Effects of Family-Center Empowerment Model on the Lifestyle of Heart Failure Patients: A Randomized Controlled Clinical Trial

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ABSTRACT
Background: Cardiovascular diseases are the most prevalent disorders in developed countries and heart failure is the major one among them. This disease is caused by numerous factors and one of the most considerable risk factors is unhealthy lifestyle. So the aim of this research was to study the effect of family-center empowerment model on the lifestyle of heart failure patients.
Methods: This is a randomized controlled clinical trial on 70 heart failure patients referring to Hazrare Fatemeh heart clinic in Shiraz. After convenience sampling the patients were divided into two control and intervention groups using block randomization Method. The intervention based on family-center empowerment model was performed during 5 sessions. Research tools are lifestyle and demographic information questionnaires.
Results: Both intervention and control groups were similar regarding their demographic information (P>0.001). Before the intervention on lifestyle, all measures of the two groups were equal (P>0.001) but after the intervention; statistically significant differences were reported in all dimensions of lifestyle, the total lifestyle score in the intervention group was 70.09±16.38 and in the control group -6.03±16.36 (P<0.001).
Conclusion: Performing the family-center empowerment model for heart failure patients is practically possible, leading to improvement or refinement of their and their families’ lifestyle.
Trial Registration Number: IRCT 2014072018468N3

KEYWORDS: Nursing model; Heart failure; Lifestyle

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INTRODUCTION

Nowadays, cardiovascular diseases are considered as the most prevalent disease in developed counties and are main cause of mortality in all ages and races. In the beginning of the 20th century, mortality caused by heart disease was less than 10% of the world’s mortality, but in the late 20th century, nearly half of the death statistics in industrial countries and a quarter of the deaths in developing countries are attributed to heart diseases.

Heart failure is defined as an acute clinical condition that involves different aspects of the patients’ life despite available treatments. It is one of the most common causes of admission and re-admission of patients over 65 years old. Also, among the chronic diseases, heart failure is ranked the first for the rate of repeated hospital admission. The prevalence rates of re-admission among these patients have been reported 40%. Therefore, this necessitates improvement of the nurses’ capabilities regarding these patients in the caring process. In this regard, some studies have been done on quality of life and also dietary regimen of heart failure patients.

Cardiovascular disease and also heart failure are caused by a vast number of factors, the most important of which is unhealthy lifestyle. The availability of lots of evidence showing and proving a relationship between lifestyle and heart diseases, the necessity of lifestyle improvement is reasonable as an important factor in determining the prognosis and symptoms of this disease. In this regard, and based on the results of researches performed in industrial countries modifying the lifestyle could reduce the cardiovascular disease mortality during the last 25 years.

Based on their results, some researchers reported that heart disease could last the whole life of a person and additionally can affect his or her family and even society, so the patients deserve to be rehabilitated for a better lifestyle and to appropriately control the disease. This is why rehabilitation is in the focus of many medical and nursing researches and considered as a necessity of nursing profession. Family-center empowerment model is an Iranian model whose main aim is to enforce the family system (patient and other family members) to promote health level.

This model has been implemented and used in some studies (iron deficiency anemia, thalassemia, hemophilia, diabetes, asthma and epilepsy) to improve the quality of life of these chronic patients. The results indicated improvement in their quality of life.

Regarding the significance of heart failure patient’s lifestyle in addition to the importance of lifestyle improvement, especially for these patients, the majority of studies on heart failure patients have only focused on the other aspects and pay less attention to the patients’ lifestyle, especially on the improvement of lifestyle by involving family members. Therefore, this study aimed to determine the effects of family-center empowerment model on the lifestyle of heart failure patients.

MATERIALS AND METHODS

Participants and Procedures

The present study is a randomized controlled clinical trial. Research samples were patients (18–65 years age range) whose heart failure was confirmed by a cardiologist (at least in the class II); they had referred to Al-Zahra clinic and were selected through convenience sampling method. The researcher recruited the patients by attending Al-Zahra clinic and selecting the patients based on inclusion and exclusion criteria, between May 2014 and January 2015.

All patients were provided with explanations about research aims, probability of withdrawing from participation and anonymity of the research data. After obtaining written informed consent, questionnaires about their lifestyle and demographic information were completed. Then the patients were divided into intervention and control groups by performing balanced block randomization method with a total of 6 blocks; we randomly selected block size of 4. The design protocol of study is shown in Figure 1.
The tendency of the patient and one of his or her family to participate in the study, having the writing and reading knowledge, and Persian language skill besides not having any acute psychological disease were the exclusion criteria. The exclusion criteria were having no more tendency to participate in the research either by the patient or his or her family member in the rehabilitation program and lack of attendance in the sessions. The sample size was determined using the following formula and the previous studies.\(^{10}\) The first type error was equal to 5%, the test power was reported 90%, and Mean=7.63 and SD=0.72 determined the sample size equal to 3 persons (for each group). This small sample size indicates the effectiveness of the model in previous studies. But in the present study according to the prediction of sample attrition and with regard to the resources available in each group, the sample size was increased to 35.

\[
N = \frac{\left(z_{1-\alpha} + z_{1-\beta}\right)^2 (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2}
\]

\(\alpha=0.05, \ \beta=0.1, \ \mu_1=22.54, \ \mu_2=30.17, \ \sigma_1=2.7, \ \sigma_2=3.42\)

**Measures**

The instruments used were lifestyle and demographic information questionnaire and daily events recording form.

a) Demographic information questionnaire was designed through related research and document review and under the supervision of cardiovascular specialists. This questionnaire contained seven questions and was completed for each patient by researcher.

b) Lifestyle questionnaire was designed...
by Walker and Pender (1992). It contains 52 items of lifestyle behaviors. These items are responsibility regarding health (9 items), physical activity (8 items), interpersonal communication (9 items), spiritual growth (9 items), nutrition (9 items), and stress management (8 items).

Overall these 6 types of lifestyle items could reach the score 208 and the obtained scores were divided into 4 categories of weak (less than 52), medium (53-104), good (105-156), and excellent (157-208). Psychometrics of this questionnaire was reported 0.82 for validity and 0.94 for reliability.13 The Cronbach’s alpha of this questionnaire in Iran was reported by Safabakhsh to be 0.83.14 Besides in another research the reliability of this questionnaire was reported by Mohammadian et al. to be 0.84.15

**Intervention**

This study was approved by Ethics Committee of Shiraz University of Medical Sciences (No CT-9378-7058). The research was conducted on two groups (intervention & control), and the intervention was performed on the intervention group, lasting for 2 months.

The family-center rehabilitation model was used in this study. Therefore, the operational stage of the intervention included 4 steps performed about “threat perception (two sessions with 1-2 hours)”, “self-effectiveness (one session with 1-2 hours)”, “solipsism (one session with 1 hour)”, “evaluation (Process evaluation: performed throughout the study and final evaluation: A month and half after performing the intervention)”.

The control group received routine and prevalent education. Then at the end of the study an educational pamphlet about heart failure was given to the control group participants. After a month and half from the end of the intervention, the lifestyle questionnaire was completed by both control and intervention groups.

**Data Analysis**

All data collected through the lifestyle questionnaire were statistically analyzed regarding the study aims. These data were quantitatively analyzed using SPSS version 19 (SPSS Statistics; IBM Corporation, Chicago, Illinois, USA). Descriptive statistics were performed to characterize the samples.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention group</th>
<th>Control group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean±SD)</td>
<td>50.23±8.28</td>
<td>52.20±9.49</td>
<td>0.52</td>
</tr>
<tr>
<td>Body mass index</td>
<td>24.23±5.62</td>
<td>23.69±4.04</td>
<td>0.62</td>
</tr>
<tr>
<td>Affliction duration</td>
<td>23.23±40.73</td>
<td>30.12±64.34</td>
<td>0.59</td>
</tr>
<tr>
<td>Educational level (number (percent))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary school</td>
<td>11 (31.4%)</td>
<td>21 (36.8%)</td>
<td>0.56</td>
</tr>
<tr>
<td>Guidance school</td>
<td>7 (20%)</td>
<td>7 (20%)</td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>9 (25.7%)</td>
<td>2 (19.7%)</td>
<td></td>
</tr>
<tr>
<td>Diploma</td>
<td>2 (5.7%)</td>
<td>2 (19.1%)</td>
<td></td>
</tr>
<tr>
<td>Upper than diploma</td>
<td>6 (17.1%)</td>
<td>1 (18.5%)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>21 (60%)</td>
<td>19 (54.3%)</td>
<td>0.80</td>
</tr>
<tr>
<td>Male</td>
<td>14 (40%)</td>
<td>16 (45.7%)</td>
<td></td>
</tr>
<tr>
<td>Diabetes affliction history</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Afflicted</td>
<td>13 (37.1%)</td>
<td>9 (25.7%)</td>
<td>0.44</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Afflicted</td>
<td>14 (40%)</td>
<td>9 (25.7%)</td>
<td>0.31</td>
</tr>
<tr>
<td>Hypertension history</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Afflicted</td>
<td>15 (42.9%)</td>
<td>9 (25.7%)</td>
<td>0.21</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>10 (28.6%)</td>
<td>13 (37.1%)</td>
<td>0.45</td>
</tr>
</tbody>
</table>
Frequencies and percentages were calculated for categorical variables, and means and standard deviations for continuous variables. Independent and paired T-test were performed to examine lifestyle and quantitative demographic information. Chi-square test was done to analyze the demographic information. Statistical significance was set at the 5% (P<0.05) level.

**RESULTS**

In this study, there were no significant relationship between demographic parameters (age, body mass index and duration of disease affliction) (P>0.001). In the study of qualitative parameters of demographic information including education level, sex, diabetes history and hyperlipidemia and smoking, it was shown that the majority of research cases were females having primary school level education. Data revealed that both control and intervention groups were similar regarding their qualitative parameters (P>0.001). Full demonstration of the study cases are shown in Table 1.

The significant difference was shown in all dimensions of lifestyle between the control and intervention groups after the intervention (P<0.001). Also a significant difference was found in all dimensions of lifestyle of the intervention group members before and after the intervention (P<0.001). Major changes were shown in spiritual growth and the least changes were found in physical activity. All patients of both control and intervention groups dada low grade lifestyle score before the intervention but after that the lifestyle score of the intervention group increased to the good level. The mean lifestyle level of the control group did not change significantly but it increased to the middle level. Table 2 shows comparison of life-style dimensions differences in mean scores before and after the intervention between the two groups. Also, the means of lifestyle dimension before and after the intervention of both study groups was shown in Table 3.
DISCUSSION

The present study is a research designed in Iran on heart failure patients. The effects of family-center empowerment model on the lifestyle of heart failure patients were evaluated in this study.

Generally, the results of this study revealed that heart failure patients showed more positive changes in their lifestyle after the educational intervention compared with before; that is, they have a better condition about their lifestyle toward 6 six dimension including nutrition, spiritual growth, stress management, physical activity, interpersonal communications, and health responsibility.

In other words, the results showed that the difference of all the above-mentioned dimensions was statistically significant before and after the intervention. Significant differences in all lifestyles dimensions were shown between the intervention and control groups. Additionally, paired T-test showed significant differences in all lifestyle dimensions of the group before and after the intervention. This could be a clear evidence for effectiveness of family-center rehabilitation model on the lifestyle of heart failure patients.

Regarding the findings of the present study, the important point is significant changes in the lifestyle of the intervention group compared with the control group. This change manifests itself in promoting lifestyle of the intervention group from weak to good. Before the intervention, the majority of patients had weak nutritional status, physical activity and stress management, but after that all of these factors promoted to a desirable and statistically significant level.

The results are in the same line with those of a research performed on the effect of family-centered habilitation model dimensions change (nutrition, physical activity and stress) and the differences were statistically significant.12 The results of a fairly similar study revealed that patients who had participated in training class of nutrition with their wives or one of their family member had more weight loss compare to patients who participated without their wives or one of their family member.16 These results confirm those of the present study, it is suggested that patients’ education with family involvement can be more effective. Also, the results of current study are consistent with the findings of a study on the effects of family-based diet for patients with cardiovascular risk factors.17 Therefore, previous studies also consider the effectiveness of family-centered training to improve the patient’s lifestyle.

Some researchers studied the effect of nutrition as the sole effective lifestyle dimension on cardiovascular patients. In the mentioned study, the differences of carbohydrate consumption, the percentage of fiber consumption present in fruit and vegetable, fruit consumption, whole cereal consumption and meat consumption were statistically significant between the intervention and control groups.18

In another research, the effects of family-center intervention on patient nutrition models after myocardial infarction were studied; they showed that the modification nutrition model was significantly better than in the intervention group compared to the control group.19

Also, comparison of the impacts of family-based and individual-based training on body mass index decrease and lifestyle promotion was done in another study. The researcher concluded that after the intervention the mean body mass index decreased in both groups; besides, the mean of diary and fruit consumption and physical activities significantly increased.20 One of the most attractive investigations in the field of lifestyle is a research in which the first theme resulting from profound interviews with patients was the excavating and control of disease through successful lifestyle improvement.21 One of the inputs leading to this theme is that all participants believed that personal responsibility about health was an essential element of every program to successfully change the situation. This could be the key
point of family-center rehabilitation model, because it is the patient that rehabilitates himself—but not the researcher. In all stages of the program, the researcher accompanies the patients and does his/her caring duties to make the desirable conditions available for them. The results of another study showed that cardiovascular disease prevention can be effectively performed via lifestyle interventions in the United States. The results proved that not only giving up smoking, but also continuing physical activity, nourishment with a healthy diet, weight management and stress avoidance are important parts of cardiovascular disease prevention program, and vulnerable individuals should improve their lifestyle in addition to drug therapy.22 Nowadays, researches on the patients’ lifestyle and its improvement strategies are becoming more and more important in nursing. In fact, lifestyle is a related concept to nursing field and is one of the nursing aims to be reached. Regarding the importance of the study and improvement in the heart failure patients’ lifestyle, this study was an attempt to improve the lifestyle of these patients using family-center rehabilitation model.

In this study, due to the age of the participants, there were some problems for their attendance in the verbal-physical session of the educational sessions; hence, it is recommended that further studies should be conducted in virtual classes and web-based meetings for this group of patients. In this way, we may reduce some of the problems in this regard.

CONCLUSION

This research was performed regarding the abundance of heart failure cases, the extent of its effects on the patient’s life, and the importance of lifestyle in controlling and even preventing this disease. It is necessary for the nurses to keep looking for better ways to improve the patients’ lifestyle. This study revealed the effect of family-center rehabilitation model on the lifestyle of these patients. Therefore, it can be concluded that this model is applicable for modification and improvement of heart failure disease patients’ lifestyle.

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CONFLICT OF INTEREST: None declared.

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