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Effectiveness of auditory sensory stimulation on level of consciousness and cognitive function in traumatic brain injury patients: A randomized controlled clinical trial

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ABSTRACT

Background & Aim: Coma is one of the severe complications of traumatic brain injury. The study aimed to determine the effect of auditory sensory stimulation on the level of consciousness and cognitive function of patients with traumatic brain injury.
Methods & Materials: This study is a triple-blind randomized controlled clinical trial on 60 patients with traumatic brain injury selected using consecutive sampling. They were then randomly assigned to control and intervention groups. The patients in the intervention group received auditory sensory stimulation (twice a day for 15 minutes), while those in the control group only received the routine sounds of the ward (through headphones) for six days. The data were measured daily using the Glasgow Coma Scale and the Rancho Los Amigos Scale. SPSS software version 22 and descriptive and inferential statistics were used for data analysis.
Results: According to the independent samples t-test, there was a significant increase in the level of consciousness on the third, fifth, and sixth days after the intervention among the patients in the intervention group compared to the control group (P=0.001). The findings of two-way repeated measures ANOVA revealed that auditory sensory stimulation could lead to a statistically significant improvement in the cognitive function of patients in the intervention group compared to the control group (P= 0.003).
Conclusion: Because of the improvement of the level of consciousness and cognitive function resulting from auditory sensory stimulation, this method is recommended to improve consciousness and cognitive function in patients with traumatic brain injury.

Introduction

Traumatic brain injury (TBI) is regarded as a major health problem in the world; it is also known as "a silent epidemic" due to its high prevalence (1). It is reported that about 69 million people (including 5 million Americans) suffer from TBI around the globe each year. TBI has led to more than 235,000 people hospitalized in the intensive care unit (ICU) and more than 52,000 deaths yearly (2). Trauma is considered the second leading cause of death among people under forty in

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Iran, where road traffic injury (RTI) leads to 685611 cases of injury each year (3).

Although the mortality rate of patients with TBI has decreased due to advances in diagnostic, medical treatment, and rehabilitation (4), there is an increase in the number of patients with longer duration of coma. It is reported that about 221 billion dollars are spent annually to provide the necessary care for such patients in the United States (5). Besides, coma is regarded as an adverse consequence of TBI. Coma refers to a long-term unconscious state where the patient is unable to wake up and respond to painful stimuli as well as light and noise and experiences motion and cognition functional disorder. The patient will face life-threatening conditions, including respiratory failure, pneumonia, pressure ulcer, and airway aspiration, with any increase in the duration of coma (6). Furthermore, TBI patients admitted to ICU due to coma are prone to other complications, such as sensory deprivation or sensory overload (7).

Different factors such as ambient noise, excessive light, lack of a familiar face at the patient's bedside, as well as perceptual, cognitive, and emotional disorders can lead to those problems (8). Despite the extensive demand to improve coma arousal after TBI, no standards have been established to direct the rehabilitation treatments (9). Accordingly, improving awareness and cognitive conditions are among the significant challenges of the health care system. Medicine interventions, multimodal sensory stimulation, magnetic stimulation through the skull, deep brain stimulation, and hyperbaric oxygen therapy have facilitated patients' recovery (10,11). Recently, complementary medicine (CM) has been popular in managing consciousness disturbance caused by TBI and is increasingly employed by the healthcare system (12). CM is based on the idea that enhancing the environment and sensory stimulation (SS) can help increase brain flexibility. It can help improve the patient's level of consciousness (LOC) (13). It is noteworthy that providing familiar sensory stimuli to the patient is regarded as an example of complementary medicine (7).

SS is a non-invasive, safe, inexpensive, and direct rehabilitation approach widely examined among patients with consciousness disturbance (11). The SS program can facilitate recovery and prevent sensory deprivation by exposure to specific sensory stimulation control (14). SS includes visual, auditory, tactile, olfactory, taste, and balanced stimulation, which can be performed in a unidimensional or multidimensional (stimulation of several senses in patients) manner (15). The stimulation of the auditory sense is considered a unidimensional stimulation. Besides, hearing is the last sensation that disappears in a comatose patient, and there is no barrier to using it (16).

Implementing auditory stimuli, such as music, is one of the methods of sensory stimulation for hearing (16). The use of music after a neural injury can facilitate necessary changes to improve the sensory process and cognitive functions (7). Music is considered a tool to enhance perception and diagnosis in patients with low consciousness levels (17). It is believed that mind responsiveness is more likely to improve by comparing a variety of pleasant auditory stimuli, familiar stimuli, and neutral stimuli for patients in coma. There is a gap in existing studies concerning the implementation of the same pleasant auditory stimulus for all patients, which includes music, the patient's name (18), and the recitation of the Qur'an (10). Researchers have sought to cover this gap, which has plagued the findings of previous studies. Therefore, pleasant auditory stimuli, such as mild music and the voice of a family member, will be employed in the present study.

Numerous studies have also examined the positive effects of auditory sensory stimulation (ASS) on LOC, executive function, anxiety, and mood disorders (19-21).

Nevertheless, some other studies have concluded that sensory stimuli using music therapy did not have any significant impacts on cognitive functioning and LOC (22). Similarly, the findings of the latest systematic review study have shown that although music therapy interventions have led to a relative improvement in the LOC, it is necessary to conduct studies with greater caution and a larger sample size to investigate the effects of music therapy (16). However, this study was conducted to investigate the effectiveness ASS on LOC and Cognitive Function in TBI.

Methods

Study design

This study is a parallel triple-blind randomized controlled clinical trial.

Participants

The study population includes all the TBI patients admitted to the Shahid Kamyab Hospital ICU in Mashhad, Iran, from September until December 2018. Inclusion criteria consist of: age between 14-60 years, no more than three days of hospital stay, TBI approved by a neurologist and GCS score between 6 and 12, stable electrolyte and hemodynamic status (systolic blood pressure, heart rate, respiration rate, and body temperature), no hearing impairment, no record of skull fracture and bleeding or temporal lobe surgery (based on CT SCAN report) and no history of temporal lobe injury or surgery. If the patient's family members or legal representatives were reluctant to participate or, in case of severe changes (recurrent bleeding or the need for emergency surgery) and instability of vital signs (bleeding or moving to other medical centers), they would be excluded.

According to the findings of a similar study, the appropriate sample size was measured, given the 95% confidence level and 80% power. For this purpose, the effect size was determined at 0.7 based on the GCS score; thus, it was estimated that a sample size of 26 patients is optimal for each group. Meanwhile, the researchers considered a 15% increase in participants due to the attrition rate. In the end, it was decided to include 30 patients in each group to obtain a greater confidence level.

A consecutive sampling approach was used to select the patients based on the inclusion and exclusion criteria, and they were randomly and equally allocated to the control and intervention groups. For this purpose, the randomization procedure was adopted from http://www.randomizer.org and applied to 60 participants. Then, sixty cards were designed so that each card was labeled either A or B to represent the control or intervention group, and were kept in an envelope for confidential issue.

Instruments

The data were collected using a demographic information questionnaire, GCS, and the Rancho Los Amigos Scale (RLAS).

Demographic information

The patients' demographic information in the present study included age, sex, marital status, education, and employment status. The clinical status of the patients was measured based on the duration of coma, LOC and cognitive function, hypertension, diabetes, and hyperlipidemia. The required information was collected through interviews with the patient's family members or based on their clinical background. Moreover, all the questionnaires were completed and measured by the researcher who was in charge of data collection.

Glasgow coma scale

One of the LOC's most common and most accurate measures is the GCS, particularly among patients with TBI. GCS score ranges between 3 and 15. It measures eye-opening (1–4), motor activity (1–6), and verbalization (1–5). Regarding reliability and

validity, it enjoys inter-rater reliability of r=0.95 and internal consistency of α=0.82, which are considered acceptable values (23). GCS sensitivity and specificity were also reported as acceptable at 72% and 73%, respectively (24).

RLAS

RLAS was developed by Hagen et al. in 1972 and translated into Thai by Chaiwang and Sukonthasarn in 2006 (25) and is a 10-level scale. It is used to evaluate brain injury's behavioral and cognitive patterns. The scale represents the progression of recovery of cognitive structure as demonstrated through behavioral change. The RLA score is recommended to determine the level of function within commonly and randomly fluctuating environments and within a structured setting where environmental stimuli are purposefully manipulated. Scores of responses range from 1-10, with 1 indicating no response (total assistance) and ten purposeful and appropriate responses (modified independent) of cognitive function, where higher scores indicate more efficient cognitive functions (26). The reliability of the RLA scale was assessed by McCauley et al., and a Kappa coefficient of 0.92 was reported. The reliability of the Persian version of this questionnaire was calculated by Sargolzaei et al. using the inter-raters method on ten patients. Then, the obtained reliability coefficient was 0.86 (23).

Interventions

The study intervention was ASS through familiar voices and music. Accordingly, in the intervention group, the researcher initially talked to the patients' families in order to determine the patients' favorite family members. Then, the study's objective and importance were described to the families, and they were asked to cooperate with the researcher in developing the required content based on the oral and written instructions regarding the content and length of the audio files (ten-minute voice message). The audio files should include two parts: first, the selected family member should introduce himself/herself, clarify the time and place, and briefly describe what happened to the patient (six minutes). In the second part, which lasted four minutes, they were asked to recall and talk about positive memories, such as pleasant family gatherings or trips.

Finally, they were asked to state positive and encouraging comments about the patient's recovery, the patient's return to home, as well as some plans for the patient. This message was recorded, using a voice recorder, in the visitation room of the ICU in the first 24 hours after recruitment to the study. The audio files were then reviewed and approved by three university faculty members. The audio files were mixed with soft instrumental music (a mild and relaxing soundtrack by Arnd Stein about the sounds of birds and ocean waves) for 5 min. After developing the content and receiving approval for the stability of the patient's hemodynamic status, the hearing stimulation began with the audio files. The patient would listen to the audio file using headphones. The intervention would continue for six consecutive days and twice a day. Each auditory stimulation session would take 15 minutes, and there would be a minimum of a 30-minute interval between the two music therapy sessions each day.

In order to maintain the blinding process on the assessor, the patients in the control group also listened to an audio file that only included the familiar sounds of the ICU. The audio files played on a headphone with the same duration. In the end, all the patients' GCS and RLA scores were measured and recorded after each round of intervention. Moreover, the mean score of both sessions on each day was reported for statistical analysis.

Blinding

The study is triple-blind. In other words, the researcher who was collecting the data was unaware of the allocation of patients into the two groups, the patients did not know whether they were assigned to the intervention or control group, and the statisticians were unaware of the allocation procedure.

Ethical considerations

The patient's family members were asked to deliver their written consent for participation in the present study. In addition, adherence to the required ethical considerations was approved by the Ethics Committee of the Mashhad University of Medical Sciences, Iran, on July 3rd, 2018 (no. IR.MUMS.NURSE.REC.1397.016); the interventions were also acknowledged as a clinical trial study (no. IRCT20180602039947N1). At first, the necessary explanations regarding the purpose of the study and the confidentiality of the information were provided to the participants. And then, they would freely choose to participate in the study and were also granted the opportunity to leave the study at their will.

Data analysis

The data were analyzed using SPSS v.22. The patients' demographic information and clinical information at the baseline were compared between the two groups using Fisher's exact test, Chi-square, and Independent Sample t-test. In addition, Kolmogorov–Smirnov test, Kurtosis, and Skewness were employed to evaluate the normal distribution of the data. The two-way repeated-measures ANOVA was used to evaluate the effects of ASS on cognitive function and LOC over six consecutive days. The level of significance was considered as $p<0.05$.

Result

Notably, two patients were excluded from the intervention group (one died, and another was sent to another medical center). Two patients were excluded from the control group (both died). In the end, 28 patients remained in each group (Diagram 1).

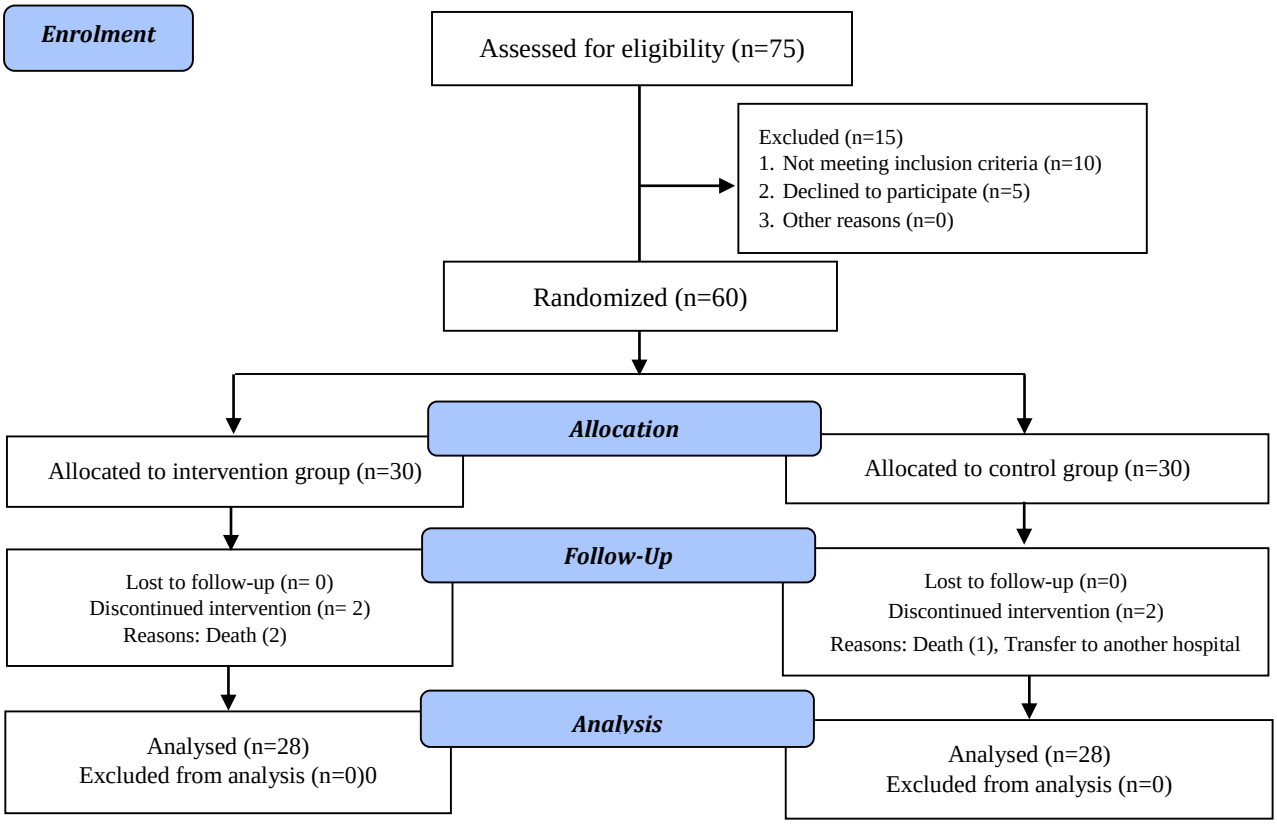

Diagram 1. CONSORT flow diagram

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

Socio-demographic variables		Intervention group n (%)	Control group n (%)	P-value
Gender	Male	18(64.3)	23(82.1)	0.131[a]
	Female	10(35.7)	5(17.9)	
Marital status	Single	6(21.4)	8(28.6)	0.179[a]
	Married	22(78.6)	17(60.7)	
	Widow	0(0)	3(10.7)	
Age group (year)	Mean(SE)	42.46(2.42)	40.32(2.75)	0.311[d]
Education level	Elementary	6(21.4)	5(17.9)	0.917[b]
	Secondary	3(10.7)	5(17.9)	
	Diploma	13(46.4)	11(39.3)	
	University	6(21.4)	7(25)	
Employment status	Employee	10(35.7)	6(21.4)	0.202[a]
	unemployed	3(10.7)	2(7.1)	
	Retire	6(21.4)	3(10.7)	
	Other	9(32.1)	17(60.7)	
Coma duration	One day	18(64.3)	17(60.7)	0.783[a]
	Two days	10(35.7)	11(39.3)	
Diabetes		3(10.7)	2(7.1)	>0.90[a]
Hypertension		10(35.7)	8(28.6)	0.567[a]
Hyperlipidemia		6(21.4)	4(14.3)	0.729[c]
Levels of consciousness*	Mean(SE)	7.4(1)	7.2(1.1)	0.516[b]
Levels of cognitive**	Mean(SE)	3.6(0.15)	3.53(0.14)	0.743[b]

[a] Chi-square, [b] Mann–Whitney, [C] Fisher's exact test, [d] Independent samples test

*Levels of consciousness measured with the Glasgow Coma Scale

**Levels of cognitive measure with Rancho Los Amigos

The demographic information and clinical characteristics of the participants in both groups, including age, marital status, sex, level of education, employment status, duration of coma, diabetes, hypertension, and hyperlipidemia, are shown in Table 1. The results of the statistical tests showed that, at the beginning of the study, there was no statistically significant difference between the participants in the intervention and control groups in terms of these variables.

Glasgow coma scale

According to the independent t-test, the mean and standard error scores of the intervention and control groups were 7.35(0.17) and 7.21(0.2) at the baseline, respectively. Hence, there were no statistically significant differences between the two groups in terms of GCS before the intervention (P> 0.05). Given that the group-time interaction effect was significant in two-way repeated-measures ANOVA, we employed independent samples t-test with Bonferroni correction. In this way, the level of significance was considered at 0.008. According to the findings of the independent samples t-test, there was a significant increase in the level of consciousness on the third, fifth, and sixth days after the intervention among the patients in the intervention group compared to the control group (P=0.001). (Table 2).

Cognitive function

The results of the independent t-test revealed that the mean and standard error scores of the intervention and control groups were measured at 3.6 (0.15) and 3.53(0.14) at the baseline, respectively. Hence, there were no statistically significant differences between the two groups in terms of RLAS before the intervention (P> 0.05). The results of the repeated measure analysis of variance indicated that the cognitive function significantly increased in the intervention group compared to the control group

(P=0.003). In addition, the partial eta-squared was calculated at 0.15 for cognitive function, indicating the intervention's significant medium effect (Table 2).

As demonstrated in figures 1 and 2, the GCS and cognitive function increased from the third day in the intervention group compared to the control group.

Table 2. Rancho Los Amigos and Glasgow Coma Scale in intervention and control groups

Outcome	Rancho Los Amigos			Glasgow Coma Scale		
	Intervention Mean(SE)	Control Mean(SE)	P-value	Intervention Mean(SE)	Control Mean(SE)	P-value
Baseline	3.6(0.15)	3.53(0.14)	0.743[a]	7.35(0.17)	7.21(0.2)	0.605[a]
Day 1	3.63(0.16)	3.51(0.14)		7.4(0.17)	7.19(0.2)	0.607 [a]
Day 2	3.8(0.16)	3.66(0.13)		7.44(0.17)	7.42(0.18)	0.605 [a]
Day 3	4.42(0.13)	3.58(0.11)	P=0.003[b]	8.37(0.19)	7.35(0.2)	0.001 [a]
Day 4	4.5(0.14)	4.12(0.14)	η_p^2=0.15[c]	8.66(0.18)	7.94(0.23)	0.022 [a]
Day 5	5.14(0.15)	4.32(0.12)		9.55(0.19)	8.5(0.14)	0.001 [a]
Day 6	5.46(0.11)	4.39(0.12)		10.25(0.18)	8.51(0.15)	0.001 [a]

[a] Independent samples test, [b] repeated measure of variance, [c] η_p^2=partial eta-squared

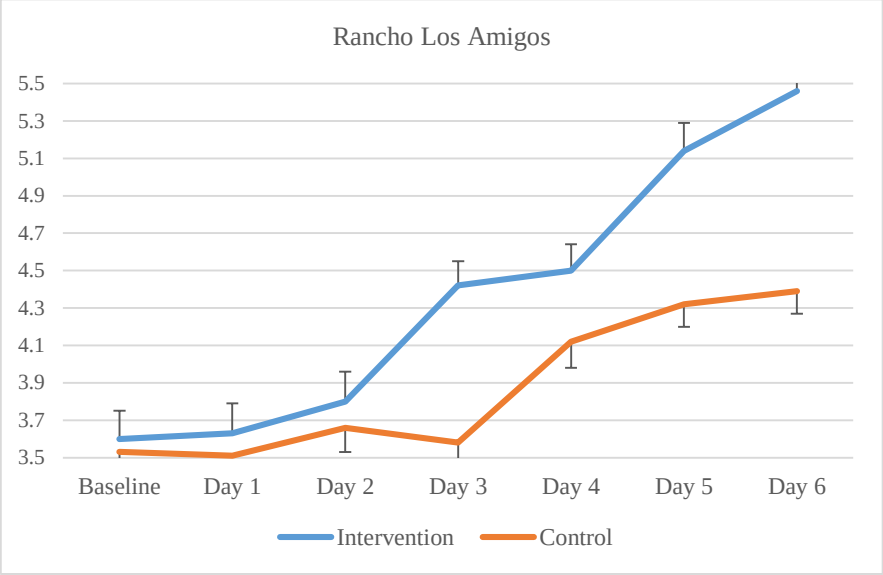

Figure 1. The Mean of Rancho Los Amigos depends on the day

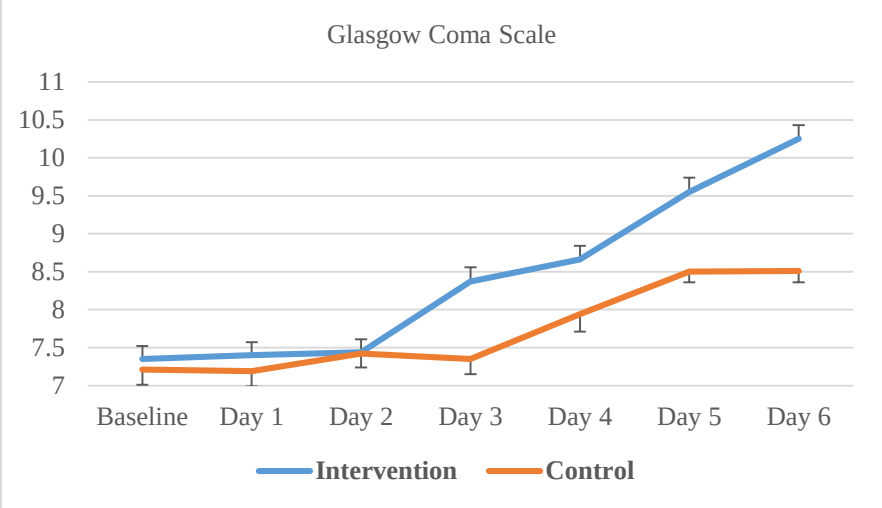

Figure 2. The mean of the Glasgow Coma Scale depends on the day

Discussion

Although there was no statistically significant difference between the two groups regarding GCS and cognitive function at the onset, these scores meaningfully increased in the intervention group starting on the third day. Accordingly, it can be concluded that ASS with the voice of family members and its integration with music might improve the patients' consciousness and cognitive function.

The findings of our research are consistent with some previous studies. For instance, a study by Mohammadi et al. (2019) showed that auditory stimulation with the voice of a family member has significantly increased the Glasgow coma scores in patients (20). Both studies have investigated the use of ASS with the voice of a family member. However, the duration of the intervention (the first three days of admission of the patient), the GCS of below 8, and the type of intervention (ASS with the voice of a family member only once a day) were different between the two studies. They reported that the LOC during the three days of intervention significantly increased in the intervention group, which is consistent with the present study's findings. Therefore, it can be concluded that the LOC in the two groups has changed due to the time factor, i.e., the treatments received by the patients. In addition, both groups showed a moderate improvement. However, in Mohammadi's study (2019), no significant difference was observed between the two groups, except for intragroup differences (20). In the present study, otherwise, the significant difference in the LOC between the two groups of intervention and control could be due to the effect of research intervention, i.e., applying a music therapy program integrated with recollection by a family member and longer intervention time (6 days).

In 2016, Moattari et al. conducted a study to examine the effect of sensory stimulation programs by the nurses and the patient's families on the LOC and cognitive function in comatose patients with brain trauma. For this purpose, they employed auditory, visual, olfactory, and tactile stimulation both in the morning and then in the evening for seven days. The results showed that the provision of stimulation by the families could lead to a significant increase in the LOC and cognitive function among the patients in the intervention group compared to the control group (26). Although different sensory stimuli were used in their study, these results are in line with the present study's findings.

The findings of our study are consistent with the findings of another study conducted by Park et al. (2016). This cross-sectional clinical trial study used direct and indirect ASS in order to improve the LOC. The results showed that ASS could lead to a significant increase in the LOC in both groups. In addition, it was claimed that short-term music therapy sessions (15 minutes) are more desirable (14).

The results showed that consciousness and cognitive function increased significantly, especially from the third day after the intervention. Moreover, the results of another study by Hoseinzadeh et al. in 2017 showed that the LOC increased significantly after the second day (27). Another study also indicated that significant changes in the LOC could emerge from the fifth day after Multimodal Sensory Stimulation (28). Based on these results, it can be concluded that the ASS by familiar sounds can effectively improve the LOC within the early days of coma.

In line with the present study, Davis and Gimans found that ASS could improve cognitive function in TBI patients in a coma. The researchers used AS programs for patients with auditory stimuli such as familiar sounds and the patient's favorite music. They observed that patients' cognitive function significantly increased based on the RLA score (16). Their study is in line with the

present study as both studies have implemented an auditory stimulation program. The differences, however, lie in the onset of stimulation which was after three days of hospitalization, the sample size which is lower (12 male patients), and the GCS value which is fewer than 8. On the other hand, the results of their research are consistent with the results of the present study in terms of the effect of auditory stimulation on RLA scores.

Contrary to the results of the present study, Çevik et al. (2018) reported no significant change in GCS scores three days after auditory stimulation in Comatose Patients in ICU. This is probably because the study population consisted of elderly patients who were in deep coma, which has led to insignificant results. Meanwhile, male nurses performed relatively short-run auditory stimulation interventions (29).

It can be concluded from the results of the present study that the implementation of a music therapy program integrated with the voice of a family member has led to the improvement of the scores of consciousness and cognitive function among patients with TBI because of the daily increased in the average scores of consciousness level and cognitive function during six days of intervention for the patients in the intervention group. In addition, comparing the findings of the present study with the findings of other studies that have used familiar and unfamiliar auditory stimuli or other sensory stimuli has shown that the interventions in the present study were more effective on patients.

It is suggested that a similar study be conducted in the future, focusing on patients with non-traumatic brain injuries such as stroke and poisoning. These studies should also investigate children and infants as well as adults.

The fact that the study is triple-blind, examining patients on consecutive days and using headphones to play the familiar voices of the ward in the control group can indicate the strengths of the present study. Nevertheless, there were some limitations while conducting this study, including the fact that it was difficult for the patient's family members to decide over participating in the study at the beginning due to concerns about their patient's condition. In addition, the patients' contextual conditions (e.g., environmental stimuli and the extent of sensory input) before the injury influenced their responsiveness to auditory stimuli as well as their sensory stimulation threshold, which is regarded as a unique characteristic, was also out of control for the researchers.

Conclusion

According to the results of this study, music therapy programs integrated with recollection can positively affect the LOC and cognitive function of TBI patients. Therefore, medical personnel can perceive the usefulness and importance of auditory stimulation for patients with reduced consciousness, design a similar program for such patients, or even use simple verbal communication while caring for the patient. It is also suggested to plan purposeful visits for family members of the patients in the intensive care unit in order to provide familiar sensory stimuli, primarily through recollection by their family members.

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Conflict of interest

All of the authors of this manuscript have no conflict of interest to declare.

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