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Investigating the effect of implementing a sensory stimulation program by family members on delirium status of brain injury patients hospitalized in the intensive care unit: A randomized clinical trial

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Abstract:

BACKGROUND: Delirium is the most common psychological disorder in brain injury patients hospitalized in the intensive care unit (ICU), one of the leading causes of which can be sensory deprivation or sensory overload. This study aimed to determine the effect of implementing a sensory stimulation program by family members on the delirium status of ICU-hospitalized brain injury patients.

MATERIALS AND METHODS: In this randomized controlled clinical trial, 66 brain injury patients hospitalized in the ICUs were assigned to intervention and control groups using stratified random sampling. For the intervention group, a sensory stimulation program was implemented by family members for 1 h a day during the ICU stay. The control group received routine care. Patients' delirium status was assessed daily using the confusion assessment method for the intensive care unit (CAM-ICU). Data were analyzed by the SPSS software version 22, using Chi-square, independent *t*-test, and Binary logistic regression model tests, at a significance level of 0.05.

RESULTS: Odds of delirium Incidence in the intervention group was 94% lower than in the control group (OR = 0.057, 95% CI 0.017, 0.19, P = 0.001). There is a significant difference between the two groups in terms of length of delirium (P = 0.001), stay in ICU (P = 0.001) and mechanical ventilation (P = 0.001). The mean of all three variables in the intervention group was lower than the control group.

CONCLUSIONS: Implementing of sensory stimulation program by the family members, as a non-pharmacological method, can reduce the incidence of delirium in brain injury patients admitted to ICU.

Keywords:

Brain Injury patients, delirium, family members, intensive care unit, sensory stimulation program

Introduction

Delirium, a syndrome characterized by an acute change in attention, awareness and cognition, is caused by a medical condition that cannot be better explained by a pre-existing neurocognitive disorder.[1] This cognitive disorder is a prevalent issue in intensive care unit (ICU), affecting up to one-third of critically ill patients,[2] so that its incidence rate in ventilator -dependent patients is 80.6%.[3] Delirium is associated with

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negative outcomes such as longer length of stay in ICU and higher mortality rates.[2,3]

In addition, delirium incidence during ICU stay causes many complications, such as cognitive dysfunction, functional disability, and reduced patients' quality of life after discharge from the hospital.[4] However, two-thirds of delirium attacks are unfortunately ignored in the ICU.[5] Delirium is a widespread problem with a complex etiology in the ICU, but one of its most common causes can be sensory deprivation or sensory overload.[2,3]

The rate of sensory deprivation or overload in ICU hospitalized patients, especially patients with brain injury, is higher than patients in other wards of the hospital,[6] for various reasons such as damage to the brain structure and function, the ward isolated and unfamiliar environment, failure to receive appropriate and balanced sensory stimulation for the five primary senses, overdose of sedatives, excessive and meaningless sensory stimulation such as excessive staff noise and devices in the ward along with abundant painful, invasive procedures, and sleep disturbance.[7] Experts and researchers believe that the rapid, accurate, and scientific care delivery and primary treatments for brain injury patients in the emergency room and ICU will help accelerate the recovery process and prevent permanent mental and physical complications and disabilities in these patients.[8] One of these cares, which is among the vital nursing cares for these patients in the ICU, is the prevention of delirium and its leading causes such as sensory deprivation and overload.[9]

Many medications are used in the ICU to prevent and treat delirium, but these medications themselves can have many complications that affect different systems in the body. Therefore, today the emphasis is on using various non-pharmacological methods and interventions alone or in combination with pharmacological methods for more effectiveness in preventing delirium in ICU-hospitalized patients. One of these interventions can be reducing and eliminating the delirium risk factors, such as sensory deprivation and overload.[10] The results of many studies indicate the positive effect of implementing balanced sensory stimulation on ICU patients, especially the consciousness state of brain injury patients.[11-14] In fact, using a balanced sensory stimulation program as a non-pharmacological method can improve the rate and degree of recovery from coma and possibly synaptic innervation by providing environmental inputs for all five senses at the same frequency, intensity, and length.[12]

In this regard, the results of a systematic review study by Li *et al*. (2020)[13] showed that implementing a balanced sensory stimulation led to an increased level of consciousness and arousal in ICU-hospitalized brain injury patients. In this study, researchers suggested the investigation of other substantial consequences in addition to the consciousness state, such as delirium. On the other hand, the results of many studies have shown that if sensory stimulation is implemented by individuals close to the patient, such as family members, it has better consequences for the patient.[15-20] For example, Adinehvand *et al*. (2013)[15] concluded in their study that ICU-hospitalized brain injury patients receiving sensory stimulation from family members had better consequences in terms of an increased level of consciousness and hemodynamic stability than the group receiving it from nurses. The results of Eghbali-Babadi *et al*.'s.[21] study also showed that visiting family members led to a reduced delirium incidence in patients hospitalized in the cardiac surgery ICU. However, to date, the effect of the codified implementation of a sensory stimulation program on other consequences of ICU-hospitalized brain injury patients (such as delirium status) has been less studied.

Therefore, considering the materials mentioned above and the importance of the prevention of delirium in ICU-hospitalized brain injury patients and also the need for further studies in this field, the present study was conducted aiming to determine the effect of implementing a sensory stimulation program by family members on the delirium status of ICU-hospitalized brain injury patients in 2021.

Materials and Methods

Study design and setting

This single-blind randomized controlled clinical trial was performed from June 2021 to December 2021; aimed at Investigating the Effect of Implementing a Sensory Stimulation Program by Family Members on Delirium Status of Brain Injury Patients Hospitalized in the ICUs, in Golestan hospital affiliated to Ahvaz Jundishapur University of Medical Sciences, Iran.

Study participants and sampling

In this study using convenience sampling method 66 individuals were selected from among patients who had the study inclusion criteria and then would be allocated randomly in two groups of intervention (n = 33) and control (n = 33) by using Stratified random sampling method. In this way, first, categories were created based on age group with an interval of 10 years (18-27, 28-37, 38-47, 48-57 and 58-67 years) and then in each category, a random sequence would be created by using a table of random numbers.

P1 (incidence of delirium in intervention group) and P2 (incidence of delirium in control group) in a

pilot study respectively were estimated 0.15 and 0.5. Therefore, according to confidence level of 95% and test potency of 80%, the estimated sample size was 27 people in each group. Considering the possible sample loss and to increase accuracy, final sample size (With a 20% increase) was determined 33 people per each group.

Patients eligible were those diagnosed with acute brain injury, obtaining a Glasgow coma score (GCS) between 6 and 12 on admission, receiving similar medications to prevent delirium, being intubated and under ventilator, receiving no prescribed neuromuscular blocking agents, being aged between 18–67 years, having pupillary reflexes, and having no history of alcohol and substance abuse and absence of delirium before study. Family members eligible were those be a main member of the family (father, mother, sister, brother, child) and over 18 years old. Moreover, patients were excluded from the study if they were transferred to other hospitals during the study, entered persistent vegetative state, had hemodynamic instability or were on continuous administration of neuromuscular blocking agents during the study and that unwillingness of their family to continue participating in the study.

Intervention

In this study, patients in the intervention group received sensory stimulation program by a family member (father, mother, sister, brother, or child) for 1 hour per day, from 4 to 5 pm during their ICU stay. This family member could not be replaced during the study. The sensory stimulation program was taught to the family members before the intervention by the researcher, and they were asked to perform it strictly based on this program. They were regularly checked in this regard by the researcher during the study. The control group received ward routine care. In routine care scenario, patients do not receive any specific sensory stimulation program to stimulate all their senses, and the ICU patients' families are usually allowed to visit their patients sporadically only for a short and limited time.

The sensory stimulation program used in this study was developed by the researchers based on the review of sources and studies conducted in this field.[15,18,19,22-24] This program was performed as follows: First, consciousness stimulation was performed by saying the patient's name as well as the time and place near the patient's ear thrice per hour. Then, the patient's favorite music or family members' voices were played for 10 minutes for auditory stimulation. Next, for visual stimulation, family photos, videos, and beautiful pictures of interest were kept in front of the patient's eyes for 10 minutes. Then, aromatic stimuli and aromas to which the patient was more habituated were given for 10 seconds before the patient's nose for olfactory stimulation. In the next stage, tactile stimulation was performed once an hour by hand pressure, massage, and rubbing of the limb skin, first on one side of the body and then on the other side. Motor stimulation was performed in the last stage by moving the joints of the limbs, wrists, hips and shoulders in the normal range of motion by flexion and extension and alternatively moving the arms and legs up and down, 15 times per hour for each limb.

Data collection tool

The study was done single blindly and patients did not know the nature of their group at the time of the study. The person who collected outcome data also was blinded to group assignment. The primary outcome of this study includes Patients delirium status (Incidence rate, length, and type), and secondary outcomes include Length of mechanical ventilation, ICU death rate and length of stay in the ICU.

A two-part form was used to collect data. The first part of this form was a 12-item questionnaire on the demographic and baseline characteristic of patients and their families (E.g., age, gender, diagnosis, initial GCS, APACHE and SOFA scores) which was completed by reviewing the patient's record and questions from the family and the nurse in charge of the patient. The second part of the data collection form consisted of a checklist containing information about the patient's clinical consequences, such as delirium incidence and its type, delirium length, ICU stay length, mechanical ventilation length, and ICU mortality were checked and recorded.

The patient's delirium type and status were assessed daily using the confusion assessment method for the intensive care unit (CAM-ICU) instrument during the patient's stay in the ICU. In this scale, the patient's level of consciousness is first checked in the last 24 hours. If there is fluctuation in the level of consciousness (averagely, a decrease of less than one score), the patient's sedation-agitation score is measured using the Richmond agitation-sedation scale (RASS). If the obtained score is zero, the patient does not have delirium, but if it is a score other than zero, the patient has delirium. If the RASS value is + 1 or higher, the delirium will be of the hyperactive type, and if it is -1 or less, the delirium will be of the hypoactive type.[25]

The CAM-ICU scale is a standard and widely used instrument globally,[26,27] and also proposed by the Ministry of Health of Iran to assess delirium in ICU-hospitalized patients.[28] In 2019, Arbabi *et al*.[29] showed that this scale had a sensitivity and specificity of 75% and 96%, and a positive and negative predictive value of 92% and 85%, respectively, and a kappa coefficient equal to 0.74. In the present study in a pilot study, 10 brain injury patients hospitalized in ICU

selected and screened for delirium by two independent evaluators (applying CAM-ICU). Inter-rater reliability between the two evaluators was assessed by the Kappa coefficient. There was good agreement between the two evaluators in terms of delirium diagnosis with the Persian-CAM-ICU (kappa coefficient = 0.76, $P < 0.001$).

Statistical analysis

In this study, descriptive and analytical statistical analysis methods were used in SPSS software (version 22, SPSS Inc., Chicago, IL). Quantitative variables were reported as mean, standard deviation, and minimum and maximum, and qualitative variables were reported as frequency (percentage). The normality of quantitative variables was assessed using the Shapiro–Wilk test. Independent *t*-test, Binary logistic regression model (for estimating the Odds ratio in dependent dichotomous variable), independent samples *t*-test (To compare the mean of continuous variables in two group) and Chi-square test (To compare nonparametric variables in two group) were used to data analysis. The statistical significance level was considered to be 0.05.

Results

In the current study, a total of 66 brain injury patient were assessed. The sampling details were explained in consort flow diagram [Figure 1].

In this study, the mean age of participants was 36.18 ± 13.92 in the intervention group and 37.21 ± 13.98 in the control group and the mean Initial GCS of participants was 6.93 ± 0.7881 in the intervention group and 6.93 ± 0.74 in the control group. The mean APACHE IV score (Acute Physiology and Chronic Health Evaluation version IV) of participants was 43.09 ± 2.69 in the intervention group and 42.75 ± 2.53 in the control group. The mean SOFA score (Sequential Organ Failure Assessment) of participants also was 9.21 ± 1.34 in the intervention group and 9.09 ± 1.07 in the control group. In the present study, 49 (74.2%) participants were male and 17 (25.8%) females. In terms of hospitalization diagnosis, most cases included 18 people (27.3%) Intra Cerebral Hemorrhages (ICHs), 15 people (22.7%) Subdural Hematomas (SDHs), and 15 people (22.7%) Diffuse Axonal Injuries (DAIs). In terms of the cause of brain injury, most cases (44 people = 66.7%) were accidents [Table 1].

In terms of the person who performed the sensory stimulation program for the patient in the intervention group, 10 (15.2%) were fathers, 2 (3%) were mothers, 7 (10.6%) were brothers, 3 (4.5%) were sisters, 7 (10.6%) were children, and 4 (6.1%) were spouses of the patients. The mean age of them was 48.12 ± 8.21 and 22 (66.66%) of them were male 11 (33.34%) female.

The results of comparison the delirium incidence, delirium type, and ICU death rate in the intervention and control groups are presented in Table 2. The results of binary logistic regression model showed; the odds of incidence of delirium in the intervention group was 94% lower than in the control group (OR = 0.057, 95% CI 0.017, 0.19, $P = 0.001$). But the results of this model showed there was no evidence of a statistically significant difference between the two groups in terms of delirium type (OR = 0.55, 95% CI 0.11, 2.71, $P = 0.468$), in 61.1% of cases, delirium was of hyperactive type.

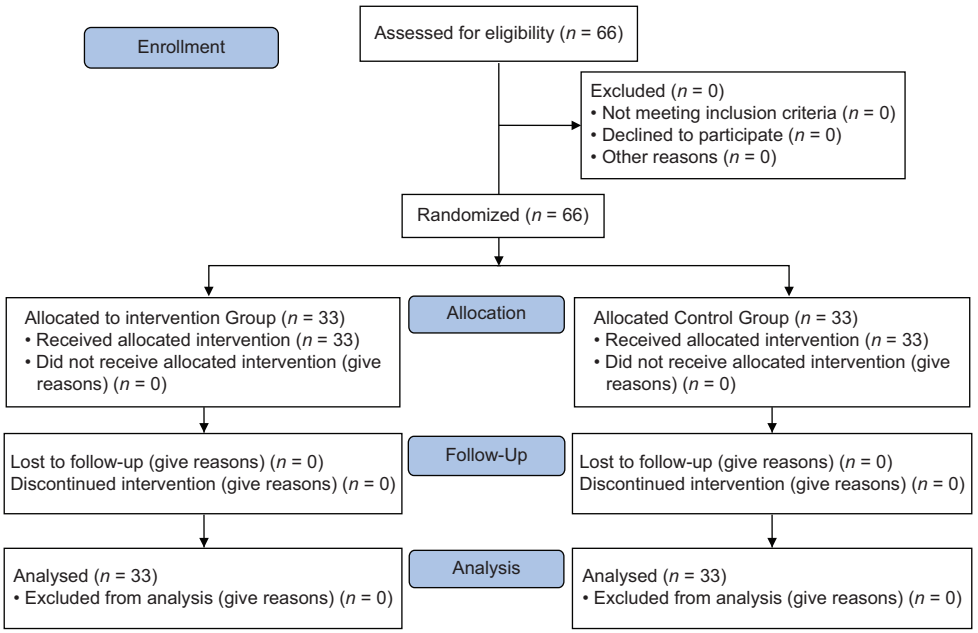

Figure 1: The consort flow diagram of patients participating in the study

Table 1: Demographic characteristics of the ICU patients of this study (*n*=66)

Variable	Group		Total	*P*
	Intervention (*n*=33)	Control (*n*=33)		
Age Mean (SD)	36.18 (13.92)	37.21 (13.98)	36.69 (13.85)	0.765
Initial GCS Mean (SD)	6.93 (0.78)	6.93 (0.74)	6.93 (0.76)	0.961
APACHE IV score Mean (SD)	43.09 (2.69)	42.75 (2.53)	42.92 (2.61)	0.607
SOFA score Mean±SD	9.21 (1.34)	9.09 (1.07)	9.15 (1.20)	0.686
Diagnosis *n* (%)				
EDH	3 (4.5)	4 (6.1)	7 (10.6)	0.604
SDH	7 (10.6)	8 (12.1)	15 (22.7)	
ICH	7 (10.6)	11 (16.7)	18 (27.3)	
IVH	4 (6.1)	2 (3)	6 (9.1)	
SAH	4 (6.1)	1 (1.5)	5 (7.6)	
DAI	8 (12.1)	7 (10.6)	15 (22.7)	
Cause of Brain Injury *n* (%)				
Accident	20 (30.3)	24 (36.4)	44 (66.7)	0.527
Fall	4 (6.1)	2 (3)	6 (9.1)	
Internal problems	9 (13.6)	7 (10.6%)	16 (24.2)	
Gender *n* (%)				
Male	26 (39.4)	23 (34.8)	49 (74.2)	0.398
Female	7 (10.6)	10 (15.2)	17 (25.8)	

SD: standard deviation, EDH: Epidural Hematoma, ICH: Intracerebral hemorrhage, SAH: Subarachnoid Hemorrhage, ICU: Intensive Care Unit, SDH: Subdural Hematoma, IVH: Intraventricular Hemorrhage, DAI: Diffuse axonal injury, APACHE IV: Acute Physiology and Chronic Health Evaluation IV, SOFA: Sequential Organ Failure Assessment

Also, there was no evidence of a statistically significant difference between the two groups in terms of ICU death rate (OR = 0.80, 95% CI 0.21, 2.94, $P = 0.741$).

The results of comparison of the length of delirium, length of ICU stay, and mechanical ventilation length in the intervention and control groups are presented in Table 3. According to the results of the independent *t*-test, there was a significant difference between the two groups in terms of the length of delirium at the time of ICU stay ($P = 0.001$). There was also a significant difference between the two groups in terms of ICU stay ($P = 0.001$) and mechanical ventilation length ($P = 0.001$). In all three variables, the mean of the intervention group was lower than the control group.

Discussion

The present study results showed that delirium incidence and length in the intervention group, who received the sensory stimulation program by family members during ICU stay, were less than the control group. This result is consistent with the results of Rosa *et al*. (2017),[30] Álvarez *et al.* (2017),[31] Junior *et al*. (2018),[32] and Eghbali-Babadi *et al*. (2017) studies.[21]

Various mechanisms can explain this positive result. If the central nervous system deprived of balanced sensory stimuli (which is very common in ICU patients), human behavior will lose its integrity. This can lead to Cognitive dysfunction and related complications such as impaired consciousness.[33,34] In fact, long and frequent visits between patients and their families and implementing the sensory stimulation program by the family can provide an environment rich in balanced sensory stimuli for ICU patients to improve and recover nerve function and prevent cognitive impairments such as delirium. Of course, in the present study the odds of delirium incidence in the intervention group are 94% lower than the control group, but in the mentioned studies, this amount is different. For example, in the Rosa *et al*.[30] study the relative risk of delirium incidence in intervention group that receive extended ICU visitation model is 50% lower than the control group. There can be many reasons for this, for example; different diagnosis and mean age of patients under study, different sample size and study type, amount of delirium incidence in the whole study population, Type of statistical analysis, but one of the reasons can also be the type and method of intervention. The sensory stimulation program was used for all five patients' senses during the visits in this study. However, the mentioned studies do not mention a systematic program to stimulate all five patients' senses.

The present study results showed that most delirium cases were of the hyperactive type. Although in many studies on this topic, the type of delirium has not been studied.[10,21,30,31,32,35] The main reason for this issue may be that the current research was performed only on brain injury patients with low mean ages (36.69 years) who mainly were injured due to an accident. In fact, in elderly patients unlike young patients, hypoactive delirium is usually more likely to occur than hyperactive.[36]

The results of this study showed that the intervention reduced patients' ICU stay and mechanical ventilation length. These results are consistent with the results

Table 2: Comparing of patients in the intervention and control groups regarding Delirium incidence rate, Delirium Type and ICU death rate (*n*=66)

Variable	Group	Situation		Total	χ^2	Df	OR (95% CI)	P^b
		Happened	Not happen					
Delirium incidence	Intervention							
	n	8	25	33	24.559	1	0.057 (0.017-0.19)	0.001
	% within ID	24.2	75.8	100				
	Control							
	n	28	5	33				
	% within	84.8	15.2	100				
	Total							
	n	36	30	66				
	% within ID	54.5	45.5	100				
	Group	**Situation**		**Total**				
		Hyperactive	**Hypo active**					
Delirium Type	Intervention				0.534	1	0.55 (0.11-2.71)	0.468
	n	4	4	8				
	% within ID	50	50	100				
	Control							
	n	18	10	28				
	% within	64.3	35.7	100				
	Total							
	n	22	14	36				
	% within ID	61.1	38.9	100				
	Group	**Situation**		**Total**				
		Happened	**not happen**					
ICU death rate	Intervention							
	n	5	28	33	0.109	1	0.80 (0.21-2.94)	0.741
	% within ID	15.2	84.8	100				
	Control							
	n	6	27	33				
	% within	18.2	81.8	100				
	Total							
	n	11	55	66				
	% within ID	16.7	83.3	100				

*ID: intra-group comparison, OR: odds ratio, CI: confidence interval, Df: Degrees of freedom, *Independent variable; receiving intervention and dependent variable; delirium type, delirium incidence, ICU death rate

Table 3: Comparing of patients in the intervention and control groups regarding Length of Delirium, Length of ICU stay and mechanical ventilation

Variable	Group	*n*	Mean (day)	SD	Total Mean (SD)	*t*	Df	*P*
Length of Delirium	Intervention	8	3	0.75	7.33 (6.60)	8.661	34	0.001
	Control	28	8.57	3.09				
Length of ICU stay	Intervention	33	14.30	3.90	19.27 (7.54)	7.104	64	0.001
	Control	33	24.24	7.02				
Length of mechanical ventilation	Intervention	33	7.54	3.17	11.95 (6.72)	7.034	64	0.001
	Control	33	16.36	6.46				

SD: standard deviation, Df: Degrees of freedom

of the studies by Rosa *et al*. (2017),[30] Álvarez *et al*.,[31] Junior *et al*. (2018),[32] and Sahawneh *et al*. (2021).[35] Given the reduced delirium incidence and length in the intervention group, these results can be expectable because delirium can increase length of ICU stay and mechanical ventilation in the ICU patients.[2]

The results also showed no significant difference between ICU mortality in the intervention and control groups in this study. This finding has been replicated in several similar studies[21,30-32,35]. Given that widespread and complex factors such as sepsis, ventilator-associated pneumonia (VAP), hydro electrolytical disorder, and medication side effects affect patients' ICU mortality,[37,38] it can be said that this finding is scientifically justifiable. Of course, maybe in the future, in a similar study with a larger sample size, this difference will be significant. Because delirium can also be one of the important

predictor factors of mortality in ICU patients,[2,34,37] and our study showed that receiving sensory stimulation program from family members can reduce the incidence and length of delirium in these patients.

Limitations

The first limitation of our study is that the families were not allowed to be present at the patient's bedside for more than 1 h a day due to the coincidence of the study with the prevalence of Covid 19 disease and the hospital's strict policies for visiting patients. The second limitation is that the first author (MA) was involved in the in the course execution process and this can lead to bias. The final limitation was that due to the need to monitor the implementation of the intervention by the researcher, this study was performed as a single blind that can lead to bias. Age was one of the confounding variables in this study, therefore, to evenly distribute the patients in terms of age in two groups, a stratified sampling according to the range of age was used. Also, receiving medication to prevent delirium could be one of the confounding variables, so patients who received similar medications to prevent delirium were included in this study.

Conclusion

The present study results showed that implementing a codified sensory stimulation program by family members for ICU-hospitalized brain injury patients reduced delirium incidence and length and also length of mechanical ventilation and ICU stay in these patients. Although more evidence is still needed in this regard, the results of this study and several similar studies indicate the need to pay attention to using nonpharmacological methods, such as the implementation of a sensory stimulation program to prevent delirium in ICU-hospitalized patients. So, it is recommended that future researches will evaluate and develop nonpharmacological Strategies (Especially benefit more and more coherently from the presence of patients' family) to prevent delirium in ICU patients.

Ethical consideration

This study was approved by the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (ethics code: IR.AJUMS.REC.1400.014). Ethical considerations were in accordance with the Helsinki Declaration 1995, revised 2001. The aim and method of the study were explained to the family member of patients and their questions were answered by the first researcher. Family members and their patient could withdraw from the study at any time without any effect on the caring process of patient. The written informed consent form was signed by family member (patient's legal guardian) who willingly agreed to take part patient in this study. The confidentiality and anonymity of patient information were ensured throughout the study process. Each participant was assigned a unique ID number to protect her identity, and the listing that linked the participant to the ID number was kept separate from the questionnaires. This investigation was registered in the Iranian Registry of Clinical Trials Center (IRCT20120414009469N4).

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Conflicts of interest

There are no conflicts of interest.

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