Original Article

The Effect of Cognitive-Behavioral Training Versus Conventional Training on Self-care and Depression Severity in Heart Failure Patients with Depression: A Randomized Clinical Trial

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Abstract

Introduction: Psychological factors including depression and anxiety are the most critical risk factors in the treatment and prognosis of heart failure which should be addressed in treatment and care programs. The purpose of this study was to examine the effect of cognitive-behavioral training (CBT) on depression severity and self-care ability of patients with heart failure.

Methods: This study was a randomized clinical trial that carried out on 80 patients with heart failure who had been hospitalized in 2018. The participants were divided into the CBT group (n= 40) and the conventional training (CT) group (n= 40), randomly. Data were collected using Beck Depression Inventory (BDI) and the Self-Care of Heart Failure Index (SCHFI) version 6.2 before and 8 weeks after the educational interventions. Data were analyzed in SPSS 21 using paired t-test, independent t-test, chi-square test, and covariance analysis.

Results: The mean score of self-care in the CBT group turned out to be significantly higher than the CT group after receiving the intervention. Also, the mean depression score of the CBT group 26.95 (5.53) after intervention was significantly lower than the CT group 36.04 (8.45).

Conclusion: Cognitive-behavioral intervention, compared with conventional training, had a greater positive impact on improving self-care and alleviating the severity of depression symptoms. Therefore, it is recommended that the principles of cognitive-behavioral therapy be integrated into routine educational programs.

Introduction

Heart failure is considered one of the most commonly diagnosed chronic heart diseases and is a major health problem worldwide.1,2 Heart failure is the ultimate end of all cardiovascular diseases. One should expect further increase in its prevalence due to the aging of populations and the improved survival rates for other cardiovascular diseases.3 Thus, 2% of hospital beds and 5% of patient admission in emergency centers are related to heart failure.4 According to the World Health Organization, there are about 26 million patients with heart failure in the world, and by 2030, more than 48% of the population will be affected by heart failure.5 In Iran, due to changes in lifestyle, the incidence of heart failure is on the rise, so that the number of patients is estimated to be about 3.3 per 100 population.6 Heart failure is associated with negative consequences including high mortality, frequent hospitalization, and serious physical harms, and it still imposes heavy burdens on patients, caregivers, and healthcare systems.7

The disability associated with this disease is not only due to physical symptoms but also psychological distress such as depression and anxiety. Numerous studies have shown that, apart from the physiological severity of the disease, depression is the most important risk factor for disability and mortality caused by heart failure. A three-month period of depression in heart failure patients increases the risk of mortality by 2.5 times; it also increases the risk of re-hospitalization by 3.5 times within one year.8 The prevalence of depression in conjunction with heart failure is very high, ranging from 9 to 60%.9,10 Various studies have demonstrated that depression in patients with heart failure is multifactorial and may be due to fear and anxiety following diagnosis, debilitating symptoms, limitation in physical function, uncertainty about the future, and reduced confidence in one's ability to play personal, social, and professional roles, doubts about doing certain activities, low self-esteem, and negative self-concept.11-14

Depression, associated with poor prognosis, is characterized by symptoms that affect the cognitive,
emotional, and behavioral processes of patients with heart failure. However, the precise mechanism of the impact of depression on undesirable therapeutic outcomes has not been discovered. Some believe it to be due to a combination of behavioral effects and their interaction with physiological responses. In addition to behavioral effects, depression can reduce the likelihood of adherence to treatment and modifying lifestyle behaviors, which in turn aggravates treatment outcomes. Depression caused by social rejection, lack of interest in behavioral changes, low treatment motivation, prolonged illness, interference with treatment and care, and delayed recovery worsen symptoms and lead to frequent hospitalization.

Depressed patients with heart failure have lower self-care abilities than their non-depressed counterparts due to their depression symptoms. Depression and its associated symptoms such as passive coping styles, lack of planning, negativity, and reduced energy significantly influence self-care behaviors. Therefore, beside psychological problems, the other challenge of these patients is self-care, which is considered one of the ways to control heart failure. Navidian et al., reported that routine self-care training has a much lower impact on the knowledge and self-care behaviors of heart failure patients who are depressed than those who are not; they recommended that heart failure management programs which are tied to depression symptoms should take account of patients’ psychological problems.

Therapeutic goals for heart failure underline receiving treatment, patient education, and self-care. The rate of non-participation in educational programs has been reported to range between 25 to 35%; in this regard, depression has been observed as a major factor contributing to the lack of patients’ cooperation in treatment programs. The purpose of training is to raise awareness, but providing information alone does not translate to controlling the symptoms. On the other hand, resolving psychological problems of heart failure patients is known to affect prognosis. In fact, depression and its consequences in these patients confirm the need for effective therapeutic measures.

Depression is a modifiable risk factor in the treatment and prognosis of heart failure, and it is imperative for those in charge of disease management programs to design and implement appropriate interventions in heart clinics and other related centers. Although using selective serotonin reuptake inhibitors medication to treat depression is not a serious risk for heart failure, its effect on depression is uncertain. Therefore, there seems to be an even more pressing need to adopt psychological therapies to cure patients with heart failure. Therapists can increase the likelihood of recovery in depressed patients with heart failure, choosing the most effective treatment with the least side effects. This has led to the emergence of specific psychological treatments, of which cognitive-behavioral training (CBT) is an example. This training is an active, organized, time-limited, and goal-directed approach aimed at finding solutions for patient’s problems through cognitive-behavioral strategies. This treatment is a gradual process, helping an individual move step by step towards modifying his/her behavior.

Various studies have accentuated the role of psychosocial factors in cognitive-behavioral therapy of heart failure patients. However, few studies on depressed heart failure patients have employed psychological training based on short-term cognitive-behavioral approaches in order to reduce depression and improve self-care behaviors. Depression has not been adequately addressed in relation to heart failure, such that only one study has tested psychological interventions on depression, as reported by recent meta-analyses.

In Iran, education is provided to heart patients exclusively during hospitalization with no attention to psychological problems; furthermore, there are no specific cardiac rehabilitation programs. In current educational programs, the role of psychological factors such as depression is not taken into account. Consequently, the impact of routine training on heart failure patients with depression is ambiguous and doubtful. Since depression symptoms negatively affect self-care behaviors of heart failure patients, it is essential to devise and test the impact of psychological interventions on improving the quality of education by targeting depression. Reviewing previous studies, one would find the novelty of the current study in its (1) specific subjects (depressed heart failure patients, not all patients with heart failure), (2) design of the educational intervention (self-care education based on cognitive-behavioral therapy rather than self-care education per se), and (3) dependent variables (depression along with self-care). In this context, the present study intends to determine the effect of CBT versus conventional training on self-care and the severity of depression symptoms in patients with heart failure.

Materials and Methods

The present study is a two-group clinical trial with a pretest-posttest design which has been registered in Iranian Registry of Clinical Trials (identifier: IRCT20160924029954N9). The study population consisted of all patients with heart failure who had been hospitalized in the Cardiology Ward of the teaching hospitals affiliated with Zahedan University of Medical Sciences. Convenience and continuous sampling was carried out among qualified patients. Considering the 95% confidence interval and 0.95 test power, and according to the mean and standard deviation of depression in similar study the authors estimated 23 individuals for each of the two groups. However, given the sample size of similar studies in Iran and considering the possible attrition, the authors eventually chose 40 patients and randomly assigned 40 members to each of the two groups.
Detection of heart failure based on patient’s records, obtaining a score of at least 21 from Beck Depression Inventory (BDI), depression diagnosis based on mental status examination (MSE) by the clinical psychologist, the absence of other known psychiatric diseases based on self-reporting, ejection fraction lower than 40, time lapse of at least 6 months since the illness, complete consciousness and awareness, no communication problems, no addiction or substance abuse, and no simultaneous participation in rehabilitation, counseling or other training programs constituted the criteria for the patients to be included in the study. On the other hand, a participant was excluded from the research if his/her condition became critical, or in case of death, any unexpected incident during the study, early discharge from the ward, and absence or non-participation in more than one treatment session.

The data gathering tool in this study was a questionnaire comprising the following: demographic questions and disease information, BDI, and the Self-Care of Heart Failure Index (SCHFI). BDI was developed to assess the severity of depression, with an emphasis on the cognitive and behavioral dimensions of the disorder. It contains 21 self-report questions, each composed of 4 statements (with a score of 0-3) which describe the increasing rate of intensity. The minimum score in this test is zero and the maximum score is 63. The cut-off point of this tool is 21, and it measures the physical, behavioral, and cognitive symptoms of depression. By adding one's individual scores, the total score can be obtained directly. The validity and reliability of this tool have been investigated and confirmed by many studies in Iran.37

The SCHFI version 6.2. was introduced by Riegel et al., in 2004.38 In 2009, a new grading method was proposed for this scale. This questionnaire is a reliable tool for measuring self-care among patients with heart failure. It consists of 22 questions and 3 sub-scales (self-care, management of symptoms, and confidence). Responses are four-item statements with a scale ranging from 1 to 4, showing different degrees of self-care behaviors. The scores are converted to 100, so the range of scores varies between 0 and 100. The validity and reliability of this questionnaire in Iran were established by Zamanzadeh et al., and Moadab et al.39,40

After obtaining permission from the Ethics Committee and a letter of introduction from the office of Vice-Chancellor for Research and Information Technology of the university, the researchers referred to the teaching hospitals. After the necessary arrangements were made with the head of the hospital, nurse supervisor, and the personnel of the related ward, the process of sampling was undertaken between July and October, 2018. The qualified patients diagnosed with heart failure were selected, using convenience sampling and based on the inclusion criteria. Considering that the study population included depressed patients with heart failure, eligible patients with a score above 21 were identified using BDI. Then, a psychiatrist followed MSE to ascertain the depression of heart failure patients. A total of 114 eligible individuals were examined, 34 individuals were excluded. As a result, the study was conducted and followed-up on 80 subjects (Figure 1).

Participants who had been thus selected were randomly assigned to the two groups of CBT and conventional training. To this end, 80 colored balls (40 white balls for the CT group and 40 red balls for CBT group) were randomly taken out of a vase; based on the color of the ball picked at each time, the members of each group were

![Figure 1. Flowchart of study.](image-url)
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...determined. After referring to the research site as well as selecting and registering eligible patients, the authors determined established the group each patient belonged to, and performed the intervention, subsequently. From the second day of admission, if a patient was assigned to the CT group, after the pre-test and completion of the questionnaires, he/she individually received 4 sessions of conventional education on a daily basis during the time of admission. The training, based on the routine processes of the ward, was provided, face-to-face using audio-visual instruments. The content were: first session (Introduction, review of heart failure, definitions, causes, symptoms, and course of illness.), second session (The importance of self-care, diet, weight control, resting and activity, and measurement of urine volume.), third session (Monitoring worsening symptoms and taking necessary actions, vaccination, restricted alcohol consumption and smoking cessation, and importance of medication adherence.), fourth session (Short movie about heart failure, question and answer about previously raised topic, and conclusion.). Eight weeks post-intervention, the questionnaires were completed again by the patients either at their house or in the heart clinic upon their referral.

If the patient was randomly assigned to the CBT group, after the pre-test and completion of the questionnaires, he/she individually received 5 sessions (each lasting 90 to 100 minutes on average, with a rest time per session) of cognitive-behavioral therapy on a daily basis. The content, presented at the patient's bedside, were: first session (Living with heart failure and disease management: Knowledge transfer about heart failure, signs and causes of symptoms, care and treatment), second session (Depression and heart failure: knowledge transfer about diagnosis, relationship between depression and heart failure, identifying concerns about depression, and treating depression), third session (Cognitive-behavioral activation: relationship between behaviors, thoughts, and creativity, identifying automated thoughts, behavioral assessment, behavioral training, and preparing a table for interesting behaviors), fourth session (Cognitive-behavioral activation: cognitive rehabilitation, reducing negative thoughts, self-monitoring, preparing a checklist to deal with potential obstacles), fifth session (Training coping skills: patient's recognizing and perceiving the problems, training problem-solving in a constructive manner, problem-solving practice). Considering the degree and type of intervention as well as individual differences of patients, if necessary, part of the intervention would be presented over the telephone after the patient's discharge. Alternatively, their possible questions were answered in the same way. Similar to the CT group, eight weeks post-intervention, the questionnaires were completed again as a post-test by the patients of the CBT group either at their house or in the heart clinic upon their referral.

Having reviewed interventional studies and other related clinical trials, the authors prepared the initial content of the sessions. To increase the scientific validity of the materials, a number of related faculty members including cardiologists, cardiac nurses, counselors, and clinical psychologists were consulted. After experts' opinions were summarized and applied, the final format of cognitive-behavioral intervention was prepared. Under the supervision of a Ph.D in Counseling, the intervention was presented by a senior psychiatric nurse with clinical experience in the cardiology ward. The materials for conventional training were gathered from the approved educational content proposed in previous studies in Iran such as Seraji et al., and Navidian et al., which had been conducted on patients with heart failure.

The data were analyzed using IBM SPSS (Statistical Package for the Social Sciences), version 21.0 (IBM Corp., Armonk, NY, USA). Paired t-test was then used to compare pre- and post-intervention means. Independent t-test was later used to compare the mean score between intervention and control groups. The significance level in this study was considered to be 0.05.

**Results**

According to Table 1, the mean (SD) age of heart failure patients in the CBT group was 53.08 (10.11) (in the range of 32-70 years); and in the CT group, mean (SD) age was 51.63 (8.33) (in the range of 37-69 years). The majority of patients in the CBT group (65%) and CT group (67.3%) were non-employed. In terms of gender, 55% and 60% of patients in the CBT and CT groups were males, respectively. Also, 90% and 87.5% of patients in the CBT and CT groups lived with their spouses. Both groups had...

*Table 1. Demographic characteristics of intervention and control patients*

| Variable          | Intervention group (CBT) No. (%) | Control group (CT) No. (%) | P value |
|-------------------|---------------------------------|---------------------------|---------|
| Sex               |                                 |                           |         |
| Women             | 18 (45)                         | 16 (40)                   | 0.65*   |
| Men               | 22 (55)                         | 24 (60)                   |         |
| Total             | 40 (100)                        | 40 (100)                  |         |
| Education         |                                 |                           | 0.7*    |
| Lower than diploma| 30 (75)                        | 28 (70)                   |         |
| Higher than diploma| 10 (25)                        | 12 (30)                   |         |
| Total             | 40 (100)                        | 40 (100)                  |         |
| Marital status    |                                 |                           | 0.9*    |
| Single            | 4 (10)                          | 5 (12.5)                  |         |
| Married           | 36 (90)                         | 35 (87.5)                 |         |
| Total             | 40 (100)                        | 40 (100)                  |         |
| Occupation        |                                 |                           | 0.8*    |
| Employee          | 14 (35)                         | 13 (32.5)                 |         |
| Unemployed        | 26 (65)                         | 27 (67.5)                 |         |
| Total             | 40 (100)                        | 40 (100)                  |         |
| Age               | 51.08 (10.11)                   | 51.63 (8.33)              | 0.48†   |
| Duration of the disease | 4.85 (2.90) | 3.75 (2.54) | 0.1‡   |

*Mean (SD), ‡Chi-square, †Fisher's exact test, ‡t-test.
Cognitive-behavioral training on depression in HF

The findings of the research regarding the effect of intervention on self-care behaviors in depressed heart failure patients showed that the mean (SD) score of self-care behaviors in the CBT group increased from 38.97 (9.31) before the intervention to 65.14 (7.01) after that; in the CT group, this values changed from 36.27 (8.92) before the intervention to 40.59 (8.25) after that. Independent t-test illustrated that the mean score of self-care behaviors in depressed heart failure patients after the intervention was significantly different in the two groups (P = 0.0001).

As shown in Table 2, regarding the main purpose of the study, the results showed that the mean (SD) score of depression in heart failure patients had dropped from 39.02 (8.08) to 26.95 (5.53) in CBT group and in CT group the mean (SD) score had dropped from 37.52 (7.65) to 36.04 (8.45); however, there were no noticeable changes. Independent t-test demonstrated that depression score after the intervention significantly differs between the two groups (P = 0.0001). The mean (SD) drop in the depression score of the CBT and CT groups was -12.07 (6.79) and -3.64 (1.23), respectively. Independent t-test illustrated that the mean score of self-care behaviors in depressed heart failure patients after the intervention was significantly different in the two groups (P = 0.0001). On the other hand, paired t-test showed that the mean depression score decreased considerably for the CBT group in the post-test compared to the pre-test (P = 0.001), this change, however, was not significant in the CT group (P = 0.39). The results of analysis of covariance indicated that there was a significant statistical difference in terms of the mean score of self-care (P = 0.0001) and depression (P = 0.0001) of patients in the two groups (Table 3). Consequently, the implementation of the CBT gave rise to a significant increase in the mean value of self-care and decrease of depression among the participants in the intervention group.

Discussion

The results of this study indicate that self-care education based on the principles of cognitive-behavioral therapy promotes adherence to self-care behaviors in depressed heart failure patients as compared with conventional self-care training. If psychological approaches (including the principles of cognitive-behavioral therapy used in this study) are combined with conventional training and treatment methods, the effectiveness of the latter will increase as a result of enhanced motivation and commitment, reduced resistance and barriers, and modified beliefs and perceptions. In general, it can be said that educational programs which address some of the structures of behavior change are more effective in boosting adherence to self-care behaviors among patients

Table 2. Self-care behavior and depression scores in the intervention and control groups before and after cognitive-behavioral education

| Variable                  | Before Mean (SD) | After Mean (SD) | Changes Mean (SD) | Paired t-test |
|---------------------------|------------------|-----------------|-------------------|--------------|
| Total self-care score     |                  |                 |                   |              |
| Intervention (CBT)        | 38.97 (9.31)     | 65.14 (7.01)    | 26.16 (6.87)      | 0.0001*      |
| Control (CT)              | 36.27 (8.92)     | 40.59 (8.25)    | 4.19 (6.3)        | 0.01         |
| Independent t-test        | 0.19             | 0.0001*         | 0.0001*           |              |
| Depression score          |                  |                 |                   |              |
| Intervention (CBT)        | 39.02 (8.08)     | 26.95 (5.53)    | -12.07 (6.79)     | 0.0001*      |
| Control (CT)              | 37.52 (7.65)     | 36.04 (8.45)    | -1.23 (3.64)      | 0.39         |
| Independent t-test        | 0.2              | 0.0001*         | 0.0001*           |              |

*Statistically significant.

Table 3. The results of covariance analysis on the scores of depression and self-care of patients after intervention by adjusted the pre-test effect

| Source of change | SSa | df | MSa | F   | P-value | ¦   | Powerc |
|------------------|-----|----|-----|-----|---------|----|--------|
| Depression       |     |    |     |     |         |    |        |
| Pretest          | 2180.54 | 1  | 2180.54 | 93.27 | 0.0001* | 0.54 | 1      |
| Group            | 9141.88 | 1  | 9141.88 | 391.04 | 0.0001* | 0.83 | 1      |
| Error            | 1800.13 | 77 | 23.17 |       |         |     |        |
| Total            | 70011 | 80 |     |       |         |     |        |
| Self-care        |     |    |     |     |         |    |        |
| Pretest          | 2201.72 | 1  | 2201.72 | 71.42 | 0.0001* | 0.48 | 1      |
| Group            | 14238.23 | 1  | 14238.23 | 461.88 | 0.0001* | 0.85 | 1      |
| Error            | 2373.65 | 77 | 30.82 |       |         |     |        |
| Total            | 227870.61 | 80 |     |       |         |     |        |

*aSum of Square, bMean Square, cPartial Eta, dObserved power, *Statistically significant.
with heart failure. Thus, Zakerimoghadam et al., showed that education based on correcting the common perception of the disease has a positive and significant impact on self-care behaviors of patients with heart failure.42 Also, Shojaifar et al., observed that patient education based on the theories/approaches of behavior change can enhance self-care behaviors, increase perceived benefits, and reduce perceived barriers to self-care behaviors in heart failure patients.43

When heart failure is exacerbated by psychological problems originating from depression, the need for interventions based on different psychological approaches seems to be much more pronounced. In such circumstances, conventional self-care education not only does not affect the self-care capacity of depressed heart failure patients, but also fails to reduce the severity of depression. Two studies by Navidian et al., on patients with depressed heart failure illustrate that, compared with conventional self-care education, instructing self-care behaviors based on motivational interviewing could have a greater impact on improving self-care behaviors and symptom management self-efficacy.30,31

Regarding the main purpose of this study, the results of the present research exhibited that self-care education based on the principles of cognitive-behavioral therapy, besides increasing self-care ability, may significantly reduce the severity of depression symptoms in patients with heart failure. In line with this finding, Freedland et al., reported that treatments based on cognitive-behavioral therapies which simultaneously target depression and self-care behaviors in heart failure are effective in lowering and even eliminating the symptoms of depression.34 In a clinical trial on the application of cognitive-behavioral approaches for patients with heart failure, Cajanding observed that nurse-led cognitive-behavioral therapies can increase the quality of life in terms of self-esteem, sharply decreasing the depression score of Filipino patients.35 Given that low self-esteem and depressed mood are indicators of depression, the findings of their study are substantiated by the present research. Similarly, it has been reported that Internet-based cognitive-behavioral therapy of patients with heart failure could lead to a significant decline in depression after the intervention; furthermore, in the long-term follow-up, no patient showed an increase in his/her depression score. According to the study by Kalter-Leibovici et al., although the comprehensive disease management program, compared with the usual care program, did not affect the rate of re-admission and mortality in patients with heart failure, it improved the quality of life of patients and reduced their depression in the follow-up period.41

The other psychological interventions have also had a positive impact on the related variables of heart failure. For instance, Sherwood et al., found that teaching effective coping skills over the telephone not only enhances self-management and health behaviors, but also helps ease psychological distress.45 Moreover, educational intervention based on mindfulness has been suggested to alleviate the symptoms of depression and anxiety in the short term and reduce the severity of symptoms of heart failure in the long term (i.e., one year).4

Negative thinking is pervasive among patients with heart failure. This trait could be associated with negative self-concept, inability to play roles, inappropriate physical function, poor quality of life, and shorter lifespan.24 Cognitive-behavioral therapies target this negative thinking and help patients 1) become aware of their major core beliefs which influence their emotions, 2) recognize the destructive nature of negative recurring thoughts, and 3) develop adaptive skills through creating cognitive patterns based on healthy new insights. Improving cognitive patterns gives rise to the adoption of healthy behaviors and modified self-concept and enhances emotions as well as creativity.11

In this study, training self-care behaviors along with principles of cognitive-behavioral therapy has been an effective intervention in mitigating the symptoms of depression and promoting self-care. According to Dekker, cognitive interventions aimed at reducing negative thinking via thought stopping and affirmation seem to be convenient and feasible methods for heart failure patients to increase their treatment adherence.44 Perhaps, the decrease in the severity of depression in this study has contributed to improving self-care behaviors of depressed heart failure patients. In the same vein, Graven and Grant believe that having confidence in one’s self-efficacy, which is drastically reduced in depression, does not act as an independent but a mediator variable for self-care in heart failure patients, and its reinforcement helps treat depression and enhance commitment to self-care behaviors.46 To explain the promotion of self-care behaviors along with the decline of depression in the current study, it could be stated that self-care education based on cognitive behavioral principles or any other psychological training for heart failure patients which target coping skills and symptom management can increase self-care behaviors and reduce the severity of symptoms. This relative improvement in the severity of symptoms and patients’ physical condition might have, in turn, elevated their mood and reduced the severity of depression symptoms. Part of the fall in the severity of depression symptoms in the current study can be attributed to this process.

Two things make this research distinctive among similar works: first, its unique intervention, which simultaneously raised self-care capacity and relieved psychological symptoms such as depression; second, its samples, which included depressed patients with heart failure and not any patient with heart problems. Nevertheless, given the possible variations in the quality of care systems in different countries, one must be cautious in generalizing the results to other contexts. In this study, the effectiveness of the proposed intervention on two variables of
depression and self-care was probed. It is recommended that future studies deal with other related psychological and clinical variables. Besides, it should be highlighted that the long-term effects of the proposed intervention were not investigated in this research.

Conclusion
This study provided evidence that instructing self-care behaviors based on behavior change theories such as cognitive-behavioral therapy brings about a reduction in the severity of depression symptoms and fosters self-care behaviors in depressed patients with heart failure. Therefore, it is recommended health care providers screen heart failure patients due to the high prevalence of psychological symptoms in these individuals; moreover, in order to increase the effectiveness of conventional training approaches, it is suggested that the principles of cognitive-behavioral therapy be incorporated into these programs so as to devise a synergetic intervention which could greatly promote the physical and psychological well-being of heart failure patients.

Acknowledgments
The authors are grateful to all the HF patients in the Cardiology ward who participated in the study. The authors would like to express their gratitude to the Deputy of Research and Technology in Zahedan University of Medical Sciences.

Ethical Issues
This randomized clinical trial was approved by the Ethics Committee of Zahedan University of Medical Sciences (IR. ZAUMS.REC.1397.175). Providing information on the process and time of research, the type of intervention and the need for written informed consent were among ethical considerations observed in this study.

Conflict of Interest
The authors declare no conflict of interest in this study.

Authors’ Contributions
Study concept and design: NR; data collection: RKh; data analysis, interpretation and study supervision: AN; manuscript preparation: MSh; All authors have reviewed and approved the manuscript for submission.

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