

Effects of an Empowerment Program on Self-Care Behaviors and Readmission of Patients with Heart Failure: a Randomized Clinical Trial

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Background: The prevalence of heart failure, as a serious health problem, is increasing around the world due to underlying factors, such as hypertension and diabetes. Although the patient's cooperation in the treatment process plays a crucial role in treatment, only a few combinations of different approaches have been investigated so far. This study aimed to determine the effects of an empowerment program on the patients' self-care behaviors and hospital readmission.

Materials and Methods: In this randomized clinical trial, 120 patients with heart failure were divided into experimental and control groups. In the experimental group, the empowerment program, including face-to-face training, educational booklets, and follow-up via Telegram messaging application, was implemented, while the control group only received standard care. Data were collected before the intervention and six months after the intervention, using a researcher-made questionnaire. The Self-Care of Heart Failure Index (SCHFI) was completed for both groups.

Results: The results indicated that all three self-care scales, namely, self-care maintenance, self-care management, and self-care confidence, significantly improved in the experimental group compared to the baseline ($P=0.000$), while the scores of these scales decreased in the control group ($P=0.000$). The frequency of hospital admission and the length of hospital stay also reduced in the experimental group ($P=0.000$ and $P<0.001$, respectively). There was no significant difference in terms of the demographic characteristics between the two groups.

Conclusion: The empowerment program significantly improved the patients' self-care behaviors and reduced the frequency and duration of hospitalization. Therefore, implementation of such programs is strongly suggested, especially in heart failure clinics.

Key words: Heart failure; Self-care; Readmission

INTRODUCTION

Heart failure (HF) is defined as a clinical syndrome, caused by a decrease in the cardiac output due to cardiac filling or ejection problems that are associated with a structural or functional loss in the heart (1). HF can be a

possible consequence of heart attack, cardiomyopathy, or hypertension. There are also some other conditions that contribute to HF, such as congenital heart disease, viral heart disease, heart arrhythmia, and cancer treatment (i.e., chemotherapy) (2).

So far, different classes of HF have been defined, depending on the disease progression. The New York Heart Association (NYHA) has introduced a system to help physicians classify patients with HF into four stages (I, II, III, and IV), according to the disease severity. Patients with class I HF are capable of physical activity without any limitations. Patients with class II HF have slight physical limitations; they do not have any signs at rest, although regular physical activity can cause shortness of breath, palpitation, and fatigue. Patients with class III HF do not have any signs at rest, although they are recommended to have less physical activity than usual due to shortness of breath, palpitation, and fatigue. Finally, patients with class IV HF not only fail to perform usual physical activities, but also have symptoms of failure at rest (2, 3).

According to statistics, about four to five million people suffer from HF in the United States, and 5,500,000 new cases annually add up to this number (4). HF is a costly cardiovascular disease in the United States due to its high resource usage (5). In Iran, cardiovascular disease is the first known cause of death, which imposes a significant financial burden on the community (6). The annual cost of HF treatment in the United States is about 3.7 billion dollars, including medical care, medications, and lost workdays (7).

Shortness of breath and exercise intolerance affect the HF patients' daily activities. Common medications for these patients include diuretics, beta-blockers, and angiotensin-converting enzyme (ACE) inhibitors. Depending on the individual's characteristics and stage of disease, digoxin and vasodilators can be also added to the treatment regimen (8-10). Research suggests that drug treatments can reduce the mortality rate among patients. Besides, effective implementation of treatment and lifestyle changes can ameliorate the symptoms of HF and delay disease progression (9). Nevertheless, at least 50% of patients with HF do not follow the recommended treatments, resulting in readmission, complications, and exacerbation of the disease (11). On the other hand, educational and supportive programs can reduce the

readmission rates and related costs (12).

Empowerment refers to the process of increasing the capacity of individuals, groups, or communities to control their circumstances, improve their abilities, and achieve their goals to help themselves and others reach the highest quality of life (12). Overall, providing appropriate information for these patients about self-care is an essential strategy to help them live a long high-quality life. In HF patients, self-care refers to the person's responsibility to make some lifestyle changes for a higher quality of life (e.g., limiting or stopping smoking, limiting alcohol use and salt intake, proper medication use, limiting fluid intake, daily weighing, and early monitoring of symptoms) (13). However, some findings are inconsistent regarding the effectiveness of educational programs and self-care awareness of HF patients. In this regard, one study reported the positive effects of a training program on reducing hospitalization and improving the patients' knowledge of HF, medication use, and low-sodium diets (14), whereas another study found no significant difference in the rates of readmission and mortality in the intervention group (15).

Given the importance of empowerment programs, the present study aimed to determine the effects of an educational program on the self-care behaviors and readmission of HF patients.

MATERIALS AND METHODS

This experimental clinical trial was conducted on 120 patients, who were referred to the HF clinic or hospitalized in the cardiac ward of a hospital from April 2018 to the end of September 2018. This project was approved by the Ethics Committee of Kashan University of Medical Sciences, Kashan, Iran (IR.KAUMS.NUHEPM.REC.1396.32). This study was also registered in the Iranian Registry of Clinical Trials (IRCT20110704006946N2). All subjects had volunteered to participate in the study and signed an informed consent form. They were all informed about the study before participation and could withdraw from the study at any time. The empowerment program was

implemented for the patients without any cost. Also, a second educational self-care program was planned for the control group after collecting the data so that they could benefit from the program advantages.

The patients were selected by continuous sampling method and classified into experimental and control groups (n=60 per group) by using a randomized four-block design. The minimum sample size was equal to 45 subjects per group, according to a study by Seraji et al. (16) at a 95% confidence level and 80% test power. Considering the possible attrition rate, a total of 60 patients were selected for each group; finally, 48 subjects remained in each group.

The inclusion criteria were as follows: 1) willingness to participate in the study; 2) age >18 years; 3) diagnosis of HF by a cardiologist (ejection fraction [EF] <40% according to a recent echocardiography); 4) class II, III, or IV dyspnea according to the American Heart Association criteria; 5) lack of simultaneous participation in another similar study; 6) no hearing or visual impairment; and 7) literacy. On the other hand, the patients were excluded if they died during the study; did not consent to the follow-up; had prolonged absence in the six-month follow-up; or underwent a heart transplant.

Data were collected by evaluating the patients' self-care behaviors, using a researcher-made questionnaire on demographic information and hospitalization and a standard tool, called the Self-Care of Heart Failure Index (SCHFI). The patients in the experimental group participated in the educational program (i.e., face-to-face training, video presentations on a tablet, and educational booklet) in the presence of their family members for 30-60 minutes. This program focused on the following content: cardiac disorders; symptoms of HF; ways of changing lifestyle and behavior, depending on the existing symptoms; the necessity of adherence to the medication use guidelines, dietary guidelines, and a low-sodium diet (replacing salt); introducing and removing foods with a hidden salt content; restricting the consumption of water and foods containing water; regulating the type and extent of physical activity; control of peripheral edema and daily

weight; injection of influenza vaccine at the end of summer; injection of the pneumococcal vaccine as prescribed by the physician; warning signs and complications of warfarin and other anticoagulant medications; immediate referral to a physician in case of specific symptoms (e.g., dyspnea, severe swelling, chest pain, ecchymosis, or abnormal bleeding); and sending the results of coagulation tests to the physician to adjust the warfarin dosage.

The abovementioned educational content was based on a checklist of home care needs of HF patients and their caregivers, which was adapted from authoritative nursing books (16), scientific websites (17), and the researcher's experiences. The researcher answered all questions of the patients and their families at the end of the training session. Next, the patients and their families were given a contact number to discuss any further concerns or questions. Also, the prescribed medications for the experimental group were evaluated, and the patients were instructed about the mechanisms of action and side effects of drugs, as well as important considerations for their consumption.

All patients in the experimental group were included in a Telegram group; if a patient was unable to work with this application, his/her closest attendant was added to the group. In the Telegram group, the educational content was provided according to the content of in-person educational sessions for the patients. Moreover, upon discharge, an educational booklet (including the definitions of HF, physical activity, diet, and instructions on medication use, cessation of smoking, social activities, vaccination, program, and treatment) was given to the patients. The booklet language was simple, with a colorful graphic design for better understanding. The patients and their attendants (or the closest caregiver at home) were asked to apply home training. To discuss self-care after the training sessions, phone calls were made to the patients at the end of each week in the first month and then once a month.

On the other hand, the patients in the control group received routine care and a standard drug regimen during their stay in the hospital or clinic. For HF patients in the experimental group who visited the clinic, all stages of the

educational program were performed in the same manner after examination and leaving the physician's office.

Data collection instruments

To sum up the score of each scale, the scores were converted to fall on a scale from 0 to 100, with higher scores indicating better self-care; scores above 70 indicated appropriate self-care (18). The validity and reliability of the instrument, which was previously translated into Persian by Siabani et al., have been reported elsewhere (19).

SCHFI

SCHFI version 6.2 (20) consists of three self-care scales (22 items): self-care maintenance, self-care management, and self-care confidence. Self-care maintenance includes 10 items, where each item is rated on an ordinal scale, ranging from one to four, with one indicating the lack of adherence or rare adherence to self-care maintenance, and four indicating consistent adherence to self-care maintenance; the global score of self-care maintenance ranges from ten to 40. Also, self-care management consists of six items on symptom recognition, treatment implementation, and treatment evaluation; the maximum and minimum raw scores are 24 and four, respectively. Finally, self-care confidence consists of six items, and the maximum and minimum scores are 24 and six, respectively. The reliability and validity of this instrument have been confirmed in previous research, and it is recommended to score the three scales individually (score range: 0-100) rather than measuring the total summary score (20). Overall, higher scores of the index represent greater self-care, and adequate self-care is determined by a score of >70 on any scale.

Data analysis

After collecting the data, they were entered in SPSS version 22, and Chi-square test was used to analyze the data on sex, age, occupation, education, place of residence, underlying diseases, duration of HF, EF in echocardiography, and functional class based on the NYHA classification. A paired t-test was performed to compare the level of self-care before and after the intervention in each group. Independent t-test was also used to compare changes in different self-care scales between the control and experimental groups. Moreover, McNemar's test was used to compare the hospitalization

rate and maximum length of hospital stay in the groups. The significance level was set at 0.05.

RESULTS

In the present study, 96 patients were divided into experimental and control groups (n=48 per group). Analysis of the demographic and disease-related information showed that the majority of patients in both groups were married with high school education. Also, the majority of patients were urban residents with no comorbidities, more than three years of HF diagnosis with a 10-20% EF, and HF functional class II, III, or IV, according to the NYHA classification. Also, most patients were in the age range of 30-60 years. The results of Chi-square test showed no significant difference between the groups in terms of demographic characteristics (Table 1).

The results of data analysis indicated that all three self-care indices, including self-care maintenance, self-care management, and self-care confidence, increased significantly in the experimental group (paired t-test) (Table 2). In the experimental group, the maximum scores of these three scales significantly increased to over 70 (McNemar's test) (Figure 1). Also, the frequency and duration of hospitalization decreased significantly after training in the experimental group (McNemar's test). Meanwhile, all three self-care scales decreased significantly in the control group (paired t-test) (Table 2), and the maximum scores of all three indices significantly decreased to below 70 (McNemar's test) (Figure 1).

Moreover, the frequency of hospitalization and the length of hospital stay increased significantly after training (McNemar's test) (Table 3). Changes in self-care maintenance, management, and confidence significantly increased during six months of training in the experimental group as compared to the control group (independent t-test) (Table 3). Also, the frequency of hospitalization and the length of hospital stay significantly decreased in the experimental group as compared to the control group over six months (independent t-test) (Table 3).

Table 1. Demographic characteristics of patients in the control and experimental groups before intervention

Contextual specifications		Control group		Experimental group		P value
		Number	Percentage	Number	Percentage	
Gender	Female	14	29.1	8	16.7	0.112
	Male	34	70.9	40	83.3	
Age(y)	18-30	5	10.42	6	12.5	0.238
	30-60	31	64.58	31	64.5	
	> 60	12	25	11	22.9	
	Mean \pm SD	53 \pm 15		50 \pm 16		
Marital Status	Single	5	10.42	6	12.5	0.098
	Married	43	89.58	42	87.5	
Education	Up to High school	24	50	32	66.6	0.500
	Diploma and higher	24	50	16	33.3	
Place of residence	City	44	91.6	44	91.6	0.634
	Village	4	8.4	4	8.4	
Comorbid disease	Yes	19	39.5	10	20.8	0.073
	No	29	60.5	38	79.2	
Duration of heart failure	<6 months	11	22.9	6	12.5	0.445
	6-12 months	4	8.3	6	12.5	
	1-2y	6	12.5	8	16.6	
	2-3y	5	10.41	4	8.3	
	>3y	22	45.8	24	50	
	30% -40%	8	16.7	7	14.5	
Ejection fraction	20%-30%	16	33.3	11	22.9	0.852
	10%-20%	22	45.8	26	54.1	
	<10%	2	4.2	4	8.3	
NYHA classification	Class II	6	12.5	5	10.41	0.71
	Class III	20	41.6	17	35.4	
	Class IV	22	45.8	26	54.19	

Table 2. Average of self-care indices including self-care maintenance, self-care management, and self-care confidence in the experimental and control groups before and after the intervention

Experimental group				
	Mean SD	t	df	P value
Self-care maintenance before the intervention	65 \pm 15	-8.1	47	0.000
Self-care maintenance after the intervention	89 \pm 11			
Self-care management before the intervention	50 \pm 21	-6.2	47	0.000
Self-care management after the intervention	65 \pm 16			
Self-care confidence before the intervention	62 \pm 18	-9.3	47	0.000
Self-care confidence after the intervention	86 \pm 16			
Control group				
Self-care maintenance before the intervention	59 \pm 14	9.42	47	0.000
Self-care maintenance after the intervention	46 \pm 11			
Self-care management before the intervention	45 \pm 18	8.2	47	0.000
Self-care management after the intervention	29 \pm 10			
Self-care confidence before the intervention	59 \pm 18	6.8	47	0.000
Self-care confidence after the intervention	44 \pm 14			

Table 3. Changes in self-care score indices including self-care maintenance, self-care management, and self-care confidence in the experimental and control groups before and after the intervention

Variable	Group	Number of items	Mean	Standard deviation	Standard error	P value
Changes in self-care maintenance after the intervention	Experimental	48	24.01	8.04	19.3	<0.001
	Control	48	-13.44	6.3	10.2	
Changes in self-care management after intervention	Experimental	48	15.7	16.3	2.3	<0.001
	Control	48	-16.2	13.5	1.9	
Changes in self-care confidence after intervention	Experimental	48	24	17.7	2.5	<0.001
	Control	48	-15.1	12.1	1.7	
Duration of hospitalization after intervention	Experimental	48	-7.5	8.04	1.1	<0.001
	Control	48	-0.06	6.3	0.91	

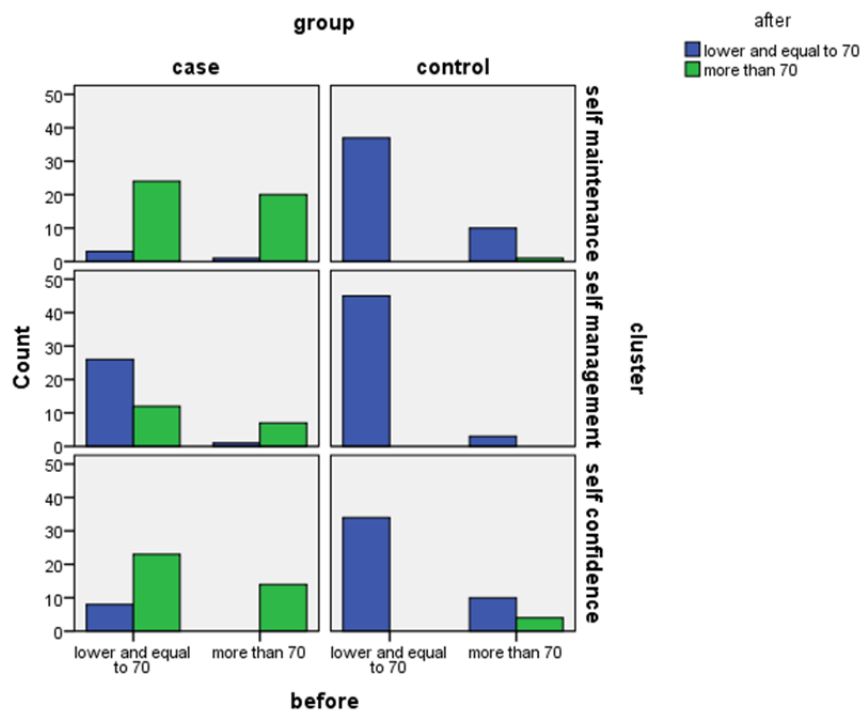


Figure 1. Changes in self-care indices above the 70 in the experimental and control group before and after the intervention

DISCUSSION

The present study aimed to determine the effects of an educational empowerment program on the self-care behaviors and readmission of patients with HF. The results indicated that the empowerment program was effective in both self-care behaviors and readmission rate. While the subscales of the self-care index increased in the experimental group, the frequency of hospitalization and its duration decreased. Also, in the present study, most patients in the experimental and control groups were

married, with primary and secondary school education. The majority of patients resided in cities, had no underlying diseases, and had been diagnosed with HF for more than three years. Based on the echocardiographic results in the patients' medical files, most of them had a 10-20% EF with a functional HF class III or IV (according to the NYHA classification). Also, the patients were mostly in the age range of 30-60 years. However, Chi-square test showed no significant difference between the groups in terms of the mentioned characteristics.

According to the results, changes in all three self-care scales, including self-care maintenance, self-care management, and self-care confidence were positive and increased in the experimental group. However, in the control group, not only the self-care indices were not stable, but also the changes were declining, and the results of paired t-test showed a significant difference in this group ($P < 0.001$). In this regard, Liou et al. conducted a trial to investigate the effect of a self-care program on HF patients in China. They reported that the self-care program had significant effects on self-care behaviors, including self-care maintenance, management, and confidence in the study group. Also, the stage of HF in the experimental group significantly improved after discharge as compared to the control group (17).

According to a study by Kato et al. (2016) in Japan, the training program increased the patients' knowledge in the intervention group and improved their adherence to a low-sodium diet (a self-care behavior examined in the present study in both scales of self-care management and confidence) over six months (18). Moreover, Rich et al. studied the impact of nursing education on the quality of life, 90-day readmission rate, and cost of care for HF patients aged above 70 years. They reported that nursing-led training significantly increased the quality of life of patients in the experimental group and reduced the costs. However, this study only examined the effect of nursing-led training and did not include educational pamphlets or follow-up using Telegram social networking application. The improvement of quality of life and cost savings can be somehow related to improved self-care, similar to the present study (11).

Moreover, Koelling et al. reported that one hour of training upon discharge improved the patients' clinical outcomes, increased their self-care behaviors, and decreased the hospital costs; these findings are similar to the results of the present study. In the mentioned study, only discharge training was provided, and three phone calls were made to complete the researcher-made form, while no training was provided during patient contact. On

the other hand, in the present study, follow-up and reminders via Telegram were also provided. Nonetheless, the results reported by Koelling et al. are remarkably similar to the present study (20). According to a study by Shearer et al., home-based patient follow-ups, besides a standard patient education program, could be used as an effective strategy for enhancing self-care management. The results of the present study also indicated that face-to-face training, along with telephone follow-ups and reminders via Telegram, had significant effects on improving self-care behaviors; however, the independent contribution of each factor was not specified (21).

Furthermore, the results of a study by Ghahremani et al. indicated that educational programs were effective in increasing awareness and improving self-care behaviors, while the patients' performance in the control group decreased in a three-month follow-up compared to the baseline (22). It is noteworthy that the level of self-care significantly decreased in the control group after six months of reassessment in the present study. This finding might be due to prolonged illness, hopelessness and fatigue, and worsening of symptoms that could create a defective cycle in the course of disease. Therefore, hopeless patients experience more symptoms and have less motivation for self-care, resulting in their failure to adhere to self-care behaviors, worsening of symptoms, and hopelessness; overall, ongoing follow-up of training might be effective in stopping this cycle (20).

Additionally, Salehi et al. in their study empowered home caregivers and then examined the self-care behaviors of patients with HF, who were treated by these caregivers; they reported that self-care improved in these patients. Although they did not directly train the patients, since training was held in the presence of the patients' attendants, they were also influenced by the training program, and changes were reported in self-care behaviors due to their interactions with the patient in the living environment (23). Moreover, the present study indicated that the hospitalization index significantly decreased after the intervention in the experimental group after six

months, whereas it increased in the control group; also, the results of McNemar's test indicated a significant difference ($P=0.000$). The length of hospitalization significantly decreased in the experimental group over six months as compared to the control group ($P<0.001$). These results are in line with the findings of numerous studies from different countries.

In this regard, studies by Rich et al. (11), Ghahremani et al. (22), and Salehi et al. (23) showed that training and empowerment programs had positive effects on reducing the readmission rate in the experimental group. In the study by Ghahremani et al., the level of self-care even decreased in the control group at the end of the program, which is consistent with the present study (22). On the other hand, in a study by Kato et al., which examined the length of hospital stay, the results indicated that training and empowerment programs had positive effects on decreasing the length of hospital stay (18). Also, Vavouranakis et al. conducted follow-up and home visits for HF patients to evaluate the effects of care and educational interventions over one year. They found that the readmission rate decreased in patients after the nursing interventions (24).

In addition, Stewart and Horowitz conducted a study to examine the effects of home-based interventions on elderly patients with HF. They found that patients, who received educational interventions, were less likely to require readmission, compared to those who received routine training (25). Also, two studies indicated that higher levels of knowledge were associated with a decreased likelihood of hospitalization (24, 25). In the study by Kato et al., higher levels of knowledge decreased the frequency of early hospitalization after discharge (18).

Moreover, Holland et al. conducted a study to assess post-discharge follow-up among HF patients in the presence of a nurse and a pharmacist; they found that the hospital readmission rates did not decrease (26). In another study, although the readmission rate decreased in the experimental group, it was not statistically significant, which contradicted the results of the present study (27).

The discrepancy between the findings might be due to differences in the methods of intervention between their study and the present research, in which the patients' performance was followed-up via Telegram application and face-to-face training and educational booklets were provided for the patients; however, none of the previous studies have employed such interventions. In conclusion, continuous encouragement of patients could motivate them to adhere to their medication regimen and diet; it also reduced their fluid and salt intake, visits to clinics, and other readmission-related issues.

Limitations

There are some limitations in the present study. First, some care-related feedback was provided by phone calls for the patients in the present study. Second, some patients might not have provided accurate information about their self-care behaviors. Third, occasional Internet interruption or lack of access was another limitation of this study. Fourth, in face-to-face visits, although some patients did not have enough time for discussions, they tended to pursue phone follow-ups and remain in the study. Finally, considering the data collection method, it was not possible to blind the samples or researchers to the groups.

CONCLUSION

Although HF is a serious disease, there are many interventions that can decelerate the course of disease, reduce the symptoms, and lead to a higher quality of life if the patient adheres to them. The present results indicated that the implementation of an empowerment program for HF patients, including face-to-face training, educational pamphlets, and Telegram-based follow-ups (for regular medication use under the physician's supervision, daily blood pressure, heart rate, and weight monitoring, adherence to a low-sodium diet with adequate calories, regular exercise, quitting smoking, social activities, and regular visits of the treatment team) improved all three scales of self-care behavior, namely, self-care maintenance, management, and confidence. Moreover, it decreased the hospitalization rate and duration. Since the empowerment

program significantly increased self-care behaviors and decreased the frequency of admission in patients with HF, it is strongly suggested to implement such programs in health centers, especially subspecialized HF centers, to help these patients and reduce the costs on the healthcare system.

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