

Research Article

Functional capacity of heart failure patients following the empowerment program based on telenursing in caregivers of patients: Randomized Clinical Trial

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ABSTRACT

Introduction: Most of the Heart Failure (HF) patients suffer from decreased functional capacity and dyspnea. Telephone follow-up is considered as an efficient way to manage symptoms, early recognition of complication, and prevent hospital re-admission. Thus, this study aimed to identify the impact of empowerment program based on telenursing in caregivers of HF patients on the functional capacity and dyspnea of patients.

Method: In this clinical trial, 66 HF patients aged 65-75 years were randomly assigned to control, intervention-1 and intervention-2 groups. Firstly, the functional capacity of all patients was examined through Six Minute Walking Test and dyspnea was measured via Burg Scale. Then Patients and their caregivers in intervention-1 and 2 groups received education by a nurse in the clinic. In addition, during three months, we followed only caregivers of patients in intervention-2 group through telephone and gave them advice on physical activity, diet, medication, and vital signs monitoring of patients. After 3 months, the functional capacity and dyspnea of patients were assessed in each group. The descriptive statistic, chi-square, t-test, ANOVA and scheffe post hoc test in SPSS software V.16 was used to analyze the data.

Results: At the end, there was significant deference between intervention-2 group with control and intervention-1 group in dyspnea mean. But, don't show significant deference in exercise tolerance mean of patients between three groups.

Conclusion: Structured telephone support and tele-monitoring can lead to decreasing of dyspnea in HF patients, thus use of this program is recommended as benefit method for recovery of patient's clinical status.

Keywords: Heart Failure; Telephone; Cardiac rehabilitation; functional capacity; Dyspnea

INTRODUCTION

Heart Failure (HF) is one of the chronic diseases with high prevalence over the world which causes a significant burden of mortality, morbidity, and cost to the healthcare systems (1). According to the latest statistics, the HF prevalence in Asia is 1.3-6.7% which is twice in Iran (2). Elderly people are more vulnerable to HF to the extent that its rate increasing to 5% in the population

aged 65–75 years and 10–20% in those older than 80 years. In fact, HF represents the first cause of hospital admission in individuals older than 64 years and is the third cause of in-hospital death (3). Most of the elderly patients with HF suffer from decreased physical activity. It is for this reason that heart and lungs mechanisms are closely related because they both supply oxygen

to the body and limited physical movement is mainly due to dysfunction of the respiratory system in such patients that resulted from abnormalities in ventilation, perfusion, or both of them.

In this way, breathing exercise and functional capacity improvement have substantial potential to promote physical performance in HF patients (4). The limited movement makes elderly depend on others in doing their daily activities, require assisted personal attention, ongoing medical care, self-management education, and support to reduce the risk of long-term disability, prevent complications, and decrease the cost of hospital readmission.

In addition to limited physical activity, results of several studies have shown that elders with HF have a high rate of re-hospitalization which is often caused by excess sodium dietary, improper use or reductions in taking prescribed medications, and respiratory infections, which most of them can be prevented if family caregivers help while they were educated to be alerted for these problems (5-8).

There are many HF management programs which have been developed for the elderly population and contain components such as education, different kinds of follow-up, psychological support, and physical exercise to better control of the disease and prevent complications (9).

Among the various programs, education and follow-ups are considered as the key elements due to their solid similarity and frequent occurrence in these programs. Moreover, these two components are recommended as the essential and effective elements in HF disease management (10). Telephone follow-up is an inexpensive and simply structured intervention as well as a good manner to manage symptoms, early complication recognition and also to transfer information between patients and healthcare providers and promote health education. For this reasons, this study was conducted to evaluate the effect of empowerment program based on telenursing in caregivers of patients on

functional capacity and dyspnea in elderly patients with HF.

METHOD

1.1 Study design and participants:

This research was a randomized clinical trial and prospective study performed on 66 HF patients who were referred to Taleghani hospital's clinic from November 2015 to February 2016 in Abadan city in Iran. The researcher attended the clinic from June 2015 through August 2015, and the patients referred to the clinic were invited to participate in the research. Among 132 patients, 75 patients who met the inclusion criteria were selected for participation in the study (Figure 1). Inclusion criteria were: HF class II and III, age over 40 years; Ejection fraction less than 40% on echocardiography; enjoyment of a literate caregiver at home and being able to make phone calls with the nurses. Exclusion criteria were: having a major psychiatric disorder and restrictive diseases e.g. musculoskeletal disorder, cancer, unstable angina, and a heart attack in one month before starting the study. Patients who had caregivers that were unable or not willing to phone calls at the determined times were excluded from the study. Patients were randomly assigned to one of three groups: control, intervention-1 and intervention-2 groups.

1.2 Study cohort and intervention:

Firstly, the informed consent and demographic information form were completed by patients and introduced caregivers that all of them were from their family members. The form contained the age, gender, level of education, job, duration of HF disease, history of other diseases, history of smoking, HF class, and caregiver's age, gender, and level of education.

Afterward, the patients' functional capacity was measured by using Six Minute Walk Test (6MWT) based on American Thoracic Society (ATS) guidelines (11) in which the distance an individual is able to walk over a total of six minutes on a hard, flat surface is measured. The goal is for the individual to walk as far as possible in six minutes. The individual is allowed to self-pace and rest as needed as they traverse back and

forth along a marked walkway. The studies specified the reliability of this test as 0.91 and 0.92 (12). After the walking test and according to the ATS guideline the dyspnea of patients measured through Borg Dyspnea Scale, a numerical scale for assessing dyspnea from 0 representing no dyspnea to 10 as maximal dyspnea. Its reliability calculated as 0.78 (13).

Then, patients and their caregivers in intervention-1 and 2 groups participated in two in-person training sessions within two weeks that each one lasted one hour and thirty minutes. In the sessions, they were educated by a nurse about the HF disease, medications, diet, monitoring vital signs, evaluating peripheral edema, lifestyle, stress management, behavior change, self-management and follow-up of treatment.

In addition to training sessions, we made a structured 3-months telephone follow-up for the intervention-2 group that was two phone calls per week in the first month (first four weeks), one phone call per week in the second month and one phone call at every two weeks in the third month. In every 20-minute duration call, the nurse asked the caregivers about their patients' status and reminded them about the matters she/he educated during in-person sessions. Patients in the control group did not receive any intervention. After 3 months, the functional capacity and dyspnea rate of all patients in control, intervention-1 and intervention-2 groups were examined again by the 6MWT and Borg Dyspnea Scale.

1.3 Sample size and data analysis:

Based on a two-tailed test by the formula $\frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (S_1^2 + S_2^2)}{d^2}$ with $\alpha = 0.05$, power = 0.80, effect size = 1, $S_1 = 0.98$ and $S_2 = 1.1$ (based on a pilot study on 20 patients with HF in 3-months), a sample size of 17 per group was originally calculated for comparison of means using a two-sample t-test. Taking into account an anticipated dropout rate, 25 patients were assigned to each group to ensure an adequate final sample size.

To analyzing data, we used the descriptive statistic, chi-square, t-test, ANOVA and scheffe post hoc test in SPSS software V.16. The statistical significance level was $p < 0.05$.

1.4 Ethical considerations:

The initial plan of the study was approved by the Ethics Committee of Abadan School of Medical Sciences with code No.IR.ABADANUMS.REC.1394.7. This study was recorded with randomized clinical trial code: [IRCT201608082918N2](#) in the clinical trial center in Iran. All participants completed a written informed consent when they entered the study and they were given the right to withdraw the study at any time. We assured the participants that their registered information will be confidential. Moreover, No cost for any services provided to patients and caregivers.

RESULTS

Of the 132 older patients with HF referred to the clinic, 75 patients were eligible and satisfied to participate in the study. They were divided into three equal groups ($n=25$). During the 3-months intervention, four participants from the control group ($n=21$), two participants from intervention-1 group ($n=23$), and three from intervention-2 group ($n=22$) did not continue the study. Of these, 66 were involved until the end of the study. (Figure 1) According to the statistical tests, there were no significant differences in demographic variables among the three groups. The mean age of participants was 63.1 years, mostly women (54.6%), and they mainly had an elementary education (41.1%). Most of them were unemployed (69.8%). The mean Disease duration of participants was 2.75 years. It was found that most patients had no history of smoking (54.9%) and had HF grade 2 (68.4%). (Table 1) Data analysis through using one-way ANOVA test showed that at the beginning of the study regarding functional capacity mean through 6MWT, there was no statistically significant difference between the three groups. Surprisingly, after the 3-months intervention we did not found

significant differences between the three groups ($p=0.14$). (Table 2)

The comparison of dyspnea mean through Borg scale between the groups showed that at the baseline there was no significant difference among the groups while after the intervention a significant difference was observed between the groups ($p<0.007$). Also, data analysis through using scheffe post hoc test showed that there was significant difference between intervention-2 group with control group ($p<0.001$) and intervention-2 group with intervention-1 group ($p<0.01$) in dyspnea severity. But, there was no significant difference in dyspnea severity among intervention-1 group with control group ($p<0.06$). (Table 3)

DISCUSSION

The comparison of the patients' average of functional capacity in the three groups had not any statistically significant difference both at the beginning and at the end of 3 months. Thus, at the end of the study duration, functional capacity was decreased in intervention-1 and control groups but increased in intervention-2 group while these changes were not statistically significant. The results of Wang et al's (14) study has shown an increase in quality of life in patients with HF after using educational sessions, telephone follow-up and in a home setting medical encounters. Also, the study by Clark et al (15) demonstrated significant improvements in functional status according to an in-home education support intervention for HF patients which these results are inconsistent with the findings of our study. In the present study, the old HF patients limit their physical activities due to the fear of falling and breathe shortness that leads to cardiovascular function decline. Referring to Clark et al study, using long-term educational interventions and follow-up can increase patients' awareness of the importance of their physical activity and raise the functional capacity but in our study, it was not possible to follow-up the patients for a long time. Therefore, educational programs and behavior

change interventions for patients and caregivers during a long period of time seem necessary.

The findings also indicate that there was not any significant difference between the groups regarding dyspnea severity mean at the beginning of the study while at the end of 3 months, a significant difference observed between the groups. After 3 months, the dyspnea severity mean in the intervention-1 group and control group did not change significantly but it considerably decreased in the intervention-2 group. Also, findings showed that there was significant difference between intervention-2 group with control group, and between intervention-2 group with intervention-1 group. But, there was no significant difference in dyspnea severity among intervention-1 group with control group. There is not any similar study that shows the impact of follow-up intervention on dyspnea severity in HF patients, however, the study held by Heidari et al (16) has shown a decrease in breath shortness mean in patients with the chronic obstructive pulmonary disease after using supportive interventions. It must be understood that with the chronic and complex nature of HF, the incidence of dyspnea, fatigue and functional intolerance in these patients is the common and inevitable situation which can affect functional status of these patients but the results of this study showed that adding the regular telephone follow-up to in-person supportive educational programs for patients and caregivers and involvement in self-care, can play an effective role in reducing the severity of breath shortness.

Limitations of study and Areas for Further Research:

However, the findings of this study should be generalized to other HF patients and other situations with caution. We suggest assessing the effects of these plans on the self-efficacy and autonomy of patients in future studies. Additionally, the evaluation of the long term effects of such programs are recommended for future researches. In future studies, subsets of HF patients that are most receptive to such interventions need to be identified, and the

effectiveness of intervention programs targeting complex comorbid patients should be studied. One of the most important limitations we had in the study was the conditions and problems that patients have in their living environment which could affect patients' activities and could not be controlled by the study team. Another factor that limited the study was selecting only patients with HF class II and III. It is recommended that all classes of HF be studied in future. Also, our intervention only lasted 3 months and could not demonstrate the impact of the supportive program on the clinical outcomes in a long time. Therefore, using long-term educational interventions and telephone follow-up is suggested.

CONCLUSION

Although empowerment program based on telenursing in caregivers of patients for HF patients have received little attention by researchers, our results show that if a supportive program such as educational interventions and telephone follow-up is designed based on the needs of HF patients and their families, it can be effective in motivating them to change behavior and thus improve their clinical status such as decrease of dyspnea. Also, this follow-up program can decelerate the progress of the disease and prevent exacerbation of the disease. Since structural educational interventions and telephone follow-up are simple and cost effective, this is easy to use for improving functional condition in these patients. We would therefore recommend the use of this supportive program as an easy option for nurses to help patients.

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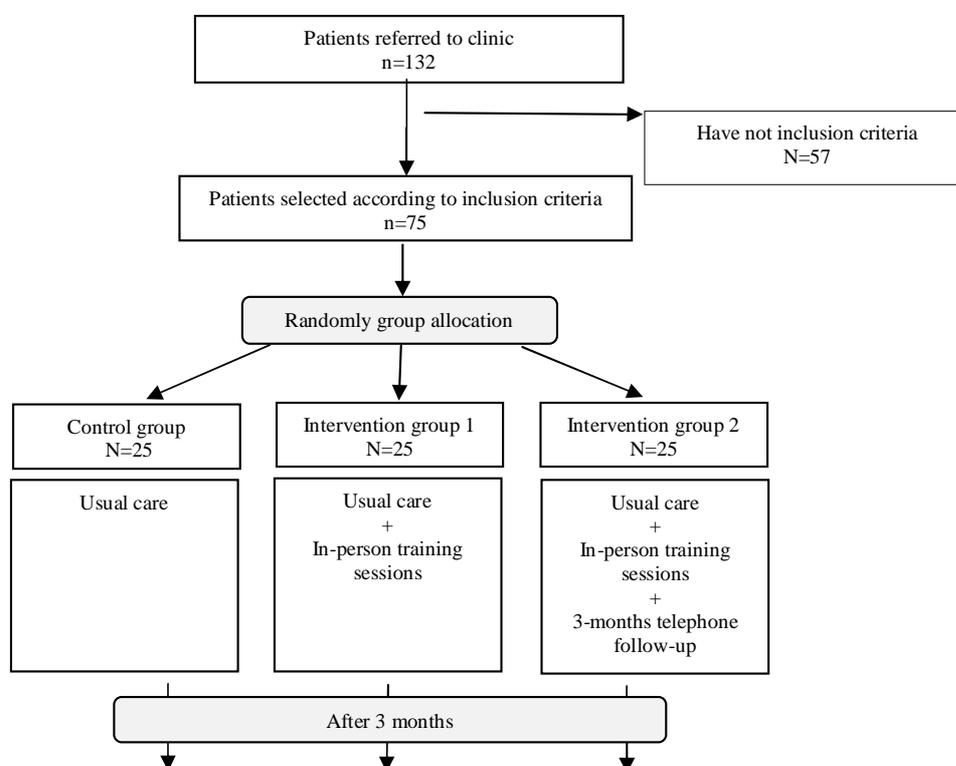
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Figure 1: flowchart of recruitment



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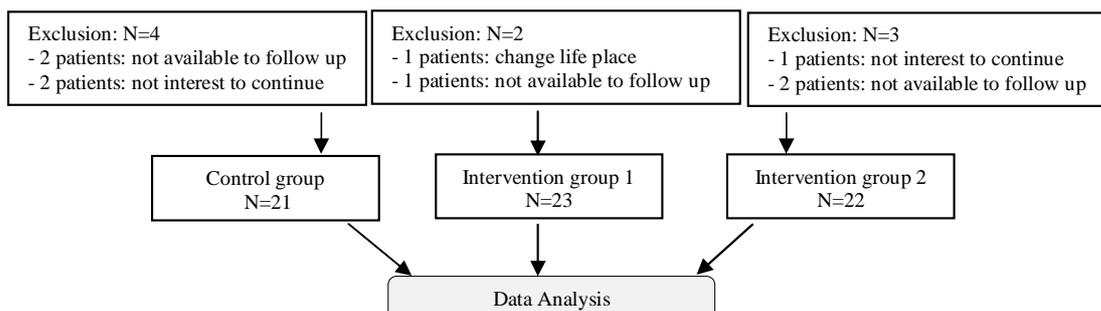


Table 1- Baseline characteristics of the participants and their caregivers

Variable		Control group N=21	Intervention group 1 N=23	Intervention group 2 N=22	<i>p</i> - <i>vale</i>
Age (Mean±SD)		63.8±4.8	62.5±3.4	63.2± 3.5	0.68
Gender Frequency (%)	Male	9 (42.9)	10 (43.5)	11 (50)	0.12
	Female	12 (57.1)	13 (53.5)	11 (50)	
Education Frequency (%)	Uneducated	6 (28.6)	10 (43.5)	7 (31.8)	0.12
	Primary	10 (47.6)	8 (34.8)	9 (40.9)	
	Upper	5 (23.8)	5 (21.7)	6 (27.3)	
Occupation Frequency (%)	Employed	5 (23.8)	7 (30.4)	8 (36.4)	0.54
	Unemployed/retired	14 (76.2)	16 (69.6)	14 (63.6)	
Disease duration[Year] (Mean±SD)		2.85±1.5	3.14±1.7	2.26±1.2	0.38
History of other diseases Frequency (%)	Yes	12 (57.1)	15 (65.2)	10 (45.5)	0.18
	No	9 (42.9)	8 (34.8)	12 (54.5)	
Smoking Frequency (%)	Yes	11 (52.4)	10 (43.5)	8 (36.4)	0.82
	No	10 (47.6)	13 (53.5)	14 (63.6)	
HF grade Frequency (%)	II	16 (76.1)	14 (60.9)	15 (68.2)	0.44
	III	5 (23.9)	9 (39.1)	7 (31.8)	
Caregiver's age (Mean±SD)		31.2±6.7	29.7±6.2	34.5±5.8	0.87
Caregiver's gender Frequency (%)	Male	5 (23.8)	6 (26)	3 (13.6)	0.1
	Female	16 (76.2)	17 (74)	19 (86.4)	
Caregiver's education Frequency (%)	Primary	8 (38.1)	7 (30.4)	10 (45.5)	0.58
	Upper	13 (61.9)	16 (69.6)	12 (54.5)	

Table 2- The comparison of functional capacity in the control and intervention groups in base-line and after 3 months

Groups	Base line Mean±SD	After 3 months Mean±SD	<i>p</i> - <i>vale</i> **
Control group (n=21)	400.47±47.8	391.75±52.7	0.081
Intervention group 1 (n=23)	421.32±51.2	416.54±48.9	0.228
Intervention group 2 (n=22)	407.68±42.9	409.49±46.5	0.36
<i>p</i> - <i>vale</i> *	0.541	0.14	-

*ANOVA

**Paired t-test

Table 3- The comparison of dyspnea in the control and intervention groups in base-line and after 3 months

Groups	Base line Mean±SD	After 3 months Mean±SD	<i>p</i> - <i>vale</i> **	<i>p</i> - <i>vale</i> ***
Control group (n=21)	4.8±0.99	4.7±1.1	0.57	Intervention 2 / Control 0.001
Intervention group 1	5.2±1.2	5.6±0.97	0.161	Intervention 2 / Intervention 1

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(n=23)				0.01
Intervention group 2 (n=22)	5.5±1	4±1.1	0.001	Intervention 1 / Control 0.06
<i>p-value*</i>	0.126	0.007	-	-

*ANOVA

**Paired t-test

Scheffe post hoc test