



## Effects of family-centered program on the specific quality of life of patients with a pacemaker: A nursing intervention study

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### Original Article

#### Abstract

**BACKGROUND:** Cardiac problem causes changes in different aspects of life in patients, including their activities of daily living (ADL). Because of the important role of family in caring for patient after pacemaker implantation, this study was done to evaluate the effect of family-centered empowerment model on ADL of patient after pacemaker implantation.

**METHODS:** This randomized clinical trial study was performed on 70 patients who underwent pacemaker implantation in Shahid Chamran Hospital, Isfahan, Iran. Patients and their family in the intervention group received educational program according to family-based empowerment program. The control group only received routine interventions. Data were collected using a valid specific quality of life (QOL) questionnaire and analyzed by SPSS software.

**RESULTS:** Patient's self-efficacy, self-esteem, and personal QOL have been improved after the empowerment program compared with the baseline and the control group ( $P < 0.05$  for all).

**CONCLUSION:** The QOL in patients with pacemaker is relatively low. Similar to previous studies, family-centered empowerment model, due to participation of the patients and their families in education, learning, and taking care of the patients, could be an appropriate model to implement.

**Keywords:** Family; Empowerment; Quality of Life; Pacemaker; Artificial

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#### Introduction

The cardiovascular diseases (CVDs) are among the most common chronic, progressive, and life-threatening diseases. According to the World Health Organization (WHO) report, 41.3% of all deaths in Iran in 2005 were because of the CVD; this percent is predicted to reach to 44.8% by 2030.<sup>1-3</sup> Arrhythmia has been reported responsible for a large burden of cardiac mortalities.<sup>4</sup> Pacemaker implantation is the principal treatment of symptomatic bradycardias.<sup>5</sup> Life of about 3 million people all around the world is dependent on the pacemakers and about 600000 new pacemakers are annually implanted.<sup>6</sup> About 550 new permanent pacemakers are annually implanted in Iran.<sup>7,8</sup> Moreover, the number of patients requiring cardiac pacemaker implantation is constantly increasing due to increasing life expectancy and advanced and developed technology of pacemakers.<sup>9,10</sup> The statistics suggest that the electrical interventions which are used to treat the arrhythmias and heart

problems have many complications for patients.<sup>6,11</sup> The experience of multiple symptoms in these patients has caused intolerance of the activities that this also affects the patients' satisfaction and quality of life (QOL). The created limitations lead to problems in job and family responsibilities as well as the social life of the patients and cause social isolation, psychological problems, and depression, and, thus, change their QOL.<sup>6,12</sup> QOL is an important and vital indicator which has multiple dimensions, including the physiological, functional, and existential aspects of people and is the main and important indicator to identify the effect of a therapeutic intervention on the health of the patient.<sup>6,11,12</sup>

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van Eck et al. examined 818 patients with a pacemaker and found that the implantation of a pacemaker improved their QOL in comparison with the pre-implantation period, but it was lower than the overall population.<sup>13</sup>

The meetings after discharge are essential to give information to patients, train self-care methods to them, and respond to their concerns. Follow-up care also provides better communication between the treatment team members and the patients, increases the patients' self-confidence, and provides the opportunity to express their doubts and concerns.<sup>14</sup> Improving the self-care behaviors can help the patients not to lose their control over their life and adapt to the complications of their disease; this adaptability will lead to improvement of the QOL in these patients.<sup>15</sup> On the other hand, studies in patients with electronic intracardiac devices have indicated that most of these patients did not receive any information about the device and how to care for it, and they really needed to be trained in the self-care field.<sup>7</sup> Today, several interventions are done by the nurses to train self-care behaviors to the clients worldwide.<sup>16</sup> The family-based empowerment model is among the models which have recently emerged as a successful model in adopting proper care and health behaviors, gaining independence, and improving lifestyle and the QOL; it is evaluated to be positive and is presented as a guide for patients and their health care providers.<sup>17,18</sup> This model has four basic steps including: 1) perceived threat, 2) problem solving, 3) training participation, and 4) evaluation. The family-based empowerment model is a healthcare philosophy that regards the family as the focal and the focus point in all health cares. Nurses have special relations with patients' family members and are able to provide the patients' families with the required knowledge, skills, and supports to increase the home-care quality.<sup>19</sup> The effect of using this model to improve the QOL of the mothers with a child with urinary tract infection and also children with asthma has got attentions and supports, as well.<sup>20,21</sup>

Therefore, with regard to the fact that most studies are currently conducting on the bases of patient's training, it seems that the family-based empowerment model can be more effective besides independent empowerment of patients to motivate the families to care and advance the treatment.

The current study was conducted with the aim of determining the effect of family-based empowerment model on the QOL in patients with permanent cardiac pacemakers.

## Materials and Methods

This randomized clinical trial study (IRCT2017103137143N1) was conducted in two groups with the pre- and post-test design on 70 patients with pacemaker. The inclusion criteria were: age of 18 to 80 years, the satisfaction and ability to communicate, and at least one of the family members (as a caregiver) to be willing to cooperate with the researchers. In the case of any physical or psychological problems, hospitalization, or the events like the death of one of the loved ones that could affect the QOL of the patients, they should be excluded from the study. The Ethics Committee of Shahrekord University of Medical Sciences, Shahrekord, Iran, approved the study (IR.SKUMS.Rec.1396.172). The convenience sampling method was used and the samples were divided into two groups using random allocation software. The data were collected using a demographic information checklist and the standard questionnaires named Assessment of Quality of Life (AQOL), Sherer Self-Efficacy Scale, and Rosenberg Self-Esteem Scale. AQOL questionnaire consists of 24 questions about physical changes after pacemaker implantation, with a five-point scale. Each person dedicates the options (very high = 0, average = 1, low = 2, very low = 3, never = 4) to all items and gets a score between 0 and 96. The reliability of this questionnaire was examined by Ali Akbari et al., and the Cronbach's alpha coefficient was calculated 0.85.<sup>6</sup>

Sherer Self-Efficacy Scale was developed on a Likert scale with 17 questions and has three subscales (effort, perseverance, and initiative). It is scored on a 5-choice rating scale from 1: "strongly agree" to 5: "strongly disagree". The lowest score is 17 and the highest score is 85, with scores above 50 indicating stronger self-efficacy and scores below 50 indicating weaker self-efficacy. In Saffari et al.'s study, Cronbach's alpha coefficient for Persian translation of this questionnaire was reported to be 0.83.<sup>22</sup>

The Rosenberg Self-Esteem Scale is designed to provide an overview of positive and negative attitudes about oneself. It uses a scale of 0-30, where a score less than 15 may indicate a problematic low self-esteem. Cronbach's alpha coefficient for the Persian version of this questionnaire has been reported 0.84.<sup>23</sup>

The researcher then paid a visit to the Pacemaker Clinic of Shahid Chamran Hospital in Isfahan, Iran, with his letter of introduction and met the patients having the permanent pacemaker after obtaining their permission and coordination with

them; finally, they were put in the study after obtaining their written informed consent. Before interventions, the questionnaires were completed by the participants in both groups. The second stage included the empowerment intervention, which was done only in the intervention group; the family-centered empowerment model is based on the four steps, including 1) understanding the threat, 2) self-efficacy, 3) self-confidence, and 4) assessment.<sup>18,19</sup> These stages were conducted in the following order.

In the first step, which includes an increase in the perceived threat of the empowering agent, i.e., patient, we had 2 single-handedly sessions with the patient in which the participant was provided with materials and subjects to increase knowledge about physiology, symptoms, disease complications, therapeutic measures, and treatment regime during the treatment plan as well as mental and physical conditions after pacemaker implantation (the goal of this step was to increase the knowledge by enhancing the perceived threats). At the end of each session, we made a conclusion and answered the patients' questions. In order to perform the second step, the Self-Efficacy Scale was first completed by the intervention group for assurance of completion of first step and participant readiness to go to the next step (and for control group to compare the results with intervention group). Then, three 30-minute group sessions were held in groups of 4-6 people. The patients were also faced with their problems and the solving process in practice, and discussed with each other under the supervision of the researcher, giving objective examples about their situations and what they would do to solve similar problems of others and, therefore, they collaborated with each other to choose the solutions. In this step, the correct actions were confirmed and the mistakes were corrected by the researcher. At the end of the sessions of the second step, both groups re-completed the Self-Efficacy Scale. In the third step, the Rosenberg Self-Esteem Scale was first completed by both groups. In this step, we asked the patients to participate in three 30-minute training sessions with the active member of their family to get acquaintance with the pacemaker implantation-related issues. In these sessions, each patient said whatever had learned in previous sessions to the active member of the family. In this step, the family participated in the research as an essential source of support in the learning process of the interventions to enhance the patient empowerment through improving the self-efficacy and self-esteem. At the end of each session, a

general conclusion of the sessions was made and the questions were answered. In addition, the educational pamphlets were given to the other family members by the researcher.

Formative evaluations were performed at the beginning of each session to evaluate knowledge, self-efficacy, and self-esteem of participants. Summative evaluation was conducted at a time interval of 6 weeks after the last session. Telephone follow-up was done during this period and the participants' questions were answered. Control group only received routine care. Finally, after completing the intervention and the questionnaires in the post-test, all of the training materials were presented for control group in the form of a pamphlet and a training booklet. The data were analyzed through SPSS software (version 21, IBM Corporation, Armonk, NY, USA) and statistical tests including paired t-test, independent t-test, and repeated measures analysis of variance (ANOVA) were used to compare the results.

## Results

At the end of the follow-up, 31 participants in the intervention and 30 subjects in the control group completed the study. The study results showed that the mean and standard deviation (SD) of participants' age in the family-centered empowerment group was  $62.50 \pm 13.20$  years and in the control group was  $60.23 \pm 12.86$  years. Most of the participants were men, 24 (77.4%) in the intervention group and 22 (73.3%) in the control group. In terms of marital status, the majority of the participants were married, 28 (90.3%) in the intervention group and 30 (100%) in the control group. In terms of the employment status, the majority were unemployed, 18 (58.1%) in the intervention group and 17 (7.56%) in the control group. In terms of the literacy level, the majority had finished elementary school, 16 (6.51%) in the intervention group and 17 (7.56%) in the control group. Both groups showed no significant difference ( $P > 0.05$ ) in demographic variables (Table 1).

**Table 1.** Demographic data of study participants

Variable	Control	Intervention	P
	(n = 30)	(n = 30)	
	Mean $\pm$ SD	Mean $\pm$ SD	
Age (year)	62.50 $\pm$ 13.20	60.23 $\pm$ 12.86	0.49
Weight (kg)	70.90 $\pm$ 13.33	74.73 $\pm$ 11.22	0.22
Height (cm)	168.17 $\pm$ 9.17	167.60 $\pm$ 7.44	0.79
BMI (kg/m <sup>2</sup> )	24.89 $\pm$ 3.22	26.61 $\pm$ 3.56	0.05

P-value < 0.05 is significant

SD: Standard deviation; BMI: Body mass index

**Table 2.** Comparison of patients' specific quality of life (QOL) parameters in two study groups before and after the intervention

Variable	Control (n = 30)	Intervention (n = 30)	P
Self-efficacy before the intervention	49.26 ± 8.31	54.43 ± 6.38	0.009
Self-efficacy after the intervention	72.83 ± 6.09	56.00 ± 5.30	< 0.001
P	< 0.001	0.470	
Self-esteem before the intervention	-0.13 ± 3.09	1.93 ± 2.20	0.004
Self-esteem after the intervention	6.39 ± 1.20	2.80 ± 3.18	< 0.001
P	< 0.001	0.520	
QOL before the intervention	38.84 ± 18.53	42.40 ± 15.60	0.420
QOL after the intervention	81.94 ± 7.59	47.73 ± 9.78	< 0.001
P	< 0.001	0.650	

P-value < 0.05 is significant  
SD: Standard deviation; QOL: Quality of life

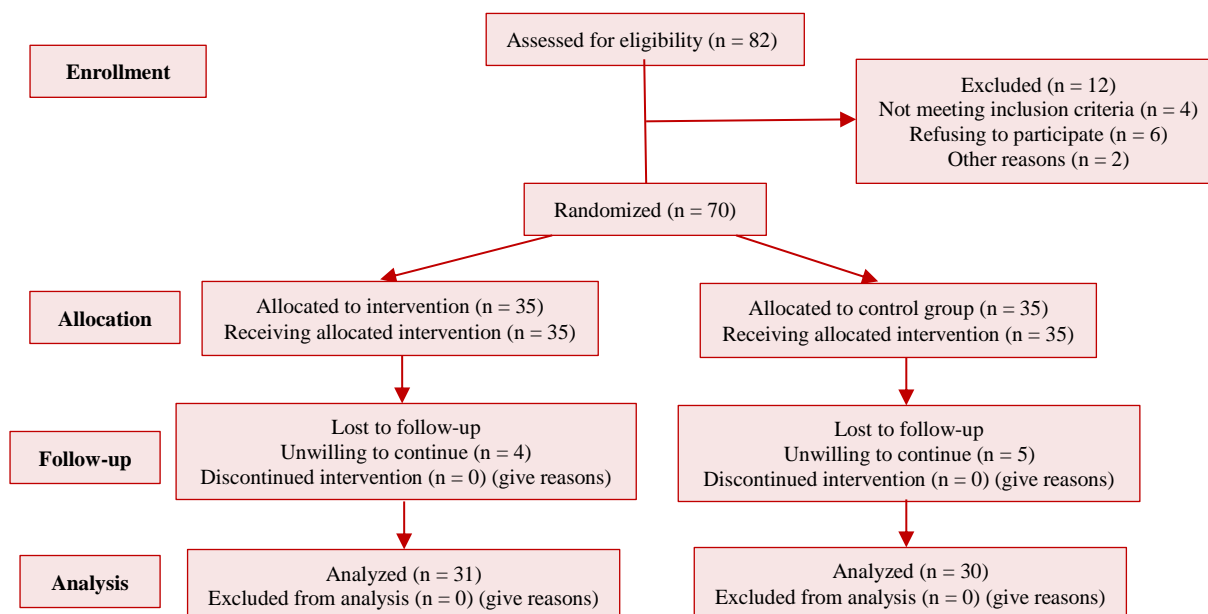
The comparison of the mean scores of patients' self-efficacy, self-esteem, and QOL before and after the intervention using independent t-test showed that the control group had higher scores at baseline, but the intervention group obtained higher scores after the intervention (Table 2). One-way univariate ANOVA was used and post-intervention measurements were adjusted with baseline QOL parameters (Figure 1). As described in table 3, patients' self-efficacy, self-esteem, and QOL of intervention group improved after the intervention with significant difference in comparison with the control group.

### Discussion

The purpose of this study was to investigate the effect of the family-based empowerment model on the specific QOL in patients with permanent pacemaker. The QOL parameters were relatively

low in both groups before the intervention. After utilizing the empowerment model, self-esteem, self-efficacy, and QOL improved in the intervention group in comparison with the control group.

In this regard, the results of Wahlin et al. study showed that providing information for families and empowering the family caregivers caused self-care to increase and thereby, the patients' QOL would improve.<sup>24</sup> Wichit et al. conducted a family-oriented self-management program study on 140 patients with type 2 diabetes. The study results showed that the self-care, self-efficacy, and the QOL improved after intervention.<sup>25</sup> The results of the Schrag et al. study also showed that the families played an important role in the self-care process of people with Parkinson's disease (PD) in the acquisition and preservation of independence, improving patient's QOL and reducing their fall risk.<sup>26</sup>



**Figure 1.** Consort diagram

**Table 3.** One-way analysis of variance (ANOVA) of post-intervention comparison with adjustment of baseline measurements

Variable	F	P
Self-efficacy after the intervention	169.98	< 0.001
Self-esteem after the intervention	38.16	< 0.001
QOL after the intervention	51.82	< 0.001

QOL: Quality of life

The results of Ali Akbari et al. study about the effect of telephone intervention on the pacemaker patients' QOL showed that the patients' QOL in the experimental group increased after the intervention.<sup>6</sup> Ataei et al. conducted a study on 80 patients with permanent pacemaker as well and the results showed that the QOL was higher in the experimental group after the intervention. Other studies also acknowledge that participation of patients' families in caring process can make decision-making easier for the patients and increase their self-efficacy.<sup>27</sup> Sanaie et al. also showed that the implementation of the family-based empowerment model in patients who underwent the surgery could provide good conditions to improve the patients' self-efficacy. They explained the process of the disease and the surgery to the patients; patients participated in the decision-making of their care and the families also participated in the training activities. The results were evaluated positively, and led to increase of the family collaboration in following the treatment regime of these patients.<sup>28</sup> Generally, the results of the recent study and the related studies showed that the family-based empowerment model could increase the patients' QOL. In contrast, no significant difference was observed in the spiritual aspect of QOL in two groups which can be due to different conditions of people in the groups and high religious beliefs of Iranian people.<sup>29</sup> Results of current research reflected that implementing an empowerment program improved QOL of patients; therefore, it can be used as a cost-effective and easy method for follow-up. In addition, it can boost the patient's self-esteem and improve capability in caring.

The strengths of this study were using a convenient and comprehensive model of family-based empowerment and assessment of different aspects of QOL. However, relatively small number of participants and short duration of follow-up were the limitations. Larger studies and longer follow-up are recommended for future studies.

### Conclusion

With regard to low QOL of the patients with

pacemaker, the education and participation of the patients and their families in educational self-care programs seems essential. According to the results of this study, implementing a model to improve patients' QOL seems necessary. Family-centered empowerment model, due to participation of the families in education, learning, and taking care of the patients, would be an appropriate model with improving QOL and maybe more favorable outcomes; thus, it is recommended to hospital managers and clinical nurses to use it in follow-up of patients with chronic condition. This indicates that use of the results of this study can be reflected in the educational, research, and clinical fields and in the area of chronic diseases.

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### Conflict of Interests

Authors have no conflict of interests.

### Authors' Contribution

FA contributed to design of study, data collection, analysis, and drafting the manuscript. MT contributed to doing intervention and follow-up, data collection, analysis, and drafting the manuscript. FD contributed to design of study, data analysis, and reviewing the manuscript. FA contributed to drafting of manuscript and supervision.

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