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The Effect of White Noise on Pain in Unconscious Patients with Traumatic Brain Injury

Zeynab Solimani[1], Naser Mozafari[2], Mohammad Taghi-Savadpour[3], Mehdi Ajri-Khameslou[4*]

Abstract

Background: Most patients with traumatic brain injury (TBI) admitted to the intensive care unit experience pain. Nurses have a major role in pain management in patients with TBI.

Aim: This study was performed aimed to investigate the effect of white noise on pain in unconscious patients with TBI.

Method: This single-blind clinical trial study was performed in 2019 on 52 unconscious patients with TBI admitted in neurological intensive care unit in Ardabil. They were randomly assigned to the control and intervention groups. In the intervention group, patients received 30 minutes white noise for 3 consecutive days. In the control group, patients rested only on the bed at the same time. The demographic characteristics form and behavioral pain scale were used to collect data. $P<0.05$ was considered statistically significant.

Results: The mean difference of behavioral pain score during three consecutive days 10 minutes before and 30 minutes after the intervention was 0.82 ± 0.1 in the intervention group and 0.18 ± 0.01 in the control group. Data analysis showed that the behavioral pain score in the intervention group significantly reduced compared to the control group ($P <0.001$).

Implications for Practice: The results of this study showed that white noise could relieve the behavioral score of pain in unconscious patients with TBI. Therefore, it is recommended to use white music noise along with routine treatments to reduce the pain of unconscious patients with traumatic brain injury in the neurological intensive care unit.

Keywords: Intensive care unit, Pain management, Traumatic brain injuries, Unconsciousness, White noise

1. MSc student, Students Research Committee, Department of Critical Care Nursing, School of Nursing and Midwifery, Ardabil University of Medical Sciences, Ardabil, Iran
2. Assistant Professor, RN, Department of Critical Care Nursing, School of Nursing and Midwifery, Ardabil University of Medical Sciences, Ardabil, Iran
3. MSc, Department of Medical- surgical nursing, School of Nursing and Midwifery, Ardabil University of Medical Sciences, Ardabil, Iran
4. Assistant Professor, Department of Critical Care Nursing, School of Nursing and Midwifery, Ardabil University of Medical Sciences, Ardabil, Iran

* Corresponding author, Email: ajri.mehdi@gmail.com

Introduction

TBI is a life-threatening condition. The prevalence of TBI in the United States is 3.2 to 5.3% (1). In Iran, the rate of TBI is reported to be higher than in developed countries due to the high prevalence of traffic collisions (2). TBI is classified as mild, severe, and moderate. The moderate to high type of traumatic brain injury requires hospitalization in the neurological intensive care unit (ICU) (3).

The Neurological ICU is designed to care for patients with severe injuries and life-threatening conditions. Patients admitted to ICU undergo the procedures which are associated with pain and discomfort (3, 4). The study by Nazari et al. showed that 40% of brain trauma patients admitted to the ICU experience pain (5).

Patients with TBI cannot express their pain due to loss of consciousness, mechanical ventilation, and sedative drugs, which prevents the treatment of pain (5, 6). Pain activates the sympathetic nervous system, which affects the cardiovascular system and causes increase in heart rate, blood pressure, oxygen demand, and intracerebral pressure (7). In addition to physical effects, pain affects the mental state and causes fear, panic, sleep disturbance, nightmares, and aggression (4, 8).

There are pharmacological and non-pharmacological methods to control pain. Although medication is routinely used to control pain and is always easily prepared, they are expensive and have side effects (9, 10). Painkillers have many side effects including: allergies, immunosuppression, cardiac arrhythmias, increased intracranial pressure, respiratory depression, xerostomia, histamine release, urinary retention, and pruritus (11). Non-pharmacological methods of pain management are simpler and cheaper than pharmacological methods (12, 13). Today, non-pharmacological methods of pain relief is more emphasized. Relaxation methods, touch therapy, acupuncture, and music therapy are among these methods (14).

Music is a pleasant resource for the general public (15). Florence Nightingale first performed music therapy to heal the wounds of war wounded in the mid-1800s (16). Music therapy has expanded as a nursing intervention to manage pain in the last two decades (17). Listening to music is cheap with low side effects and non-invasive approaches to relieve pain. Music can be successfully used as a safe nursing intervention to manage stress and pain in hospital wards (18).

However, not all types of music can improve comfort and reduce pain. The first step in music therapy is to evaluate the patient's mood and interest in music. The selection of familiar and appropriate music is the key point of this intervention (15, 19). It is difficult to select a type of music, especially in the intensive care unit, due to the patients' unconsciousness; it is one of the challenges for researchers in conducting research.

Among the pleasant and familiar sounds, the sound of ocean waves and rain have been mentioned as white noise in the studies (20, 21). White noise reduces the sympathetic system's activity (22) and can help decrease pain (23). White noise is compatible with most people's interests (24). The results of an experimental study showed that white noise reduces pain during vaccination in infants (23). However, there is a need for extensive research on the impact of white noise and its use on vulnerable populations, including ICU admitted patients (23).

Searching literature found no study on pain control in unconscious TBI patients with a focus on reducing pain intensity using white music. Therefore, this study was performed aimed to determine the effect of white noise on reducing pain in unconscious patients with TBI admitted to the neurological intensive care unit.

Methods

This single-blind clinical trial study was performed in 2019 on all patients with TBI who couldn't communicate verbally and were hospitalized in the neurology intensive care unit of Fatemi teaching hospital in Ardabil city.

The sample size was determined as 23 participants at 95% confidence level and 80% power, and assuming that the effect of white music on reducing patients' pain is at least d = 1.2 points, so that the effect of music was considered statistically significant, also the standard deviation of pain was 2. Considering the possibility of sample loss, 20% was added to the sample size. Therefore, the sample size was determined as 26 people in each group.

The inclusion criteria were: age 18 to 60 years, TBI with 7-13 FOUR score, hospitalization in the neurological ICU for more than one week, stable hemodynamic status, the existence of pain based on

the behavior pain scale, no hearing problem (history of using the hearing aids, deafness, no auditory canal and cochlear injury, no trauma of the temporal lobe and Wernicke area based on the findings of brain CT Scan), no taking the ototoxic drug for more than one week, inability to express pain verbally, lack of quadriplegia and extensive facial injuries and muscle dysfunction, intubated patient, and history of listening to music (through interviews with the patient's family). Exclusion criteria were: increasing and decreasing the dose of sedatives and anesthesia during the study, injecting analgesics during the study, receiving neuromuscular blocking drugs, patient's death, transferring to other hospitals or discharge, the need for emergency procedures or cares during the study and positive covid-19 test.

The patients who met the inclusion criteria were selected based on the convenience sampling method. The informed consent was obtained from the patient's legal guardian, and then the patients were randomly assigned to the intervention and control groups by coin-flipping (Simple randomization). Sampling was performed in the neurology intensive care unit of Fatemi teaching hospital in Ardabil city, Iran from December 2019 to September 2020. A total of 62 patients were included in the study. However, five patients in the control group were excluded from the study, one due to extubation, two due to transfer to other hospitals, and two due to increased dose of sedative. Also in the intervention group, five patients were excluded from the study, one due to positive covid-19 test, one due to increased dose of sedative, and three due to extubation (figure 1).

Data collection tools included the patient's selection form, demographic characteristics form, Behavioral Pain Scale (BPS), and FOUR scale.

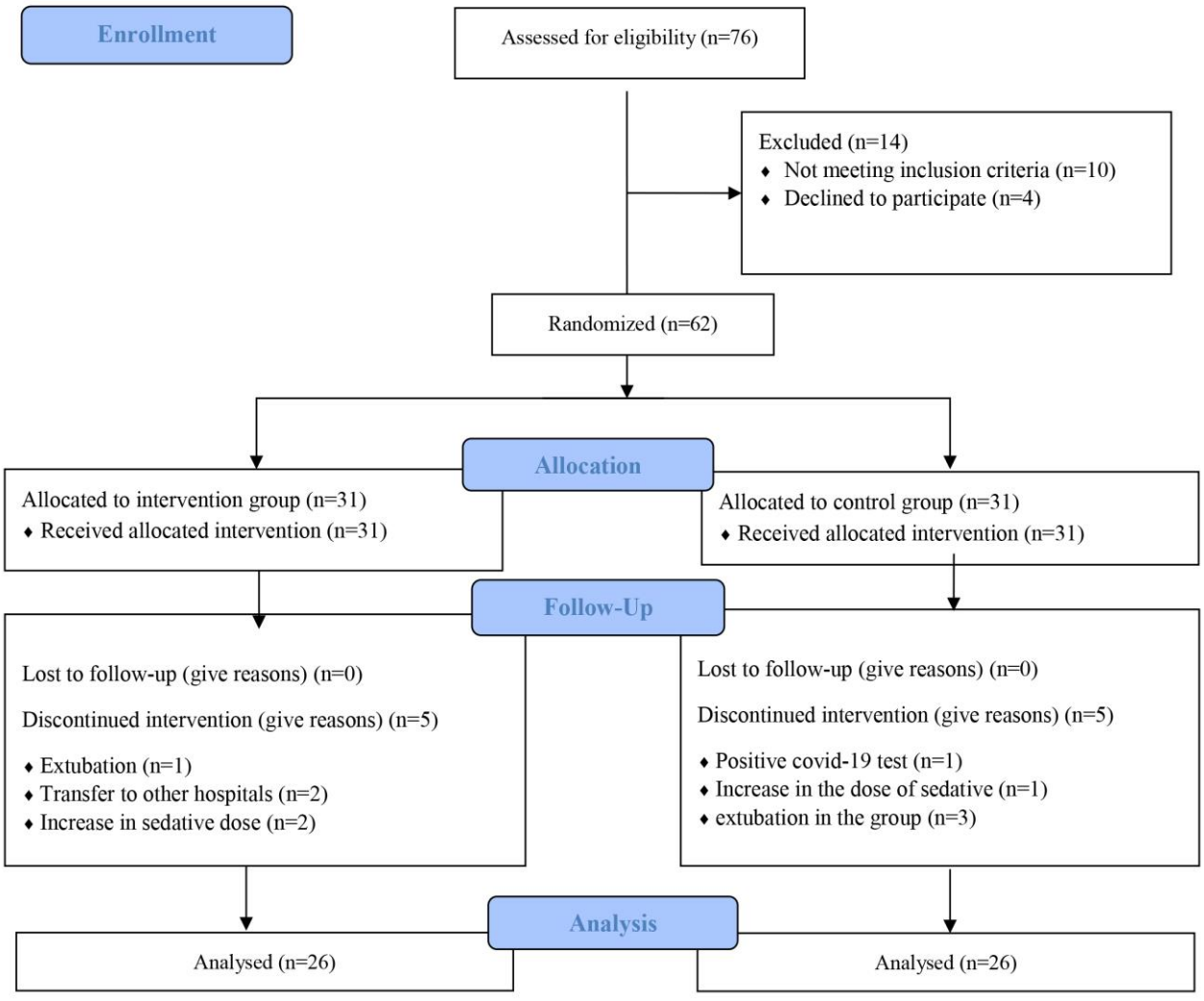

Figure 1. CONSORT Flow Diagram of study

The patient's selection form consisted of the inclusion and exclusion criteria and was completed by the researcher using the patient's file information and also interviews with the patient's family.
Demographic characteristics form included age, sex, marital status, history of hospitalization, level of consciousness, history of opioids use, sedatives use, level of education, and history of listening to music. The form was completed through interviews with the patients' family members or patient's file information.
The BPS was developed by Payen et al. in 2001 for pain assessment in nonverbal patients (25). In the study by Wongtangman et al. in 2017, the validity of the BPS was 89%, and the reliability using Inter-rater agreement was 0.91 with a 95% confidence level. The BPS contains 3 subscales: facial expression, upper limb movements, and compliance with mechanical ventilation. Each subscale is scored from 1 to 4. Therefore, BPS scores range from 3 (no pain) to 12 (maximum pain) (26). BPS psychometry in Iran has been performed by Heidarzadeh et al. in 2017; the validity of this tool has been reported as 74.99 and its reliability is 0.78 (27).
The FOUR scale was used to measure patients' consciousness. In the study of Iyer et al., the reliability of the FOUR scale was estimated to be 95% (28). The FOUR scale contains 4 subscales: Eye response, Motor response, Brainstem reflexes and Respiration. Each subscale is scored from 0 to 4. Therefore, FOUR scale scores range from 0 to 16. In the study of Assadi et al., the reliability of the FOUR scale using Cronbach's alpha method was 0.88 (29).
The pain intensity of the participants was measured 10 minutes before the intervention by the outcome assessor using the BPS in the two groups. In the intervention group, patients received white noise (sound of the sea) for three consecutive days for 30 minutes once a day during 4-5:30 pm. White noise was played by an MP3 player and headphones. The headphones and MP3 player were calibrated to produce a maximum of 60 decibels with a preset sound level. The duration of the intervention was three consecutive days for 30 minutes during 4-5:30 pm. Thirty minutes after the intervention, the pain was again assessed using the BPS in the two groups by the outcome assessor (the outcome assessors were blinded to treatment allocation).
It should be noted that before the study, the outcome assessor had received the necessary training to use the BPS by the first author of the article; then, the degree of interrater reliability was obtained as 98%. In the control group, the pain score was evaluated 10 minutes before and 30 minutes after the intervention. In the control group, patients rested on the bed for 30 minutes without intervention for three consecutive days.
Data were analyzed by SPSS software (version 10). Data normality was checked using Kolmogorov-Smirnov test that had a normal distribution. Mean and standard deviation was used to analyze the descriptive data. T-test, Chi-square, and Fisher's exact test were used to evaluate the homogeneity of the two groups in terms of demographic variables. ANCOVA was used to assess the behavioral pain score before and after the study in the control and intervention groups. $P<0.05$ was considered statistically significant.
Inform consent was obtained from the legal guardian of all patients. They were assured that their information would be confidential and they could leave the study at any time.

Results

According to the findings of the present study, the mean age of participants was 44.69±14.93 years. Most of the research population (75%) were men. The mean level of consciousness of the participants was 9.87±1.88. Most of the patients (50%) had the history of listening to music on some days. The results showed no significant difference between the intervention and control groups in terms of demographic characteristics except for age (Table 1).
Since the two groups were significantly different in terms of age, Ancona was used for data analysis. According to the results of the Ancona statistical test with control of age and pre-test variables, a significant difference ($P <0.001$) was observed between the two groups in terms of BPS score on the first, second, and third days of the intervention (Table 2).
The mean BPS score during three consecutive days 10 minutes before the study was 5.15 ± 1.09 in the control group, and 4.98 ± 084 in the intervention group. Also, mean BPS score 30 minutes after the intervention was 4.16 ± 074 in the intervention group and 4.97 ± 1.08 in the control group ($P<0.001$).
The results of the Ancona analysis showed a significant difference ($P <0.001$) between the two groups in terms of mean BPS score during the three days (Table 3).

Table 1. Socio-demographic characteristics and clinical status in the intervention and control groups

socio-demographic characteristics and clinical status		Intervention group N (%)	Control group N (%)	P-value
Gender	Male	22(84.6)	17 (65.4)	χ^2= 2.56
	Female	4(15.4)	9(34.6)	0.109*
Age (year)	18-30	12(46.2)	4(15.4)	t= -2/546
	31-40	1(3.8)	2(7.7)	0.029**
	41-50	5(19.2)	4(15.4)	
	51-60	8(30.8)	16(61.5)	
Marital status	Single	9(34.6)	5(19.2)	χ^2= 2.564
	Married	17(65.4)	21(80.8)	0.199*
Education level	Illiterate	8(30.8)	13(50)	χ^2=2/797
	Diploma	7(26.9)	6(23.1)	0.424*
	Higher education	11(42.3)	7(26.9)	
Duration of hospitalization (day)	7-20	16(61.5)	17(65.4)	t=- 0.210
	21-30	3(11.5)	4(15.4)	0.834**
	31-40	5(19.2)	1(3.8)	
	41-50	2(7.7)	4(15.4)	
Hospitalization history	Yes	10(38.5)	13(50)	χ^2= *0.702*
	No	16(61.5)	13(50)	0.402*
History of drug abuse	Yes	2(7.7)	3(11.5)	χ^2= *0.221*
	No	24(92.3)	23(88.5)	0.638*
Drugs Sedation and analgesia	Yes	11(42.3)	13(50)	χ^2=0.221
	No	15(57.7)	13(50)	0.619*
Level of consciousness	7-9	10(38.5)	7(26.9)	t= -0.073
	10-11	9(34.6)	14(53.8)	0.942**
	12-13	7(26.9)	5(19.2)	
listening to music	Everyday	2(7.7)	2(7.7)	
	Sometimes	15(57.7)	11(42.3)	χ^2=4.573
	Occasionally	7(26.9)	5(19.2)	0.208*
	Rarely	2(7.7)	8(30.8)	

** Independent T test * Chi-square

Table 2. Comparison of behavioral scores of pain on the first, second and third days 10 minutes before and 30 minutes after the intervention in the two groups

Groups time	Day1				Day 2				Day 3			
	Intervention		control		Innervation		control		Intervention		Control	
	Pre	post	pre	post	pre	post	pre	post	pre	post	pre	post
Mean	5.34	5.57	5.26	5.19	5.96	3.61	5.30	4.96	3.65	3.30	4.88	4.76
Standard deviation	1.12	1.50	1.25	1.13	1.53	0.80	1.15	1.11	0.89	0.54	1.10	1.27
Mean difference	+0.23±0.38		-0.07±0.12		-2.35±0.73		-0.34±0.04		-0.35±0.35		-0.12±0.17	
ANCOVA	F= 0.193 P =0.743				F=34.78 P < 0.001				F=6.60 P < 0.001			

Table 3. Comparison of the mean of behavioral pain score during three days 10 minutes before and 30 minutes after the intervention in the two groups

Groups	Intervention		Control	
	10 min before	30 min after	10 min before	30 min after
Mean	4.98	4.16	5.15	4.97
Standard deviation	0.84	0.74	1.09	1.08
Mean difference	0.82 ± 0.1		0.18 ± 0.01	
ANCOVA	F= 22.64 P < 0.001			

Discussion

The present study was performed aimed to investigate the effect of white music on pain in patients with TBI admitted to intensive care units. Various factors such as age, sex, and history of hospitalization affect the severity of pain (30). The results of the present study showed that all demographic variables except age were homogeneous in the control and intervention groups. Due to the significance of the age variable in the two groups, Ancona was used to control this disturbing variable (age) to evaluate the pain score in the control and intervention groups.

The results of the present study showed that the BPS score had a significant decrease in the intervention group compared to the control group. Considering the control of pre-test and age variables, receiving white music in the intervention group compared to the control group could significantly reduce the pain score in the intervention group, indicating the effect of white music intervention in reducing behavioral pain score of patients with TBI admitted to the intensive care unit.

In the study by Ozer et al. (2014) that examined the effect of music on physiological parameters of patients after open-heart surgery, pain self-report tools were used to measure pain intensity. The two groups were homogeneous in terms of pain intensity before the study. There was a significant reduction in pain intensity in the intervention group compared to the control (31), which was consistent with the results of the present study. In the Ozer's study, the participants were conscious patients, but in the present study, non-conscious patients who were unable to express pain verbally were selected as the research participants. Therefore, in the present study, BPS was used to measure the effect of white music on pain.

In the study by Foroutan et al. (2020), music therapy significantly reduced blood pressure and respiratory rate in traumatic brain patients (32). In their study, physiological parameters were used to evaluate the effect of music therapy, but in the present study, behavioral parameters were used as the gold standard for measuring pain in unconscious patients, the results of the present study were consistent with the Foroutan's study. Moreover, in the study of Yaghoubinia et al. in 2016, the use of Arnd Stein music was effective in reducing pain in patients with loss of consciousness (33), which is in line with the results of the present study. Since soothing and classical music was not compatible with the musical tastes of most Iranians (34,35), white music was used to perform the intervention in the present study.

Kucukoglu et al. (2016) conducted a study on the effect of white noise on pain relief in preterm infants during vaccination. The white noise was effective in reducing pain of the intervention group (23). Their results were consistent with the results of the present study indicating that white music could reduce pain in nonverbal patients. However, more research is needed in this regard.

The present study had several limitations. The results were not generalizable bacause of the small sample size and convenience sampling method. In addition, the age variable was significance in the two groups and ancova was used to manage this limitation.

In unconscious patients who are unable to express pain, behavioral or physiological tools should be used. In the present study, the researcher used behavioral criteria based on the BPS tool to measure the effect of the intervention. One of the strength of the present stuy was the choice of white music in unconscious patients, because the choice of music for unconscious patients is one of the major challenges in performing interventions, using white music that suits most people's musical tastes can be helpful, but more studies are needed.

Implications for practice

Music therapy is a non-pharmacological and noninvasive nursing intervention to relieve pain. Most

Patients with TBI cannot express their pain due to loss of consciousness. In patients with loss of consciousness, use of BPS will be useful to assess pain. White noise has an acceptable effect on behavioral parameters of pain in unconscious patients with TBI. Critical care nurses are recommended to use white music as low-cost and no side effects intervention for patients with TBI.

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Conflicts of interest
The authors declared no conflict of interest.

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