

Effect of Educational Program on Quality of Life of Patients with Heart Failure: A Randomized Clinical Trial

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ABSTRACT

Introduction: Heart failure is one of the most common cardiovascular diseases which decrease the quality of life. Most of the factors influencing the quality of life can be modified with educational interventions. Therefore, this study examined the impact of a continuous training program on quality of life of patients with heart failure. **Methods:** This randomized clinical trial study was conducted during May to August 2011. Forty four participants with heart failure referred to Shahid Madani's polyclinics of Tabriz were selected through convenient sampling method and were randomly allocated to two groups. The intervention group (n = 22) received ongoing training including one-to-one teaching, counseling sessions and phone calls over 3 months. The control group (n = 22) received routine care program. Data on quality of life was collected using the Minnesota Living with Heart Failure Questionnaire at baseline as well as three months later. **Results:** The statistical tests showed significant differences in the physical, emotional dimensions and total quality of life in intervention group. But in control group, no significant differences were obtained. There was not any significant association in demographic characteristics and quality of life. **Conclusion:** Ongoing training programs can be effective in improving quality of life of patients with heart failure. Hence applying ongoing educational program as a non-pharmacological intervention can help to improve the quality of life of these patients.

Introduction

Heart failure (HF) is one of the most common chronic cardiovascular disorders with progressive and debilitating results. The prevalence of the HF has increased dramatically throughout the world over the last decade.¹ Heart disease accounts for about half of our country's mortalities.² The complex, progressive nature of HF often results in adverse outcomes. Heart failure causes multiple physical symptoms which lead to activity intolerance in patients and changes in life that affects their quality of life (QOL).³

Some studies have presented that 76.4% of patients with heart failure had relatively poor QOL and heart failure has a negative effect on QOL.⁴ Patients in class II and III heart failure of New York Heart Association (NYHA) classification cannot normally do their daily activities. On the other hand the primary source of depression and poor QOL in these patients is due to the multiple physical symptoms of the disease.⁵ With development in treatment and increased lifespan in patients with heart failure, improving their QOL becomes more important.⁶

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It has been shown that continuous nursing educational and caring interventions are associated with less readmission. Since the hospital stay in these patients is associated with high economic costs, attention to strategies that promote QOL is critical to reduce readmissions.⁷

One way to prevent frequent readmissions and improve positive health outcomes in patients with HF is to ensure that these patients have adequate knowledge and ability for self-care.⁷ Inadequate education of patients and families are important risk factors in preventable re-hospitalization of these patients.⁸ The Heart Failure Society of America has training modules for patients with heart failure, which offer guidance for disease control, medication, self-care, physical activity, feelings, tips for family and etc. The guidelines are simple and have clear explanation. Since the disease has effects on all aspects of the patient's physical, psychological and social conditions, nurses should do more accurate planning by collecting comprehensive information about patients.

It is expected that patient training enhances quality of life; however, only a few studies have reported continuous teaching programs in heart failure. Some studies showed reduction in readmissions in HF patients with ongoing care.⁹ Therefore, it was proposed to regard improvement of QOL for these patients as important duties of the nurses.

Despite numerous studies on QOL of patients with heart failure, its complexity and the extent of dimensions, demands new studies on the issue.¹⁰ In addition, much of the previous researches were focused on HF symptom management and did not encompass a boarder view about continuous training. Therefore, studies about QOL could be seen in terms of reduced symptoms and cost effectiveness. This study was performed to determine the effect of ongoing training on QOL dimensions in patients with heart failure.

Materials and methods

This study was a randomized clinical trial, with the control group, registered in Iranian Registry of Clinical Trial (IRCT) and was approved by ethics committee of Tabriz University of Medical Science (Figure 1). Following determination of eligibility and obtaining consent, using the www.randomizer.org website, the participants who referred to the Tabriz Shahid Madani Heart Polyclinic from May to June 2011, were randomly assigned to control and intervention groups. Random allocation was performed by a person other than the researchers.

The sample size was estimated 14 for each group according to a pilot study on eligible subjects who fulfilled inclusion criteria, with $\alpha = 0.05$, a power of 90%, [\bar{X} (SD): 65.7 (3.3)] in quality of life. However, for more accuracy, 22 subjects were selected in each group ($n = 44$). The control group received usual care and training ($n = 22$) but the intervention group received usual care plus the three months ongoing training program ($n = 22$).

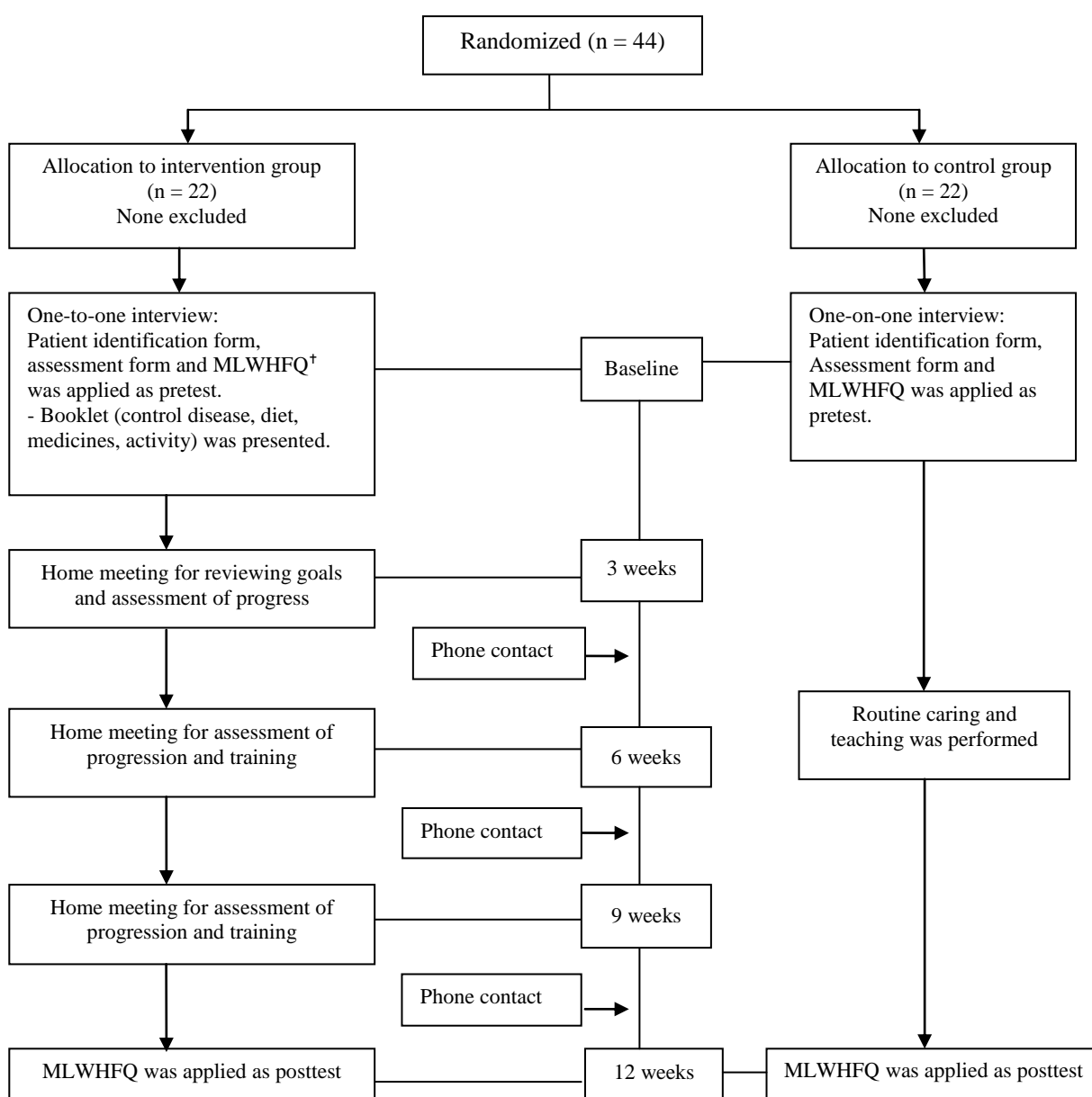
Inclusion criteria comprised of patients above 18 years of age, diagnosed with heart failure approved for at least one month by the cardiologist team, in class II or III heart failure of NYHA, literacy, ability to communicate, no acute medical problems or mental problems and no self-reported addiction. Exclusion criteria were unwillingness to continue the study and any medical problem during the training period. None of the participants was excluded during the study.

Eligible patients were given a detailed explanation regarding their follow up schedule. Interventions in this study was according to Heart Failure Society of America Modules included education related to control of heart failure, low salt regimen, medicines, self-care, physical activity, feelings, tips for family, etc., which have been published for outpatients and patients in

hospitals, to improve the awareness, prevention, treatment and recovery.

Within three months, the control group received only routine caring and teaching. But the intervention group first received one-to-one meeting for introducing the objectives of study, content of program and taking educational needs of participants and pretest. At the first appointment, each patient in the intervention group was given a booklet, entitled 'How can I learn to live with heart failure' based on modules, provided by the researcher.

Then home meeting happened every three weeks, took approximately one hour for reviewing previous goals and progression toward goals. To ensure between these meetings, a phone call were given to answer patients' questions in the intervention group. After three months of training and follow-up, QOL questionnaire of participants were completed through self-report or structured interviews by the researcher (Figure 1).



[†]MLWHFQ: Minnesota Living with Heart Failure Questionnaire

Figure 1. Flowchart of teaching program

Data was collected using a characteristic and physical information form and the Minnesota Living With Heart Failure Questionnaire (MLWHFQ). It contains 21 items using a 6-point (zero to five) Likert scale, with a maximum score of 105. The lower scores indicate better QOL. The instrument consists of three separate dimensions: physical, emotional and total score. Total score is used as the best measure of the impact on disease prevention and it is considered to measure the effects of symptoms, functional limitations and psychological distress on quality of life. The sum of responses reflects the overall effects of heart failure and treatments on individual's quality of life.¹¹

After forward-back translation process, validity of questionnaire was obtained by content validity method. Reliability calculated as the internal consistency responses of 20 patients who had inclusion criteria in which Cronbach's alpha was obtained 0.89.

Data was presented using descriptive statistics including frequency, percentage, mean with standard deviation (SD). Moreover, independent t-test, paired t-test, and ANOVA were used to compare the means. All analysis was performed in SPSS version 13 (SPSS, Inc., Chicago, IL, USA). In all tests, p-value less than 0.05 was considered statistically significant.

Ethical considerations

This study was approved by the Research Ethics Committee in Tabriz University of Medical Sciences. So to follow the ethical considerations, the researcher described the study objectives to the participants and assured them for confidentiality of information and they were free to leave the study. Moreover, the control group received routine caring and training.

Results

A total of 44 participants were enrolled in the

study. The majority of participants [25 (56.8%)] were male, 30 (68.2%) were married, and 21 (47.7%) lived with spouse and children. Most subjects [30 (68.2%)] were at elementary education level, 15 (34.1%) were self-employed and 25 (58.8%) reported low income. The mean age of participants was 61.7 ± 9.4 years and duration of HF was 34.5 ± 3.1 months. There were no statistically significant difference between experimental and control groups in terms of sex, marital status, lifestyle, occupation, income, age and duration, except for educational level. In physical characteristics, 30 (68.2%) subjects did not have hypertension, 38 (86.4%) did not reported diabetics, 43 (97.7%) subjects were without history of ischemia and 38 (86.4%) without myocardial infarction. Eighteen subjects (40.9%) had 30-35% ejection fraction (Tables 1 and 2). Thirty subjects (68.2%) were using ACE inhibitors, 36 (81.8%) β blockers, 38 (86.4%) anticoagulants and 23 (52.3%) diuretics.

At baseline, there were no significant differences between the two groups in terms of QOL. The interventional group showed significant ($p < 0.01$) decrease on physical, emotional and total dimensions of QOL over three months, indicating improvement due to ongoing teaching program (Table 3). Independent t-test showed significantly increase in all three dimensions of QOL compared to control group after training programs. In control group, no significant differences observed (Table 4). The relationship between QOL and demographics was not statistically significant.

Discussion

The main goal of this study was to improve the QOL of patients with heart failure. These patients suffer from lack of enough knowledge about the disease, its treatment, proper diet, activity and self-care as well as impaired QOL.^{4,5,7} According to some studies, there is lack of comprehensive training programs in this area, and the QOL of these patients is in low level.

Table 1. Demographic profile of participants in intervention and control groups (n = 22 in each group)

Characteristic	Control Group	Intervention Group	Statistical indicators
	N (%)	N (%)	
Sex			
Male	13 (59.1)	12 (54.5)	t = 0.18, P = 0.67, df = 42
Female	9 (40.9)	10 (45.5)	
Marital status			
Married	17 (77.3)	13 (59.1)	t = 1.66, P = 0.20, df = 42
Single	5 (22.7)	9 (40.9)	
Life style			
Alone	3 (13.6)	6 (27.3)	F = 0.97, P = 0.32, df = 3
With spouse	3 (13.6)	3 (13.6)	
Wife and children	12 (54.5)	9 (40.9)	
With children	4 (18.2)	4 (18.2)	
Education			
Primary	12 (54.5)	18 (81.8)	F = 5.25, P = 0.02, df = 4
Secondary	3 (13.6)	2 (9.1)	
High school/ diploma	4 (18.2)	2 (9.1)	
College	1 (4.5)	-	
Graduated	2 (9.1)	-	
Occupation			
Office worker	5 (22.7)	1 (4.5)	F = 1.79, P = 0.18, df = 5
Unemployed	3 (13.6)	5 (22.7)	
Worker	1 (4.5)	1 (4.5)	
Military	3 (13.6)	-	
Retired	5 (22.7)	5 (22.7)	
Self- employed	5 (22.7)	10 (45.5)	
Income			
Low	11 (50)	14 (63.6)	F = 0.97, P = 0.67, df = 2
Medium	11 (50)	6 (27.3)	
High	-	2 (9.1)	
Age (year)[†]	60.6 (9.5)	62.8 (9.5)	t = 0.74, p = 0.46, df= 42
Duration (month)[†]	28.0 (2.2)	41.0 (3.8)	t = 1.38, p = 0.17, df = 42

[†]Values are expressed as Mean (SD), F: indicates ANOVA test

Table 2. Physical profile of participants in intervention and control groups

History	Control Group	Intervention Group
	N (%)	N (%)
Hypertension	Yes	14 (63.6)
	No	8 (36.4)
Diabetic mellitus	Yes	10 (45.5)
	No	12 (54.5)
Ischemic heart disease	Yes	6 (27.3)
	No	16 (72.7)
Myocardial infarction	Yes	5 (22.7)
	No	17 (77.3)
Smoking history	Yes	4 (18.2)
	No	18 (81.2)
Smoking duration (years)[†]	15.2 (8.5)	43.7 (4.7)
Numbers/day[†]	4.78 (13.7)	20.0 (1.2)
Frequency/day[†]	11.0 (2.0)	12.0 (6.9)
	15-20	-
	20-25	2 (9)
	25-30	6 (27.3)
Ejection fraction (%)	30-35	7 (31.8)
	35-40	7 (31.8)
		-

* Reported as mean (SD)

Table 3. Comparison of quality of life dimensions in intervention and control groups based on Minnesota Living with Heart Failure Questionnaire

Dimensions	Intervention Group (n = 22)			Control Group (n = 22)		
	Mean(SD)	Mean difference (CI†%95)	Statistical indicators	Mean(SD)	Mean difference (CI%95)	Statistical indicators
Physical			df=21			df=21
Baseline	28.1 (1.4)	18.5 (15.6-21.4)	t=3.40	28.2 (4.0)	2.72 (1.19-6.67)	t=1.46
3 months	9.6 (6.8)		P< 0.01	23.2 (6.9)		P=0.16
Emotional			df=21			df =21
Baseline	15.5 (1.0)	11.1 (9.3-12.9)	t=3.48	9.7 (1.2)	1.30 (0.5-3.11)	t= 1.49
3 months	4.4 (3.5)		P< 0.01	11.0 (5.8)		P= 0.14
Total			df=21			df= 21
Baseline	67.8 (3.3)	42.2 (36.6-47.8)	t=1.36	61.8 (2.7)	5.05 (49.3-64.2)	t= 1.69
3 months	25.5 (2.8)		P< 0.01	56.8 (3.5)		P= 0.10

†CI: confidence interval; t: paired t-test

Table 4. Comparison of mean pretest-posttest differences of quality of life dimensions based on Minnesota Living with Heart Failure Questionnaire

Dimensions	Groups Intervention (n = 22)	Control (n = 22)	Total (n = 44)	CI 95%	Statistical indicators		
	Mean difference (SD)	Mean difference (SD)	Mean difference (SD)		df	t	p
Physical	14.7 (1.3)	3.7 (1.8)	11.9 (2.3)	7.46-16.50	21	5.36	< 0.01
Emotional	11.1 (0.8)	1.3 (0.8)	12.4 (1.2)	9.98-14.90	21	4.52	< 0.01
Total	42.2 (2.6)	5.0 (2.9)	37.3 (4.2)	29.10-45.30	21	9.25	< 0.01

CI: Confidence Interval; t: Independent t-test

In this study, there was no difference between groups in baseline QOL. After three months educational intervention based on training modules there were significant differences in QOL in experimental group compared to control group. In addition, compared to baseline, there were statistically significant differences in QOL for participants in the experimental group, so that they had significantly improved QOL. However, no significant differences were observed in the control group. Considering the similarity of participants in the two groups, the improvement of QOL in intervention group could be related to ongoing teaching program.

The improvement in self-care behaviors is one of the non-pharmacological goals of nurses. Sadeghi *et al.* in 2009 conducted a study concerning the effect of sustained training program on QOL in heart failure patients.¹² In their study, 30 male and 19 female with HF were under follow-up training program. The interventions included training about medications, duration of activity, diet, complications, changing behaviors and lifestyle. The results presented significant improvement in three dimensions

of QOL. The mean QOL during four months in their study was 71, 41.7, 37.7 and 33.5, respectively. These findings about effects of ongoing training program on QOL are consistent with our study that showed a decrease in total QOL scores during three months from 67.8 to 25.5. Moreover, in Rezai *et al.* study in 2009, entitled "The impact of self-care education on QOL of patients with heart failure" high mean scores of QOL and self-care in the intervention group was due to self-care educational program.¹³

In Meyer *et al.* study about the impact of a comprehensive rehabilitation program on QOL of patients with heart failure, by interventions such as medication, exercise and physical activity, education, counseling and training over 12 weeks, statistically significant improvement in QOL and activity capacity was observed.¹⁴ In this regard, Scott *et al.* study entitled "The effect of nursing interventions on QOL and mental health" were also consistent with results of the two studies.¹⁵

Proper education about nutritional diet and medicines for patients and their families in many cases would reduce the exacerbation of heart failure and prevents serious problems

and the high cost of treatment in heart failure.¹⁶ In addition, Jolly et al. showed that exercise training at home over a 6-month period by a specialist nurse in cardiac care improved QOL in heart failure patients with reduced costs paid for treatment in intervention group compared to control group.¹⁷

Dracup et al. in a clinical randomized trial on 173 patients with heart failure gave exercise training and walking at home by a nurse specializing in cardiac care in the intervention group. In a 12-months follow-up of cardiac function, quality of life, readmission to hospital and mortality were evaluated. In the intervention group compared to the control group, no significant differences were observed in heart function, mortality and quality of life. However the mean hospitalization rate was reduced in the intervention group compared to the control group.¹⁸

Several other studies also showed similar results consistent with findings of this study.¹⁹⁻²² Generally, if patients with chronic diseases, especially heart disease were followed by the treatment team and received additional visits for treatment, drugs and self-care needs, they would present reduced rate of hospitalization except for the designated time for training.²³ Comprehensive heart failure management programs including patient education, self-control strategies that are followed by multidisciplinary team of specialists, showed QOL improvement and reduction in hospital admissions.²⁴⁻²⁶

Abedi et al. study showed that women had lower physical functioning and mental health compared to men but except for these two dimensions of QOL, there were no significant differences in their quality of life. Moreover, they showed a significant relationship between age and quality of life so that ageing and smoking worsen the physical functioning, but this was not consistent with our study.²⁷

Conclusion

Our findings highlighted the significant impact of consistent educational interventions

on promotion of quality of life in patients with heart failure. Ongoing education improved the physical and emotional dimensions of QOL as well as total QOL in these patients. With regard to the impact of chronic diseases on social health, ongoing educational programs are necessary for consistent promotion of self-care behaviors, controlling symptoms and prevention of complications. Therefore, with increasing heart failure rate, consistent programs are recommended.

Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interests in this study.

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