Original Article

The Effect of Continuous Care Program on the Self-Efficacy of Patients with Implantable Cardioverter Defibrillator: A Randomized Control Trial

Shirin Afshar Ghahreman Khani[1], Pegah Matourypour[2], Majid Haghjoo[1], Masoumeh Zakerimoghadam[2]

[1]Cardiac Electrophysiology Research Center, Rajaie Cardiovascular Medical and Research Center, Tehran, Iran, [2]Medical-Surgical Nursing Department, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran

Abstract

Background: The majority of cardiac disorders resulting from ventricular dysrhythmias are fatal. The Implantable Cardioverter Defibrillator (ICD) is one of the most common treatments of ventricular dysrhythmias. Despite the benefits of ICD in preserving life, patients with ICD experience adverse physical, psychological, and social consequences. This study investigated the effects of the continuous care program on self-efficacy in patients with ICD. **Materials and Methods:** The present study was a randomized clinical trial. Based on the inclusion criteria, 80 patients attending an educational cardiovascular center in Tehran during 2017–2018, were randomly assigned to two intervention and control groups (40 in each). The intervention included the continuous care program, an educational session, and a follow-up program undertaken for the patients receiving the ICD. The control group received routine care. Self-efficacy was then measured by ICD (SE-ICD and OE-ICD) questionnaires and compared between the two groups. **Results:** The results showed no difference between the two groups before the intervention ($p > 0.05$). However, there was a significant difference in the mean self-efficacy score between the two groups after the intervention, being significantly higher in the intervention group ($t_{77} = 4.9$, $p < 0.001$). **Conclusions:** The results of the present study indicated that providing a continuous care program can increase self-efficacy in patients with ICD and can be used as an effective model in the nursing care of patients with ICD.

Keywords: *Defibrillators, patient care planning, self efficacy*

Introduction

Cardiovascular diseases are among the most common chronic diseases in the world.[1] According to the World Health Organization, about 17 million people worldwide died of Cardiovascular Diseases (CVD) in 2021, which accounted for 30% of all global deaths; this figure is projected to increase to over 23 million worldwide by 2030.[2] CVD is the first leading cause of mortality and a million Disability Adjusted Life Years (DALYs) led to 46% of all deaths and 20%–23% of the burden of disease in Iran. Although coronary heart disease is the most common fatal heart disease,[3,4] arrhythmias and particularly ventricular arrhythmias can cause life-threatening complications if left untreated.[3,5] Sudden Cardiac Death (SCD) due to ischemia or other causes is often the result of Ventricular Fibrillation (VF). Sometimes, ventricular fibrillation is caused by the development of monomorphic or polymorphic ventricular tachycardia.[3] One method of rapid diagnosis and treatment of dangerous ventricular arrhythmias (ventricular tachycardia causing hemodynamic dysfunction or drug-resistant ventricular fibrillation) is the use of the Implantable Cardioverter Defibrillator (ICD) in the body.[6] With the advancement of science, ICD has long been used as the treatment of choice for secondary prevention of SCD.[7]

The results of two studies conducted on patients with ICD showed that 97% of patients did not have accurate and complete information about device care, and this posed significant medical, social, and financial problems for them.[8,9] Sandhu quotes on behalf of Sandhu *et al.*,[10] proper self-care greatly reduces disease recurrence and the number of hospitalizations, which in turn increases the quality of life and reduces the cost of treatments and drugs. Ninety percent of patients have questions about self-care, diet, and medication at the

Address for correspondence:
Dr. Masoumeh Zakerimoghadam, Medical-Surgical Nursing Department, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran.
E-mail: zakerimo@tums.ac.ir

Access this article online

Website: https://journals.lww.com/jnmr

DOI: 10.4103/ijnmr.ijnmr_467_21

Quick Response Code:

How to cite this article: Khani SA, Matourypour P, Haghjoo M, Zakerimoghadam M. The effect of continuous care program on the self-efficacy of patients with implantable cardioverter defibrillator: A randomized control trial. Iran J Nurs Midwifery Res 2023;28:455-60.

Submitted: 11-Dec-2021. **Revised:** 08-Dec-2022.
Accepted: 20-Dec-2022. **Published:** 24-Jul-2023.

time of discharge and during daily activities at home.[11] Controlling risk factors and lifestyle modification in these patients plays an important role that leads to the ability of these patients to take care of themselves.[12,13]

One of the most important factors in patient recovery after surgery is self-efficacy.[13] The concept of self-efficacy is recognized as a determinant of many behavioral changes in health promotion/education, and emphasis is laid on learning and empowering people to have a sense of control over their health.[13] Self-efficacy assessment is an important part of the care program for cardiac patients, and various studies have shown that improving self-efficacy can improve lifestyle and cardiovascular risk factors and correct the use of medications, and also prevent readmission of cardiac patients.[14] The results of one study show that self-efficacy is a key psychological factor in adapting to chronic diseases.[15] In this regard, nursing care can increase awareness and self-efficacy among patients at the same time.[13] Earlier studies show that—as a psychological factor—self-efficacy can improve quality of life and adaptation to chronic disease, especially cardiovascular diseases.[13-15] Thus, implementing interventions within the care program framework that can affect self-efficacy in such patients can improve self-efficacy and other variables related to it.

Continuous care can play an effective role in the control of chronic diseases. Research results emphasize that cardiac patients, including patients with a history of cardiac shock, need continuous care, as they face many psychological and physical problems. To date, no study has been conducted on the effectiveness of the continuous care model on the self-efficacy of patients with ICD in Iran, so there was a need to conduct such a study. Given that heart diseases and arrhythmias are among chronic and debilitating diseases in the world and in Iran, the present study aimed to investigate the effect of the continuous care program on self-efficacy in patients with ICD with implantable cardioverter defibrillator.

Materials and Methods

This study was a randomized controlled clinical trial) IRCT20100725004443N24(that was part of a larger study conducted between 2018 and 2019. The study setting was the electrophysiology clinic, Coronary Care Unit (CCU) and medical/surgical wards of Shahid Rajaei Cardiovascular Center in Tehran. The sample consisted of all patients with a history of cardiac arrest or life-threatening dysrhythmia who were first on the list of receiving the ICD. Inclusion criteria were being 20–80 years old, having ICD implanted for the first time, being able to read and write and speak Persian, and having a phone. Exclusion criteria included the presence of comorbidities that keep patients in the hospital, existence of cognitive disorders, and participation in another intervention program. Allocation of patients to the intervention and control groups was done by random block allocation based on the patient list. The allocation sequence was generated using the web-based system available at: http://www.randomization.com. Using the sample size formula and relevant literature, considering Z1 = 96.10, ZB = 0.85, a standard deviation of 6.1 in both groups, and means of $\mu 1 = 21.69$ in the control group and $\mu 2 = 22.48$ in the intervention group,[16] the sample size was calculated at 37; however, upon taking into account attrition 40 patients were considered for each group. Of the 194 patients admitted to receive ICD for the first time and based on the inclusion and exclusion criteria, 80 patients remained, who were randomly allocated into two groups by blocked randomization with no attrition [Figure 1]. The intervention was undertaken upon patients' discharge, so the control group did not know about the intervention's details and there was no contamination. The two groups were the same by random allocation so we decreased the confounders' effects as much as possible.

In this study, three questionnaires were used to collect data: A demographic and disease information questionnaire, self-efficacy expectations in patients with ICD (SE-ICD), and outcome expectations in patients with ICD (OE-ICD) questionnaires. The demographic and disease information questionnaire included 14 questions about the personal information (such as age, body mass index [BMI], height, weight, gender, marital status, level of education, and home and mobile phone number), and disease information (including Charlson Comorbidity Index, Short BleSSed Test Score, cause of ICD implantation,

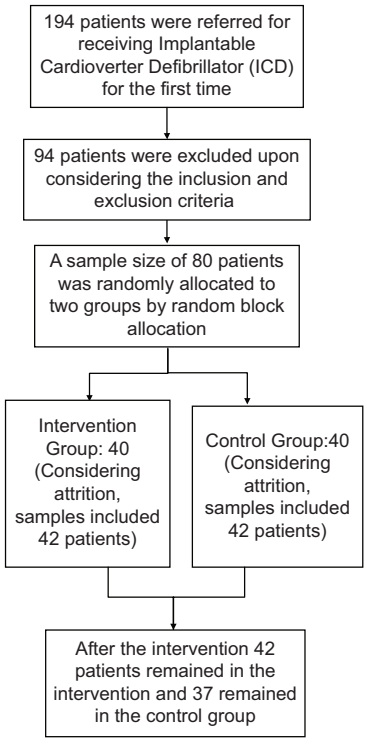

Figure 1: Random allocation figure

cardiac Ejection Fraction [EF], and history of myocardial infarction). This questionnaire was made by the researcher. The self-efficacy expectations after ICD implantation questionnaire was developed by Dougherty *et al*., (2007) to measure self-efficacy expectations in survivors of sudden cardiac arrest who had received ICD. The first part of this 16-item questionnaire focuses on the individual's self-efficacy expectations regarding one's ability to manage common problems faced after implanting an ICD; each question scores between 0 and 10. The first eight items, which are graded before the intervention, are related to the individual's expectations of self-efficacy, and the next eight items show the functional status of a person after the desired period. The validity and reliability of the self-efficacy expectations and outcome expectations of patients following ICD implantation scales have been reviewed by Dougherty *et al*.[17] in 2005. However, since the scales had not been used in Iran, their validity and reliability needed to be measured. To this end, first, they were translated into Persian and then back-translated into English and adapted to the original text by a person fluent in both Persian and English and who was not familiar with the study subject. Then, the differences were reviewed and corrected. To determine the content validity; the translated scales were reviewed by 10 faculty members at the heart center and afterward their corrective opinions were applied. The internal reliability of the self-efficacy and outcome expectations scales was assessed by Cronbach's alpha coefficient (0.75), which was acceptable.

In addition to the usual care provided at the heart center, the patients in the intervention group received the continuous care program. Two face-to-face 1.5-h-long training sessions were held by the researcher individually at the time of discharge (sensitization phase) and at the electrophysiology clinic, a month later. During the first session, the patient's state of anxiety and self-efficacy were assessed using the demographic and disease information questionnaire as well as the self-efficacy questionnaire. The researcher then established an initial relationship with the patient to gain their trust, examine their learning style, and build up a close relationship (by introducing herself and calling patients by their first names). Thereafter, she discussed the goals and methods of the study, communication methods, nurses' expectations at different stages of the study, and the patients' and their families' expectations. During the second session (a month after discharge), patients were taught self-care methods and the necessary lifestyle changes, device function, what to expect when energy is discharged, what to do after each shock, how to record shocks, and warnings that need to be followed-up orally (practical with training) and written regarding age and learning styles were given to patients. Moreover, necessary explanations were provided to them about communicating with family members and others. The researcher described the methods that can be used to reduce patients' anxiety, such as listening to music, saying prayers, relaxation, and methods of distraction, and based on the patient's desire, explained the selected methods and practiced with them if required. At the end of the second session, patients were given an educational booklet that contained two sections: (1) The first section explained the heart in general, the types of ICDs, and high-risk to low-risk conditions for the device in simple language and (2) The second or descriptive section contained patients' statements about their experiences in the first year of recovery following the ICD insertion. Finally, the patient's contact number was taken and the intervention was undertaken for about 10 to 20 min per day according to the patient's needs. Follow-up was done by weekly phone calls and at the patient's chosen time, between 8 AM to 8 PM. Phone calls were made once a week for 8 weeks to provide support such as verbal encouragement, answering patient's questions, helping to make decisions, solving everyday problems, and reinforcing the training provided (control phase). At the end of the eighth week after discharge, the self-efficacy questionnaire was completed by both groups (evaluation stage). In the control group, after receiving routine care at the heart center and before discharge, patients completed the self-efficacy and outcome expectations questionnaires as well as the anxiety questionnaire. Twelve weeks after discharge, patients' self-efficacy, anxiety, and short-term outcomes were assessed with the abovementioned questionnaires.

In the present study, data were analyzed by Statistical Package for Social Sciences (SPSS; version 16; SPSS Inc., Chicago, Illinois). Dispersion indices such as mean and frequency percentage were used to describe the data, and parametric and nonparametric tests, independent *t* test/(Mann–Whitney *U*), and paired *t* test/(Wilcoxon) were used to compare the data.

Ethical considerations

The study was approved by the ethics committee of Shaheed Rajaie Cardiovascular, Medical Research Center (IR.RHC.REC.95.2), on June 10, 2017. Written informed consent was taken from the participants after explaining the purpose of the study and ensuring anonymity.

Results

Demographic findings are shown in Table 1. In terms of income level, 35.10% of the subjects in the control group had somewhat sufficient income, 48.60% had insufficient income, and in the intervention group, 47.60% had somewhat sufficient, and 45.20% had insufficient income. Moreover, 59.50% of the subjects in the control group and 64.30% in the intervention group were covered by social security insurance. The mean Charlson Comorbidity Index (CCI) was mean (SD) 3.40 (1.60) in the control group and mean (SD) 3.20 (−1.90) in the intervention group The mean Survey 10y of patients was 60.9%. The causes of ICD implantation for 43.20% of the subjects in

Table 1: Demographic data in patients with Implantable Cardioverter Defibrillator (ICD) in the two intervention and control groups

Variable	Control group *n* (%)	Intervention group *n* (%)	Statistics (df)	*p*
Marital status				
Single	6 (16.20)	2 (4.80)		0.138*
Married	31 (83.80)	40 (95.20)		
Gender				
Female	10 (27)	9 (21.40)	0.30 (1)	0.561**
Male	27 (73)	33 (78.60)		
Literacy				
Under Diploma	21 (56.80)	25 (59.50)		
Diploma	8 (21.60)	8 (19)		
Higher	8 (21.60)	9 (21.50)	0.617	0.536****
History of previous Myocardial Infarction				
No	15 (40.50)	14 (33.30)	0.40 (1)	0.507**
Yes	22 (59.50)	28 (66.70)		
	Mean (SD)	Mean (SD)		
Age (year)	54.50 (11.00)	51.10 (12.50)	1.30 (77)	0.21***
Height (cm)	166.80 (9.60)	170.0 (10.10)	1.40 (77)	0.156***
Weight (kg)	76.50 (13.60)	76.20 (11.90)	0.10 (77)	0.91***
Body Mass Index (BMI)	27.50 (4.10)	26.50 (4.20)	1.10 (77)	0.258***
Ejection Fraction (EF)	23.80 (7.60)	25.60 (10.40)	0.527	0.60****

*Fisher's, **Chi-square, ***Independent t test,**** Mann–Whitney test

the control group and 43% in the intervention group were VT or VF in ElectroPhysiology studies (EP). A total of 13.50% of the subjects in the control group and 28.6% in the intervention group had VT>"30.

Before the intervention, the means and standard deviations of the self-efficacy expectations score were 5.80(1.40) in the control group and 5.30(1.40) in the intervention group and the independent *t* test did not show a significant difference (t_{77} = 1.70, p = 0.091). However, after the intervention, the means and standard deviations of the self-efficacy expectations score increased to 7.40(1.30) the control group and 8.40 (1.20) in the intervention group, where the Mann–Whitney test showed a significant difference (F = 40, $p < 0.001$).

In the control group, the self-efficacy expectations Mean (SD) score increased by 1.60(1.30), which was a significant increase according to the paired *t* test (t_{36} = 7.50, $p < 0.001$). In the intervention group, the self-efficacy expectations Mean (SD) score increased by 3.10(1.40) which, according to the Wilcoxon test ($p < 0.001$), was a significant increase too [Table 2].

Discussion

The aim of this study was to investigate the effect of the continuous care program on self-efficacy in patients with ICD. Based on our findings, the mean self-efficacy expectations scores were higher in the intervention group compared with the control group after the intervention, indicating the effectiveness of the continuous care program. Our findings are in line with the results of existing studies. For instance, the results of a study by Nisakorn Vibulchai *et al.* (2016),[18] which investigated the effect of the self-efficacy promotion program on the rehabilitation of patients after myocardial infarction in Thailand, showed that the intervention group had obtained higher scores in general self-efficacy than the control group. Our study is similar to this study in terms of the main variable and the effect of the intervention on this variable, but it is different in terms of the intervention program and samples.

Sarrafzadegan *et al.* (2019)[4] learnt that the continuous care model could increase and improve self-care management in patients with heart failure. Bagaei *et al.* (2015)[19] also showed that the implementation of effective care models and training and follow-up, along with lifestyle changes in heart failure patients could improve and increase their quality of life. Elsewhere, Haghdoost *et al.* (2015)[11] indicated that the continuous care model improved the quality of life and reduced the incidence of complications after surgery in patients after coronary artery bypass graft surgery. Therefore, the continuous care program was effective in other heart disease patients as well.

In a study conducted by Dougherty *et al.* (2022)[17] on short-term self-efficacy in the United States, a telephone intervention was carried out by a cardiologist on patients with ICD. In terms of the care plan, the intervention was similar to ours, but in the short term, neither did not affect self-efficacy in patients with ICD nor the skills required for their safe care, which is different from our results. However, her study on long-term self-efficacy showed that the telephone intervention was significantly effective

Table 2: Intergroup and intragroup comparison of means and standard deviations of the self-efficacy expectations score before and after the intervention in the two intervention and control groups

Self-efficacy expectations	Mean (SD)		Results of intergroup tests		
	Control group	Intervention group	Statistical test	df	*p*
Before intervention	5.80 (1.40)	5.30 (1.40)	t=1.70	77	0.091*
After intervention	7.40 (1.30)	8.40 (1.20)	U=431.50		p<0.001
Pre and postintervention difference	1.60 (1.30)	3.10 (1.40)	t=4.90	77	p<0.001
Test result	t=−7.50, df=36	Z=−5.60			
Intragroup difference	p<0.001***	p<0.001****			

*Independent *t* test, **Mann-Whitney test, ***Paired *t* test, ****Wilcoxon test

on short-term self-efficacy after ICD implantation, which is similar to our findings. Therefore, following up with patients and laying emphasis on the long-term effect of the intervention is important.

Kaveh *et al*. (2012)[20] conducted a study in Iran with the aim of investigating the effect of a self-management program on improving self-efficacy in patients suffering from primary hypertension. In terms of variables and results, the intervention was similar to our study, however, in terms of the care program and participants, it was different. Even so, their results indicated that the intervention significantly improved self-efficacy ($p < 0.05$).

Among the limitations of the present study are the effect of adverse environmental conditions and factors on the patients' mental and emotional states, and the time limit. We recommend that in future studies, the effects of the continuous care program on self-efficacy and its long-term consequences in patients with ICD be evaluated and its cost-effectiveness be assessed to determine its various aspects.

Conclusion

The continuous care program can be used as an effective care model for patients with ICD and to reduce the burden of disease. As a domesticized model, it has the potential to be used by the health system and also be presented as a comprehensive program by increasing its strengths and reducing its possible shortcomings. This program can also be included in nursing education curricula to enable nursing students to benefit from it and to improve knowledge, attitude, and skills among nurses in this field.

Acknowledgments

The authors thank all of the participants during the different stages of this study. This research received funding from Shaheed Rajaie cardiovascular research and medical center. This research project has been approved by the research ethics committee of Shaheed Rajaie ardiovascular research and medical center and was recorded in IRCT center.

Financial support and sponsorship

Shaheed Rajaie cardiovascular research and medical center

Conflicts of interest

Nothing to declare.

References

1. Gephine S, Simonelli C, Vagheggini G, Evans R, Ward TJ. The impact of the meta-analysis of pulmonary rehabilitation by Lacasse and colleagues: Transforming pulmonary rehabilitation from "art to science". Breathe (Sheff) 2022;18:220021.
2. WHO report on the global tobacco epidemic 2021: addressing new and emerging products. Available from: https://www.who.int/publications-detail-redirect/9789240032095 [Last accessed on 2022 Nov 24].
3. Rahmani A, Moradi Y, Saadat S, Alinezhad V. The effect of nurse-peer-led support intervention on quality of life in patients with an implantable cardioverter-defibrillator: A randomized clinical trial. Nurs Midwifery J 2019;17:227-38.
4. Sarrafzadegan N, Mohammmadifard N. Cardiovascular disease in Iran in the last 40 years: Prevalence, mortality, morbidity, challenges and strategies for cardiovascular prevention. Arch Iran Med 2019;22:204-10.
5. Abbasi M, Negarandeh R, Mollazadeh R. Explaining the tribulations of life with implantable cardioverter-defibrillator: A Qualitative study. Sci Inf Database 2016;5:105-14.
6. Oshvandi K, Keshmiri K, Salavati M, Emkanjoo Z, Musavi S. Effectiveness of education based on Orem's self-care model in self-care activity of patients with implantable cardioverter defibrillators. Hayat 2014;19:47-55.
7. Urden LD, Lough ME. Thelan's Critical Care Nursing: Diagnosis and Management. 9th ed. 2020. Elsevier. 2022.
8. Vijgen J, Botto G, Camm J, Hoijer CJ, Jung W, Le Heuzey JY, *et al.* Consensus statement of the European Heart Rhythm Association: updated recommendations for driving by patients with implantable cardioverter defibrillators. Eur J Cardiovasc Nurs 2010;9:3-14.
9. Janice L Hinkle KHC. Brunner & Suddarth's Textbook of Medical-Surgical Nursing (Brunner and Suddarth's Textbook of Medical-Surgical). 14th ed. Wolters Kluwer; 2018.
10. Sandhu U, Nguyen AT, Dornblaser J, Gray A, Paladino K, Henrikson CA, *et al.* Patient-reported outcomes in a multidisciplinary electrophysiology-psychology ventricular arrhythmia clinic. J Am Heart Assoc 2022;11:e025301.
11. Haghdoost Z, Nourozi K, Hosseini M. Effect of application of continuous care model on quality of life and prevention of complications in coronary artery bypass graft surgery patients. Iran J Rehabil Res Nurs 2015;1:1-9.
12. Rahimi-Bashar F, Salesi M, Gohari-Moghadam K, Jouzdani AF, Pourhoseingholi MA, Vahedian-Azimi A. Assessment of 5-year outcomes of life satisfaction in survivors after rehabilitation programs: A multicenter clinical trial. Sci Rep 2022;12:1497.

13. Mohsenipouya H, Majlessi F, Shojaeizadeh D, Rahimiforooshani A. The effect of educational intervention based on the pender's health promotion model on patients' self-efficacy for self-care behaviors following heart surgery. Iran J Nurs Res 2017;12:16-23.
14. Zakiei A, Vafapoor H, Alikhani M, Farnia V, Radmehr F. The relationship between family function and personality traits with general self-efficacy (parallel samples studies). BMC Psychology 2020;8:88.
15. Cameron J, Lannin NA, Harris D, Andrew NE, Kilkenny MF, Purvis T, *et al.* A mixed-methods feasibility study of a new digital health support package for people after stroke: The recovery-focused community support to Avoid readmissions and improve participation after stroke (ReCAPS) intervention. Pilot Feasibility Stud 2022;8:241.
16. Aghamohammadi Kalkhoran M, Karimollahi M. Religiousness and preoperative anxiety: A correlational study. Ann Gen Psychiatry 2007;6:17.
17. Dougherty CM, Liberato AC, Streur MM, Burr RL, Kwan KY, Zheng T, *et al.* Physical function, psychological adjustment, and self-efficacy following sudden cardiac arrest and an initial implantable cardioverter defibrillator (ICD) in a social cognitive theory intervention: Secondary analysis of a randomized control trial. BMC Cardiovasc Disord. 2022;22:369.
18. Vibulchai N, Thanasilp S, Preechawong S. Randomized controlled trial of a self-efficacy enhancement program for the cardiac rehabilitation of Thai patients with myocardial infarction. Nrus Health Sci 2016;18:188-95.
19. Bagaei R, Khalkhali H, Mashalahi A. The effect of applying continuous care model on the quality of life in heart failure patients. J Urmia Nurs Midwifery Fac 2015;13**:**666-75,
20. Kaveh SO, Zakerimoghadam M, Gheyasvandian S, Kazemnejad A. Effect of self-management program on self-efficacy in hypertensive patients. Journal of Mazandaran University of Medical Sciences 2012. 10;22:19-28.