

Original Paper

Effect of Auditory Stimulation With Occupational Noise on the Consciousness Level in Comatose Traumatic Brain Injury Patients: A Clinical Trial Study



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ABSTRACT

Introduction: Auditory stimulation is a treatment method for sensory deprivation of comatose patients, which helps wake up the patient by activating the choroid plexuses in the brain.

Objective: This study aims to determine the effect of auditory stimulation with occupational noise on the consciousness level of comatose patients with traumatic brain injury (TBI).

Materials and Methods: This clinical trial was conducted on 50 comatose patients with TBI hospitalized in intensive care units of one of the hospitals in Qom City, Iran. They were randomly assigned to two groups of control (n=25) and intervention (n=25) using the block randomization method. The intervention group received auditory stimulation with occupational voice for 10 days in the morning and evening shifts, each for 15-20 minutes. The consciousness level of patients was evaluated before and after stimulation using the Glasgow Coma Scale (GCS). The obtained data were analyzed using descriptive statistics, the Chi-square test, the independent t test, and the generalized estimating equations model.

Results: The Mean±SD ages of the patients were 35.92±14.68 years in the intervention group and 33.32±13.74 years in the control group. No significant difference was observed between the two groups regarding demographic or disease-related variables. The Mean±SD scores of GCS before the stimulation were 5.28±1.81 in the control group and 5.12±1.90 in the intervention group. This difference was not statistically significant. The Mean±SD scores of GCS after the stimulation were 6.60±3.25 in the control group and 8.80±4.05 in the intervention group. This difference was statistically significant (P=0.038). The level of consciousness in the intervention group increased more than in the control group in the 10th day of study.

Conclusion: Auditory stimulation with occupational noise can increase the consciousness level of comatose patients with TBI. Auditory stimulation can raise the consciousness level of these patients hospitalized in intensive care units.

Keywords:

Coma, Auditory stimulation, Traumatic brain injury, Glasgow coma scale

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Highlights

- Traumatic brain injury is the main cause of death due to trauma in Iran.
- Sensory deprivation in intensive care units is one of the threats for comatose patients.
- Various rehabilitation techniques are used to increase the consciousness of comatose patients with traumatic brain injury.
- Organized auditory stimulation may affect the consciousness of comatose patients.

Plain Language Summary

Sensory stimulation helps patients awaken from a coma sooner. Generally, people spend a significant amount of time in their workplaces and are used to the sounds specific to their job. Given the lack of research on the effect of auditory stimulation with occupational noise on the consciousness level of comatose patients in Iran, this study was conducted to determine the effect of auditory stimulation with occupational noise on the consciousness level of comatose patients with traumatic brain injury. Based on the results, auditory stimulation with occupational noise for 10 days, twice a day, each for 15-20 minutes, can increase the consciousness level of these patients.

Introduction

Traumatic Brain Injury (TBI) is one of the most common causes of death and long-term disability worldwide, such that its annual incidence is estimated to be 27-69 million cases [1, 2]. TBI is also common in Iran, for which road accidents are the most important cause [3]. Studies show that TBI is the most common cause of coma [4, 5]. Coma is a state in which the level of consciousness decreases with the diminution in the ability to wake up and lack of response to visual, auditory, and tactile stimuli. Patients with coma caused by TBI experience impaired levels of consciousness in different severities [6, 7]. A change in the level of consciousness is usually the first neurological during brain involvement and damage [8]. During the coma, patients experience sensory disorders due to damage to brain tissue and structures responsible for maintaining wakefulness and consciousness, as well as long-term immobility, social isolation, and special conditions in intensive care units (ICUs). Staying in environments where sensory stimuli are limited, such as ICUs, increases the risk of sensory deprivation in patients. The rehabilitation of these patients is a complex and long-term process that begins in the ICU and continues in the context of society. In comatose patients, although the primary problem is brain damage, sensory deprivation can lead to common damage to mental and cognitive processes. For this reason, sensory deprivation in the ICU is one of the common threats to the comatose patient [9, 10].

Nursing care of patients with TBI in the rehabilitation phase is an important challenge for nurses because they are responsible for patient care [11]. Various studies have shown that maximum brain reorganization after a coma occurs within the first few weeks after brain injury. Therefore, to facilitate the recovery process and prevent sensory deprivation after a brain injury, a sensory stimulation program such as early auditory stimulation can be beneficial. This stimulation can often accelerate the process of increasing the level of consciousness [11, 12]. Evidence shows that organized auditory stimulation may affect comatose patients. However, the ICU nurses cannot have adequate verbal communication to provide organized auditory stimuli for the patients [13]. Sensory stimulations that can be performed on ICU patients are non-invasive, safe, cost-effective, and simple. Auditory stimulation is more important than stimulation of other senses because, on the one hand, the sense of hearing is the last sense that is lost in comatose patients. On the other hand, unlike other senses, there is no barrier to stimulating this sense, and the ICU nurse can easily stimulate the patient's hearing while performing nursing care. Comatose patients may be more likely to respond to familiar voices like family members than strangers. In this case, we can record the sounds from their home or workplace and play them back [11]. The studies conducted in this field have used different sounds to stimulate the hearing sense in comatose patients, including a familiar person's voice, a nurse's voice, music, the sound of birds, and the sound of television and radio. Each of these sounds is a special auditory stimulation that ex-

erts its effect; hence, familiar sounds, as a special auditory stimulus, may impact comatose patients [12]. This study aims to assess the effect of auditory stimulation using occupational noise on the level of consciousness in patients with coma caused by TBI.

Materials and Methods

This research is a single-blind clinical trial conducted in the ICU of one of the hospitals in Qom City, Iran, for 5 months from February 2018 to July 2019. To determine the sample size, a similar study by Cevik [14] was used to identify at least one unit difference in the Glasgow Coma Scale (GCS) score. Then, considering the type I error of 5% and the test power of 95%, the sample size was determined to be 25 for each group [15]. In the first step, using a convenience sampling method, eligible patients in the first 72 hours of TBI were selected and randomly assigned to either control or intervention groups using the block randomization method. This method includes using random numbers from the permutations AABB, ABAB, ABBA, BBAA, BABA, BAAB, and so on; the remaining two samples were selected from one of the blocks BA or AB based on the oddness or evenness of the number from the random number table by the first author.

The inclusion criteria were as follows: the presence of coma caused by TBI, GCS score ≤ 8 , aged 15-65 years, no history of previous brain damage, no hearing impairment or loss (according to the patient's family report), no skull fracture or bleeding (according to the CT scan report) or surgery in this area (because damage to the temporal brain area may cause damage to the auditory nerve), no blood or cerebrospinal fluid leaking out of the ear and nose, hemodynamic stability of the patient, no use of sedatives, and being employed before the accident (not being disabled, retired, unemployed, or a housekeeper). The exclusion criteria were as follows: transferring to other treatment centers during the study, having surgery during the study, the patient's family refusing to continue participating in the study, the need for cardiopulmonary resuscitation, and having any critical condition such as hemodynamic instability and death.

Patients in the control group received auditory stimuli with the sounds of the ICU (normal sensory stimuli, staff voices, device alarms, a companion's voice during visits, etc.). In addition to receiving the routine sounds of the ICU, the patients in the intervention group listened to their occupational sounds recorded by their families in their workplaces using a voice recorder (Sony model ICD-PX470) twice a day for 10 days (20 times in total) at 11:00 AM and 5:00 PM each time for 15-20 minutes through

headphones (Sony model MDR-XB250). The intensity of the recorded sounds was adjusted by an audiometric expert using a sound level meter such that all played sounds had a noise level of 60-70 dB [16]. At the time of auditory stimulation, no invasive diagnostic, treatment, or care procedures were performed for the patients.

Demographic and disease-related information of patients were recorded and completed by the first author at baseline by a questionnaire that surveyed age, sex, marital status, education level, history of hospitalization in ICU, drug addiction, cause of coma, type of brain damage, and having/not having surgery. The GCS questionnaire was completed by the second author (who was unaware of the allocation of groups) in both groups 30 minutes before and after each intervention. Teasdale and Jennet designed GCS in 1974 to standardize the observational and accurate assessment of the level of consciousness [17]. This tool has been used in several studies [18, 19]. GCS has three subscales of eye-opening (4 points), verbal response (5 points), and motor response (6 points). The minimum score is 3, which indicates a lack of excitability and a brain-dead state, and the maximum score is 15, which indicates a fully awake person; a score of 8 or less indicates coma. In the present study, the Persian version of GCS was used [20]. Figure 1 shows the flowchart of the study process.

After collecting data, descriptive and inferential statistics were used to analyze them. The Chi-square and independent t tests were used to compare the two groups in terms of demographic factors and assess the relationship between demographic factors and changes in consciousness level. The independent t test was also used to compare the mean GCS scores of the two groups before and after the study, and the Generalized Estimating Equations (GEE) model was used to investigate the relationship between the study variables and changes in the consciousness level in the two groups.

Results

The demographic and disease-related information in the two control and intervention groups are given in Table 1. The Mean \pm SD ages of the patients were 35.92 \pm 14.68 years in the intervention group and 33.32 \pm 13.74 years in the control group. No significant difference was observed between the two groups in terms of demographic or disease-related variables. The mean \pm SD scores of GCS before the stimulation were 5.28 \pm 1.81 in the control group and 5.12 \pm 1.90 in the intervention group ($P=0.038$), this difference was not statistically significant. The mean \pm SD scores of GCS after

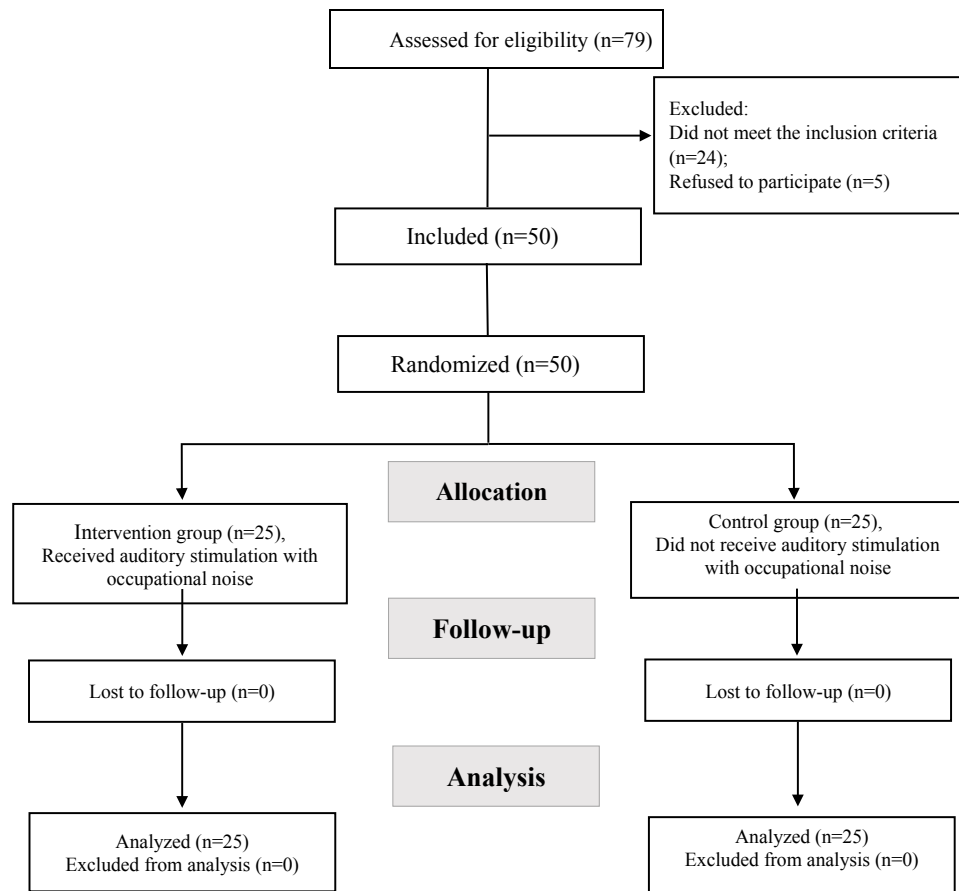


Figure 1. CONSORT flow diagram

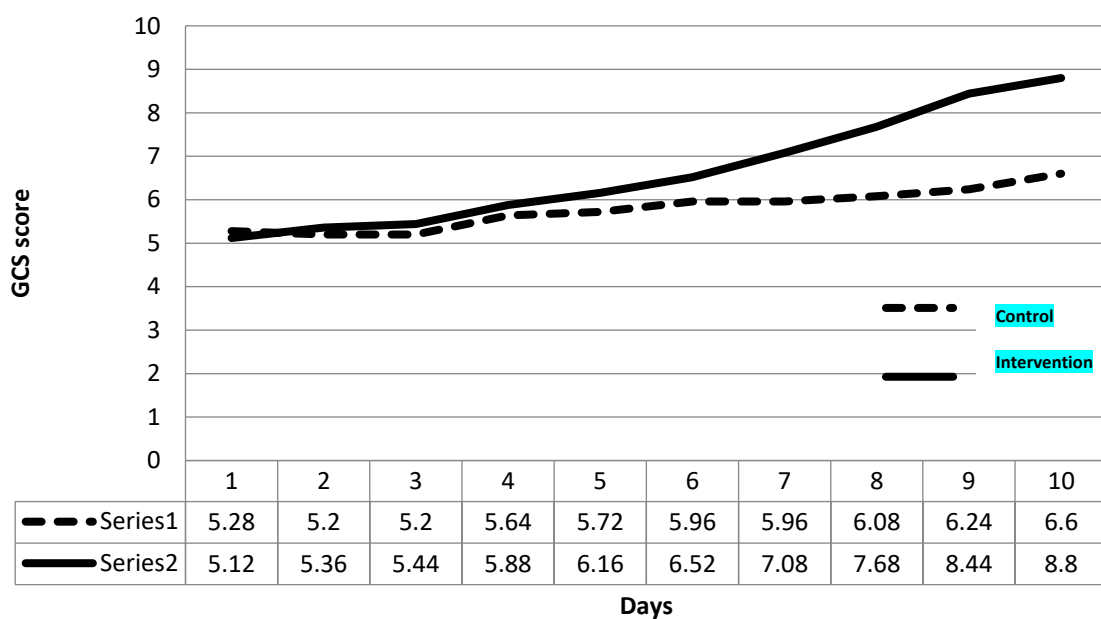


Figure 2. Comparing the changes in the mean score of the Glasgow Coma Scale (GCS) in the two study groups during 10 days

Table 1. Demographic and disease-related characteristics of the patients in the two study groups

Variables	No. (%)		P
	Control Group (n=95)	Intervention Group (n=25)	
Sex	Male	21(84)	0.48*
	Female	4(16)	
Age (y)	15-24	9(36)	0.522**
	25-34	6(24)	
	35-44	4(16)	
	45-54	3(12)	
	55-65	3(12)	
Marital status	Single	13(52)	0.830*
	Married	11(44)	
	Widowed	1(4)	
Educational level	Illiterate	2(8)	0.7*
	Elementary and middle school	7(28)	
	High school and diploma	8(32)	
	College education	8(32)	
Occupation	Student	6(24)	0.91*
	Self-employed	14(56)	
	Employed	5(20)	
History of hospitalization in the ICU	Yes	1(4)	0.552*
	No	24(96)	
Drug addiction	Yes	4(16)	0.713*
	No	21(84)	
Cause of coma	Traffic accidents	22(88)	0.721*
	Falling	1(4)	
	Fight	1(4)	
	Sports accidents	1(4)	
Type of brain injury	ICH	3(12)	0.774*
	IVH	0(0)	
	SAH	2(8)	
	SDH	7(28)	
	EDH	5(20)	
	Contusion	5(20)	
	DAI	0(0)	
Mixture	3(12)		
History of surgery	Yes	11(44)	0.91*
	No	14(56)	

*The Chi-square test; **The independent t test. Abbreviations: ICH, intracerebral hemorrhage; IVH, intraventricular hemorrhage; SAH, sub-arachnoid hemorrhage; SDH, subdural hemorrhage; EDH, epidural hemorrhage; DAI, diffuse axonal injury

Table 2. Mean scores of the Glasgow Coma Scale (GCS) before and after the intervention in the two study groups

Time	Mean±SD		P*
	Control Group (n=25)	Intervention Group (n=25)	
Pre-test	5.28±1.81	5.12±1.90	0.7
Post-test	6.60±3.25	8.80±4.05	0.038

*The independent t test

Table 3. The GEE results for assessing the changes in the GCS score from day 1 to 10 in the control group

Time		Day 1	Day 2	Day 3	Day 4	Day 5	
Pre-test	Mean GCS	5.28±1.81	5.20±1.82	5.20±1.82	5.64±1.82	5.72±2.09	
	GEE results	β	0	-0.080	-0.080	0.360	0.440
		P	Ref.	0.524	0.682	0.110	0.120
Post-test	Mean GCS	5.24±1.85	5.20±1.89	5.52±1.89	5.68±2.01	5.88±2.04	
	GEE results	β	0	-0.040	0.280	0.440	0.640
		P	Ref.	0.653	0.178	0.075	0.061

Time		Day 6	Day 7	Day 8	Day 9	Day 10	
Pre-test	Mean GCS	5.96±2.09	5.96±2.22	6.08±2.46	6.24±2.86	6.52±3.28	
	GEE results	β	0.680	0.680	0.800	0.960	1.240
		P	0.021	0.044	0.035	0.028	0.012
Post-test	Mean GCS	6.00±2.21	6.04±2.37	6.24±2.84	6.48±3.22	6.60±3.25	
	GEE results	β	0.760	0.800	1.000	1.240	1.360
		P	0.015	0.025	0.022	0.009	0.005

the stimulation were 6.60±3.25 in the control group and 8.80±4.05 in the intervention group. This difference was statistically significant (Table 2). The evaluation of the mean scores of GCS from the first to the tenth day showed that the level of consciousness in the intervention group increased more than in the control group (Figure 2). Based on the result of the GEE test in Table 3, the increase in the consciousness level in the control group was significant after the morning of the sixth day, after the 11th measurement (P<0.05). This outcome indicates the effect of time. In the intervention group, this increase was significant (P<0.05) after the evening of the third day, after the sixth measurement (Table 4).

Discussion

The results of the present study showed that although there was no significant difference between the two groups of patients in GCS score at baseline, after ten days of auditory stimulation, this score increased significantly in the intervention group compared to the control group. Therefore, auditory stimulation with occu-

pational sound effectively improved the consciousness level of comatose patients. The results are consistent with the results of Goudarzi et al., which was a quasi-experimental study on 30 comatose patients hospitalized in the ICU. In their research, the consciousness level of patients was evaluated for 14 days and twice a day before and after auditory stimulation with a familiar voice (the voice of a family member). The difference in the GCS scores before the study between the control and intervention groups was not statistically significant, but the difference after the intervention was significant [21]. Our results are also consistent with the results of Tavangar et al. on 40 patients with coma caused by brain trauma. In their study, the patients received auditory stimulation with the recorded voice of a family member twice a day. The difference in the consciousness level between the control and intervention groups was significant after auditory stimulation. In their study, only patients with subdural hematoma were included [22]. The results of the present study are also in agreement with the results of Parveen et al. in a study on 80 comatose patients who received auditory stimulation

Table 4. The GEE results for assessing the changes in the GCS score from day 1 to 10 in the intervention group

Time			Day 1	Day 2	Day 3	Day 4	Day 5
Pre-test	Mean GCS		5.12±1.90	5.36±1.91	5.44±1.80	5.88±1.92	6.16±2.13
	GEE results	β	0	-0.040	0.360	0.800	1.200
		P	Ref.	0.705	0.063	0.001	0.0001
Post-test	Mean GCS		5.16±1.86	5.48±1.82	5.72±1.81	6.16±2.01	6.24±2.22
	GEE results	β	0	0.320	0.560	1.000	1.080
		P	Ref.	0.110	0.042	0.0001	0.0001

Time			Day 6	Day 7	Day 8	Day 9	Day 10
Pre-test	Mean GCS		6.52±2.27	7.08±2.67	7.68±3.11	8.44±3.73	8.72±4.10
	GEE results	β	1.560	1.880	2.880	3.520	4.000
		P	0.0001	0.0001	0.0001	0.0001	0.0001
Post-test	Mean GCS		6.68±2.41	7.48±3.10	8.08±3.53	8.60±4.17	8.80±4.05
	GEE results	β	1.520	2.320	2.920	3.440	3.640
		P	0.0001	0.0001	0.0001	0.0001	0.0001

with the recorded voice of a family member twice a day for 14 days. On the 14th day, the difference in the consciousness level between the two control and intervention groups was significant [23]. Our results are not consistent with the findings of Park et al., who conducted a study on 9 patients with coma caused by brain trauma. One group received direct auditory stimulation with the voice of a family member, orientation by a nurse, and familiar music. The other group received non-direct auditory stimuli, which were less familiar, less interactive, indirect, and not lively such as general music and TV sounds. The patients received auditory stimulation for 5 days, 5-8 times a day, each for 15 minutes. Although the GCS score of the patients increased after auditory stimulation in both groups, this increase was not statistically significant [24].

Auditory stimulation with occupational noise twice a day for 10 days, each session for 15-20 minutes, can increase the consciousness level of comatose patients with TBI. The ICU nurses should provide this care in a way that causes fewer complications for the patient. In comatose patients, one-way communication between the nurse and the patient may harm the nurses' motivation to conduct auditory stimulation. By increasing their knowledge of various methods of sensory stimulation, especially auditory stimulation with a familiar voice, such as occupational sounds, ICU nurses can improve the consciousness level of comatose patients. Although the families cannot currently visit the comatose patients in ICUs due to special hospital considerations, hospital managers are recommended to allow the families for

face-to-face visits to increase sensory stimulation of patients or provide conditions to play familiar voices for the patients, such as their occupational sounds. The effect of the auditory stimulation threshold on patients is important, but it was not controlled in this study which can be one of the study's limitations. In future studies, it is recommended to use three groups of control (routine care), auditory stimulation with occupational sounds, and auditory stimulation with white noise.

Ethical Considerations

Compliance with ethical guidelines

This study obtained its ethical approval from the Ethics Committee of [Tehran University of Medical Sciences](#) (Code: IR.TUMS.FNM.REC.1397.2) and was registered by the Iranian Registry of Clinical Trials (IRCT20171209037801N1). After explaining the study's objectives, informed consent was obtained from the patient's family. They were assured of the confidentiality of their information and were free to leave the study at any time.

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Authors' contributions

Design, data interpretation, and writing the initial draft: Mohammad Goudarzi Rad; Design and supervision:

Masoumeh Zakerimoghadam and Maryam Esmaeili; Data collection: Mahsa Haji Mohammadhoseini; Data analysis: Amir Hamta; Approval of the final draft of the article: All authors.

Conflict of interest

The authors declared no conflict of interest.

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