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Effect of self-management program on health status of elderly patients with heart failure: a single-blind, randomized clinical trial

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ABSTRACT

Objective: To determine the effect of self-management program on the health status of elderly patients with heart failure.

Methods: The present study was a single-blind, randomized clinical trial, and conducted on 90 patients with heart failure of stages II-III at one teaching hospital in eastern Iran in 2017. The participants were randomly assigned into two groups: the intervention group and the control groups, with 45 patients in each group. Self-management programs including awareness and recognition, problem-solving process, diet, exercise, and stress management were carried out. The participants were trained for six weeks and were followed for two months. Data of the health status were collected before, after and eight weeks after intervention by Kansas City Cardiomyopathy Questionnaire. Data analysis by *chi*-square, independent *t*-test, Fisher, ANOVA with repeated measures was conducted.

Results: Patients in both groups were matched in terms of demographic characteristics before the intervention. There was no significant difference in the mean scores of health status between the two groups ($P=0.1$) before the intervention. However, the second measurement after intervention showed a significant difference in the mean scores between the two groups ($P=0.001$).

Conclusions: Self-management program can improve the different dimensions of health (except in the subscale of sign and symptoms). Therefore, this supportive method can be used to improve the health of patients and manage problems caused by heart failure.

1. Introduction

Cardiovascular diseases are the first cause of death in the world, accounting for more than a third of all deaths (39%), and are also the most important challenge to the health system[1,2]. Global Burden of Disease Study also ranked cardiovascular diseases the

first reason for causing mortality in the world[3]. Heart failure (HF) is one of the most prevalent chronic illnesses among the aging population. HF is a complex clinical syndrome with chronic, progressive and debilitating effect on the patients[2], which can lead to shortness of breath, fatigue, intolerance of physical exercise,

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mental confusion, general weakness, pulmonary and organ edema (swelling), chest pain, palpitations in the patients, and ultimately poor quality of life and high costs for the individual and society[4]. An estimated 38 billion dollars is spent annually on HF healthcare in the United States[5,6]. The prevalence of HF continues to rise over time with the aging population. In NHANES data, an estimated 6.2 million American adults ≥ 20 years of age (2.2%) had HF between 2013 and 2016 compared with an estimated 5.7 million between 2009 and 2012[7]. The prevalence of HF in Iran is 8%, which is higher than other regional and even global statistics[8]. By the year 2030, one out of every 33 people is expected to suffer from HF, and the cost of the treatment will increase by 3 times[9]. The cost of hospitalization of these patients in Iran is estimated as 400 billion Rials per year, which warns us to find preventive measures with a lower cost. Therefore, it is important to find methods for controlling HF and its complications, and reducing the risk of readmission[10]. One of the most suitable ways to prevent the onset and progression of the complications is efficient self-care behaviors that play an effective role in reducing the rate of hospitalization and mortality of the patients with HF[11]. Self-care is viewed as a core component of disease management and is a relative process associated with targeted behaviors and choices reflecting the attitude and knowledge of each individual[10]. Therefore, regarding the treatment, more focus has been shifted to receiving treatment and self-care in recent years[12]. Compliance with self-care behaviors in HF patients can reduce the cost of treatment for 6 months, and increase the 5-year survival rate of the patients up to 50%[13]. In fact, self-management is the daily task that a person must take to control or reduce the physical effects of a disease on health conditions. These tasks and strategies are carried out with the help of expert physicians and other professional caregivers[14]. The results of a few studies have also shown that demographic factors, such as high age, will affect self-management in a negative way. Also, the socioeconomic factors, such as low education and low income; social factors, such as weak personal and family relationships; health system factors, such as dissatisfaction with health care and inadequate experiences of patient-based care, including inaccurate participatory decision-making, as well as poor therapy communication, have caused self-management process to confront with serious problems[15]. However, in this regard, some people will be able to handle HF self-management well and undertake the responsibility for disease management and the consequences, and successfully integrate HF self-management with their daily life[16]. The death rate of women and patients with right bundle branch block was also higher than other patients[17]. The most important factors affecting the incidence of HF are type 2 diabetes, hypertension, stroke, and age. The incidence of HF is higher in Asian countries, including Japan, China, and Malaysia than other parts of the world[18,19]. In these countries, it was reported that the incidence ranged from 3.9 to 7.6[18,20,21]. Changes of the lifestyle due to industrial revolution, unhealthy eating habits (binging, sugar, white flour, caffeine and simple carbohydrates, lack of exercise) and aging are significant for the increase of HF[19]. Considering that, studies of Radzewitz *et al.* is meaningful on general health, mental

health, and quality of life of patients with HF[22]. The study of Auld also showed that self-management program had a positive effect on self-care and quality of life of advanced patients[23]. And the study of McDowell *et al.* has been effective in weight loss for patients with HF[24]. On this basis, due to the age increase of population and the undeniable side-effects of chronic diseases, especially HF, and the lack of sufficient management program for patients with HF in the educational treatment centers of the country, we conducted the research to determine the effect of self-management program on the health status of the elderly with HF.

2. Materials and methods

2.1. Study design, registration, and outcome

This study was a single-blind (for patients) random clinical trial, and was performed among 84 elderly patients with HF in the 22 Bahman Hospital in Neyshabur city from February to July 2017. The protocol of the present study was approved by Institutional review board and Ethics Committee of University of Social Welfare and Rehabilitation Sciences (Thesis ID: 921208008, ethic code: IR.USWR.REC.1394.157), and the clinical trial protocol was registered at the Iranian Registry of Clinical Trials (IRCT-ID: IRCT2016052628089N1). The CONSORT checklist was used to report the study[25]. Written and oral informed consents were obtained from all participants. The main preliminary outcome was the health status of the elderly with HF. To enhance the quality of measurements, we employed trained assessor to measure the main outcome.

2.2. Eligibility criteria

The criteria were as following: patients over 60 years old; having reading and writing skills; having grade 2 and grade 3 HF according to echocardiography ($40\% > EF > 30\%$); with physician approval based on American Heart Association[26]; having no previous training on the self-management program and willingness to participate in the program. Patients with deterioration of disease and the emergence of physical disorder during the study, death due to the disease, and refusing to continue the program were excluded.

2.3. Procedure

The sample sizes were determined as 41 people in each group with a 95% confidence coefficient and 80% test capability, but considering the probability of the loss of 10% of samples, 45 individuals were considered for each group, among whom 6 people were excluded from the study due to the severity of disease (2 people) and the 4 participants refusing to continue the study were also excluded. Ultimately, the number of samples in each group was reduced to 42 people (Figure 1). This study was single-blind, and the patients were aware of being involved in the study, but not aware

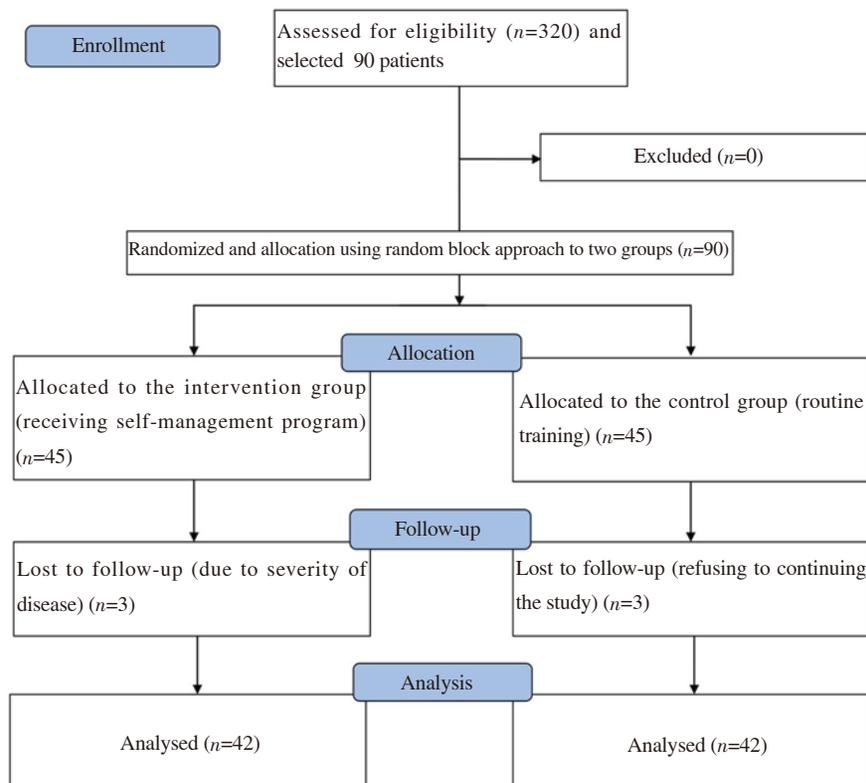


Figure 1. Flow chart of the included patients.

of which group they were in at the time of intervention. First, the researcher provided explanations about the method and the objective of the research to all patients. And then the samples were selected by consecutive sampling method. Allocation of samples into two groups by random blocks with four blocks was conducted, and patients were assigned into two groups, including the intervention group (receiving self-management program) and the control (routine training) group. The control group received routine training which received education about using low-salt and low-fat diet.

Before the implementation of self-management program in the intervention group, the researcher gave some necessary explanations to the participants after obtaining informed consent from them. The patients were asked to refer to the clinic on the given dates. Then the patients completed the questionnaires of demographic characteristics and health status. The training sessions were conducted by the researcher in the intervention group at the clinic site in three groups with 14 people each group, and the frequency is one day per week and each session for 90 min in 6 weeks. The content of the self-management program, including knowledge and recognition of disease and treatment, diet, exercise, problem-solving methods, negative stresses control, and muscle relaxation, was confirmed by reliable sources, cardiologist and research team. During the training sessions, the patients actively raised their problems by designing examples of real-life, and were educated from the problem-solving process. The content of program was included: introduction of program and its purposes to patients, education about medications, diet, elimination of unhealthy behaviors, and education about problem-solving techniques including stress management methods, appropriate muscular techniques.

Subsequently, under the supervision of the inquirer, their performance was discussed with the objective examples of their status or others' similar problems. Practical trainings in the classroom were proceeded through questions and answers, to encourage the patients to provide positive and negative experiences on each one of the topics, and raise issues related to controlling and managing probable illness-related problems. The patients also had time to solve the problems by the methods that combined what their learned and the participations of other patients. At the end of the sixth session, participants were asked to complete questionnaires about the health status again. The self-report checklist was then given to the patients to apply and record self-management programs for 8 weeks to stabilize their behaviors at home, and the researcher also used telephone tracking once a week to monitor the program. At the end of the 8th week, the interventions group and the control groups were asked again to refer to the clinic on a certain date and complete the mentioned questionnaires. The main outcomes were assessed three times, before the intervention, at the end of 6 weeks of the intervention, and 8 weeks (two months) after the intervention. In order to comply with the ethical standards, at the end of the research, the mentioned instruction booklet was also provided for the control group.

2.4. Instruments

The data were collected via the demographic characteristics questionnaire, which included 21 questions, with 10 personal information questions including (age, gender, marital status, educational level, employment status, etc.), and 11 questions related

to the disease (duration of infection, discharge rate, disease class, etc.), and the Kansas City Health Status Questionnaire, specific for HF patients, designed by Green, *et al.* in the University of Missouri, Kansas City, in 2000[27], which is a self-report questionnaire with 23 items in six sections that include physical constraints, heart signs and symptoms, disease durability and stability, self-efficacy, social performance, and life quality of patients with HF. Items are measured by Likert's five, six, or seven-degree scale and their score is from 1 to 7. Total score of questioner was 0 to 100. The higher score indicates the desired quality of life. The reliability of questioner was approved using the internal consistency method with Cronbach's alpha 0.88.

2.5. Statistical analysis

SPSS Version 18.0 for Windows (SPSS Inc., Chicago, IL, USA) was used to analyze the data. Normality of data was determined by Kolmogorov-Smirnov statistical tests. To describe the characteristics of research units, firstly the descriptive statistics including central (mean and standard deviation) indicators and frequency distribution were calculated, and then independent and paired *t*-test, Fisher, analysis of variance with repeated measures and Friedman test for the analysis of main variables were used.

3. Results

3.1. Demographic characteristics

Altogether 84 HF patients participated in the present study of randomized clinic trial. The mean age of the participants in the intervention group and the control group were 70.04±8.04 and 68.16±5.81, respectively. Most of the participants in the two groups were male (57.1% in the intervention group and 54.7% in the control group); had a medium-income (45.2% in the intervention group and 54.8% in the control group); had elementary level of education (57.1% in the intervention group and 57.1% in the control group); had a 1-5 years' history of HF disease. In terms of demographic characteristics and disease characteristics, there was no significant difference between two groups ($P>0.05$) (Table 1).

3.2. Main outcome measure

Regarding to health status, the average score showed no significant difference between the two groups ($P>0.05$) before the program. However, after the implementation of the program, the results showed that there was a significant difference in health status during the three measured periods between the two groups. The LSD post hoc test indicated that self-management training program had a positive impact on the average health status of the patients in the intervention group, and it improved the health status of the elderly

with HF and this difference was statistically significant ($P<0.05$) (Table 2).

About health status subclasses, Friedman test was used to compare the mean of these variables in three times, and the results showed that there was no significant difference in the mean of all subscales of self-efficacy, social function, quality of life and severity of symptoms at different time points in the control group ($P>0.05$). The differences were significant at different time points in the intervention group ($P=0.001$). And the findings showed that the self-management program had a positive effect on patient self-esteem and improved self-efficacy and quality of life for elderly patients with HF (Table 3).

Table 1. Demographic and disease information of the two groups.

Variables	Intervention group	Control group	P
Age (mean±SD)(years)	70.04±8.04	68.16±5.81	0.2
Gender [n (%)]			
Male	24 (57.1)	23 (54.7)	0.8
Female	18 (42.9)	19 (45.2)	
Income [n (%)]			
Low	6 (14.2)	5 (11.9)	0.7
Medium	19 (45.4)	23 (54.8)	
High	17 (40.4)	14 (33.3)	
Education [n (%)]			
Elementary	24 (57.1)	24 (57.1)	0.8
Guidance	10 (23.8)	12 (28.5)	
Diploma	6 (14.3)	2 (4.7)	
Academic	2 (4.8)	4 (9.5)	
History of HF [n (%)]			
Less than one year	9 (21.4)	13 (31.0)	0.1
1-5 year (s)	19 (45.2)	23 (54.8)	
6-10 years	14 (33.3)	6 (14.3)	

HF: heart failure.

Table 2. Average health status before, immediately after and two months after the intervention in elderly patients with heart failure.

Groups	Before intervention	At the end of intervention	Two months after intervention
Control	80.57±10.07	81.40±9.71	81.09±9.68
Intervention	77.07±15.42	87.11±13.99	85.54±12.86
P-value	0.20	0.03	0.07

Table 3. Subscales of health status of elderly patients with heart failure at different time points.

Groups	SE	SP	QL	SS
Intervention				
Before intervention	1.02	1.06	1.16	1.20
After intervention	2.94	2.67	2.50	2.51
Two months later	2.04	2.27	2.34	2.29
Control				
Before intervention	1.83	2.13	2.02	2.10
After intervention	1.90	1.83	1.88	1.76
Two months later	2.26	2.04	2.10	2.14

SE: Self-efficacy; SP: Social performance; QL: Quality of life; SS: Severity of symptoms.

4. Discussion

HF is a major cause of hospitalization, therefore, prevention of hospitalization in patients with HF is a key priority[26]. The aim of this study was to determine the effect of self-management program on health status of elderly patients with HF. The findings showed that the self-management program was effective on the elderly with HF. Also, in other aspects of health status, such as severity of symptoms, self-efficacy, social function, and quality of life in the intervention group increased. The findings of the present study are consistent with the findings of Meng *et al.*[28], Sol *et al.*[29], Liou *et al.*[30], Shin *et al.*[31], Shao *et al.*[32], and Mosca *et al.*[33] studies. A study performed by Shively *et al.*, in the United States which evaluated the effect of behavioral management on quality of life at the baseline, 4, 10, 16 months later. The results showed that in respect to physical performance, a significant improvement was showed in the intervention group, although no significant changes were obtained in the psychological dimension[28]. Also, the results of the present study were consistent with some previous studies that assessed the effect of self-management program on health status of different sample participants[34-40].

Considering that in the present research, the participants have all been elderly, and individual differences, cultural, social and economic factors, as well as other underlying illnesses of the health status of patients could be raised as confusing problems, which are beyond the control of the researcher, and can affect the results of the research. With the functional decline and the increasing age, the elderly usually had complication with one or two chronic diseases that can lead to the loss of autonomy, and dependence on the people around, and hence a decline in their quality of life and the sustainability of education. The increase and improvement in health status observed in the intervention group proved the effect of self-management program training. The phenomenon of aging and age-related deficits include reduction of vision strength, hearing impairment, bending, slowness in mobility, decreased muscle strength, disorder and disturbances in memory and perception, disturbance in navigation, decreased capacity and efficacy of the lungs and the cardiovascular system. The elderly HF patients looking for meaning of the life at the end of his life, all of these factors, along with other diseases that the elderly may face with are among the reasons that could impact on the success of performing self-management programs in promoting self-care behaviors[41].

Among the limitations of this research, the individual differences in response to health care as well as psychosocial and mental support and performing care by family members in each patient can be different and hard to monitor, which can affect the results of the research. In addition, the living environment is effective in implementing home-based interventions that it would be impossible for the researcher to assimilate it. According to the findings of the present research, it is hoped that the self-management program for HF would be considered as an intervention with the easy, low-cost, and effective implementation in the treatment plan for patients with HF. It is also suggested that similar studies should be conducted

with a long-term follow-up (6, and 12 months) to assess the sustainability ratio of self-management interventions.

The findings of the present study showed that self-management interventions have been effective in promoting the health status of patients with HF. Therefore, it is recommended to use self-management programs to change the behaviors and promote health status of patients with HF. One of the clear points of this study is the exploitation of a community-oriented approach to implement a self-management program.

Conflict of interest statement

The authors report no conflict of interest.

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