The Effect of Education, Telephone Monitoring on Self-Efficacy and Shock Anxiety of Implantable Cardioverter Defibrillator Patients

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ABSTRACT

Objective: Implantable cardioverter defibrillators (ICDs), which are used in the treatment of fatal ventricular arrhythmias, have many life-saving benefits. On the other hand, it has negative effects in terms of physical, social and psychological aspects by commonly causing anxiety and depression. The aim of this study is to examine the effects of education and telephone monitoring on self-efficacy and shock anxiety in patients with implantable cardioverter defibrillator implantation.

Methods: 65 patients hospitalized for ICD insertion were randomly divided into intervention (n=33) and control (n=32) groups. The intervention group was given a training booklet prepared by one-on-one training about ICD. Telephone monitoring was performed once every two weeks for three months and then once a month. No intervention was applied to the control group. Self-Efficacy and Outcome Expectation Scales, Florida Shock Anxiety Scale were applied in the third and sixth months after ICD implantation in both groups.

Results: The self-efficacy scores at the sixth month were higher in the intervention group than in the control group (p=.03). There was no difference between the shock anxiety scores at 3 months (p=.58) and 6 months (p=.64) between the groups. Shock anxiety mean scores of both groups in the 6th month are lower than the mean scores in the 3rd month (p<.01). It was found that self-efficacy and outcome expectation scores decreased as shock anxiety scores increased.

Conclusion: It was determined that the intervention increased the level of self-efficacy and did not make a difference in terms of and shock anxiety. It should be aimed to reduce shock anxiety and accompanying physical problems by supporting patients with various nursing interventions that will increase self-efficacy during adjustment periods.

Keywords: Implantable cardioverter defibrillator, self-efficacy, anxiety, phone call, training.

1. INTRODUCTION

Implantable cardioverter defibrillators (ICDs) are technical devices that automatically detect fatal ventricular arrhythmias such as ventricular fibrillation and ventricular tachycardia and apply the necessary treatment. ICDs have been frequently used to provide out-of-hospital early defibrillation since the 1980s (1-5) There has been a noticeable reduction in cardiovascular death rates after the initiation of treatment of arrhythmias with the ICD (5,6)

It is known that living with an implanted device and experiencing ICD shock causes various harms to the patient and the family (7). Patients with ICD are at risk for symptoms related to anxiety disorders and depressive episodes due to sudden exposure to shock, and concern that the device is not working properly or that any activity in daily life could cause shock (8). In different studies, the levels of clinical anxiety and depression have been shown to be 24-87% and 24-33%, respectively (9-12)

Shock anxiety is defined as fear of possible shocks and avoidance of activities that may trigger shock (13,14). Even in individuals who have not experienced shock, fear of shock can increase anxiety and avoid some behaviors, create a feeling of limitation in activities in daily life, and can be an important cause of morbidity (15-19). Diagnosis and treatment of anxiety is important for the prevention of morbidity (18).

Self-efficacy may be a key factor in post-implantation compliance of ICD patients. Those with low post-implantation belief in self-efficacy may overestimate the difficulties in the adaptation period (1,20). Studies have emphasized that training on living with ICD is important during the compliance period (21,22). Telephone monitoring method has been used in many studies due to its convenience and cost-effectiveness in reaching patients with ICD and other chronic diseases (1,23). In this study,

telephone monitoring was preferred in the follow-up of patients with ICD who usually live far from the hospital and have disability in terms of driving.

2. METHODS

In our study, it was aimed to examine the effects of education and telephone monitoring on self-efficacy and outcome expectations, which are prominent in the adjustment periods of individuals with ICD, and on shock anxiety, which is a common problem.

The research was conducted between March 2016 and March 2017 in the Cardiology Department of a Training and Research Hospital in Istanbul. The research was planned as quasi-experimental and prospective.

2.1. Sample

Power analysis was performed using the G*Power (v3.1.7) program to determine the number of samples. According to Cohen's effect size coefficients; it was decided that the number of cases in the groups should be taken as a minimum of 30, considering that there should be at least 26 people in the groups and there might be losses during the study process after the calculation made by assuming that the evaluations to be made between two independent groups would have a large effect size (d=0.80). The study inclusion criteria were patients over 18 years of age, about to have/newly inserted ICDs, being reachable by phone, who usually live far from the hospital and have disability in terms of driving and agreeing to participate in the study. Exclusion criteria were hearing and cognitive problems (such as dementia), presence of uncontrolled co-morbidities (such as cancer), use of medication for anxiety/depression, and refusing to participate in the study.

Among the 69 patients who were found to be eligible for inclusion criteria in a training and research hospital in Istanbul between March 2016 and 2017; two patients were excluded from the study because they were not discharged because of mental retardation and one patient was not discharged due to co-morbidities. In order to ensure randomization, the patients were divided into intervention group and control group, including 34 and 32 patients respectively, according to the odd or double admission date. A patient included in the intervention group was excluded from the study because of reporting that the follow-up will continue in another hospital. The study was terminated with 65 patients, 33 in the intervention group and 32 in the control group (Figure 1).
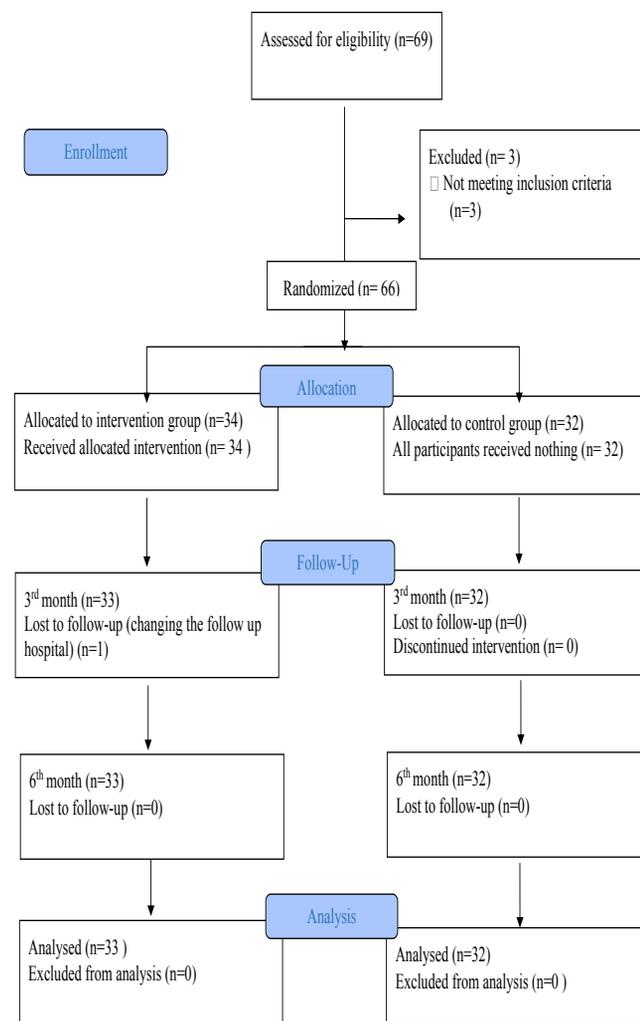

Figure 1. Flow chart of the inclusion and exclusion of participants.

2.2. Data Collection Tools

Self-efficacy and outcome expectations scales after ICD implantation were developed by Dougherty, Johnston, and Thompson in 2007 to measure self-efficacy and outcome expectations of ICD patients. The scale has two sub-dimensions: self-efficacy and outcome expectations after ICD implantation. Items are scored in the range of 0 (not at all sure) to 10 (very sure). Higher scores obtained from the scale mean that self-efficacy increases. The outcome expectations scale, on the other hand, consists of seven items and focuses on perceived self-management behaviors after ICD implantation. Items are scored between 1 (definitely true) – 5 (definitely not true). Higher scores obtained from the scale mean that outcome expectations increase (20). The validity and reliability of the scales for the Turkish population was made by Alkan and Enç in 2014. After the validity and reliability study, the scale consisted of a total of 15 items. Cronbach's alpha coefficients were found to be .87 and .75 (24). Cronbach's Alpha coefficients for self-efficacy at 3rd and 6th months in our study was found to be .96 and .94, respectively. On the other hand, Cronbach's Alpha coefficient

for outcome expectations at 3rd and 6th months was found to be .94 and .98.

Florida shock anxiety scale: It was developed by Kuhl et al. in 2006 to determine the shock anxiety levels of ICD patients. In the evaluation of the scale, the items are scored between 1-5. The total scores obtained from the scale vary between 5 and 50, and higher scores mean that the patient's level of shock anxiety is high (15). The validity and reliability of the scale for Turkish population was made by Alkan and Enç in 2014. Cronbach's alpha coefficient was found to be .87 (25). The Cronbach's Alpha coefficients for the shock anxiety scale in our study were found to be .96 at 3rd month and .95 at 6th month.

Training Booklet: The booklet, which consists of the content of the training given to the intervention group patients, was prepared by the researcher after examining the sample booklets and consulting the expert opinion (three nursing faculty members and two cardiology physicians). It was given to patients after one-on-one training. The training booklet include information about the normal heart rhythm, abnormal heart rhythms (ventricular tachycardia and fibrillation), individuals who need the ICD, description of ICD and its placement, the practices to be performed in the clinic after the procedure, the follow-up process, the possible risks and the daily life with the ICD (driving, physical activity, when to start sexual life, etc.), points to be considered in electromagnetic interaction and frequently asked questions. Answers to the following questions: 'Answers to the questions 'Will I realize I have an ICD in my body, what will I feel when ICD shocks, will there be a warning before shocking, what should I do after shock, can I travel abroad, will I continue to take my medications, what is the difference between a pacemaker and ICD', are explained in the frequently asked questions section. It is a 25-page booklet in A4 format.

Checklist for phone calls: The form prepared by the researchers in the light of the literature (15,21,26,27) for use in telephone interviews with intervention group patients include; several questions adapted from the scales for self-efficacy, outcome expectations and shock anxiety in order to make the telephone interviews in a semi-structured order.

The checklist for phone calls includes questions such as the name of the patient who was interviewed, the number of interviews, the duration of the interview, whether the ICD shocked, how it felt if it shocked, whether there was a situation of concern or distress (walking, running, exercising, sleeping, pain, drugs, sexual intercourse, returning to work, cardiac arrest/rhythm disturbance, ICD is given shock, ICD is not given shock) .

2.3. Data Collection Method

The intervention and control group patients received the routine care applied in the hospital. In the routine care of the hospital, there is no training on ICD, only the procedure is explained in order to obtain an informed consent.

Data collection method from intervention and control groups is shown in Figure 2.

In the first interview with the intervention group patients, their consent was obtained after providing informative information about the study. The phone number of the researcher was given to the patients after filling out the patient identification form and they were told that they could call whenever they wanted. The patients were trained after completing the introduction form. One or two relatives of the patient were also included in the training. The patient was in a comfortable sitting position, the door of the room was closed, and the training was conducted in such a way that face-to-face interaction would occur. The patients and their relatives were given the opportunity to ask questions during the training. The training was carried out for durations varying between 35-60 minutes from patient to patient. At the end of the training, the training booklet prepared for the patients was delivered. In the first three months after discharge, the patients were called every two weeks, and the questions included in the checklist were asked to the patients and the questions of the patients were answered. Phone calls lasted an average of 10-15 minutes. On the control days of the third month, after the control was over, SE-ICD, OE-ICD and FSAS were filled in with a face-to-face interview. The average time to fill the scales took 20-30 minutes. During the remaining months of the follow-up, the patients were called once a month to ask the questions included in the checklist for phone interviews, and the questions of the patients were answered. SE-ICD, OE-ICD and FSAS were filled in by face-to-face interview after the control was completed on the sixth month control days.

The patients in the control group were told that they would be called by the researcher to learn the control days by filling out the patient information form face to face. In the third and sixth months, the patients were called by phone and the control days were learned. These interviews lasted an average of 2-3 minutes. SE-ICD, OE-ICD and FSAS were filled in face-to-face interviews after the control was completed on the control days in the third month and sixth month. The average time to fill the scales took 20-30 minutes. After the research was completed in the sixth month, the patients in the control group were educated and given a training booklet.

2.4. Data Analysis

While evaluating the study data, Student's t-Test for two-group comparisons of normally-distributed parameters, and Mann-Whitney U test for two-group comparisons of non-normally-distributed parameters were used when comparing quantitative data in addition to descriptive statistical methods (Mean, Standard Deviation, Median, Frequency, Ratio, Minimum, Maximum). Kruskal Wallis test was used in comparisons of three or more groups that do not show normal distribution. Wilcoxon Signed Ranks test was used for in-group comparisons of non-normally distributed parameters. Pearson Chi-Square test was used to compare qualitative data. Spearman's Correlation Analysis was used

to evaluate the relationships between variables. Significance level was determined as p< .05.

2.5. Ethical Considerations

The research was conducted in accordance with the Declaration of Helsinki. Written permission, in order to conduct the research, was obtained from the Health Sciences Institute Ethics Committee of a university, with protocol number 115 dated 26/10/2015. Written permission was obtained from the Training and Research Hospital where the study was conducted. Written consent was obtained from the patients included in the study, after they were informed about the study with an information form and necessary explanations were given. At the end of the research, the control group was trained and a training booklet was given.
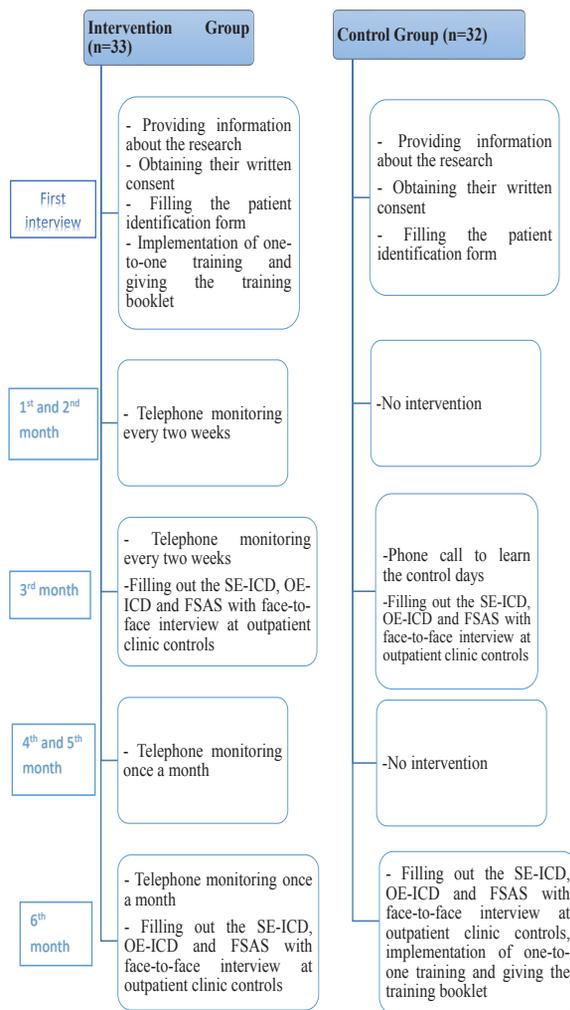

Figure 2. Study application plan

3. RESULTS

Information on demographic and some medical characteristics of the groups is given in Table 1. It was found that there was no difference between the groups in terms of these characteristics (Table 1). When the mean age of the participants was examined,

it was seen that the intervention group was 55.88±15.57, the control group was 55.72±15.79, and the majority of the patients in both groups were male (75.8%, 78.1%) and married (75.8%, 68.8%). When ICD shocks are examined; It was determined that 48.5% of the intervention group and 40.6% of the control group experienced shock at the 3rd month. On the other hand, it was determined that 27.3% of the intervention group and 37.5% of the control group experienced shock at the 6th month (Tablo 1).

Table 1. Comparison of sociodemographic and medical characteristics of intervention and control group patients

Characteristics		Intervention group (n=33)	Control group (n=32)	Homogeneity	
				X^2/t	p
Age (year)	Min-Max (Median)	18-79 (58)	20-76 (58)	0,041	c0,97
	Meant±SD	55,88±15,57	55,72±15,79		
Gender; n (%)	Female	8 (24,2)	7 (21,9)	0,051	d0,82
	Male	25 (75,8)	25 (78,1)		
Marital status; n (%)	Married	25 (75,8)	22 (68,8)	0,398	d0,53
	Single	8 (24,2)	10 (31,2)		
Educational status; n (%)	Literate	3 (9,1)	3 (9,4)		
	Primary school	18 (54,5)	12 (37,5)		
	Secondary school	5 (15,2)	3 (9,4)	1,847	d0,17
	High school	6 (18,2)	10 (31,2)		
	University	1 (3,0)	4 (12,5)		
	Primary school and below	21 (63,6)	15 (46,9)	8,741	d0,07
	Secondary school and above	12 (36,4)	17 (53,1)		
Working status; n (%)	Working	9 (27,3)	14 (43,7)	2,226	d0,33
	Not working	10 (30,3)	6 (18,8)		
	Retired	14 (42,4)	12 (37,5)		
Economic status; n (%)	Income less than expenses	4 (12,1)	4 (12,5)	0,002	0,96
	Income equal to/ more than expenses	29 (87,9)	28 (87,5)		
Living with; n (%)	With spouse	13 (39,4)	11 (34,4)	0,807	d0,67
	Spouse and child	12 (36,4)	10 (31,2)		
	Other	8 (24,2)	11 (34,4)		
Chronic disease; n (%)	Not present	15 (45,5)	12 (37,5)	0,423	d0,52
	Present	18 (54,5)	20 (62,5)		
3rd month shock status; n (%)	Not present	17 (51,5)	19 (59,4)	0,406	d0,52
	Present	16 (48,5)	13 (40,6)		
6th month shock status; n (%)	Not present	24 (72,7)	20 (62,5)	0,777	d0,38
	Present	9 (27,3)	12 (37,5)		

cStudent-t test; dPearson Chi-Square Test

While the 3rd month self-efficacy scores did not differ according to the groups (p=.32 p> .05); It was seen that the 6th month self-efficacy scores were higher in the intervention group than in the control group (p= .03). It was found that the 6th month self-efficacy scores were higher than the 3rd month scores in both groups (p< .01) (Table 2).

Table 2. Comparison of self-efficacy, outcome expectation, and shock anxiety of intervention and control group patients

Scales	Follow-up time		Intervention group (n=33)	Control group (n=32)	Z	ᵃp
Self-efficacy	3rd month	Min-Max (Median)	26-90 (60)	25-90 (54)	-0,992	0,32
		Mean±SD	59,09±19,26	54,25±18,42		
	6th month	Min-Max (Median)	44-100 (75)	36-100 (61,5)	-2,123	0,03*
		Mean±SD	72,67±15,21	63,69±16,41		
		Z	-4,886	-4,700		
		ᵇp	<.01	<.01		
Outcome Expectation	3rd month	Min-Max (Median)	15-25 (21)	5-25 (20,5)	-0,930	0,93
		Mean±SD	21,00±3,23	20,63±4,51		
	6th month	Min-Max (Median)	5-25 (23)	18-25 (25)	-0,624	0,53
		Mean±SD	22,24±4,05	23,06±2,56		
		Z	-2,889	-3,476		
		ᵇp	<.01	<.01		
Shock Anxiety	3rd month	Min-Max (Median)	10-44 (23)	10-45 (21,5)	-0,560	0,58
		Mean±SD	23,30±10,32	22,13±10,18		
	6th month	Min-Max (Median)	10-37 (20)	10-39 (16,5)	-0,466	0,64
		Mean±SD	19,33±8,75	19,81±8,47		
		Z	-4,347	-3,451		
		ᵇp	<.01	<.01		

ᵃMann Whitney U Test; ᵇWilcoxon Signed Ranks Test; *p<,05

The 3rd month (p= .93) and 6th month (p= .53) outcome expectation scores did not differ between the groups. It was found that the 6th month outcome expectation scores were higher than the 3rd month scores in both groups (p< .01) (Table 2).

Shock anxiety scores at 3 months (p= .58) and 6 months (p= .64) did not differ between the groups (p> ,05). In both groups, 6th month shock anxiety scores were lower than 3rd month scores (p< .01) (Table 2).

Table 3. The Relationship between self-efficacy, outcome expectation, and shock anxiety

Scales		Total (n=65)		Intervention group (n=33)		Control group (n=32)	
		3rd month	6th month	3rd month	6th month	3rd month	6th month
Self-efficacy – Outcome expectation	r	0,476	0,334	0,443	0,368	0,518	0,418
	p	<.01	<.01	0,01*	0,03*	<.01	0,02*
Self-efficacy – Shock anxiety	r	-0,756	-0,690	-0,792	-0,680	-0,750	-0,692
	p	<.01	<.01	<.01	<.01	<.01	<.01
Outcome expectation – Shock anxiety	r	-0,548	-0,466	-0,534	-0,362	-0,550	-0,596
	p	<.01	<.01	<.01	0,04*	<.01	<.01

r: Spearman's Correlation Coefficient; *p<,05; **p<,01

4. DISCUSSION

In this study, it was found that the self-efficacy of individuals with ICD who underwent training and telephone follow-up was increased compared to the control group, and there was no difference in outcome expectations between the groups. In another study in which telephone support was applied to individuals with ICD, it was found that self-efficacy was increased (27). After ICD implantation, patients need to develop behavioral changes in order to adapt to their new situation. Self-efficacy and outcome expectations are important concepts in developing adaptive behavior (20,28). Studies have shown that it is possible to achieve improvements in many parameters during the adjustment period of patients with ICD with various interventions. Cowan et al. (2001), applied a psychosocial education program to the intervention group patients and found that the intervention reduced the deaths from cardiovascular causes in the patients and did not affect the heart rate variability, anxiety, depression and anger in their study where they followed up every six months for two years (29). In the study of Smeulders et al. (2007), in which they applied a patient-centered self-management program to patients with ICD in groups, they found that the patients' self-efficacy levels increased and their satisfaction with the program was higher (30). Yardımcı & Mert (2019) stated that there was improvement in many sub-dimensions of the quality of life of patients with ICD, to whom they applied web-based training (31). In our study, it is seen that training and telephone counseling similarly improve self-efficacy.

As a result of this study, it was determined that there was no significant difference between the groups in terms of shock anxiety, and the shock anxiety of both groups was lower at 6 months. In another study conducted with the Turkish population, it was found that there was a significant decrease in state anxiety in patients with ICD who underwent a planned education and follow-up program, and there was no significant difference between the intervention and control

groups (17). It is thought that these two similar results are due to the fact that patients generally display a fatalistic attitude. Flemme et al. (2012) also found that one of the most common methods used by patients to cope with depression and anxiety symptoms and deterioration in quality of life is 'fatalism' (32). There is only a weak relationship between the experience of shock and shock anxiety; therefore, even in the absence of actual device firing, shock anxiety persists (33). Not knowing where and when shocking will occur, and lack of knowledge about what to do during shocking are reasons for anxiety in individuals with ICD. It has been accepted that education and post-discharge follow-up conducted with different methods in various qualitative and quantitative studies, increase the quality of life by reducing uncertainty and anxiety in patients (17,34-37).

It is a known fact that anxiety contributes to poor outcomes in morbidity and mortality in cardiology (33). Shock anxiety is an important problem that has the potential to cause different problems in individuals with ICD. Nursing interventions are needed for the patients in order to cope with problems about returning to work, sexual life and other physical restrictions in the post-ICD period (27,32,38). In the study of Mlynarska et al. (2020); having concerns about ICD has been reported to have a major impact on physical, psychological, and social vulnerability (39). In a study, it was determined that the sexual functions of those with high shock anxiety were poor (10).

It is necessary to correct the false beliefs of patients that lead them to avoid activities that may cause an increase in heart rate. In addition to training on ICDs, interventions such as simple stress management techniques such as deep relaxation or breathing exercises that provide a degree of control over heart rates and reduce distress can be planned in line with this purpose (40).

It is seen in the studies in the literature that different attempts are made to reduce the shock anxiety of patients with ICD. Sears et al. (2007) found that the stress and shock management program in six-week sessions and in a one-day psycho-educational workshop reduced the anxiety and cortisol level in saliva in patients with ICD, while the decrease in anxiety level was faster in the six-week program (41). The patients with ICD in the study of Salmoirago-Blotcher et al. (2013), received mindfulness meditation training over the phone and it was seen at the end of the study that the awareness levels and anxiety levels of the intervention group patients were more positive than the control group (36). In a study that applied a yoga program to patients with ICD (42) and in another study that applied training based on web-based social cognitive learning theory (31), it was found that the intervention group had a significant reduction in shock anxiety.

Similar results were observed for both groups at 3 and 6 months in this study when the relationship between self-efficacy, outcome expectations and shock anxiety was examined. A high level of negative correlation was found between self-efficacy and shock anxiety scores for both groups. It was observed that there was a positive weak-moderate relationship between self-efficacy and outcome expectation scores, and a moderate negative relationship between shock anxiety and outcome expectations. Morken et al. (2014) found that shock anxiety increased in patients with ICD as the support received from healthcare professionals was decreased (14). The relationship between self-efficacy and shock anxiety in our study also supports this study. Education and telephone follow-up intervention increased the self-efficacy of the patients and caused a decrease in shock anxiety.

4.1. Study Limitations

The limitations of the study are that the study was conducted in a single center, the number of samples was small, and the intervention was not blinded for the researchers and the participants.

5. CONCLUSION

This study showed that self-efficacy increased in the intervention group, which received training and telephone follow-up six months after ICD insertion, compared to the control group, while outcome expectations and shock anxiety were not different between the groups. It is noteworthy that shock anxiety decreased in both groups at the sixth month. The high negative correlation between self-efficacy and shock anxiety shows us how important nursing interventions are to increase the self-efficacy of patients. It should be aimed to reduce shock anxiety and accompanying physical problems by supporting patients with various nursing interventions that will increase self-efficacy during adjustment periods.

Author Contribution:
Research idea: BA, SO
Design of the study: BA, SO
Acquisition of data for the study: BA
Analysis of data for the study: BA, SO
Interpretation of data for the study: BA, SO
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