# THE EFFECT OF PLEASANT AUDIO STIMULATION ON THE LEVEL OF CONSCIOUSNESS OF COMATOSE PATIENT: A RANDOMIZED CLINICAL TRIAL

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***ABSTRACT***

***Background****: Sensory isolation and the type of sensory stimuli are major challenges in providing care for patients in coma.*

***Objectives****: The present study was conducted to determine the effect of pleasant audio stimulation on the level of consciousness of comatose patient*

***Methods****: The present randomized, single blind clinical trial was conducted in the intensive care units of Kermanshah educational hospitals, Iran, 2018. Seventy patients were selected randomly and allocated into two groups of intervention and control. Pleasant audio stimulants, such as the voice of family members or favorite music, were played on headphones for ten minutes during the week for subjects in the intervention group; The level of consciousness was recorded prior to, immediately after, and ten minutes after intervention every day for one week in two groups. Based on using SPSS-25 Collected data was analyzed by t-test and repeated measures analysis of variance.*

***Results****: Except for the first and second days of the intervention, the increase in the level of consciousness of the subjects in the intervention group was significant in comparison with the subjects in the control group ($p < 0.05$).*

***Conclusion****: The findings show that pleasant audio stimuli increase the level of consciousness of the patients who are hospitalized in intensive care units over time.*

***Keywords****: Coma, Audio, Stimulus, Consciousness, Clinical Trial.*

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## Introduction

Come is a hazardous situation in the intensive care unit[(1)]. Consciousness is the result of the coherence and integration of Ascending Reticular Activation System, thalamus and its cortical connections and the temporolimbic system[(2)]. This process is activated with a pleasant audio stimulation and disrupts the sensory stimuli. In this regard, Alsherbini et al found that painful and unpleasant acoustic stimuli led to the destruction of delta waves in the Electroencephalogram of comatose patients[(3)]. However, according to a study conducted by Sun & Chen, music therapy caused favorable changes in the Electroencephalogram of patients in coma[(4)].

Patients admitted to the intensive care unit face the risks of sensory isolation, and perceptual, cognitive, and emotional disturbances[(5)]. One of the measures used to prevent the sensory deprivation of patients in coma is the use of sensory stimuli through various methods[(6)]. Sensory stimulation is one of the triggers that increases the level of consciousness[(7)]. The use of audio stimuli such as music is another method of sensory stimulation[(8)]. Using music after nerve damage can facilitate changes to improve sensory processing and cognitive functions[(9)]. Music is a tool for enhancing perception and recognition in patients with reduced consciousness[(10)].

Comparing various types of pleasant acoustic stimuli, familiar stimuli are more likely to increase brain responsiveness in comparison with neutral stimuli for patient in coma[(10)]. Padilla & Domina have suggested that sensory stimuli should begin on the basis of pre-existing, frequent, and early-onset illnesses for comatose patients[(11)]. The existing gap in previous studies is that a single pleasant acoustic stimulus was used for all patients, including music[(4, 12)], first name of

patient[13], and Qur'anic voice[14]. Researchers have sought to eliminate this gap bothering the findings of previous studies. Therefore, pleasant acoustic stimuli will be selected with a variety of patient and family choices in the present study. Using non-pharmacological interventions in the care of patients in coma which reduce morbidity and costs is another significance of the present study. On the other hand, based on the experiences of the researcher, the majority of patients in the intensive care unit suffer from sensory deprivation and families tend to participate in stimulating the patient's senses. Therefore, the present study was conducted to determine the effect of acoustic stimuli on the consciousness of patients in coma.

## Methods

### *Research design and participants*

The present single-blind clinical trial was conducted in the intensive care units of Kermanshah Educational Hospitals, Iran, in 2018. Having a consciousness level of 4 to 8 based on Glasgow criteria, being aged 15-75 years, having stable vital signs after being in the intensive care unit for 24 hours, non-use of antidepressants, tranquilizers, opium or drugs affecting consciousness, absence of mental disorders (dementia or depression), no previous brain damage, no hearing impairment, no othorrhea and rhinorrhea, non-fracture, absence of bleeding and temporal surgeries, non-addiction, non-compliance, no history of cancer, non-quadriplegic, and lack of severe intracranial pressure were the main inclusion criteria. Discharge or death of the patient before 6 days, withdrawal from the study by patient's legal deputy, severe changes in the symptoms, severe changes in mental status, severe changes in intracranial pressure, and loss of brain stem reflexes during the study were the main exclusion criteria.

### *Sampling and Randomization method*

Samples were selected based on the purpose of inclusion criteria and then randomly assigned to two groups of control and intervention using enclosed envelopes. Sample size was calculated based on the Saritaş & Araç[15] study with 95% confidence and 80% probability, with 35 subjects categorized in each group. However, taking into account more than 10% probability of dropping samples, 40 subjects in each group and a total of 80 subjects were randomly selected. Finally, 70 samples were allocated to the study, taking into account the exclusion criteria and the loss of samples (Figure 1).

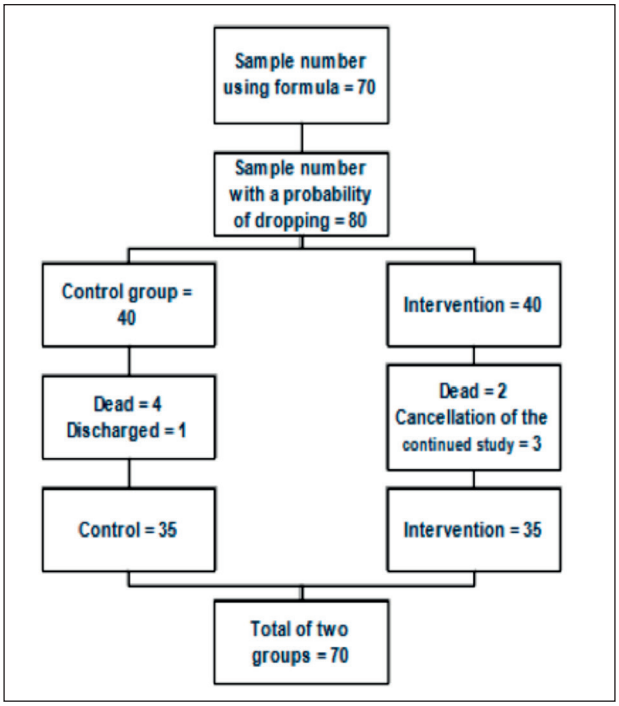


**Fig. 1**: Flowchart of sampling.

### *Intervention*

The intervention was conducted like the following; pleasant acoustic stimuli was played through headphone for 10 minutes from 3 to 6 pm. The reason for choosing this hour was the lack of intruder stimuli in the intensive care unit.

The pleasant audio stimuli were selected by the family and based on the patient's interests. In the intervention group, a detailed account of the psychological and personality traits and favorite music of the patient were recorded after asking family members. These voices ranged from silent music to voice of family members. Acoustic stimuli were approved by the family and physician prior to being played for the patient. Control group subjects were not played any pleasant acoustic stimuli. Interventions were conducted for subjects in the control group after the end of the study.

### *Blinding*

The present study was one-sided blind clinical trial. In order to blind the study, the intervention was performed by the first researcher. Due to the application of headphones in the two groups, the second researcher was unaware of the separation of the control and intervention group subjects (silent

or sensory stimuli). After placing headphones on the ears of subjects, the researcher collected data for intervention or control regardless of the type of group.

### *Data collection*

After receiving written consent from the family or patient's trustee, people with GCS of 4 to 8 years were, according to inclusion criteria, enrolled in the study. Demographic, clinical and consciousness levels were first recorded in the information sheet by the first researcher. Level of consciousness was measured by the researcher before and after the intervention, and 10 minutes immediately after the installation of the headphones.

Glasgow Coma Scale (GCS) was used to measure level of consciousness. GCS has been used since 1974 to assess the level of consciousness in traumatic patients; it consist of verbal 5, motion 6, and ocular response 4[16]. Score 3 indicates deep coma and 15 indicates complete consciousness. In this study, patients with coma were selected with a level of consciousness of 4 to 8, because the evaluation of the effects of acoustic stimuli can be evaluated at this level of consciousness[8, 17]. Sony's recording and playback device, along with Sony's headphones, was used as the standard for intervention.

### *Data analysis*

Collected data was analyzed using SPSS 25. Demographic variables were analyzed by T-test. During 7 days, repeated ANOVA and Mauchly's Test of Sphericity were used during 7 days; the results of repeated tests were accepted if the P value was significant; on the other hand, P value of Assumed Sphericity was reported in case of the insignificance of the intended value.

### *Ethical considerations*

The written consent of the patients was obtained from a family member in order to participate in the study. This study was approved by the Ethics Committee of the Kurdistan University of Medical Sciences, Iran, with the code of IR.MUK.REC.1396/176. The conducted intervention has been documented in a clinical trial with IRCT20171024036979N1 code. The subjects were informed about the study objectives and ensured about the confidentiality of the information collected from family and the patients, and they were free to participate in or leave the study at any time.

## Results

The results showed that there was no significant difference between age, sex, and primary GCS in two groups of control and intervention (Table 1).

| Group | Intervention | | Control | | P Value |
|---|---|---|---|---|---|
| Variable | Mean | SD | Mean | SD | 0.230 |
| age(year) | 65.14 | ±12.7 | 61.80 | ±10.1 | |
| Primary GCS | Mean | SD | Mean | SD | 0.758 |
| | 6.09 | ±1.52 | 6.20 | ±1.56 | |
| Gender GCS | Number | Percent | Number | Percent | 0.225 |
| Male | 23 | 66% | 18 | 51% | |
| Female | 12 | 34% | 17 | 49% | |
| Cause Coma | Number | Percent | Number | Percent | 0.153 |
| Brain Trauma | 71% | 25 | 54% | 19 | |
| MULTIPLE Trauma | 29% | 10 | 46% | 16 | |
| Total | 100% | 35 | 100% | 35 | |

**Table 1**: Frequency distribution in terms of age, primary GCS, sex and Cause coma.

There was no significant difference in the level of consciousness before and after intervention in both groups in the first and second days (Table 2).

| Group | Measurement times | Intervention | | Control | | P Value |
|---|---|---|---|---|---|---|
| | | Mean | SD | Mean | SD | |
| Day 1 | Before study | 6.20 | ±1.4 | 6.23 | ±1.5 | 0.937 |
| | Immediately after | 6.20 | ±1.4 | 6.23 | ±1.5 | 0.937 |
| | Ten minutes later | 6.20 | ±1.4 | 6.23 | ±1.5 | 0.937 |
| Day 2 | Before study | 6.57 | ±1.5 | 6.31 | ±1.6 | 0.506 |
| | Immediately after study | 6.57 | ±1.5 | 6.31 | ±1.6 | 0.506 |
| | Ten minutes later | 6.57 | ±1.5 | 6.31 | ±1.6 | 0.506 |
| Day 3 | Before study | 7.49 | ±1.9 | 6.40 | ±1.7 | 0.015 |
| | Immediately after study | 7.51 | ±1.9 | 6.43 | ±1.7 | 0.016 |
| | Ten minutes later | 7.51 | ±1.9 | 6.43 | ±1.7 | 0.016 |
| Day 4 | Before study | 8.09 | ±2.1 | 6.57 | ±2.0 | 0.004 |
| | Immediately after study | 8.11 | ±2.2 | 6.57 | ±2.0 | 0.003 |
| | Ten minutes later | 8.11 | ±2.2 | 6.57 | ±2.0 | 0.003 |
| Day 5 | Before study | 8.49 | ±3.1 | 6.80 | ±2.4 | 0.015 |
| | Immediately after study | 8.57 | ±3.2 | 6.80 | ±2.4 | 0.012 |
| | Ten minutes later | 8.60 | ±3.3 | 6.80 | ±2.4 | 0.012 |
| Day 6 | Before study | 9.26 | ±2.8 | 7.14 | ±2.5 | 0.002 |
| | Immediately after study | 9.29 | ±2.8 | 7.14 | ±2.5 | 0.001 |
| | Ten minutes later | 9.29 | ±2.8 | 7.14 | ±2.5 | 0.001 |
| Day 7 | Before study | 9.49 | ±2.8 | 7.20 | ±2.6 | 0.001 |
| | Immediately Before study | 9.49 | ±2.8 | 7.20 | ±2.6 | 0.001 |
| | Ten minutes later | 9.49 | ±2.8 | 7.20 | ±2.6 | 0.001 |

**Table 2**: Comparison of means and standard deviation of GCS variable in two groups, divided by days of study.

However, this difference was significant between the two groups at days 3 to 7. Also, there was a significant difference in variance-covariance analysis of repeated tests over seven days (Table 3).

| GCS (7Day) | Before Mauchly Test | Immediately after Mauchly Test | Ten minutes later Mauchly Test |
|---|---|---|---|
| P Value (Group*-Time) | 0.000 | 0.000 | 0.000 |

**Table 3**: Result of Mauchly's test of sphericity.

The mean GCS score immediately dropped out of the coma within 7 days immediately following the intervention in the intervention group, but this slope was lower in the control group and remained within the coma range (Table 2).

The slope by which mean GCS score lowered in the intervention group ten minutes after the intervention was quite steep, but this slope was slow in the control group and remained within the coma range (Table 2).

## Discussion

The present study was designed to evaluate the effect of acoustic stimuli on the level of consciousness of patients hospitalized in intensive care units for different causes. Regarding the fact that there was no significant difference between age and sex and initial consciousness between the two groups, the results can be more confidently attributed to interventions. The findings of the present study showed that there was a significant difference in the level of consciousness between the intervention and control groups especially from the third day of the intervention. The number of intervention days was selected based on Moattari et al study[18]. However, some studies had longer and some had shorter intervention periods[15]. Audio stimuli in various studies include Qur'anic voices[14], diverse music[8], and the voice of family members[19], regardless of the differences between individuals; while in the present study, an important milestone is considering personal interest and favorites to determine the type of stimulation implemented.

Çevik & Namik showed that acoustic stimulation twice a day for 10 days by a nurse increased GCS after the third day[17]. Although the increase in consciousness was consistent with the present study, the difference was the type of acoustic stimuli that was pleasing to the patient in the recent study. Magee & O'Kelly found that playing familiar voice had a significant effect on consciousness[20], which was consistent with the present study, although the duration of the intervention was seven days in this study. According to the findings of Tavangar et al study, which used familial voice for 5-10 minutes twice a day to stimulate auditory hearing in patients with acute subdural hematoma for 10 days, it was shown that the level of consciousness was significantly different from day 4 onwards. There was a significant difference between the two groups[6]. In the present study, the difference between the control and intervention groups was significant on the third day.

In Park & Davis study, direct sound effects included family voice along with notification conducted by the nurse or family members and music compared to indirect audio, featuring more general and lesser-sounding voices and television sound for 15 minutes; direct sounds turned out to be hugely effective on provoking and increasing the patient's consciousness[21]. The main difference between the present study and formerly conducted researches was the likelihood of the acoustic stimulus being desirable for the patient and the option of family selection. In previous studies, acoustic stimuli were the same for all patients, while in the present research; acoustic stimuli were variable according to the interest and favorite of the patient, thus increasing the impact of acoustic stimuli on the consciousness of the patient.

Short intervention period; i.e. 7 days, is one of the main limitations of the present study. It is recommended to conduct further researches with longer. One of the other limitations of this study was a plethora of patient's inability to decide on the choice of acoustic stimuli. So, the decision was made by the patient's family, which made the process of the study somehow uncontrolled.

## Conclusion

According to the results of the present study, pleasant acoustic stimuli selected by the patient or a close family member increased the level of consciousness of the patients who were hospitalized in the intensive care unit over time. It is suggested to apply this process and play pleasant stimuli for the patient to increase the level of consciousness in the intensive care unit.

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