Randomised Controlled Trial

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Effect of family-centered care on the anxiety levels among family members of patients undergoing cardiac surgery: a randomized controlled trial

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Background: The present study aims to determine the effect of family-centered care on anxiety levels among family members of patients undergoing cardiac surgery.

Materials and methods: This study was a randomized clinical trial study that was conducted on the families of Iranian cardiac surgery patients. In the intervention group, family-centered care was implemented, and the content of the intervention included providing informational and emotional support to the family member and the family member's participation in patient care according to the set framework.

Results: A total of 144 family members of patients undergoing cardiac surgery were included in this study. Among the 144 family members, 71 were in the intervention group, and 73 were in the control group. The changes in the state anxiety score before and after the intervention were significant between the two groups, and the changes were higher in the control group ($P = 0.043$). Also, there was no significant difference in the changes in trait anxiety before and after the intervention between the two groups ($P > 0.05$).

Conclusion: In general, the high prevalence of anxiety in patients' families has negative functional consequences on both patients and their families. To reduce the level of anxiety, special attention should be paid to knowing the effective factors and appropriate coping methods. Nevertheless, it is important to note that additional research is warranted to delve deeper into this matter in future studies.

Keywords: anxiety, cardiac surgical procedure, cardiac, family, family-centered nursing

Introduction

Cardiac surgery, a basic technique in the treatment of patients, is known as an intervention with a high success rate[1,2]. However, it is a stressful and life-threatening experience to be in the hospital and to be admitted to critical wards for the patients and their family members[3]. Unpleasant feelings or emotional pressure caused by stress leads to homeostasis imbalance[4]. The appearance of any problem in one of the family members affects all people, and highly stressful cases such as heart surgery disturb the whole family. Most studies have focused on the problems of heart surgery patients, and it is rare to collect information about the problems of their families[5], while all aspects of family health can be affected[6]. The inability of families to cope with the hospitalization of one of their members will probably have negative psychological consequences such as shock, anxiety, depression, and sleep disorders[7,8]. Previous studies indicated that the prevalence of anxiety and depression in patients was 28% and 47%, respectively[9], while among their relatives, the incidence rate of anxiety was 10–42% and depression was 16–35%[10]. Based on this, the family members of heart surgery patients are more anxious, so it is necessary to take appropriate measures to reduce their anxiety and improve satisfaction.

Anxiety is an advanced stage of chronic stress, and it becomes a mental health problem when it causes suffering or discomfort for individuals or their relatives, prevents the achievement of goals, or disrupts their daily and normal tasks[11]. Relieving the level of anxiety in family members is possible with various medicinal and non-pharmacological methods, the ultimate goal of all of which is

HIGHLIGHTS

- After controlling the effect, the state anxiety score before the intervention was not significant by using the analysis of covariance (ANCOVA) test ($P = 0.886$).
- The changes in the state anxiety score before and after the intervention were significant between the two groups, and the changes were higher in the control group ($P = 0.043$).
- Also, there was no significant difference in the changes in trait anxiety before and after the intervention between the two groups ($P > 0.05$).

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the ability of the family to adapt to the conditions and participate in medical care. It seems possible to solve this problem using family-centered care theory[12].

The care environment consists of patients and families, and comprehensive care includes family and patient care[13]. The concept of family-centered care was first introduced in 1987, which is a method for planning the implementation and evaluation of health care through two-way beneficial partnerships between caregivers, patients, and families and is based on the concepts of empowerment[14]. The concept of family-centered care is focused on an inclusive approach that considers the patient as an integral part of a familial unit. The healing process involves the integration of the familial unit as an essential team member. Family-centered care is a collaborative and shared approach to patient care that involves active involvement and participation from both healthcare providers and family members. This methodology stands in contrast to a unilateral approach, whereby decision-making and responsibility are wholly assumed by one party alone, either the healthcare practitioners or the patient's family[15].

Previous studies have shown that reducing the level of anxiety of patients' families can occur through the use of family presence with the patient[16], addressing educational needs[3,5,17], support programs for families[18], and participation in care[12]. The essential point in the mentioned cases is the necessity of the presence of the family in the clinical environment, which, due to the strict policies of the presence of people in intensive care units (ICUs), will practically face problems[16]. Considering the weak suggestions for family-centered care in ICUs according to the review of the literature and the need to find effective solutions to reduce the anxiety of family members based on the family-centered care model, this study was conducted to determine the effect of family-centered care on the anxiety of family members of heart surgery patients.

Methods

Study design

This study was a randomized clinical trial study that was conducted on the families of Iranian cardiac surgery patients in line with CONSORT criteria[19] (Fig. 1).

Ethics consideration

The ethics committee of The Guilan University of Medical Sciences has given its approval to this study. The participants gave informed consent after being informed of the current study's goals. It was made clear to participants that they could leave the study at any time.

Participants

As shown in Figure 1, the samples of this study were 144 family members of cardiac surgery patients. The sampling approach employed in this study involved the utilization of a simple random method. The participants were randomly divided into 71 people in the intervention group and 73 people in the control group. The inclusion criteria encompassed participants who were aged 18 years and above, had a familial relationship with the patient, possessed literacy, displayed a willingness to cooperate, were scheduled for elective surgery, had no history of addiction, neurological or mental illnesses, and were not using anti-anxiety medications. Participants whose patients had passed away or were unable to cooperate due to the patient's deteriorating health were excluded from the study. Also, if the family member did not participate in the intervention more than once or the patient returned to the operating room for any reason, they were excluded from the study.

Sample size

The sample size was determined with 95% confidence and 90% test power based on the results of Hamster *et al*.'s study, considering the clinical difference of a 10% reduction in anxiety compared to the control group, with 68 people in each group. Considering the drop level of 10% of the sample volume, 76 people were considered in each group.

Intervention

The participants were in two groups of family-centered care and control. The participants were given a questionnaire if they agreed to participate in the study. The questionnaire included the demographic characteristics of the patient (age, gender, place of residence, and history of hospitalization), demographic characteristics of family members (age, gender, marital status, living status, education level, occupation, relationship with the patient, and history of hospitalization), and the State-Trait Anxiety Inventory (STAI) questionnaire.

In the intervention group, family-centered care was implemented, and the content of the intervention included providing informational and emotional support to the family member and the family member's participation in patient care according to the set framework.

In the information support department, a 30-min training session was held for the family members individually and face-to-face at the time of admission in the patient education room of the hospital, and the materials were presented to them in the form of brochures. The content of the training included information related to familiarization with surgery, care equipment, surgical procedure and transfer to the special and surgical department, duration of operation, duration of hospitalization, expectations after the operation, permission to visit, and help in transferring the patient, how to know the patient's condition, the regulations of the departments, standard precautions and infection control, especially hand washing, conditions for entering and staying on the patient's bed, and not manipulating the patient's connections.

To involve the family members in patient care, two more training sessions were held face-to-face, one before the first meeting with the patient in the special department and one before the transfer to the surgery department for 15 min in the patient education room of the hospital.

The participation of the family member in the ward was on the first day of the operation (about 6 h after the operation) in the form of a 15–30-min meeting with the coordination and guidance of the nurses in the evening shift. Participation was on the third day after the operation during the transfer of the patient to the surgical department, where the family member participated in the 15–30-min presence in the department with the coordination and guidance of the nurses by being with the patient and helping in the transfer of the patient.

In the dimension of emotional support, at the same time as face-to-face training sessions for the family member, measures including

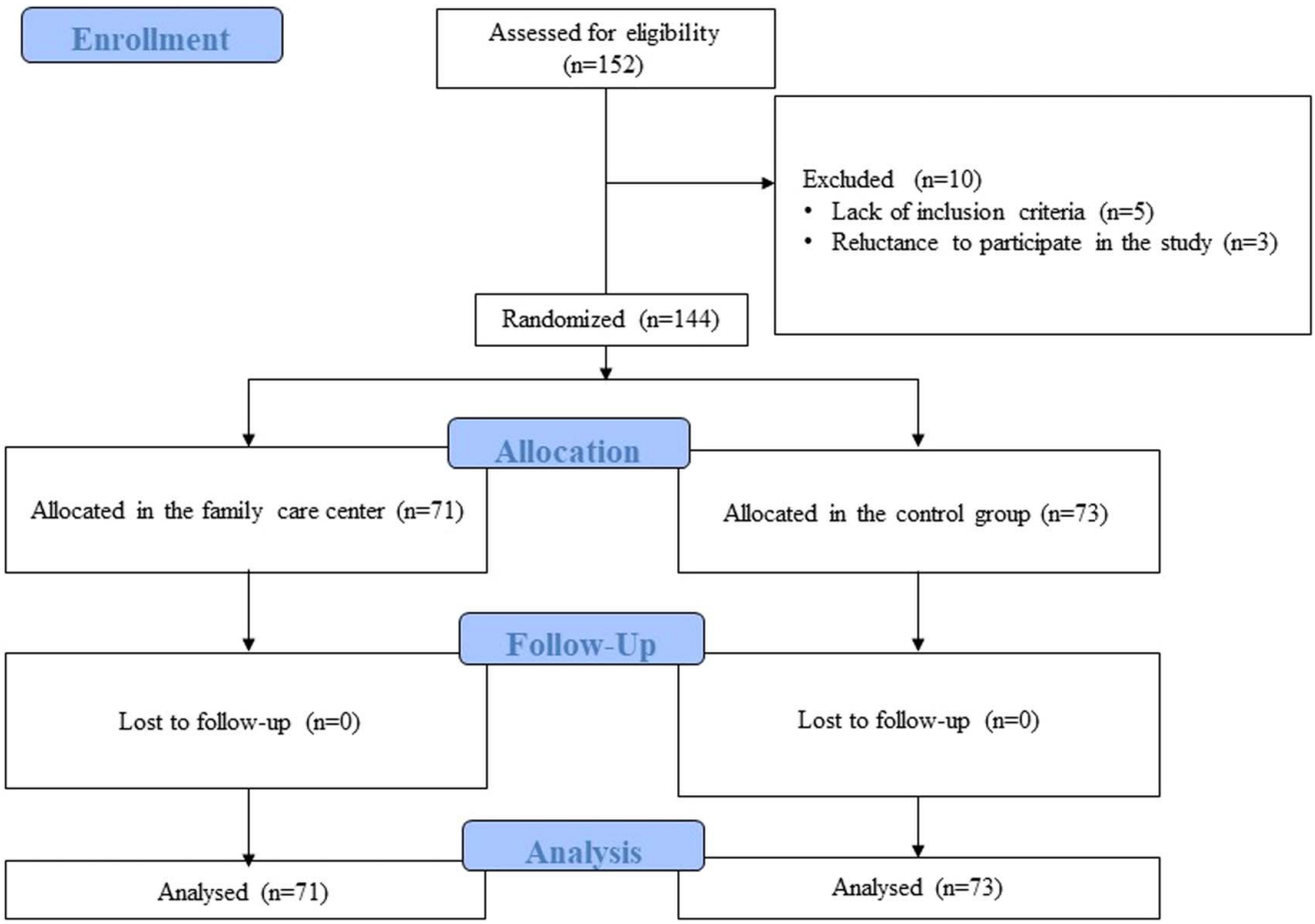

Figure 1. Flow diagram of the participants.

giving the family member enough time to talk about their concerns, assuring them about providing adequate care in the hospital, and encouraging family caregivers to hope were emphasized.

In the control group, routine care including providing pamphlets and booklets to the patient before surgery, along with educational content about surgery and the special care department, which is in plain language, was implemented. In routine care, preoperative education about surgery, devices, and care was given only to the patient, and an interdepartmental tour was given to the patients to get to know the patients who had already undergone heart surgery. Also, the necessary training on self-care is given to the companion and the patient.

STAI

STAI Spielberger is used to collect data. This questionnaire contains 40 questions, which have two parts: state anxiety and trait anxiety. The state anxiety scale contains 20 sentences that measure a person's feelings at the time of responding, and the trait anxiety scale includes 20 sentences that measure people's general feelings. Each of the statements of the questionnaire is assigned a weight between 1 and 4 based on the answer provided, where a score of 4 indicates a high presence of anxiety. Since some statements were scored in reverse, the scores of each of the two scales of state and trait anxiety will have a range between 20 and 80. For state anxiety, a score of 20–31 is mild anxiety, a score of 32–42 is moderate anxiety, a score of 43–53 is moderate to high anxiety, a score of 54–64 is relatively severe anxiety, a score of 65–75 is severe anxiety, and a score of 76 and above is very severe. For trait anxiety, a score of 20–31 is considered mild, a score of 32–42 is moderate, a score of 43–52 is moderate to high, and a score of 53–62 is relatively severe, a score of 63–72 is considered severe, and a score of 73 and above is considered very severe[20]. In this research, the reliability of the tool was checked in a pilot study on 30 family members of patients undergoing cardiac surgery using the internal consistency method. The reliability of the state anxiety scale based on Cronbach's alpha was 0.964, and the reliability of the trait anxiety scale was confirmed to be 0.853 based on Cronbach's alpha.

Statistical analysis

The data were examined using SPSS software (version 16.0, SPSS Inc., Chicago, Illinois, USA). The means, standard deviations (SDs), and frequencies (percentages), respectively, for continuous and categorical variables were provided. Data normality was assessed through the Kolmogorov–Smirnov test, which yielded a result affirming the normal distribution of the data. Demographic data in two groups were analyzed using independent t, χ^2, and Fisher exact tests. Also, independent t-test, paired t-test, analysis of covariance (ANCOVA), and multivariate analysis of covariance (MANCOVA) were used to check the level of

anxiety in the two groups and compare them. The significance level in this study was considered to be 0.05.

Results

Participants

As shown in Table 1, a total of 144 family members of patients undergoing cardiac surgery were included in this study. Among the 144 family members, 71 were in the intervention group, and 73 were in the control group. The mean age of patients was 60.69 (SD = 8.46). Among the patients, 72.92% were male, 63.19% lived in a city, and 61.81% had a hospitalization history. The mean age of family members was 42.06 (SD = 11.80). Among the family members, 61.11% were female, 77.78% were married, 54.17% lived with a husband/wife and children, 59.72% of their patients had a hospitalization history, 25.69% were retired, 38.19% were children of patients, and 54.17% had a diploma. There was no significant difference in demographic variables between the intervention and control groups ($P > 0.05$).

Anxiety among family members of patients undergoing cardiac surgery

As shown in Table 2, the difference in state anxiety between the two groups before the intervention was significant ($P = 0.010$), and the mean of the intervention group was lower than the control group. There was no significant difference in anxiety after the intervention in the two groups ($P = 0.619$). However, the changes in the state anxiety score before and after the intervention were significant between the two groups, and the changes were higher in the control group ($P = 0.043$). There was no significant difference in trait anxiety before and after the intervention between the two groups ($P > 0.05$). Also, there was no significant difference in the changes in trait anxiety before and after the intervention between the two groups ($P > 0.05$).

After controlling the effect, the state anxiety score before the intervention was not significant by using the ANCOVA test ($P = 0.886$). Also, pre-intervention anxiety scores were not significant on post-intervention scores ($P = 0.469$). In examining the effect of the intervention on the trait anxiety score in the control group and the effect of the trait anxiety score before the intervention, it was not significant ($P = 0.290$). However, the effect of the trait anxiety score before the intervention on the latent score after the intervention was significant ($P = 0.013$).

According to the MANCOVA test, intervention on state anxiety score ($P = 0.757$) and trait anxiety score was not significant ($P = 0.20$) after controlling the effects of individual social characteristics of the patient and the studied family members. Based on the results, there was only a significant relationship between the trait anxiety score before the intervention and the trait anxiety score after the intervention ($P = 0.019$). The effect rate based on the Partial Eta coefficient with the test power of 65.2 was equal to 0.041.

Discussion

The process of undergoing cardiac surgery can result in significant psychological strain for both patients and their respective family members[17,21–23]. Anxiety is a psychological disorder that

Table 1

Individual and occupational characteristics of the participants (*N* = 144)

		Groups		
	Total (*N* = 144)	Intervention (*N* = 71)	Control (*N* = 73)	*P*
Patients				
Age	60.69 (SD = 8.46)	59.87 (SD = 8.44)	61.48 (SD = 8.47)	0.256*
Sex				
Male	105 (72.92)	52 (73.24)	53 (72.60)	0.932**
Female	39 (27.08)	19 (26.76)	20 (27.40)	
Place of residence				
City	91 (63.19)	43 (60.56)	48 (65.75)	0.519**
Village	53 (36.81)	28 (39.44)	25 (34.25)	
Hospitalization history				
Yes	89 (61.81)	46 (64.79)	43 (58.90)	0.583
No	55 (38.19)	25 (35.21)	30 (41.10)	
Family				
Age	42.06 (SD = 11.80)	42.68 (SD = 11.01)	41.54 (SD = 11.38)	0.513*
Sex				
Male	56 (38.89)	24 (33.80)	32 (43.84)	0.217**
Female	88 (61.11)	47 (66.20)	41 (56.16)	
Marital status				
Single	32 (22.22)	15 (21.13)	17 (32.29)	0.755**
Married	112 (77.78)	56 (78.87)	56 (76.71)	
Living status				
Alone	8 (5.56)	3 (4.23)	5 (6.58)	0.627***
With husband/wife	58 (40.28)	31 (43.66)	27 (36.99)	
With husband/wife and children	32 (22.22)	37 (52.11)	41 (56.16)	
Hospitalization history of a family member				
Yes	58 (40.28)	29 (40.85)	29 (32.73)	0.891**
No	86 (59.72)	42 (59.19)	44 (60.27)	
Job				
Unemployed	3 (2.08)	2 (2.82)	1 (1.37)	0.899***
Housewife	21 (14.58)	11 (15.49)	10 (13.70)	
Employed	16 (11.11)	10 (14.08)	6 (8.22)	
Worker	19 (13.19)	10 (14.08)	9 (12.33)	
Self-employment	26 (18.06)	11 (15.49)	15 (20.55)	
Retired	37 (25.69)	16 (22.54)	21 (28.77)	
Farmer	13 (9.03)	6 (8.45)	7 (9.59)	
Others	9 (6.25)	5 (7.04)	4 (5.48)	
Relation to the patient				
Father	0 (0)	0 (0)	0 (0)	0.394***
Husband/wife	38 (26.39)	21 (29.58)	17 (23.29)	
Sister	25 (17.36)	14 (19.72)	11 (15.07)	
Brother	25 (17.36)	13 (18.31)	12 (16.44)	
Child	55 (38.19)	22 (30.99)	33 (45.21)	
Mother	1 (0.69)	1 (1.41)	0 (0)	
Level of education				
Elementary	16 (11.10)	7 (9.85)	9 (12.33)	0.786***
High school	42 (29.17)	21 (29.58)	21 (28.77)	
Diploma	78 (54.17)	40 (56.34)	38 (52.05)	
Bachelors	8 (5.56)	3 (4.23)	5 (6.85)	

Values are given as a mean for continuous variables and a number (percentage) for categorical variables.

*P-value was obtained with an independent *t*-test.

**P-value was obtained with a χ^2 test.

***P-value was obtained with a Fisher exact test.

Table 2

Anxiety levels of the family members ($N = 144$)

	Groups		
	Intervention ($N = 71$)	Control ($N = 73$)	*P*
State anxiety			
Pre-intervention	49.58 (SD = 3.31)	51.25 (SD = 4.24)	0.010*
Post-intervention	49.46 (SD = 4.21)	49.08 (SD = 4.97)	0.619*
P-value	0.854**	0.008**	
Differences before and after intervention	0.11 (SD = 5.13)	2.16 (SD = 6.87)	0.043*
Trait anxiety			
Pre-intervention	49.46 (SD = 2.91)	49.51 (SD = 3.49)	0.938*
Post-intervention	49.24 (SD = 3.34)	49.82 (SD = 3.26)	0.292*
P-value	0.594**	0.558**	
Differences before and after intervention	0.23 (SD = 3.55)	− 0.32 (SD = 4.58)	0.431*

Values are given as a mean for continuous variables.

*P-value was obtained with an independent *t*-test.

**P-value was obtained with a paired *t*-test.

may manifest after the admission of a family member to a healthcare facility[3]. Anxiety is a complex construct characterized by two primary underlying dimensions, namely, state anxiety and trait anxiety. State anxiety refers to people's feelings of tension, fear, self-harm, and arousal of the autonomic nervous system, while trait anxiety refers to relatively constant individual differences in susceptibility to anxiety[24]. The results of this study showed that state and trait anxiety was at a moderate to high level among the family members of patients undergoing cardiac surgery. Consistent with these results, several studies also found moderate and higher levels of anxiety in the families of cardiac surgery patients[3,25,26]. Surgery, particularly the requirement for hospitalization in the ICU, tends to elicit anxious responses from family members of patients and has the potential to interfere with decision-making during critical circumstances[27,28]. In this regard, appropriate policies in the field of health and treatment can lead to the provision of quality care and subsequent improvement of anxiety in the patients' families.

Family-centered education is one of the main concepts of nursing, intending to increase the awareness and ability of the family to provide unique care for each patient[13], which can be a vital approach to improving the quality of health care[29]. The use of family-centered care can play a significant role in the satisfaction of most families[30]. Previous studies conducted in the United States, China, and Iran confirmed the effect of family-centered care on reducing anxiety levels[3,26,31,32]. In contrast to these results, the present study showed that family-centered care is not able to reduce the anxiety of family members of patients undergoing cardiac surgery. The results of studies by Imanipour *et al.* and Bailey *et al.* also indicated that the support given to families does not affect their anxiety[33,34]. The existence of contradictions in the results of using family-centered care to reduce the anxiety of patients' families can be caused by individual and environmental confounding variables. In this regard, in this study, the results of investigating the effect of family-centered care on anxiety, by controlling the effects of confounders, revealed that trait anxiety has decreased under the influence of this care.

Limitations

There are some limitations to be mentioned in this research. Conducting the study in a health center and subsequently the small sample size has reduced the generalizability of the results. The existence of differences in the spiritual and psychological state of the participants affected their response and their complete control was not possible.

Recommendations for future research

It is recommended to conduct a multicenter study with a higher sample size and comprehensive evaluation of individual variables to get a correct estimate of the impact of family-centered care on family anxiety of patients undergoing cardiac surgery.

Conclusion

In conclusion, the high prevalence of anxiety in patients' families has negative functional consequences on both patients and their families. To reduce the level of anxiety, special attention should be paid to knowing the effective factors and appropriate coping methods. Nevertheless, it is important to note that additional research is warranted to delve deeper into this matter in future studies.

Ethical approval

The ethics committee of Guilan University of Medical Sciences, Rasht, Iran, has given its approval to this study (IR.GUMS.REC.1399.110). The participants gave informed consent after being informed of the current study's goals. It was made clear to participants that they could leave the study at any time. All study participants were assured that all reporting and publication of results would be done anonymously.

Consent

Written informed consent was obtained from the patient for publication and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

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Author contribution

Study concept and design; data acquisition; data interpretation; and drafting and revision of the manuscript: all authors. The final version of the manuscript is approved by all authors.

Conflicts of interest disclosure

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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We could not register our manuscript in the Research Registry UIN: www.researchregistry.com due to internet access restrictions and international sanctions. We live in Iran. We hardly even meet the basic needs of our daily life. We do not receive any funding for our research, and we cannot pay for our research. Please excuse us from registering this manuscript in the Research Registry UIN: www.researchregistry.com.

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Data availability statement

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Provenance and peer review

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