

Original Paper

Effects of Family-centered Interventions on Self-efficacy of Families of Patients With Low Consciousness Admitted to the Intensive Care Units: A Randomized Controlled Trial



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ABSTRACT

Introduction: Families of patients with low consciousness have an important role in supporting them and should acquire the necessary capability for patient care.

Objective: This study aimed to examine the effect of family-centered interventions on the self-efficacy of the families of patients admitted to the intensive care units.

Materials and Methods: This research was a randomized clinical trial with a pretest-posttest design conducted in intensive care units of hospitals in Khorram abad City, Iran, in 2019-2020. Seventy family members of patients were selected by convenience sampling and were assigned to the intervention (n=28) and control (n=28) groups by stratified random blocks. The study data were collected through the self-efficacy questionnaire and Hospital Anxiety and Depression Scale. The intervention was carried out using a family-centered model. The collected data were analyzed using the statistical tests of the Chi-square, independent t-test, and paired t-test. Also, the generalized linear model was used to compare changes in self-efficacy scores of the two study groups after adjusting demographic, anxiety, and depression variables.

Results: Data analysis showed that most samples were male (53.8%) with a mean age of 38.15±8.68 years. The results showed a significant difference in the mean scores of self-efficacy, anxiety, and depression between the intervention and control groups (P=0.001). The intervention significantly increased the Mean±SD of caregivers' self-efficacy (40.14±14.35, P=0.001) in the intervention group. The results showed that the self-efficacy mean score of the intervention group was 36 scores higher than the caregivers' self-efficacy of the control group (95% CI; 20.6-51.4, P=0.028).

Conclusion: The participation of family members of patients with low consciousness in the care of the patients in the intensive care unit has an effective role in the self-efficacy of caregivers of these patients.

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Highlights

- A patient's admission to the intensive care unit and recovery process are challenges for the patient's family.
- Participation of family members in patient care could positively affect the recovery process.
- Self-efficacy is an individual perception of abilities for creating the desired outcome, which can organize cognitive, social, emotional, and behavioral skills for achieving various goals efficiently.
- Family-centered interventions could improve self-efficacy in patients' families and help healthcare providers make effective decisions for their patients.

Plain Language Summary

Families of patients with low consciousness have an important role in supporting them and should acquire the necessary capabilities for patient care. This study was conducted using by randomized clinical trial methodology. Seventy family members of patients were assigned to the intervention and control groups. Data were collected to evaluate the self-efficacy, anxiety, and depression of patients' families. Results revealed that family-centered training could improve the self-efficacy, depression, and anxiety of patients' families hospitalized in intensive care units. It is suggested that hospital authorities carry out these programs based on the guidelines for patients' families from admission to the intensive care unit, during hospital stays, until discharge.

Introduction

The Intensive Care Unit (ICU), as one of the subspecialty units in hospitals, has particular conditions and equipment to which patients with critical conditions are admitted [1]. Most patients in the ICU have varying levels of consciousness. Low consciousness and coma result from traumatic and non-traumatic causes, including poisoning, metabolic disorders, infections, head injuries, and primary central nervous system lesions. Metabolic disorders and poisoning are considered the most important causes of low consciousness [2, 3]. Admission of a patient to the intensive care unit and the recovery process is challenging for the patient's family, resulting from a lack of knowledge about diagnosis, prognosis, and treatment [4]. Patients' families confront unfamiliar environments, therapeutic procedures, and unclear patient status, so they experience varying levels of fear and pressure over confronting the admission of a family member to the ICU [5, 6]. Many studies have shown that admission of a family member to the ICU can affect the mental and psychological health of other family members and result in disorders such as depression [7], anxiety, fear, and sleep complaints [8].

Patients' families are involved during admission, hospitalization, discharge, and continuing home care [9, 10]. Patients with low consciousness cannot make decisions, so healthcare providers should reach a decision

with family members, or a family member should be the attorney of decision-making [11]. Also, evidence shows that the participation of family members in patient care could positively affect the recovery process [9, 12]. This outcome requires that family members identify the situation and acquire essential self-efficacy for managing this condition. Self-efficacy is a construct that emerged in the social cognitive theory [13] and is defined as an individual perception of abilities for creating desired outcomes. Self-efficacy can efficiently organize cognitive, social, emotional, and behavioral skills for achieving various goals [14]. Many factors, such as anxiety or depression, affect self-efficacy [15]. According to studies, patients' families admitted to the ICU suffer psychological distress, which can negatively affect the family members and the patient [16]. Stressors for patients' families include invasive care, complex equipment, unfamiliar interventions, cardiopulmonary resuscitation before death, and losing the loved one in these units [17, 18]. These families continuously try to adapt to critical conditions in the intensive care unit [19].

On the other hand, the patients' families should manage the situation to make proper decisions together with healthcare providers [20]. Studies have shown that family participation in patient care positively affects their recovery process. This participation requires that patients' families acquire essential empowerment with regard to the patient's care. A study shows that patients' families in the ICU need various physical and

psychological support [4]. Another study shows that providing information about patient status, treatment plans, and psychological support are the most important needs of families [21]. The Critical Care Association has introduced a family-centered care model to involve the family in caring for patients with low consciousness. This model involves attending family members in the ICU, providing family support, communicating with family members, empowering the family for patient care, considering the appropriate environment for attending the hospital, and special consultation for palliative care [22]. Patients' families have adequate motives to participate in patient care.

On the other hand, their patients may need family care and help for months outside the hospital and at home. No program has been developed to empower caregivers of patients with low consciousness in Iran, while a program should be developed based on the evidence before providing any healthcare. This study aimed to determine the effect of the family-centered intervention on the self-efficacy of the families of people with low consciousness in the ICUs.

Materials and Methods

This randomized controlled trial was conducted on 70 family members of patients with low consciousness hospitalized in the ICUs of 2 hospitals in Khorram abad City, Iran, from November 2019 to March 2020. The inclusion criteria were as follows: being family members of patients admitted to the ICU for low consciousness, having direct contact with the patient, being primary caregiver, expected to be in the ICUs for 2 weeks, being physically and mentally healthy (based on self-expression), being literate, being willing to participate in the study, lacking an academic degree in health sciences (medicine, nursing, and midwifery), and not having experience in caring patients with low consciousness. The exclusion criteria were as follows: unavailability of cases for any reason (discharged or deceased patients), refusal to continue cooperation, lack of continuing patient care, and inappropriate physical and mental health status.

The inclusion criteria for patients were low consciousness due to traumatic and non-traumatic causes, Glasgow coma scale of 7 to 10, aged 18 to 60 years, and being at the ICU for at least 2 weeks. The exclusion criteria for patients were no access to the patient (death and transfer to the ward or other hospital) and the unwillingness of the patient's family to participate in the study.

The sample size was estimated at 28 in each group considering $\alpha=0.05$, $\beta=0.2$, $d=3$, and $SD=4$. Given the dropout of 20%, the sample size was estimated at 35 subjects for each group. To determine the value of the standard deviation, considering that no similar study was available, the value of the standard deviation was calculated based on the R/6 index. The R value of the range of changes is based on the difference between the minimum and maximum score of the questionnaire, which is calculated as 21. Also, based on the mentioned index, the standard deviation value was estimated to be 4.

Sampling was carried out using convenience and sequential methods, and subjects were assigned to the intervention ($n=35$) and control ($n=35$) groups by stratified random blocks (to match the two groups in terms of sex). By considering sex as a category in men and women, the samples were located in the studied groups in random blocks of 4. After visiting the ICU and studying the patients' files and medical histories, the researcher selected the eligible subjects. Finally, the sample size was considered to be 56 because of dropouts (Figure 1).

For data gathering, various tools, such as questionnaires for assessing demographic information, self-efficacy, and the Hospital Anxiety and Depression Scale (HADS), were used. In the demographic section, variables such as age, gender, occupation, education, and type of disease (traumatic or nontraumatic) were assessed.

In this study, a self-efficacy tool was developed based on the questionnaire by Nolan et al. [23] for examining the self-efficacy of the families of people with low consciousness. This questionnaire consists of 40 questions that examine various dimensions of caring for patients with low consciousness in the ICU. The questionnaire is scored on a 5-point Likert scale from completely disagree=1 to completely agree=5. A higher score shows better self-efficacy. The questionnaire was developed based on the ability of family members in various dimensions, including suctioning; nutrition; oxygen therapy; care of skin, mouth, and eye; and patient hygiene. The total score ranges from 40-200. A low score indicates low self-efficacy, and a high score indicates high self-efficacy of subjects in patient care. The level of self-efficacy was categorized into low (40-94 score), moderate (95-148 score), and high (149-200 score). The quantitative and qualitative methods were used to determine the content validity. In the qualitative phase, 10 healthcare providers (2 physicians, 3 clinical nurses, and 5 nursing educators) in the field of critical care assessed the content validity. In the quantitative stage, the content validity ratio (CVR) and the content validity index

(CVI) were calculated, which were found acceptable. The reliability of the questionnaire was obtained using the Cronbach α as 0.98.

In this study, anxiety, and depression were examined as moderators and assessed using the HADS questionnaire [24]. Researchers used the psychometric version of this questionnaire in the Persian language [25]. This questionnaire has two subscales of anxiety and depression, with 7 questions for each subscale. Each question is scored on a 4-point Likert scale (from 0 to 4); the respondents respond based on their feelings. A score of 3 indicates maximum anxiety and depression, and a score of 0 indicates minimum anxiety and depression. The total score of depression and anxiety scales ranges from 0 to 21. Score 14–21 indicates severe anxiety and depression, 7–14 moderate disorders, and 0–7 health status.

The study intervention was implemented based on a family-centered model [22]. Before the study, self-efficacy, anxiety, and depression questionnaires were provided for eligible caregivers to complete. The intervention was conducted in three steps for each family (Table 1). One week after all interventions, questionnaires of self-efficacy, anxiety, and depression were provided for caregivers to complete by the intervention and control groups. Considering that it was not possible to meet patients in the ICU, the researcher called the intervention group for training; thus, the control and intervention groups did not have contact with each other. In this process, the control group received routine care from healthcare providers in the ICU wards. For ethical considerations, necessary teaching was provided to the control group after completing the study.

Data analysis was carried out using descriptive and inferential statistics in SPSS v. 19. Statistical tests of the independent t-test, paired t-test, and Chi-square were used for data analysis. Also, the generalized linear model (GLM) was used to compare changes in the self-efficacy scores of the two study groups, adjusting demographic, anxiety, and depression variables. The results were reported at a significance level of 0.05.

Results

Data analysis showed that most subjects were male (53.8%) with a mean age of 38.15 ± 8.68 years (Table 2). The results showed that in the intervention group, the mean self-efficacy score of subjects before the intervention (137.78 ± 13.81) increased compared to after the intervention score (177.92 ± 12.36), and this difference (40.14 ± 14.35) was significant ($P=0.001$). The

results showed that in the control group, the mean self-efficacy score of samples before the intervention (135.78 ± 16.66) decreased compared to after the intervention (133.25 ± 21.57), and this difference (2.53 ± 26.57) was not significant. The results also showed a significant difference ($P=0.001$) in the means of self-efficacy score between the control (133.25 ± 21.57) and intervention (177.92 ± 12.36) groups, so the intervention increased the mean self-efficacy score significantly (Table 3).

The results showed that in the intervention group, the Mean \pm SD anxiety score of subjects before the intervention (15.42 ± 3.84) decreased compared to after the intervention score (9.78 ± 2.79), and this difference (5.64 ± 3.65) was significant ($P=0.001$). The results showed that in the control group, the mean anxiety score of subjects before the intervention (12.53 ± 4.85) increased compared to after the intervention score (13.21 ± 3.31), and this difference (0.68 ± 5.65) was not significant ($P=0.53$). Results of this study showed a significant difference in the Mean \pm SD of anxiety score between the control (13.21 ± 3.31) and intervention (9.78 ± 2.79) groups, so intervention decreased the mean anxiety score significantly ($P=0.001$). The results also showed that in the intervention group, the Mean \pm SD depression score of subjects before the intervention (14.53 ± 5.3) decreased compared to after the intervention score (9.07 ± 3.04), and this difference (5.42 ± 5.48) was statistically significant ($P=0.001$). The results showed that in the control group, the Mean \pm SD depression score of subjects before the intervention (11.39 ± 5.16) increased compared to after the intervention score (12.25 ± 4.35), and this difference (0.85 ± 6.24) was not significant. The results also showed a significant difference ($P=0.001$) in the mean depression scores between the control (12.25 ± 4.35) and intervention (9.07 ± 3.04) groups, so the intervention decreased the mean of depression significantly (Table 3).

To compare changes in self-efficacy scores of the two study groups, after adjusting for demographic, anxiety, and depression variables by using the generalized linear model (GLM), the results showed that the self-efficacy mean score of the intervention group was 36 scores higher than the caregivers' self-efficacy of the control group. These differences were significant statistically ($P=0.001$). The results showed, assuming the fixed value of other variables by GLM, the self-efficacy of women's caregivers was 11.38 scores higher than men's caregivers. These differences were significant statistically ($P=0.028$). Also, caregivers' self-efficacy scores of traumatic patients were 21.91 higher than non-traumatic patients ($P=0.028$), and these differences were significant statistically (Table 4).

Table 1. Steps of the intervention type for study

Sessions	Interventions
1 st	This session was carried out 24 hours after the patients' admission to the ICU. After being familiar with family members and developing trust between subjects and investigator, an explanation was provided about the patient's status, disease, possible complications, and the necessity of cooperation of family members with the healthcare team and the benefit of their communication with the patient for the patient's recovery. Care that patients need at the hospital and home was also explained, including care of skin and eyes, nutrition, urinary tract, respiratory tract, musculoskeletal tract, and prevention of bed sore for the patient. A caring booklet and pamphlet developed by the research team were also provided for family members, including content about patient care. Teaching was conducted individually in a quiet place in the resting room of the ICU staff.
2 nd	In the second step, after identifying caregivers' needs and coordinating with the head nurse of the ICU and the director of the hospital, caregivers were asked to attend three 1-hour sessions at the bedside in the evening shift, individually. Teaching was conducted over three 1-hour sessions at the bedside every other day for one week. Caregivers participated in patients' care as an assistant, and they were offered to practice. Teaching was conducted so that caregivers felt that they could participate as the assistant of the nurse in care plans. In this section, teaching was provided about hygiene, nutrition, change of position, bed sore, suctioning, etc. All theoretical and practical teaching was carried out by the investigator, who is a nurse in the ICU.
3 rd	In the third step, caregivers were asked to practice the taught content for the patient and participate in patient care. In this stage, if caregivers could not care properly or had a question regarding training and needed further teaching, the investigator taught theoretically and practically them again.

Discussion

This study showed that family-centered intervention increased self-efficacy in family members of patients with low consciousness in the ICU. In this study which

was conducted using a family-centered model, the investigator was a nurse, attended to the teaching caregivers, and provided care for the patients. Findings of another study showed that theoretical and practical teaching of informal caregivers of patients with stroke

Table 2. Comparing demographic variables between study groups

Variables	No. (%)		P	
	Control group	Intervention group		
Sex	Male	14(50)	0.789*	
	Female	14(50)		
Married	Single	8(28.5)	0.758*	
	Married	20(71.4)		
Education	Under diploma	7(25)	0.685*	
	Diploma	9(32.1)		
	Associate degree	4(14.2)		
	Bachelor	8(28.5)		
Job	Self-employment	9(32.1)	0.716*	
	Employment	5(17.8)		
	Jobless	14(50)		
Cause of admission	Traumatic	6(21.4)	0.193*	
	Non-traumatic	22(78.5)		
Age (Mean±SD)	-	37.21±8.78	39.82±8.58	0.266**

* The Chi-square test. ** The Independent t-test.

Table 3. Comparing the mean scores of self-efficacy, anxiety, and depression between two groups, before and after the study

Variables	Groups	Mean±SD			p* Within Groups	p** Between Groups
		Before Intervention	After Intervention	Mean Difference		
Self-efficacy	Control	135.78±16.66	133.25±21.57	2.53±26.57	0.62	0.001
	Intervention	137.78±13.81	177.92±12.36	40.14±14.35	0.001	
Anxiety	Control	12.53±4.85	13.21±3.31	5.65±0.67	0.53	0.001
	Intervention	15.42±3.84	9.78±2.79	5.64±3.65	0.001	
Depression	Control	11.39±5.16	12.25±4.35	6.24±0.85	0.474	0.001
	Intervention	14.53±5.3	9.07±3.04	5.42±5.48	0.001	

*The paired t-test; **The Independent t-test.

based on patients’ needs and caregivers’ abilities could increase their practical skills [26]. Education, along with the care provided, allows the caregiver to observe the educator during the performance. Resources of self-efficacy include live role models, confrontation with action, positive assessment, and mastery of activity. For confrontation with action and

positive assessment, the caregiver acts based on the guidelines and is evaluated during the action, empowering the caregivers in their tasks.

This study showed that the depression and anxiety of caregivers improved in addition to their self-efficacy. In contrast, another study conducted on caregivers

Table 4. Comparing changes in the mean scores of caregivers’ self-efficacy after the adjustment of demographic, anxiety, and depression variables using the generalized linear model

Variables	Groups	B	SE	95% CI Lower-Upper	P
Group	Control	Reference			
	Intervention	36	7.85	20.6-51.4	0.001
Marital status	Married	Reference			
	Single	2.17	6.59	-10.74-15.08	0.742
Sex	Male	Reference			
	Female	11.38	5.17	1.25-21.52	0.028
Disease	No	Reference			
	Yes	21.98	8.54	5.16-38.67	0.01
Age	-----	-0.17	0.32	-0.79-0.46	0.61
Changes of anxiety	-----	1.72	1.1	-0.45-3.89	0.121
Changes of depression	-----	-1.83	1.03	-3.85-0.19	0.76
Group* Changes in anxiety	Control	Reference			
	Intervention	-2.67	1.69	-5.98-0.65	0.115
	Control	Reference			
	Intervention	1.12	1.33	-1.51-3.74	0.4

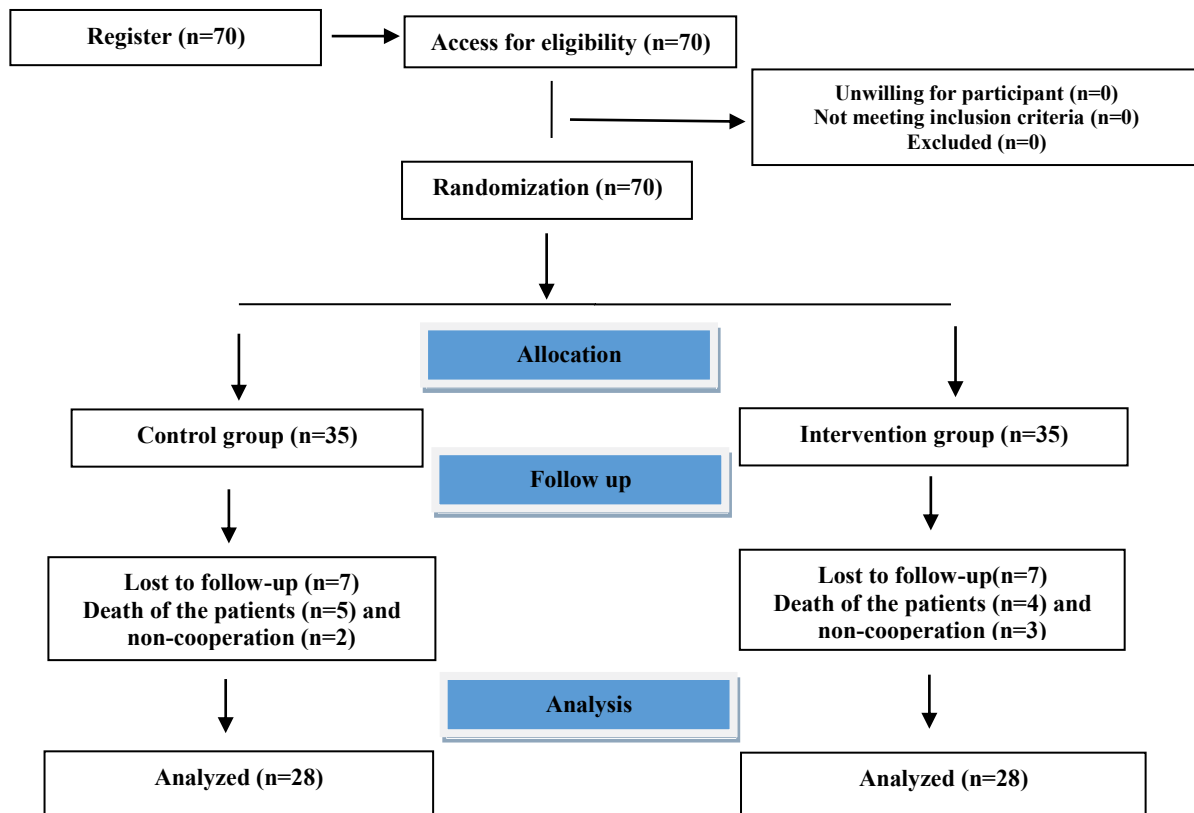


Figure 1. Diagram study based of CONSORT flowchart

of patients with cancer showed that these interventions do not affect caregivers' mental and psychological status; however, they improved their self-efficacy [27]. Inappropriate psychological status results in caregivers' inappropriate self-efficacy in interaction with healthcare providers and inappropriate expectations from the ICU and its staff [28].

This study showed the effectiveness of family-centered interventions in improving families' self-efficacy. Although empowering caregivers has many benefits in improving patients' care and facilitating cooperation with staff, it should be considered that the ICU ward is a special unit that needs silence and peace. Nosocomial infections are common in these units. Patients' caregivers should attend based on proper planning, as crowded ICUs by patients' caregivers could result in increasing nosocomial infections, busy units, and burnout in caregivers of these units. In some developed countries, there are some guidelines for supporting families of patients admitted to the ICUs, which meet family needs over the admission of patients [20, 29]. It is suggested to plan for attending to patients' families considering patient safety according to the evidence.

Another element of the family-centered model is communication and increasing knowledge of patients' families. These families spend tough days; therefore, communication with them needs particular skills. Healthcare providers in the ICU should be familiar with the principles of proper communication with the family of critically-ill patients. It is required that authorities of continuing education consider the principles of communication with family and patients and teach nurses in the ICUs on how to deliver bad news to patients' families.

Another element of the family-centered model is using specialized counselors for the peace of family of critically-ill patients. Mortality and disability rates are high in patients admitted to the intensive care unit [30] and could be a source of anxiety and depression, and low self-efficacy. These families are patients' attorneys for decision-making and should be accurately informed for proper decision-making [31]. Studies have shown that clarification and understanding of patients' families can reduce hospital stays, which can result in further vacant beds for critically ill patients and decrease costs [32, 33].

In this study, teaching was carried out by the investigator, who is a nurse in the ICU and was familiar

with patients' condition and their families. It is ideal for supporting patients' families comprehensively by healthcare professionals, including psychologists, social workers, and religious experts. Palliative care should be considered for the patient's family from admission so that the family can tolerate the suffering of the deceased patient and grieve easily and endure fewer psychological disorders [22].

One of the limitations of this study was its short-term intervention. It is suggested to conduct this study over a long-term period so that family caregivers receive proper teaching and support since the patient's admission to the intensive care unit. Then, the self-efficacy of caregivers and the effect of these interventions on patients' recovery are examined over time. In the family-centered model, various experts should be used in the healthcare team for intervention. In this study, the investigator, a nurse in the intensive care unit, carried out all interventions due to existing limitations. Another limitation of this study was that few studies had been conducted on this issue. It is suggested to conduct a further study to examine this topic from different angles. In this study, the investigator conducted teaching in the resting room of the staff. There was no place for sleep and rest of caregivers at hospitals, which could result in mental and psychological disorders in patients' families. It is suggested that hospital authorities consider these points in the management and provide places for patients' caregivers at the hospitals.

Family-centered interventions could improve self-efficacy in patients' families, and consequently, healthcare providers could make effective patient decisions. Therefore, it is suggested that hospital authorities carry out these programs based on the guidelines for patients' families from admission to the ICU and during their stays in the hospital until discharge. As less is known about the effect of these interventions on patients' recovery in the ICUs, it is suggested to examine the effect of these interventions on the recovery process and outcomes of patient care.

Ethical Considerations

Compliance with ethical guidelines

The purpose and method of the study were explained to all participants. The participants were assured of anonymity and confidentiality and the right to withdraw from the study. Informed consent was obtained from the participants. The study was approved by the Research Ethics Committee of [Lorestan University of Medi-](#)

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Authors' contributions

Data collection: Hadis Biranvand; Data analysis: Mehdi Birjandi; Study supervision: Mehdi Birjandi, Fatemeh Goudarzi, Heshmatolah Heydari; Writing-original draft: Hadis Biranvand and Heshmatolah Heydari; Methodology and Final approval of the article: All authors.

Conflict of interest

The authors declared no conflict of interest.

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