

Original Article

## Effect of training program based on Roy's adaptation model on quality of life of patients with heart failure: A randomized clinical trial

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### ABSTRACT

**Background & Aim:** Heart failure is one of the most common cardiovascular diseases which decreases the quality of life. Most of the factors influencing quality of life can be modified with ongoing educational interventions. Inadequate teaching is one of the causes of low health outcomes. Therefore, this study examined the effects of a Roy's Adaptation Model (RAM) based on quality of life of patients with heart failure.

**Methods & Materials:** This randomized clinical trial study was conducted during May to August 2011. From patients with heart failure referred to Tabriz Shahid Madani policlinics, 44 subjects were conveniently selected and randomly allocated to two groups. The intervention group (n=22) received ongoing one-to-one teaching and counseling sessions and phone calls based on RAM over 3 months. The control group (n=22) received routine teaching. Data were collected using the Minnesota Living with Heart Failure Questionnaire (MLHFQ), Interpersonal Support Evaluation List (ISEL) and the 6-Minute Walk Test (6MWT) at first as well as three months later, and analyzed through SPSS (v.13).

**Results:** The statistical tests showed significant differences in the physical, emotional and total dimensions of quality of life ( $p < 0.001$ ) in intervention group. But in control group, no significant differences were obtained. In addition there was significant differences in interpersonal support between two groups after intervention ( $p < 0.001$ ). Also there was a statistically significant increase in 6MWT between baseline and after 3 months for intervention ( $p < 0.001$ ) group.

**Conclusions:** This result showed that teaching program based on RAM was effective in improving the quality of life and in interpersonal support for patients with heart failure.

### Introduction

Heart failure (HF) is one of the most common chronic cardiovascular disorders with progressive and debilitating results. The prevalence of the syndrome of 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 in the blood flow causes the multiple physical symptoms which lead to intolerance activity and changes in life that affects their quality of life (QOL) (3).

The studies have presented that %76.4 of patients with heart failure had relatively poor QOL and HF has a negative effect on QF (4). Patients in class II, 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

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quality of life in these patients has been due to the multiple physical symptoms of the disease (5). With introduced advances in treatment and increased lifespan of patients with HF, improving their QOL becomes more critical (6).

The American Heart Failure Society has training modules for patients with HF, which offer guidance for control of disease, medication, self-care, physical activity, feelings, tips for family etc. The guidelines are simple and have clear explanation. Since the disease affects all aspects of the patient's physical, psychological and social conditions, nurses should perform more accurate planning by collecting comprehensive information of patients (7,8).

One desired outcome from patient teaching is enhanced QOL; however only a few studies have reported ongoing teaching programs in HF. Studies among these patients, who had ongoing care, presented reduced readmissions and the effect of an educational program on adaptation with HF (5,9). Therefore, they proposed to regard improvement of QOL for these patients as important duties of nurses.

Despite numerous studies on QOL of patients with HF, its complexity and the extent of dimensions, demands new studies on the issue (10). In addition, much of the previous research were focused on HF symptom management and did not encompass a broader view of ongoing teaching. This study is performed to determine the effect of ongoing training on QOL dimensions in patients with HF.

### ***Conceptual framework***

Roy's adaptation model (RAM) could be used as a theoretical framework in nursing research (11).

According to RAM, the person is an adaptive system in a state of continual interaction with the environment, or maladaptive systems that require nursing care. The environment includes all situations, circumstances and effects on evolution and behavior of a person or group, which can be divided into three types including focal, contextual and residual stimuli. The person or group through the four modes of adaptation responds to these stimuli (physiological, self-concept, role function and interdependence).

In physiological mode, the person as a living organism responds to stimuli from the environments. Self-concept includes beliefs and feelings of a person. Role function is the role related behaviors in the society and interdependence mode behaviors between individual and social systems described (12).

Every human being is composed of three main interrelated systems that include biological, psychological and social. Any biological system interacts with other systems to control its surroundings. This system function and behave interactively in response to diseases and illnesses. To the Roy opinion, physiological homeostasis is a possible balance in the physiological systems such as fluid and electrolyte. Behavior homeostasis helps creating a consistent behavior and coping with emotional and social experiences. A social system has attempted to maintain balance accompanied with physiological systems. With this system, humans can better analyze and communicate to events that occur in their environment. Psychological and social systems influence on physiological systems (and vice versa), indicating systems interaction and Holism functions that Roy mentions refers to as a common characteristic among all human (11).

The aim of our study was the effect of the QOL in patients with HF. HF is characterized as a multidimensional with social, psychological and physical constructs. Since the three physical, social and emotional variables correspond to those of RAM, we used this model as study tool (11).

In this model the processes of adaptation is divided into two regulatory and cognitive subsystems. Cognitive subsystems create an environment by cognitive and emotional channels including understanding and information processing, learning, judgment and emotions (11). In this study, we tested if cognitive subsystems are influenced by the education program based on RAM. There are several studies for adaptation to chronic diseases based on the RAM. For example, one study conducted by Gülcan & Durmaz Akyol in 2008 entitled reported significant results in the intervention group based on RAM. They reported an increased QOL and functional

capacity and social support development in interdependence mode (13).

### Methods

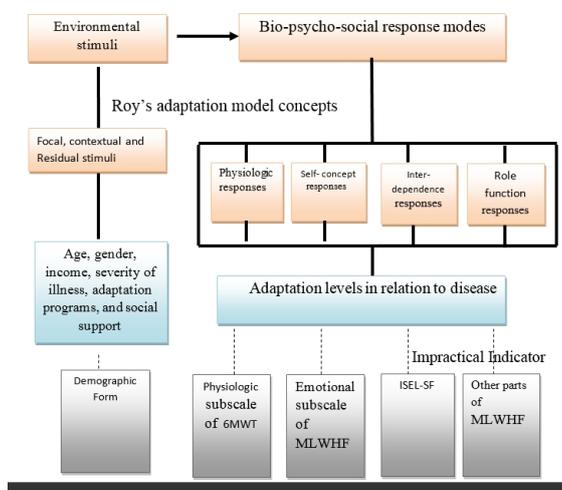
This is a randomized clinical trial study with control group, registered in Iranian Registry of Clinical Trial (IRCT) with number IRCT201101225665N1 and approved by Ethics Committee of Tabriz University of Medical Science. Following eligibility and consent, using the [www.randomizer.org](http://www.randomizer.org) website, from patients referred to the Tabriz Shahid Madani heart polyclinics during four months from May 2011 to June 2011, 44 participants were selected through convenience sampling method and randomly assigned to control and intervention groups. Random allocation was performed by a person other than the researchers. We aimed to study the QOL through educational programs based RAM.

The sample size was estimated according to a pilot study on eligible samples, with  $\alpha=0.05$ , a power of 90%, ( $\mu \pm SD$ :  $65.72 \pm 3.36$ ), 21 for each group. Therefore, for more accuracy of study, 22 participants were selected in each group ( $n=44$ ), who fulfilled inclusion criteria. The control group received usual caring and teaching ( $n=22$ ) but the intervention group received usual care plus the three months ongoing teaching program based on RAM ( $n=22$ ).

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

Eligible patients received a detailed explanation regarding their follow-up schedule. Before training, we measured QOL, social support quality and physical activity using Minnesota Living with Heart Failure Questionnaire (MLWHF), Interpersonal Support Evaluation List (ISEL) and the 6-Minute Walk Test (6MWT). Interventions in this study was according to Heart Failure Society of America Modules and based on RAM included education related to control of HF, low salt regimen, medicines, self-care, physical activity, feelings, tips for family etc. These were for help to improve the awareness, prevention, treatment and recovery processes.

Within three months the control group received only routine caring and teaching. The intervention group first assessed for eligibility in clinic and 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



**Figure 1.** Conceptual–theoretical–empirical structure of adaptation to heart failure. MLWHF, Minnesota Living with Heart Failure Questionnaire; ISEL, Interpersonal Support Evaluation List; 6MWT, 6-minute walking test.

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

Groups	Characteristic	Control	Intervention	Significance
		N(%)	N(%)	
Sex	Male	13(59/1)	12(54/5)	t=0.18
	Female	9(40/9)	10(45/5)	P=0.67
Marital	Marriage	17(77/3)	13(59/1)	t=1.66
	Single	5(22/7)	9(40/9)	p=0.20
Life style	Alone	3(13/6)	6(27/3)	
	With spouse	3(13/6)	3(13/6)	F=0.97
	Wife & children	12(54/5)	9(40/9)	p=0.32
Education	With children	4(18/2)	4(18/2)	
	Primary	12(54/5)	18(81/8)	
Occupation	Secondary	3(13/6)	2(9/1)	F=5.25*
	Diploma	4(18/2)	2(9/1)	p=0.02
	College	1(4/5)	-	
	Graduated	2(9/1)	-	
Income	Office	5(22/7)	1(4/5)	
	Workless	3(13/6)	5(22/7)	
	Worker	1(4/5)	1(4/5)	F=1.79
	Military	3(13/6)	-	p=0.18
	Retired	5(22/7)	5(22/7)	
Age (year)	Self-employment	5(22/7)	10(45/5)	
	Low	11(50)	14(63/6)	F=0.97
	Medium	11(50)	6(27/3)	p=0.67
Duration(month)	High	-	2(9/1)	
		<b>M±SD</b>	<b>M±SD</b>	
		9.51±60.68	9.53±62.81	p=0.46, t=0.74
		2.25±28.00	3.78±41.09	p=0.17, t=1.38

each patient in the intervention group received a booklet, titled 'How can I learn to live with Heart Failure' based on modules of RAM, provided by the researcher (5). The educational intervention consisted of education about disease management, medication, exercise, walking, diet, sexual activity, and stress management based on the American Heart Failure Society guidelines. Then, home meeting happened every three weeks, took approximately one hour for reviewing and progression of goals, to ensure these meetings, a phone call with patients between sessions were given for clarifying the questions in the intervention group. After three months training and follow-up, QOL questionnaires, support between individual's questionnaire-short form, and self-report questionnaire or structured interview were completed by the researcher. The measured physical activity of participants was measured using 6MWT.

Data were collected using forms of characteristics and physical status, support between individual's questionnaire-short form, and the MLHFQ. MLHFQ contains 21 items

using a 6-point, zero to five, Likert-type scale, with a maximum score of 105. The lower scores indicate better QOL. The instrument consists of three separate dimensions: physical, emotional and total scores. Total score is used as the best measure of the impact on disease prevention for showing the good life. It is considered to measure the effects of symptoms, functional limitations and psychological distress on QOL. The sum of responses reflects the overall effects of HF and treatments on individual's QOL (14). The support between individual's questionnaires is a 15-item measure of perceived social support derived from the 48-item ISEL designed by Owen. The instrument consists of three subscales: tangible support, appraisal support and belonging support. The interdependence mode of RAM was measured with the ISEL and used to assess the level of support and dependence on family and friends of patient. Cronbach's coefficient in the present study was 0.81. The 6MWT was for measuring functional status of the patient. Physical mode of RAM was assessed by this test and part one of the QOL (physical). Before and after each 6MWT

**Table 2.** Frequency distribution and percentage of participants according to physical Profile in both intervention and control groups

History	subgroups	Control		Intervention	
		N	%	N	%
BP	yes	14	63.6	16	72.7
	no	8	36.4	6	27.3
DM	yes	10	45.5	11	50.0
	no	12	54.5	11	50.0
IHD	yes	6	27.3	11	50.0
	no	16	72.7	11	50.0
MI	yes	5	22.7	9	40.9
	no	17	77.3	13	59.1
Smoking history	yes	4	18.2	5	22.7
	no	18	81.2	17	77.3
Smoking (years)		8.53±15.25		4.78±43.75	
Numbers / day		4.78±13.75		1/27±20	
Frequency/ day		2.00±11.00		6/97±12	
EF%	15-20	-	-	2	9/1
	20-25	2	9/1	3	13/6
	25-30	6	27/3	6	27/3
	30-35	7	31/8	11	50
	35-40	7	31/8	-	-

BP, high blood pressure; DM, diabetic mellitus; IHD, ischemic heart disease; MI, myocardial infarction; EF, ejection fraction

the patient's pulse, respiratory rate and blood pressure were recorded (5).

After the translation and back translation process, validity of questionnaire was obtained by content validity method. Reliability calculated with internal consistency by a study on 20 patients who had inclusion criteria with Cronbach's alpha as 0.89. Data were analyzed 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 SPSS13. In all tests, p values less than 0.05 was considered significant.

This study was approved by the Research Ethics Committee in Tabriz University of Medical Sciences. Thus, to follow the ethical considerations, the researcher described the study objectives to the participants and assured them of confidentiality of information. They also were free to leave the study at any time. Meanwhile, the control group received routine caring and teaching.

## Results

A total of 44 participants enrolled in the study. In demographic characteristics, the majority of participants, 25(56.8%) were male,

30(68. 2%) married, and 21(47.7%) lived with spouse and children. They mostly (n=30, 68.2%) had elementary literacy, 15 (34.1%) had free work and 25 (58.8%) reported low income. The mean age of participants was (61.75±9.47 years) and duration of HF was (34.54±3.16 months). There were no statistically significant difference between the two groups in terms of sex, marital status, lifestyle, occupation, income, age and duration, except for educational level.

In physical characteristics, 30 (68.2%) had no hypertension, 38 (86.4%) no diabetics, 43 (97.7%) no ischemia and 38 (86.4%) no MI. The most participants, (n=18, 40.9%) had 30-35% ejection fraction (Table 1, 2). In cardiac medicines, mostly (n=30, 68.2%) were using ACE inhibitors, 36 (81.8%) β blockers, 38 (86.4%) anticoagulants and 23 (52.3%) diuretics.

There were no significant differences between the two groups in baseline QOL, social support quality, and physical activity of participants. The interventional group showed significant decrease on physical, emotional, and total dimensions of quality of life (p<0.001) over three months. After ongoing teaching program, they showed improvement. Therefore independent t test showed significantly increased in all three dimensions of quality of life compared to control group after training

**Table 3.** Comparison of MLWHF dimensions in both intervention and control groups

Groups	intervention(n=22)				control(n=22)			
	Mean±SD		Mean dif		Mean±SD		Mean dif	
Dimensions	Baseline	3 months	CI95%	Sig.	Baseline	3 months	CI95%	Sig.
Physical	1.47±28.13	6.82± 9.59	18.54±1.37 15.68-21.40	p<.001, t=13.47	4.03±28.21	6.90± 23.27	2.72±1.87 1.19-6.67	p=0.16, t=1.46
Emotional	1.07±15.59	3.55 ± 4.43	11.15±0.86 9.35-12.95	p<.001, t =3.48	1.29±9.74	5.85 ± 11.04	1.30±0.87 0.50-3.11	p=0.14 t=1.49
Total	3.34±67.81	2.88 ± 25.52	42.29±2.69 36.69-47.89	p<.001, t =1.36	2.78±61.88	3.57 ± 56.82	5.05±2.99 49.39-64.25	p=.10, t =1.69

df=21; CI, confidence interval; t, paired t; mean dif, mean difference; MLWHFQ, Minnesota living with Heart Failure questionnaire).

**Table 4.** Comparison 6-minute walk test in both intervention and control groups

Groups	Intervention (n=22)				Control (n=22)			
	Mean±SD		Mean dif		Mean±SD		Mean dif	
Dimensions	Baseline	3 months	CI95%	Sig.	Baseline	3 months	CI95%	Sig.
6-MWT	224.7±74.6	325.5±102.18	19.44±1.50 23.59-36.63	p<.001, t=-8.93	205.6±51	63.6± 203.6	3.74±1.25 7.21-11.57	p=0.89, t=14

df=21; CI, confidence interval; t, paired t; mean dif, mean difference; 6-minute walk test.

**Table 5.** Comparison ISQ-SF in both intervention and control groups

Groups	Intervention (N=22)				Control (N=22)			
	Mean±SD		Mean dif		Mean±SD		Mean dif	
Dimensions	Baseline	3 months	CI95%	Sig.	Baseline	3 months	CI95%	Sign.
ISQ-SF	38.68±4.21	39±1.95	.31±1.01 1.73-2.37	p<.01, t=2.74	38.36±2.21	37.31±2.91	2.72±1.87 1.19-6.67	p<.10, t=.746

df=21; CI, confidence interval; t, paired t; mean dif, mean difference; SBIQ-SF, support between individual's questionnaire-short form).

programs. In control group, no significant differences was obtained (Table 3). The relationship between QOL and demographic profile was not statistically significant.

Intervention group showed a statistically significantly improved support between individual's questionnaire-short form total score and over time compared with control group (p<0.01) (Table 5). There was a statistically significant increase in 6MWT compared with baseline at 3 months for intervention (352/56±102/18m) group. There was a statistically significant decrease in 6MWT compared with baseline at 3 months for the control group (203/64±63/66 m) (Table 4).

## Discussion

The main goal of this study was to improve the QOL of patients with HF based on RAM. These patients were suffering from lack of enough knowledge about the disease, its treatment, proper diet, activity and self-care, as well as from impaired QOL. According to the studies there is lack of comprehensive training

programs in this area, and unfortunately the QOL in these patients is in low level. Therefore, by a teaching program based on RAM, we checked the quality of their life.

In this study, there was no difference in baseline QOL, social support quality and physical activity between two groups. After three months of educational intervention based on RAM and training modules, we found significant differences in QOL, social support quality and physical activity in experimental group compared to control group. In addition, compared to the baseline, there were statistically significant differences in three scales for participants in the experimental group. This indicates that teaching program based on RAM had been effective on adaptation to HF in relation to physiologic, self-concept, interdependence and role function modes. Meanwhile, no significant differences were observed in the control group. Considering the similarity of participants in two groups, the improvement of quality of life in intervention group could be related to ongoing teaching program based on RAM.

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 HF patients (15). In that study 30 males and 19 females with HF were followed up during a teaching program. The interventions included teaching about medications, duration of activity, diet, complications, changing behaviors and lifestyle. The results presented significant improvement in four dimensions of RAM.

These findings indicating the effects of ongoing program on QOL were consistent with results of our study that showed a decrease in total QOL scores during three months from 67.81 to 25.52. In one study in 2009, greater mean scores of QOL and self-care in the intervention group compared to control group was due to self-care educational program (16).

In Meyer et al. study in 2003, the impact of a comprehensive rehabilitation program was tested on QOL of patients with HF by interventions such as medication, exercise and physical activity, education, counseling and training over 12 weeks with comprehensive rehabilitation. The results indicated statistically significant improvement in QOL and activity capacity (17). In this regard, Scott et al. study results were consistent with our results (18). Proper education about nutritional diet and medicines for patients and their families in many cases would reduce the exacerbation of HF and prevents serious problems and the high cost of related treatment (19). Jolly et al. showed that exercise training at home over a 6 months period by a specialist nurse improved QOL in HF patients and reduced costs paid for treatment in intervention group compared to controls (20).

In a clinical randomized trial study by Dracub et al, 173 HF patients were divided into two intervention (n=87) and control (n=86) groups. In intervention group, exercise training and walking at home were performed by a nurse specialized in cardiac care. After a 12-month follow-up, cardiac function, QOL, re-admission to hospital and mortality were evaluated. There were no significant differences between the two groups considering heart function, mortality and QOL. However the mean hospitalization rate

was reduced in the intervention group compared to the control group (21).

Of four RAM modes of adaptation, the physiologic mode was associated with the other modes. Patients with good QOL on the physiologic dimension were found to be more able to perform their social functions when they have good emotional status and social support (13). Although a few studies found social support unrelated to QOL, in current study it was found to be related to QOL, consistent with Gülcan & Durmaz Akyol results.

Patients with higher levels of social support are having fewer physiologic defects and are physically in a better condition. Thus there was an association between support between individual's questionnaire-short form and physiologic status. Families and friends play an important role in social support, their encouragement had positive effects on the patients. Those who receive social support from their families and friends are more likely to join exercise programs (22). Levels of depression are expected to be higher among those with chronic illness and less social support (23).

Results reported in the literature indicate that social relationship with other patients and support from healthcare professionals assist patients in being able to adapt to chronic illness (24).

Rintela et al. found that social support has an important effect on life satisfaction (23). Several other studies also reported similar results consistent with this study (25-28). Generally, patients with chronic diseases (especially heart diseases) who are followed with an additional visit for treatment, and receive needed drugs and are satisfied of self-care needs, they would present reduced rate of hospitalization except for the designated time for training (29).

Comprehensive HF management programs including patient education, self-control strategies, followed by successive multi-disciplinary team of specialists, showed increase in improving the QOL and reduction of hospital admissions (30-32).

Demographic findings presented no significant differences between the two groups. Abedi et al. showed that QOL of women considering physical functioning and mental health was lower than men, and there was no significant differences between the two groups QOL status. Moreover they showed a significant

relationship between age and QOL. Increasing age and smoking reported to worsen the physical functioning, though it was not consistent with our study results (33).

## Conclusion

Our findings highlighted the significant impact of ongoing educational interventions on increase of QOL based on RAM in patients with HF. The results indicated improvement of the physical, emotional, and total dimensions of QOL, social support quality and physical activity in these patients. Due to the importance and impact of chronic diseases on social health, ongoing educational programs based on RAM are necessary for consistent promotion of self-care behaviors, controlling symptoms and prevention of complications. Therefore, with increasing HF rate relevant consistent programs are recommended. Enrolling no illiterate participant was the most significant limitation of the present study. We suggest the RAM be used to other classes of HF with illiterate subjects in future studies.

## Conflict of interest

The authors declared no conflict of interests in this study.

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