The Effects of Scheduled Visitation Policy on Depression, Anxiety, and Stress among the Family Members of Patients with Open Heart Surgery: A Randomized Controlled Trial

Abstract

Background: Visiting patients in special care units can effect depression, anxiety, and stress patients and their families. The present study aimed at evaluating the effects of Scheduled Visitation Policy on depression, anxiety, and stress among the family members of patients with Open Heart Surgery (OHS). **Materials and Methods:** This randomized, controlled, clinical trial was conducted on 66 family members of patients with OHS. They were randomly allocated to two groups of intervention ($n = 33$) and control ($n = 33$) through permuted block randomization. Participants in the intervention group received scheduled visitation policy in three 30-minute sessions for 3 consecutive days after OHS, and their counterparts in the control group were treated with routine restricted visitation. All participants completed the Depression, Anxiety, and Stress Scale DASS-21 before and after the intervention. Data were analyzed using Chi-square, paired-sample t-test and the analysis of covariance (ANCOVA) ($p < 0.05$). **Results:** The mean [standard deviation (SD)] of depression, anxiety, and stress did not change in the control group, while it significantly decreased in the intervention group [2.27 (4.06) vs 11.97 (7.13), 2.52 (3.26) vs 11.67 (7.36), and 2.45 (4.11) vs 12.93 (6.80), respectively; $p < 0.05$]. Consequently, ANCOVA test showed the mean posttest scores of depression, anxiety, and stress in the intervention group were significantly less than those in the control group ($p < 0.05$). **Conclusions:** Scheduled visitation policy significantly reduced depression, anxiety, and stress among the family members of patients with OHS. Patient-centered and family-centered interventions are needed to reduce psychological strains.

Keywords: *Anxiety, depression, family, open heart surgery, scheduled visitation, stress*

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Introduction

Cardiovascular Diseases (CVDs) are one of the most serious health problems and a leading cause of death, disability, and decrees quality of life in worldwide.[1,2] According to the World Health Organization (WHO), 17.9 million people died in 2019 due to CVD, constituting 32% of all annual deaths in the world. Estimates show that this value will reach 23.6 million people in 2030. According to the latest statistics available in Iran, CVDs cause 46% of all deaths and 20–23% of the disease burden.[3-5] Open heart surgery (OHS) is one of the most important surgical interventions for heart problems. The most prevalent indications of OHS include coronary artery revascularization, valve repair or replacement, repair of congenital or acquired structural anomalies, and cardiac transplantation.[6,7] Each year, 35–50 thousand heart surgeries are performed in Iran.[8] Patients with OHS are immediately transferred to Cardiac Surgery Intensive Care Units (CSICU) to receive mechanical ventilation and advanced care services.[9]

Post-OHS is a critical period accompanied by stressful conditions, fear, and anxiety for patients and their families, which negatively affects the quality of their social life.[8,10] A study in Iran reported that the prevalence rates of depression and anxiety among the family members of patients with altered consciousness were 35% and 71%, respectively.[11] In addition, a high proportion of relatives of ICU patients suffered from anxiety (80%), depression (70.3%), and post-traumatic stress symptoms.[12] Post-OHS Depression, Anxiety, and Stress (DAS) can significantly affect the different aspects of family members' lives. For example, anxiety can negatively affect their decision-making

ability, transmit like a contagious disease from family members to patients, nurses, and other healthcare workers, and, hence, alter their interrelationships. It can also reduce family members' physical and mental abilities and cause them different physical and mental health problems.[13] Studies showed that half of the family members could not accurately understand physicians' explanations about prognosis, diagnosis, and treatment due to their severe anxiety. Stress and anxiety among the family members of patients with OHS are mostly due to their lack of knowledge about disease prognosis and treatments and their unfamiliarity with the environment and the sophisticated equipment of the CSICU.[14,15]

Restricted visitation policy in the CSICU is one of the major influential factors on post-OHS DAS among family members.[16] The family members of patients with OHS face physical and mental barriers in establishing communication with their patients behind the closed doors of the CSICU and experience great mental strain due to waiting for patient-related information.[17] There are three main visitation policies in different clinical settings in different countries, namely, restricted, open, and scheduled policies.[18] Visitation policies vary according to the immediate context. For example, the prevalence of open visitation policy is 70% in Sweden and less than 1% in Italy.[9] The most prevalent visitation policy in ICUs in Iran is the restricted policy.[19-21] The current visitation policies in Iran were developed 40 years ago and have not been revised yet.[21] The most important reason for using restricted visitation policy is that open visitation policy may increase patient stress, threaten patient safety, and increase the risks of dyspnea, dysrhythmia, infection, and death.[13,22] However, most patients in a study highlighted that not only did visitation not increase their stress but also it improved their peace of mind and trust, and they believed that visitation should be based on patients' and families' needs.[23] Scheduled Visitation Policy (SVP) is a policy between open and restricted policies and is developed based on the immediate conditions and needs of patients, family members, and ICU staff.[24,25] Previous studies have reported the positive effects of SVP. For example, a study in Brazil found that SVP improved the relationships of healthcare providers and family members, provided family members with more opportunities to communicate their needs and emotions, and reduced their anxiety and depression.[26] Another study found that SVP significantly reduced anxiety among the family members of patients with burn injuries and improved patient recovery.[13] However, in some studies, nursing and medical teams in ICUs believe that openness and the presence of family members and loved ones are harmful.[27,28] Although some previous studies have evaluated the effects of SVP on family members, there is limited information about its effects on DAS among family members of patients with OHS. Therefore, due to the contradictory results of different studies, this study aimed to investigate the effects of SVP on DAS in family members of patients with OHS.

Materials and Methods

This randomized, controlled, clinical trial was conducted with the code IRCT20220216054043N1 in 2020–2021. Participants were 70 family members (i.e., spouses, parents, children, and siblings) of patients with OHS consecutively selected from the CSICU of Madani Hospital, Khorramabad, Iran. The sample size was calculated to be 33 per group using the PASS software (version 15.0; NCSS, LLC, Kaysville, UT, USA) and considering a potential attrition rate of 20%, a power of 0.8, an alpha of 0.05, a difference between group mean changes of 250, SD of measurements at time 1: R/6= (3000 − 0)/6 = 500, SD of measurements at time 2: R/6= (3000 − 0)/6 = 500, and a correlation between measurements of 0.8. Participants were randomly allocated to a 35-person intervention group and a 35-person control group through permuted block randomization. Using permuted block randomization with a block size of 2 and an allocation ratio of 1:1, the study weeks were assigned to study groups A and B (the A-B sequence for numbers 0–4 and the B-A sequence for numbers 5–9, based on a column of random numbers). The random assignment was performed by a statistical consultant who was a member of the research team. The study inclusion criteria comprised relatives of patients who endorsed a familial and/or sentimental relationship with the patient (i.e., spouses, parents, children, and siblings), not being afflicted by major psychiatric disorders (such as depression, schizophrenia, and anxiety), having basic literacy skills, no family problem in the past 6 months (divorce, death of immediate family members), no history of abusing substances, alcohol, or psychoactive medications, and the age range of 18 to 75 years. The study exclusion criteria were patient death, voluntary withdrawal from the study, and absence from one intervention session.

Data were collected using a demographic questionnaire and the Depression, Anxiety, and Stress Scales-21 (DASS-21). The items of the demographic questionnaire were on age, gender, educational level, and marital status. DASS-21 includes 21 questions through which signs of anxiety, stress, and depression are separately measured by seven questions. Each question is scored on a 4-point Likert scale ranging from 0 to 3 (none to many), and the scores are summed up at the end. The total score of this scale ranges from 0 to 21. Scores 0–4 show a normal level of depression, 0–3 show a normal level of anxiety, and 0–7 show a normal level of stress; 5–7 show a low level of depression, 4–5 show a low level of anxiety, and 8–9 show a low level of stress; 8–11 show a moderate level of depression, 5–7 show a moderate level of anxiety, and 10–13 show a moderate level of stress; 12–15 show a severe level of depression, 8–9 show a severe level of anxiety, and 14–17 show a severe level of stress; 25 + show an extremely severe level of depression, 10 + show an extremely severe level of anxiety, and 18 + show an extremely severe level of stress. This questionnaire was first developed by Lovibond (1995) and tested in a large sample of humans. It was adopted on numerous subjects in England, and its reliability and validity were confirmed. A previous

study in Iran reported that the Cronbach's alpha values of the DAS dimensions of the Persian DASS were 0.83, 0.75, and 0.87, respectively.[29-31] After the designed educational content was approved by two nursing faculty members and a cardiologist, it was implemented in the intervention group. The study intervention was SVP for participants in the intervention group and routine visitation policy for participants in the control group. Before OHS, patients were asked to introduce their preferred family members for postoperative family visitation. Then, the family members were invited to participate in a 10–15-minute session to receive face-to-face visitation-related educations about washing hands, wearing ICU gown and shoes cover, skin contact with the patient, communicating good memories with the patient, and avoidance from crying at the patient's bedside and touching medical equipment.[22,32-34] The training was provided by the researcher in groups of 1 to 2 people in the form of lectures and practical exercises. Family visitation was started at the time of patient arrival at the post-ICU ward. Participants visited their patients under the supervision of the first author in three 30-minute sessions for 3 consecutive days after OHS, at 15:00 on the first 2 days, and at 11:00 on the third day, and their questions were answered during visitation time. Participants in the control group visited their patients based on the routine visitation protocol of the study setting, which was a strictly restricted policy at personal request and insistence. All participants in both groups completed the DASS-21 before and after the intervention. In order to prevent between-group leakage of information, family members in the intervention and the control groups received the allocated intervention on an alternate weekly basis.

Data analysis was performed using the SPSS software (version 22.0; IBM Crop., Armonk, NY, USA). The data were described using the measures of descriptive statistics, namely, mean, standard deviation, and absolute and relative frequencies. The Kolmogorov–Smirnov test indicated the normal distribution of the data, and hence, the paired-sample *t*-test was used for within-group comparisons, while the Chi-squared test, the independent-sample *t*-test, and the analysis of covariance (ANCOVA) were used for between-group comparisons. The level of significance was set at less than 0.05.

Ethical considerations

This study has the ethical approval of Lorestan University of Medical Sciences, Khorramabad, Iran (code: IR.LUMS.REC.1399.335 date: 2021-02-16). Ethical considerations including confidentiality of participants' information, informed consent of the participants, explanation of the research goals, voluntary participation in the research, permission to leave the study at any time, and honesty in publishing the research results were taken into consideration.

Results

In total, 70 family members participated in this study, from among which four participants were excluded due to

incomplete questionnaires ($n = 2$) and patient death ($n = 2$). Thus, the data obtained from 66 participants (33 in each group) were included in data analysis [Figure 1].

Table 1 shows the demographic characteristics of the participants.

Within-group comparisons via the paired-sample *t*-test indicated no significant differences between the mean pretest and posttest scores of depression, anxiety, and stress in the control group ($p > 0.05$). However, the mean posttest scores of depression, anxiety, and stress in the intervention group were significantly less than their corresponding pretest values ($p < 0.001$). Between-group comparisons through ANCOVA also showed that after adjusting the effects of the mean pretest scores of depression, anxiety, and stress, the posttest mean scores of depression, anxiety, and stress in the intervention group were significantly less than those in the control group ($p < 0.05$) [Table 2].

Discussion

This study investigated the effects of SVP on DASS among family members of patients with OHS. The findings showed that the mean DAS scores in the intervention group were significantly reduced so that their posttest values in this group were significantly lower than those in the control group. Therefore, this method can be used to reduce tension and prevent anxiety, stress, and depression. In the past 2 decades, numerous studies have been conducted in the field of anxiety reduction, but a few studies have been conducted to reduce the anxiety of people accompanying patients. In accordance with our findings, the results of several studies showed that family-centered care (including family visits and education) was effective in significantly reducing DAS among family members of patients in ICUs.[11,35]

In this regard, the results of the study by Mehdipour-Rabori and Nematollahi[36] showed that the recommended AZKAR can reduce anxiety, stress, and depression in the families of patients undergoing OHS. Another study reported that family visitation significantly improved general health among the family members of hospitalized children.[37] Similarly, two studies found that controlled family visitation and participation in patient care significantly reduced anxiety among patients and their family members.[38,39] The results of the study by Yuan *et al*.[40] on the effect of visits on the anxiety of family members of COVID patients hospitalized in the ICU showed that there was no significant difference between the two groups. Moreover, a study indicated that family members' attendance at the burn injury ICU significantly reduced their anxiety and facilitated patient recovery.[13] Contrary to our findings, a study reported that family visitation in the ICU was associated with increased anxiety level on the sixth day of the intervention. These results may be due to providing various patient-related information to family members without assessing their educational needs as well as by the
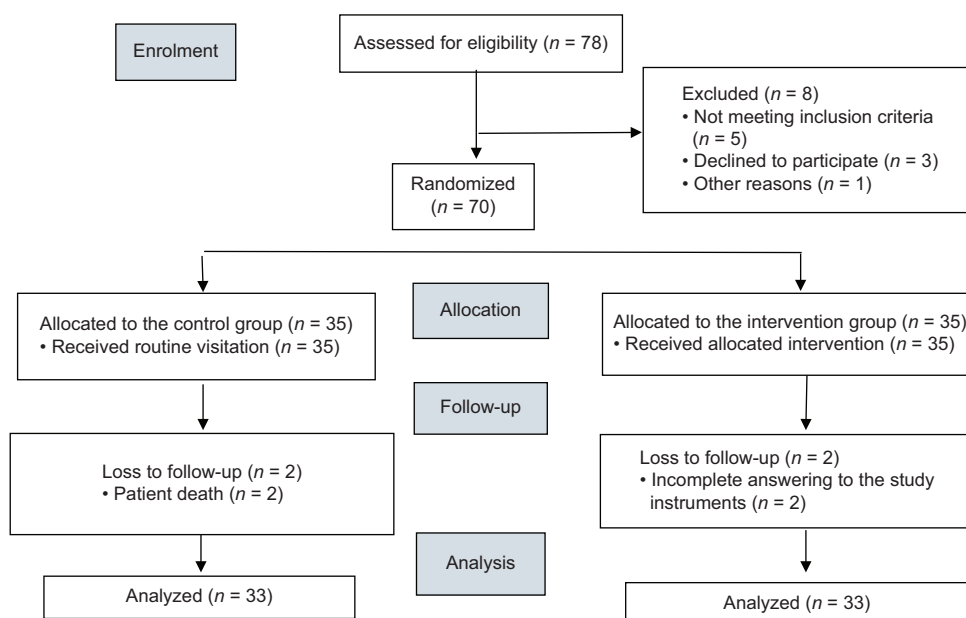
Figure 1: The flow diagram of the study

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Table 1: Participants' characteristics

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Group Characteristics		Control *n* (%)	Intervention *n* (%)	*p**
Age (Years)	<40	23 (69.70)	23 (69.70)	>0.999
	≥40	10 (30.30)	10 (30.30)	
Gender	Male	18 (54.50)	18 (54.50)	>0.999
	Female	15 (45.50)	15 (45.50)	
Educational level	Below diploma	6 (18.20)	10 (30.30)	0.435
	Diploma	14 (42.40)	10 (30.30)	
	University	13 (39.40)	13 (39.40)	
Kinship with patients	Spouse	5 (15.20)	5 (15.20)	>0.999
	Child	24 (72.70)	24 (72.70)	
	Brother	4 (12.10)	4 (12.10)	
Hospitalization history	Yes	9 (28.10)	14 (42.40)	0.301
	No	23 (71.90)	19 (57.60)	
Living with patient	Yes	20 (60.60)	17 (51.50)	0.620
	No	13 (39.40)	16 (48.50)	
Number of visitations	More than once weekly	26 (78.80)	27 (81.80)	>0.999
	Weekly or monthly	7 (21.20)	6 (18.20)	
Place of residence	Urban areas	14 (42.40)	10 (30.30)	0.443
	Suburb or rural areas	19 (57.60)	23 (69.70)	

*: The results of the Chi-square test

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Table 2: Within-group and between-group comparisons respecting the mean (standard deviation) scores of depression, anxiety, and stress

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Outcomes	Time Group	Before	After	*p**	Mean (SD) difference	*p***
Depression	Control	8.06 (7.56)	9.58 (6.44)	0.11	1.52 (5.40)	<0.001
	Intervention	11.97 (7.13)	2.27 (4.06)	<0.001	−9.70 (7.98)	
Anxiety	Control	7.67 (7.16)	8.64 (6.03)	0.32	0.97 (5.60)	<0.001
	Intervention	11.67 (7.36)	2.52 (3.26)	<0.001	−9.16 (7.82)	
Stress	Control	8.94 (7.17)	8.97 (6.06)	0.97	0.03 (4.93)	<0.001
	Intervention	12.93 (6.80)	2.45 (4.11)	<0.001	−10.48 (7.96)	

*: The results of the paired-sample *t*-test; **: The results of the analysis of covariance

direct exposure of family members to critical conditions and complex equipment of the patients in that study.[41,42]

In this regard, the results of the study by de Souza *et al.*[43] showed that flexible ICU visitation, compared to restricted visitation, was associated with a significant reduction in the 1-year prevalence of posttraumatic stress symptoms in family members.

Hospitalization in critical care units can also result in severe distressing reactions in patients' family members.[44] Family members' inability to visit their patients and their lack of knowledge about patients' conditions and treatments can also lead to their anxiety.[45] The family members of patients in CSICUs usually have difficult conditions, and hence, healthcare providers' communication with them and provision of patient-related information to them can improve their knowledge, conditions, and participation in patient care.[11,46] Moreover, the restricted visitation policy is ineffective in fulfilling patients' and their family members' needs in the ICU. Therefore, strategies are needed to improve family members' direct communication with their patients and their participation in patient care.[38,47,48]

The study limitations were a small sample size of the study and some nurses' disagreement with family visitation due to their fear over the transmission of coronavirus disease 2019. In this study, the distance from the place of residence to the hospital was not considered as a background variable that could potentially have a confounding role.

Conclusion

SVP is effective in significantly reducing DAS among the family members of patients with OHS. Nurses can use SVP and other supportive-educational strategies to reduce psychological strains among these family members and thereby improve their conditions and facilitate their patients' recovery. Studies on large samples of family members and in other critical care units are needed to produce stronger evidence respecting the effects of SVP on DAS among patients and their family members.

Conflicts of interest

Nothing to declare.

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