

Original/Research Paper

Effect of need-based education program on anxiety of relatives of patients hospitalized in intensive care units: A randomized controlled trial

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Abstract

Relatives of patients in intensive care units (ICUs) often experience high levels of anxiety. This randomized controlled trial compared needs-based educational interventions with routine education on anxiety of relatives of patients admitted to ICUs, to provide evidence to improve support and care in intensive care settings. A randomized controlled trial was conducted at Namazi Hospital, Iran, involving family members of ICU patients. Participants were assigned to intervention (n=20) and control (n=19) groups according to specific criteria. The intervention included personalized educational sessions and telephone support for seven days. The tools employed for data collection included a demographic and individual characteristics questionnaire and the Beck Anxiety Inventory-II (BAI-II). A total of 40 individuals participated in the study; however, one participant in the control group withdrew due to a lack of willingness to participate. The average age of participants in the intervention group was 39.3 (standard deviation [SD]=10.02) years, while the control group had a mean age of 37.90 (SD=9.78) years (P=0.660). Before the intervention, the intervention group had a significantly higher mean anxiety score (34.0 [SD=6.50]) than the control group (32.80 [SD=5.90]) (P=0.050). One day post-intervention, the intervention group's score decreased to 25.60 (SD=12.70), while the control group's increased slightly to 28.80 (SD=11.70) (P=0.410). By day three, the intervention group's score further decreased to 16.70 (SD=10.50), whereas the control group's mean score was 26.40 (SD=14.90) (P=0.420). However, by day seven, the intervention group's mean anxiety score was significantly lower than the control group's (P<0.001). Need-based educational interventions significantly reduced anxiety among ICU patients' relatives, highlighting their potential benefits.

Keywords: Anxiety, Education, Family Relations, Intensive Care Unit, Nursing, Nurses.

1 | Introduction

Intensive care units (ICUs) care for critically ill patients and rely on professional and interprofessional systems to provide critical care. These patients require life support and are at risk of organ failure and death [1]. On the other hand, in the ICU, unexpected and unfamiliar stimuli often elicit fear, stress, and helplessness in patients and their families [2]. These stimuli trigger a physiological stress response that suppresses the immune system and reduces blood flow and tissue oxygenation, endangering the individual's health [3]. Anxiety disorders are the most common mental disorders worldwide, which are associated with significant complications [4]. Anxiety is an essential factor in

many psychosocial injuries that, by weakening immunity, will predispose the individual's body to a large number of mental and physical diseases [5], and is also a warning sign and informs about physical threats, helplessness, failure, separation from loved ones, and ultimately a threat to the integrity of the individual, and motivates the individual to take necessary measures to confront the danger or reduce its consequences [6]. When a family member is unexpectedly admitted to the ICU, others experience disorganization and turmoil in their lives due to a lack of mental preparation. Patients in ICUs are unable to communicate due to receiving sedatives, using mechanical ventilation, confusion, and coma, which means that the burden of

decision-making and choosing the type of treatment falls on the family, which in turn can cause symptoms of stress and psychological disorders in families [7].

Family members of young patients and patients who die in ICUs seem to be at greater risk of psychological distress. Family members who are female, younger, have a greater sense of closeness to the patient, have less education, and have previous health and psychological problems are more likely to experience anxiety and psychological issues [8]. The constant experience of waiting in them causes feelings of uncertainty, lack of control, fear, anxiety, and isolation. In addition, concerns about the patient's condition and the risk of losing them exacerbate these feelings. On the other hand, the strong desire of families to be close to the patient and concerns about losing them cause them to wait for long periods of time behind the door of the ICU to learn about the patient's condition and the results of treatments. The ICU environment, with its 24-hour stimuli and the patient and family's exposure to life-threatening situations, affects the family and causes stress, anxiety, depression, and post-traumatic stress disorder [9, 10].

During the patient's hospitalization in the ICU, family members experience a change in role and feel fear and insecurity. Fear of the patient's death, doubt about his prognosis and treatment, emotional conflicts, concerns about economic conditions, and disruption of daily activities can lead to reactions such as shock, anger, despair, and anxiety. The level of anxiety in the families of patients in the ICU is high and causes changes in family functioning, frequent visits to the hospital, and high costs [11, 12]. Families of patients hospitalized in ICUs ranked five needs as more important than the others. These needs were: care, communication, respect, empathy, family member participation, and the physical quality of the ward [13, 14]. Considering the critical situation of ICU patients and the prevailing conditions in these wards, families of ICU patients need psychological and physical support. Considering the needs of patients' families hospitalized in ICUs, communicating with them is an essential responsibility of ICU nurses [15].

Education is one of the most critical roles of nursing and a standard of care in any health care setting, and it should receive special attention [7, 16]. The need to reduce hospital length of stay, the increase in the number of chronic patients, and the need to provide concise, understandable information to patients and their families as quickly as possible underscore the importance of quality education. A comprehensive education plan tailored to the client's needs can, in addition to improving the quality of care, reduce health care costs. This is useful in achieving optimal health and increasing the independence of clients and their

families. Nursing interventions can provide appropriate, needs-based education by assessing the client's and family's needs and using the most suitable methods [17]. This education should be designed before discharge and continued at home thereafter, thereby reducing health service costs [18]. Since education is a dynamic process in nursing practice, determining educational needs based on priority is considered the first step in educational planning [19]. It is important to note that education is more effective when grounded in a needs assessment, and the implementation of any academic program requires continuous evaluation of needs. It is evaluated in accordance with the existing conditions [20]. Recent studies have shown that negative views of the disease are associated with poor outcomes, and individuals' understanding of the disease can be significantly altered, creating circumstances that can improve beliefs and help them adapt to the disease and its conditions [21]. Hospitalization can cause stress for patients and their families. At the same time, given the ICU's structure, the presence of family members and family-centered care are needed to facilitate a faster recovery, despite implementation barriers [22]. In this regard, nurses in special and sensitive wards should seek to establish communication with patients' family members to reduce distress and better understand their needs [7].

Therefore, the researchers investigated the effect of needs-based education on the anxiety of patients' relatives in this study by contacting the families of patients hospitalized in ICUs, assessing their needs, and providing education and information tailored to those needs.

2 | Methods

A randomized controlled trial was conducted in the Neurosurgery ward at Namazi Hospital, a tertiary-care center. The research received approval from the Shiraz University of Medical Sciences (IR.SUMS.REC.1400.007). Additionally, the research was registered with the Iranian Registry of Clinical Trials (IRCT20160525028060N3). The criteria for inclusion in the study included a willingness to participate, being a close relative of the patient (such as a spouse, sibling, parent, or child), involvement in the decision-making process, being between the ages of 18 and 65, having the ability to communicate verbally, and being able to read and write. Additionally, participants should not have a history of known psychological disorders and must have had the patient hospitalized in the ICU for over 48 hours. Exclusion criteria encompassed incomplete questionnaire responses and refusal to continue participation in the intervention group. We aimed to include participants in each group who had

similar baseline characteristics to minimize the impact of confounding variables on our outcomes. Participants who met the eligibility criteria were randomly assigned to two groups: the intervention group ($n=20$) received a needs-based educational intervention, and the control group ($n=19$). The study population comprised family members of ICU patients. The sample size was determined based on a previous similar study by Golaghaie et al., (2016) [23], with a type I error rate (α) of 0.05 and a statistical power ($1 - \beta$) of 0.90; an initial sample size of 16 participants was calculated. To accommodate a possible 20% dropout rate, the final sample size was increased to 20 participants per group. Participants were selected from the primary relatives of patients admitted to two ICUs with similar facilities and services, in accordance with the inclusion criteria. Two groups were randomly assigned in a 1:1 ratio to either the control or the intervention group using a computer-based block-randomization technique. A biostatistician, unaware of the group assignments, conducted the randomization. The sample sizes were deemed adequate for thorough statistical analysis, and a 1:1 randomization was used to improve compliance. Although both groups received basic care, the educational intervention was provided exclusively to the group that required it. For each patient, one eligible relative is selected to participate in a structured educational intervention. The process begins with a comprehensive assessment of the selected relative's educational needs, conducted through direct communication and standardized evaluation tools. This assessment ensures that the intervention is tailored to the family member's unique informational and emotional needs [24, 25]. Based on the identified needs, an individualized educational program is developed, focusing on key areas such as the patient's medical condition, treatment options, prognosis, and practical strategies for coping with stress and providing effective support. The core component of the intervention consists of at least one face-to-face session lasting at least one hour. This session is delivered by trained healthcare professionals -such as nurses, psychologists, or social workers- who have undergone specialized training in psychoeducational techniques, communication skills, and family-centered care to ensure consistent and empathetic delivery of content. During the session, the relative receives need-based education through a combination of verbal explanations, written materials, and interactive discussions designed to enhance understanding and engagement. Following the initial session, ongoing support is provided via scheduled telephone calls over the subsequent week. These follow-up contacts clarify questions, reinforce key information, and provide additional emotional support, thereby promoting retention and practical application of

the educational content. This multi-modal, personalized approach, delivered by trained personnel, aims to empower relatives with the knowledge and skills necessary to support the patient effectively while also addressing their own well-being. The tools employed for data collection included a demographic and individual characteristics questionnaire and the Beck Anxiety Inventory-II (BAI-II). The BAI-II assesses the severity of clinical anxiety using a 21-item scale. Respondents select one of four options for each item, reflecting their level of anxiety. Each question uses a four-point scoring system, with total scores ranging from 0 to 63. The classifications are as follows: 0-7 indicates no anxiety, 8-15 signifies mild anxiety, 16- 25 represents moderate anxiety, and 26-63 denotes severe anxiety. Developed by Aaron T. Beck and colleagues in 1990, the questionnaire has demonstrated high validity ($\alpha = 0.92$) and reliability ($\alpha = 0.75$), with item correlations ranging from 0.30 to 0.76 [26, 27]. Kaviani & Mousavi (2008) [28] showed that the Persian translation of the BAI maintains strong validity ($r=0.72$), reliability ($r=0.83$), and excellent internal consistency ($\alpha=0.92$). The questionnaires were distributed at three time points: 1 day, 3 days, and 1 week after the initial session. Once data collection was complete, the data were analyzed using descriptive and inferential statistics in the Statistical Package for the Social Sciences (SPSS) version 26. Descriptive statistics for demographic and intervention variables were reported as means, standard deviations (SDs), frequencies, and percentages. For the inferential analysis, a range of statistical tests were used, including t-tests, Chi-square tests, Fisher's exact tests, analysis of variance with repeated measures, and the Mann-Whitney test. A significance level of $P<0.05$ was established.

3 | Results

A total of 40 individuals participated in the study; however, one participant in the control group withdrew due to a lack of willingness to participate (Figure 1). The groups were well matched with respect to age, marital status, relationship to the patient, patient sex, surgical history, and family admission history. The average age of participants in the intervention group was 39.30 (SD=10.02) years, while the control group had a mean age of 37.90 (SD=9.78) years ($P=0.660$). The mean age of the intervention group was 46.60 (SD=15.80) years, compared with 33.75 (SD=26.42) years in the control group ($P=0.070$). This indicated differences between the case and control groups. Table 1 establishes the comparability of the groups at baseline. Table 2 compared mean anxiety scores between the intervention and control groups. Before the intervention, the intervention group

had a significantly higher mean anxiety score (34.0 [SD=6.50]) than the control group (32.80 [SD=5.90]) ($P=0.050$). One day post-intervention, the intervention group's score decreased to 25.60 (SD=12.70), while the control group increased slightly to 28.80 (SD=11.70) ($P=0.410$). By day three, the intervention group's score further decreased to 16.70 (SD=10.50), whereas the control group's mean score was 26.40 (SD=14.90) ($P=0.420$). However, by day seven, the intervention group's mean anxiety score was significantly lower than the control group's ($P<0.001$).

4 | Discussion

The result of the present study showed that the need-based educational intervention leads to reduced anxiety in the relatives of patients admitted to the ICU. In this regard, our results are in agreement with the findings of a study by Brooke *et al.*, (2012) [29], which showed that the anxiety of the family members during the discharge from the ICU to the general ward decreased

after providing sufficient information about the disease, the environment where the patient is transferred, and the care of the patient [29].

The study by Chien *et al.*, (2006) also found that need-based education decreased anxiety among family caregivers of intensive care patients [30]. Also, Golaghaie *et al.*, (2016) [23] demonstrated that family-centered clinical interventions effectively reduced anxiety levels in family members of critically ill patients, supporting the notion that providing information and emotional support can mitigate anxiety during stressful hospitalizations [23]. The results of a study conducted by Li *et al.*, (2022) showed that anxiety and depression decreased in patients with type 2 diabetes and hypertension after receiving educational interventions about the disease and rehabilitation from its effects [31]. The results of the study by Bahrami *et al.*, (2009) showed that the anxiety and stress of the patients' families decreased after the intervention [32].

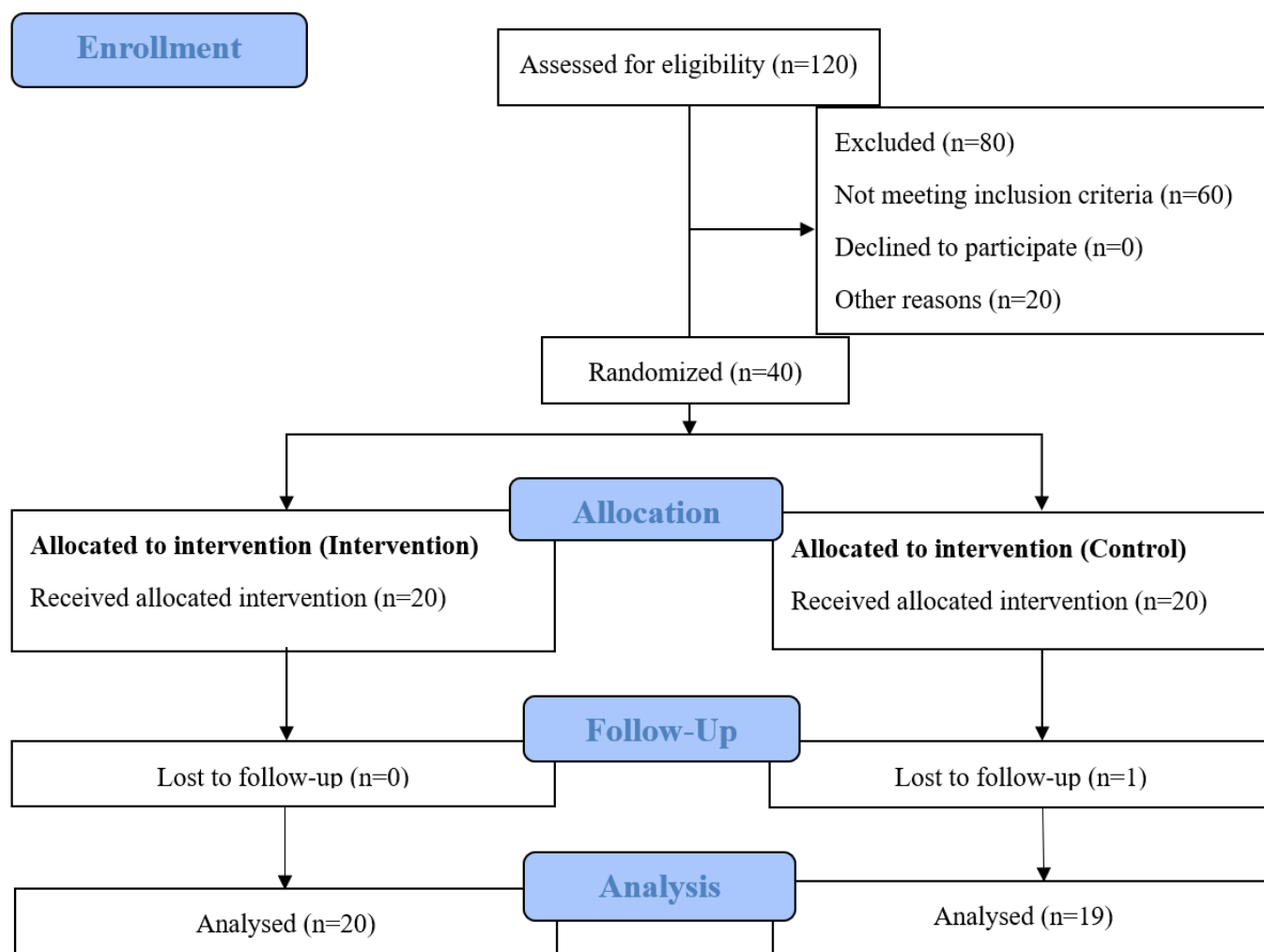


Figure 1. CONSORT flow diagram of participant enrollment.

Table 1. Baseline characteristics of all included participants (N=39).

Variables	Groups		P-value
	Intervention group (N=20)	Intervention group (N=20)	
Age (participants)	39.3 (SD=10.02)	37.9 (SD=9.78)	0.660*
Patients age	46.6 (SD=15.80)	33.75 (SD=26.42)	0.070*
Sex (participants)			
Female	8 (40)	15 (15)	0.054**
Male	12 (60)	5 (25)	
Marital status (participants)			
Single	4 (20)	2 (10)	0.660**
Married	16 (80)	18 (90)	
Relation statues			
Spouse	4 (21.1)	3 (16.7)	0.840**
Mother	2 (10.5)	5 (27.8)	
Father	2 (10.5)	2 (11.1)	
Sister	1 (5.25)	2 (11.1)	
Brother	3 (15.8)	1 (5.6)	
Children	7 (36.8)	5 (27.8)	
Patient sex			
Female	7 (35)	8 (40)	0.740*
Male	13 (65)	12 (60)	
Operation			
Yes	18 (90)	17 (85)	0.990**
No	2 (10)	3 (15)	
History of family admission			
Yes	7 (35)	6 (30)	0.740*
No	13 (65)	14 (70)	

Data are presented as numbers (percentages) and Mean (SD).

* P-value obtained with a Chi-square test.

** P-value obtained with a Fisher's exact test.

Table 2. Comparison of the mean anxiety score between the intervention and control groups before, one day after, 3 days after, and 7 days after the intervention (N=39).

Time	Groups		P-value
	Intervention group (N=20)	Intervention group (N=20)	
Before of intervention	34.0 (SD=6.5)	32.8 (SD=5.9)	0.050*
1 day after the intervention	25.6 (SD=12.7)	28.8 (SD=11.7)	0.410*
3 days after the intervention	16.7 (SD=10.5)	26.4 (SD=14.9)	0.420**
7 days after the intervention	6.7 (SD=3.9)	18.8 (SD=10.5)	<0.0001**

Data are presented as mean (SD).

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

** P-value obtained with a Mann-Whitney test.

As results of similar studies show, education based on a prior needs assessment of family members of hospitalized patients, by identifying the factors that cause confusion, worry, and anxiety in them and explaining and educating them about the unknowns, can significantly reduce family members' anxiety. In contrast to the results of the present study, the results of a survey by Gol Aghaei et al. aimed at investigating the effect of family-centered clinical intervention on the anxiety of family members of hospitalized patients in the ICU showed that the level of anxiety of the patient's family increased on the sixth day of hospitalization

compared to the second day in the intervention group with the receipt of clinical information, presence at the patient's bedside, and participation in the patient's care [23]. The differences in results may be due to the type of intervention performed or the educational content provided. On the other hand, the active presence of the family in the patient's care may have increased their anxiety.

In light of these findings, need-based educational interventions should be standard practice in ICU family care. Tailored education reduces relatives' anxiety and creates a

supportive environment that can aid patient recovery. Healthcare providers should prioritize early, personalized communication to address family members' specific concerns and needs, thereby enhancing their well-being and involvement in care. Such interventions support family-centered care and can improve overall ICU care.

4.1 | Limitations

This study has several limitations. The primary limitation is the small sample size. Additionally, the study's short duration and lack of follow-up represent further constraints. Another limitation is the absence of objective data to validate our subjective findings. The study was also limited by its single-center design. Challenges included incomplete questionnaires and the emotional distress experienced by participants due to having a loved one in the ICU, which might have influenced their responses. Since the data were self-reported, factors such as relatives' emotions, daily difficulties, and external sources of information could have impacted the results. The study did not address cultural factors affecting stress and education. Future studies should investigate cultural variations and incorporate more extended follow-up periods.

5 | Conclusions

The findings of this randomized controlled trial suggest that need-based educational interventions can effectively reduce anxiety, as evidenced by the significant decrease in anxiety scores in the intervention group compared to the control group by day seven. These results highlight the potential benefits of implementing such interventions in the ICU setting to support the psychological well-being of patients' relatives. However, further research with larger sample sizes and more extended follow-up periods is recommended to validate these findings and examine their long-term effects.

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Authors' contributions

Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work: LM, DA, ME; Drafting the work or revising it critically for important intellectual content: LM, DA, ME; Final approval of

the version to be published: LM, DA, ME; Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: LM, DA, ME.

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Ethics approval and consent to participate

The research received approval from the Shiraz University of Medical Sciences (IR.SUMS.REC.1400.007). Additionally, the research was registered with the Iranian Registry of Clinical Trials (IRCT20160525028060N3). Before participation, all individuals provided informed consent after the study's objectives were thoroughly explained.

Competing interests

We do not have potential conflicts of interest with respect to the research, authorship, and publication of this article.

Availability of data and materials

The datasets used during the current study are available from the corresponding author on request.

Using artificial intelligent chatbots

None.

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