD (pleasant nature sounds) to listen to according to their preference 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. The volume of the sound was adjusted to the patients' preference; when the patient was not able to express a preference, the volume was determined by the attending nurse.

It is noted that, in music therapy, patients may need time to accustom themselves to the music (Lee et al., 2005), unlike with the N-BS intervention; and their choices might differ because of cultural diversity between patients.

The nature sounds were played using a MP3 media player through disposable foam-lined headphones (the patients had no further stimulation). The volume of the MP3 player was adjusted to the participants' satisfaction by responding to their facial expression. 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 patients assigned to the control group were asked to wear the foam-lined headphone and rest in silence for a similar time frame as the intervention group to minimize unpleasant environmental noises or stimuli. Both groups were assessed in the last thirty minutes without headphones and sounds playing.

The environment for both groups was enhanced to promote rest and to minimize unnecessary disturbance by dimming the lights (unless contraindicated), closing curtains, partially shutting the door and posting a 'Patients Are at Rest. Please Do Not Disturb' sign. Nursing and medical staff were instructed not to disturb the patient during the N-BS intervention or rest period unless imperative.

The investigator returned to the room to record the physiological parameters of agitation and anxiety score across the two groups during the procedure. He was unaware of who was assigned to each group to limit bias in the recording of parameters and sedation scores. These parameters were being continuously monitored for each participant per ICU protocol, facilitating investigator collection with

minimal patient disturbance. Patients in both groups had physiological signs recorded immediately before the procedure, at 30, 60, and 90 min intervals throughout the procedure, and 30 min after the procedure had finished.

As the primary outcome, agitation was assessed using the RASS after the intervention, at 30, 60, 90 min (end intervention), and 30 min after finishing the intervention. As the secondary outcome, anxiety was assessed using the FAS after the intervention, at the same time intervals.

#### 2.5. Ethical considerations

The Ethics Committee of Shahed University approved the research proposal. After providing patients with brief information on the purpose of the study and before assigning them into groups, informed consent was obtained from the patients. They were assured of their confidentiality and anonymity. The patients chose the type of pleasant nature sounds intervention. Patients were told that they could withdraw at anytime throughout the study and that not participating would not have any detrimental effects in terms of the essential or regular hospital treatments and services received. No risks associated with the use of N-BS intervention as an intervention were identified in previous studies. Measurement of physiological parameters and anxiety and agitation scores was one part of routine ICU care consequently no additional burden was put on the patients. Furthermore, the previously described inclusion criteria were chosen so as not to place an additional burden on unstable patients and their relatives.

#### 2.6. Data analysis

Data were analysed using SPSS (version 16.0; for Windows). Descriptive statistics were used to summarise demographic data and clinical characteristics of participants in the groups.

Chi-square tests were used to detect any significant difference between the groups' baseline data such as age, gender, marital status, educational level, job, insurance, interest in pleasant nature-based sounds, number of ventilator-dependent days, number of days of hospitalization in the ICU. Mann–Whitney *U*-test was used to detect any significant difference in GCS, FAS, RASS scores. An independent *t*-test was used to detect any significant differences between the groups' mean values of physiologic parameters. The Kolmogorov–Smirnov test was used to test the normal distribution of variables ( $p > 0.05$ ). As there were no variables which deviated from normal distribution, different repeated measures of analyses of variance (ANOVA) were used for each variable. ANOVA was also used to examine mean SBP, DBP, RR, and HR across the intervention period, measured at 30-min intervals within groups and between groups. Mauchly's test of Sphericity was used to examine the difference between the intervals within each group and to examine the interaction between the groups and intervals. Paired *t*-test was carried out in the periods between 0 and the 30th, 0 and the 60th, 0 and the 90th, 0 and 30 min after the procedure had finished; and the 30th and 60th, the 30th and 90th, the 30th and 30 min after the procedure had finished; and the 60th and 90th, the

**Table 1**  
Patients' demographic characteristics.

Characteristics	Total (n = 60) Mean $\pm$ SD	Experiment group (n = 30)	Control group (n = 30) Mean $\pm$ SD	Statistical test and p-value
<b>Age</b>				
Mean $\pm$ SD	43.91 $\pm$ 16.14	41.23 $\pm$ 15.31	46.60 $\pm$ 16.76	$t = 1.295$ $p = .231$
<b>Gender, n (%)</b>				
Male	34 (%100.00)	14 (%41.20)	20 (%58.80)	$f = 0.96$
Female	26 (%100.00)	16 (%61.50)	10 (%38.50)	$p = .118$
<b>Educational level, n (%)</b>				
Illiterate	16 (%100.00)	9 (%56.20)	7 (%43.80)	$\chi^2 = 2.550$
Primary	24 (%100.00)	9 (%37.50)	15 (%62.50)	$df = 2$
Secondary	10 (%50.00)	6 (%30.00)	4 (%20.00)	$p = .279$
High/undergraduate school	10 (%50.00)	6 (%30.00)	4 (%20.00)	
<b>Marital status, n (%)</b>				
Single	18 (%100.00)	11 (%61.10)	7 (%38.90)	$f = .199$
Married	42 (%100.00)	19 (%45.20)	23 (%54.80)	$p = .260$
<b>Sedative recipient, n (%)</b>				
Yes	26 (%100.00)	13 (%43.30)	13 (%43.30)	$df = 1$
No	34 (%100.00)	17 (%56.70)	17 (%56.70)	$P = .603$

60th and 30 min after the procedure had finished, and finally 90th and 30 min after the procedure had finished. RANOVA was used to examine the effects of sociodemographical characteristics on the difference in physiological signs of stress occurring during the N-BS intervention in the intervention group. A Mann–Whitney *U*-test was used on Richmond scores to detect changes between the intervention and control group.

### 3. Results

#### 3.1. Demographical and baseline characteristics of the patients

In this study, 60 patients were randomly assigned to the control ( $n = 30$ ) and intervention ( $n = 30$ ) groups. In

the control group, 20 patients (66.7%) were male and 10 patients (33.3%) female. In the intervention group, 14 patients (46.7%) were male and 16 patients (53.3%) female ( $p = 0.118$ ). The mean  $\pm$  SD age of the patients were 46.60  $\pm$  16.76 and 41.23  $\pm$  15.31 in the control and intervention groups, respectively ( $p = 0.201$ ). The rate of illiteracy was 23.3% (7 patients) in the control group and 30.0% (9 patients) in the intervention group ( $p = 0.559$ ). In addition, 30 patients (23.3%) in the control group and 11 patients (36.7%) in the intervention group were single ( $p = 0.260$ ).

Tables 1 and 2 compare the clinical and baseline characteristics of the patients in the control and intervention groups. As shown in these tables, there was no significant difference in the clinical and baseline characteristics between the two groups.

**Table 2**  
Patients clinical and baseline characteristics.

Characteristics	Group	Mean $\pm$ SD	$p^*$
GCS	Control	9.93 $\pm$ 0.91	0.884
	Intervention	9.97 $\pm$ 0.85	
Hospitalization duration	Control	7.57 $\pm$ 7.28	0.937
	Intervention	7.70 $\pm$ 5.54	
Length of mechanical ventilation	Control	6.80 $\pm$ 6.24	0.850
	Intervention	6.53 $\pm$ 4.47	
Baseline systolic blood pressure	Control	136.30 $\pm$ 16.23	0.864
	Intervention	136.97 $\pm$ 13.74	
Baseline diastolic blood pressure	Control	81.60 $\pm$ 8.87	0.922
	Intervention	81.37 $\pm$ 9.39	
Baseline heart rate	Control	96.20 $\pm$ 12.91	0.730
	Intervention	94.97 $\pm$ 14.61	
Baseline respiratory rate	Control	19.53 $\pm$ 3.10	0.286
	Intervention	18.63 $\pm$ 3.37	

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

Glasgow Coma Scale (GCS) that objectively records the conscious state of a person. It is a method for evaluating the severity of CNS involvement in head injury, which measures 3 parameters – maximum score of 15 for normal cerebral function, 0 for brain death.

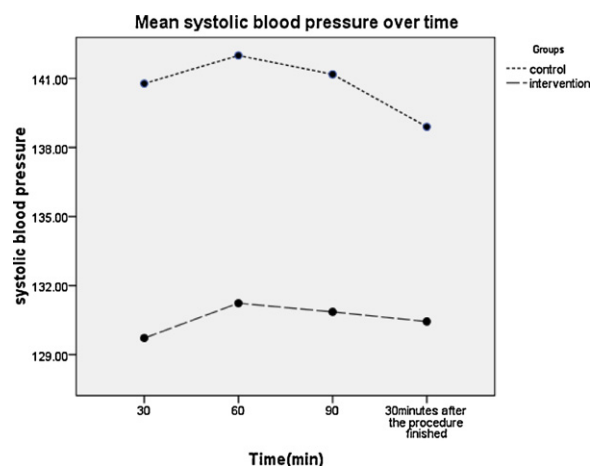


Fig. 2. Time trend of mean systolic blood pressure in the intervention and control groups.

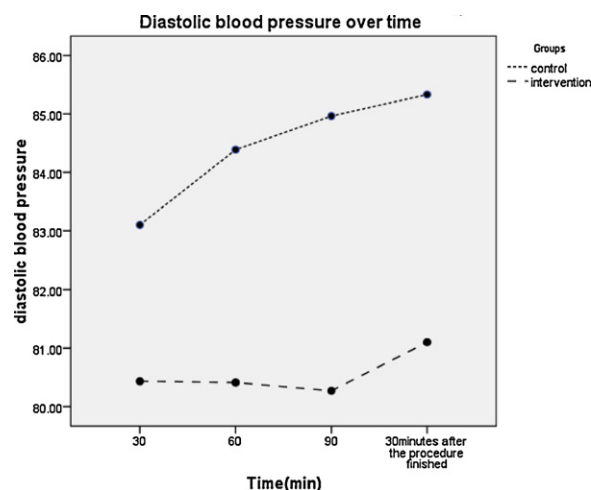


Fig. 3. Time trend of mean diastolic blood pressure in the intervention and control groups.

### 3.2. The effects of nature-based sounds' intervention

#### 3.2.1. Physiological parameters

In the next step, 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 (physiological outcomes including systolic and diastolic blood pressure, heart rate and respiration rate). In these models, the impact of baseline values of these physiological parameters on response variables was adjusted. To do this, the baseline values of the physiological parameters as a covariate in all models were included.

**3.2.1.1. Systolic blood pressure.** The results of RANOVA for systolic blood pressure showed no significant time trend ( $p=0.612$ ) and interaction between time and group ( $p=0.223$ ). However, the mean systolic blood pressure was significantly lower in the intervention group at all four times of measurement ( $p<0.001$ ). Fig. 2 displays the estimated time trend of mean systolic blood pressure in the two groups.

**3.2.1.2. Diastolic blood pressure.** The results of RANOVA for systolic blood pressure showed no significant time trend ( $p=0.825$ ) and interaction between time and group ( $p=0.110$ ). However, the mean systolic blood pressure was significantly lower in the intervention group at all four times of measurement ( $p=0.001$ ). Fig. 3 displays the estimated time trend of mean systolic blood pressure in two groups (Table 3).

**3.2.1.3. Heart rate.** The results of RANOVA for heart rate showed no significant time trend ( $p=0.157$ ). In addition, the mean heart rate was not significantly different between the two groups ( $p=0.292$ ). The interaction between time and group was statistically significant ( $p<0.001$ ). Fig. 4 displays the estimated time trend of mean heart rate in two groups (Fig. 4).

**3.2.1.4. Respiration rate.** The results of RANOVA for respiration rate showed no significant time trend ( $p=0.489$ ) and group effect ( $p=0.558$ ). The interaction between time

Table 3  
Baseline anxiety and agitation scores between the two groups.

Parameter	Score	Control group	Intervention group	<i>p</i> *
Baseline anxiety	1	0 (0.0%)	0 (0.0%)	0.750
	2	0 (0.0%)	1 (3.3%)	
	3	20 (66.7%)	20 (66.7%)	
	4	6 (20.0%)	4 (13.3%)	
	5	4 (13.3%)	5 (16.7%)	
Baseline agitation	0	0 (0.0%)	0 (0.0%)	0.160
	1	5 (16.7%)	2 (6.7%)	
	2	21 (70.0%)	21 (70.0%)	
	3	4 (13.3%)	7 (23.3%)	

\* From Mann–Whitney test.

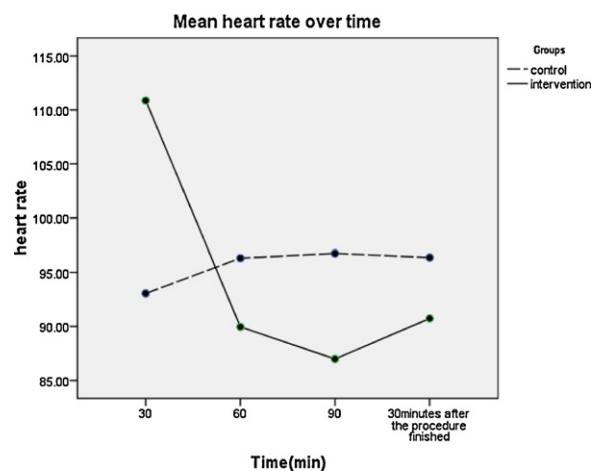


Fig. 4. Time trend of mean heart rate in the intervention and control.



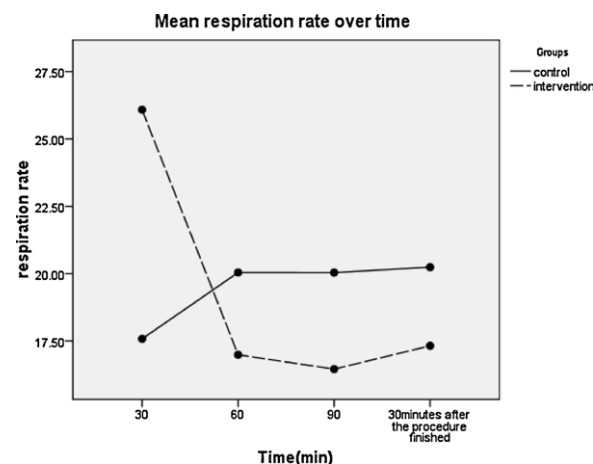


Fig. 5. Time trend of mean respiration rate in the intervention and control groups.

and group was statistically significant ( $p < 0.001$ ). Fig. 5 displays the estimated time trend of mean respiration rate in two groups (Fig. 5).

### 3.2.2. Anxiety and agitation level

In the final 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 (adjusting for baseline scores of these variables) (Table 3).

**3.2.2.1. Anxiety level.** The results of marginal modelling for anxiety scores showed no significant effect of time ( $p = 0.466$ ) and interaction between group and time ( $p = 0.055$ ). However, a significant difference was found between the anxiety scores of two groups ( $p < 0.001$ ). The estimated regression parameter for the variable group was 1.496. This means that the odds of having higher scores of anxiety in the control group was  $\exp(1.496) \approx 4.5$  times of the same odds in the intervention group (Fig. 6).

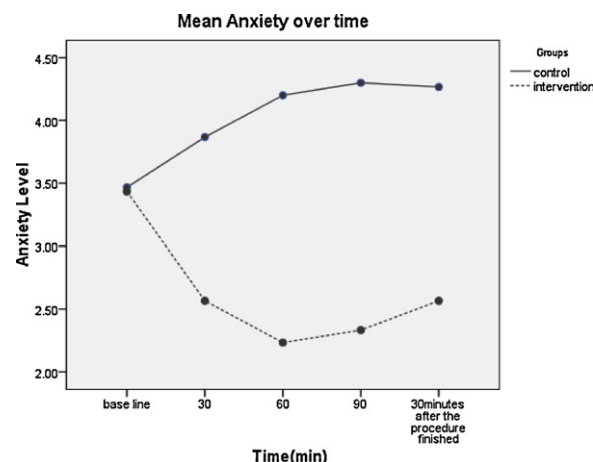


Fig. 6. Time trend of mean anxiety level in the intervention and control groups.

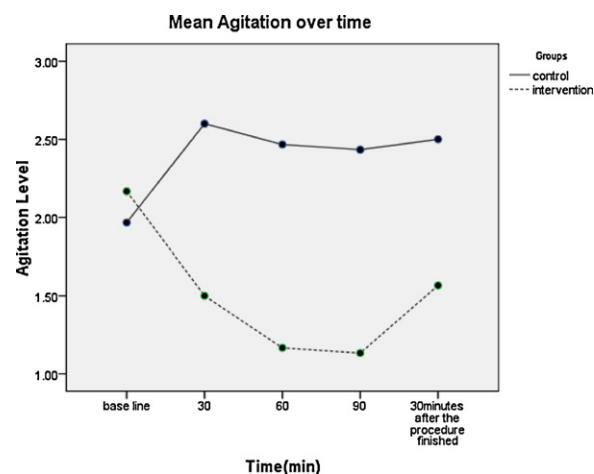


Fig. 7. Time trend of mean agitation level in the intervention and control groups.

**3.2.2.2. Agitation level.** The results of marginal modelling for agitation scores showed no significant effect of time ( $p = 0.790$ ) and interaction between group and time ( $p = 0.262$ ). However, 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 2.418. This means that the odds of having higher scores of agitation in the control group was  $\exp(2.418) \approx 11.24$  times of the same odds in the intervention group (Fig. 7).

## 4. Discussion

This study was conducted to determine the effect of the N-BS intervention on the physiological stress responses, anxiety level, and agitation of patients under mechanical ventilation support. Specifically, the anxiety responses of the patients were measured using their physiological parameters when provided with N-BS in the intervention group, and no sound for the control group.

In recent years, use of the N-BS intervention as a complementary therapy has increased and this, to some extent, may reflect the growing interest in other complementary therapies. It is known that the N-BS has various beneficial effects on human health, for instance older people who have sleep disturbance (Morita et al., 2011) and also in patients with mental disorders (Pryor et al., 2006). The N-BS intervention provides conditions that foster human and environmental health by reducing anxiety and enabling psychological and physical activity (Hansen-Ketchum and Halpenny, 2011).

Findings from this study are congruent with other similar studies suggesting that connecting with pleasurable natural environments can facilitate recovery from surgery (Ulrich, 1984), positively influence blood pressure (Pretty et al., 2005), and increase perceptions of quality of life (Ogunseitan, 2005).

Similar to other studies, Parsons et al. (1998) exposed college students to stressors and scenic drives through natural artefact dominated urban and rural settings. Stress recovery, measured by facial muscle activation, blood

pressure and electro-dermal activity were recorded before and after the exposure. It was shown that the participants experienced quicker recovery from stress through nature, although participants' narrative accounts of past and present experiences in similar settings would have helped interpret the results.

Data about what challenged engagement with the N-BS intervention in this study would have helped understand ways to strengthen and sustain the intervention. Cimprich and Ronis (2003) studied the effect of connecting with nature on attention and mental fatigue in women diagnosed with breast cancer. Analysis revealed a significant effect of the nature restorative intervention on total attention scores for those in the experimental group.

In this study, there was no statistically and meaningful relationship between demographic characteristics such as educational level and reduction of anxiety and agitation. Also, clinical characteristics such as days of ventilator dependency did not affect the results of the N-BS intervention.

#### 4.1. Limitations and suggestions for future studies

The study was limited to adult patients between the ages of 18–65 years who were receiving mechanical ventilation support. This could be a threat to the generalisability of the findings to other settings or samples. It is suggested that conducting similar studies in other settings and in different age groups would test the applicability of the findings.

It is suggested that this intervention is repeated with three groups of patients. The added group can use the intervention without wearing headphones. This condition would take into account the calming effect of the N-BS intervention associated with a reduction in background noise. Continuous N-BS intervention during hospitalization in the ICU could be done to investigate the hypothesis concerning patients' sedation levels, and stress and anxiety. Furthermore the influence of background noise in single rooms vs. a multiple-bedded room or ward can be addressed when room size and room type is considered as a potential confounding variable.

#### 5. Conclusion

This study provides evidence for the use of nature-sound as an anxiolytic intervention. The benefits of preventing physiological reactions to anxiety were demonstrated, in patients who were under mechanical ventilator support. Therefore, nature-sound can provide an easy, simple, safe and effective method of reducing potentially harmful physiological responses arising from anxiety.

This study showed that changing surrounding environmental sounds decreases environmental stimulation, which results in reduced anxiety and promotes relaxation. Our results suggest that N-BS intervention could lead to deeper sedation levels in sedated, mechanically ventilated patients in the ICU. Physiological parameters were reduced significantly after completion of the N-BS intervention. Nature-based sounds intervention as a

complementary adjunct is safe and can be applied by clinical nurses to allay anxiety and agitation in mechanical ventilator-dependent patients without risking unwanted side effects. Nurses can implement this intervention to achieve relaxation for its short-term benefits. The utilization of this intervention enables nurses to provide individualized care and help the patient manage their anxiety and achieve relaxation. For the sedated, mechanically ventilated patients in the ICU, the benefit of the N-BS may lie in the deeper level of sedation achieved. This deeper level of sedation may make the patient less susceptible to stress responses, anxiety and agitation.

The N-BS as a non-pharmacological intervention is a non-invasive, inexpensive and non-time consuming nursing intervention in the routine care of patients under mechanical ventilation support. It is a complementary intervention acceptable to patients, is economically feasible to implement, and also is within the capabilities of the nursing staff.

One of the strengths of our study was that patient preferences of N-BS type were respected. In other words, through allowing the patients to choose their favourite N-BS, the need of the patients to maintain a sense of control over their situation were recognised.

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

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