



# The effects of education based on Leventhal's self-regulation model on self-care and quality of life among patients with heart failure: A clinical trial

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## Abstract

**Background:** Patients with heart failure experience poor self-care and diminished quality of life (QOL). Enhancing the well-being of these patients necessitates the implementation of innovative educational methods.

**Objectives:** To determine the effects of education based on Leventhal's self-regulation model on self-care and QOL in patients with heart failure.

**Methods:** This clinical trial was conducted with 100 patients hospitalized with heart failure at Farshchian Hospital in Hamadan, Iran. Subjects were selected using consecutive sampling and assigned to either an intervention group or a control group, using the randomized block permutation method. Prior to and two months after the intervention, patients completed the self-care questionnaire for heart failure patients and the Minnesota Quality of Life questionnaire. The control group received routine ward education, whereas the intervention group participated in an educational program based on the Leventhal model. Data were analyzed using the chi-square, Fisher's exact, paired t, and independent t tests.

**Results:** The two groups were homogeneous in their characteristics. The independent t-test showed no significant difference in mean baseline self-care and QOL scores between the intervention and control groups ( $P > 0.05$ ). However, after the intervention, there was a significant difference ( $P < 0.05$ ), with the intervention group showing an increase in self-care and QOL compared to the control group.

**Conclusion:** Education based on Leventhal's self-regulation model resulted in improvement in self-care and QOL in patients with heart failure. It is recommended that this model be used in the education of patients with heart failure.

**Keywords:** Heart Failure, Leventhal's self-regulation model, Self-care, Quality of Life, Patient Education, Nurses.

## Introduction

Heart failure (HF) is a major global health concern affecting over 26 million people worldwide and is one of the leading causes of hospitalization and mortality in older adults.<sup>[1]</sup> Common symptoms of HF include fluid retention, dyspnea, pulmonary edema, sleep disturbance, fatigue, and loss of energy.<sup>[2]</sup> These symptoms can

interfere with patients' ability to perform daily activities, care for themselves, and maintain a good QOL.<sup>[1,3]</sup> QOL is a critical indicator of health status in chronically ill patients and can drastically decrease in individuals with HF.<sup>[1]</sup>

Poor self-care is another major problem faced by patients with HF. Studies have shown that patients with

HF have lower adherence to self-care.<sup>[4,5]</sup> This may be related to the complex nature of self-care, lack of motivation, misconceptions, lack of knowledge, and poor understanding of the importance of self-care.<sup>[4]</sup> Therefore, preventing disease progression, controlling symptoms, and improving self-care and QOL are among the key goals in caring for patients with HF.<sup>[6]</sup>

Patient education is a critical component of care programs for chronic diseases. Proper patient education can improve patients' self-care and QOL.<sup>[7,8]</sup> As the largest group in the healthcare system, nurses play a crucial role in patient education and empowerment.<sup>[9]</sup> Appropriate education can effectively shape patients' perceptions and change their health behaviors.<sup>[10]</sup> In previous studies, various educational methods such as the collaborative care model,<sup>[11]</sup> motivational interventions,<sup>[12]</sup> the teach-back method,<sup>[13]</sup> motivational interviewing,<sup>[14]</sup> and self-care education<sup>[8]</sup> have been used to improve self-care and QOL in patients with HF. However, Leventhal's Self-Regulation Model (LSRM) appears to have the potential to more effectively empower patients and lead to more robust learning by focusing on enhancing their illness perceptions and emotional state.<sup>[15]</sup>

The LSRM, also known as the Common-Sense Model can serve as a framework for effective patient education by nurses. According to Leventhal, patients' reactions to their disease and its symptoms stem from two important variables: cognition and the objective interpretation of the health threat. When patients correctly perceive their disease and its aspects, they are more likely to follow instructions and recommendations,<sup>[15]</sup> which in turn, impact adaptation, disease management, self-care, and overall health outcomes, including QOL.<sup>[16]</sup> A study showed that using this model to raise diabetes awareness improved patients treatment adherence and QOL.<sup>[10]</sup> Another study also showed that using the Leventhal model reduced menstrual distress in adolescents.<sup>[17]</sup>

Despite advances in the medical field, self-care and QOL remain poor in patients with HF.<sup>[3,18]</sup> Nursing interventions that focus on self-care behaviors and modifiable variables are therefore needed to improve self-care and QOL in patients with HF. Some studies have shown the positive effects of education based on LSRM on improving outcomes in patients with diabetes, hypertension, and tuberculosis.<sup>[10,19-21]</sup> However, the effectiveness of this model has not yet been studied in Iranian patients with HF.

## Objectives

This study aimed to determine the effect of education

based on LSRM on the self-care and QOL of patients with HF.

## Methods

### Study design and participants

This randomized controlled trial was conducted on two groups of patients with HF who referred to the cardiac ward of Farshchian Hospital in Hamedan, Iran. The study was conducted over one year, from January 1 to December 30, 2022. With reference to a previous study,<sup>[22]</sup> and given a confidence level of 0.95 and power of 0.80, with the variance of the two groups being equal to 16.84 and a significant difference of 10 units between the two groups, and accounting for a possible 10% attrition, a sample size of 50 individuals was estimated for each group [Formula 1].

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2} \approx 45$$

**Formula 1.** The sample size calculation formula

The inclusion criteria were as follows: age between 25 and 70 years, at least 6 months have passed since the onset of the disease, ejection fraction less than 40%, ability to read, write, and understand the Persian language, lack of medical or related education for the patient and his/her family, and having HF class 2 or 3 according to the American Heart Association (AHA) classifications. Exclusion criteria included the occurrence of acute complications during the study, early discharge, death, reluctance to continue participation, and failure to complete the questionnaire.

Patients were consecutively selected from eligible patients referred to the aforementioned hospital and randomly allocated to a control and an intervention group, using a random permuted block method. Before data collection, the study supervisor prepared a plan for permuted block randomization using an online number generator (i.e., <https://www.sealedenvelope.com/simple-randomiser/v1/lists/>). The putative participants were randomly allocated into 17 blocks of 6 to be assigned to a control or an intervention group, 50 in each group.

### Data collection instruments

The data collection instruments included a demographic profile questionnaire, the 21-item European Heart Failure Self-care Behaviour Scale (EHFScBs), and the Minnesota Living with Heart Failure Quality of Life Questionnaire. The demographic questionnaire collected information on age, sex, body mass index, marital status, education level,

occupation, income level, concomitant diseases, medication use, family history of illness, disease duration, number of hospitalizations, disease classification, and cardiac ejection fraction.

The Minnesota Living with Heart Failure Quality of Life Questionnaire (MLHFQ) consists of 21 items in three subscales, namely physical (8 items), emotional (5 items), and social (8 items). All items are rated on a 6-point Likert scale ranging from 0 to 5, with zero indicating no restriction and five indicating maximum restriction. The MLHFQ total score ranges from 0 to 105, with higher scores indicating poorer QOL.<sup>[23]</sup> The content validity of the Persian translation of the MLHFQ was verified by Eskandari et al., and the reliability coefficient for the entire questionnaire was reported to be 0.90 based on Cronbach's alpha.<sup>[23]</sup> In this study, the Cronbach's alpha for the questionnaire was 0.91.

The European Heart Failure Self-care Behaviour Scale (EHFScBs) consists of 12 questions rated on a 5-point Likert scale ranging from "absolutely true: 5" to "not at all: 1". The total score ranges from 12 to 60, with higher scores indicating better self-care.<sup>[24]</sup> The validity of this questionnaire in Iran was evaluated and confirmed by Asadi, and its Cronbach's alpha was reported to be 0.71.<sup>[24]</sup> In this study, the Cronbach's alpha of the EHFScBs was 0.78.

### Procedures

Before allocating participants to their respective groups, demographic, self-care, and QOL questionnaires were completed in the form of self-reports at the patient's bedside in the ward. The participants were then randomly assigned to either the intervention or the control group. The control group received only routine education from the ward nurses and doctors.

In addition to the routine ward training, the intervention group received education based on the LSRM from the main researcher. Four individual, face-to-face educational sessions, each lasting 60 minutes, were conducted for each patient on four consecutive days.

During the first session, patients' perceptions of the nature and symptoms of the disease and of how to care for themselves were assessed. Emphasis was placed on correcting patients' misconceptions. Additionally, factors that may exacerbate symptoms, such as extreme physical activity, mental and physical stress, improper diet, smoking, and medication-related problems were discussed from the patient's perspective, and any misconceptions were corrected.

In the second session, after reviewing the topics covered in the previous session, the patient's beliefs about the disease outcome, duration, control, and treatment were discussed according to their perception, and any misconceptions were corrected.

In the third session, the issues discussed in the previous sessions were reviewed. Then, patient's perception of medication use, the reasons for taking them, how to use them, the care measures required before and after taking the drugs, and potential side effects were assessed. Incorrect information was corrected, and information about medications was provided both verbally and in writing.

In the fourth session, the content of the previous session was reviewed, and patients were asked to express any concerns they had about their illness. Emotional issues were also considered, and patients were asked to express their feelings during a normal day and when they experienced sudden changes in symptoms. Patients were helped to become aware of their emotional reactions to the disease and to express any symptoms and complications caused by the disease. Patients were also informed about the importance of treatment adherence and the risks associated with inappropriate psychological reactions, such as denial, ignoring symptoms, lack of follow-up, and non-compliance with treatment and care plans, which can lead to delays in controlling the disease and aggravation of symptoms and signs. Patients were encouraged to inform family, friends, and colleagues about their illness, treatment, medications, diet, and care principles so that they could provide the necessary assistance in the care and control of the disease or in cases of sudden problems.

Two months after the end of the intervention, the self-care and QOL questionnaires were completed again in both groups in the form of self-reports during a follow-up visit.

### Statistical analysis

Data were analyzed using SPSS version 16 software (SPSS, Inc., Chicago, IL, USA). Normality of the data was evaluated using the Kolmogorov-Smirnov test. Homogeneity of the two groups with respect to categorical variables was checked using the chi-square or Fisher's exact tests. The independent-samples t-test was used to compare the means of quantitative variables between the two groups. The paired t-test was also used to compare the means of quantitative variables in each group before and after the intervention. P-values less than 0.05 were considered statistically significant.

### Ethical consideration

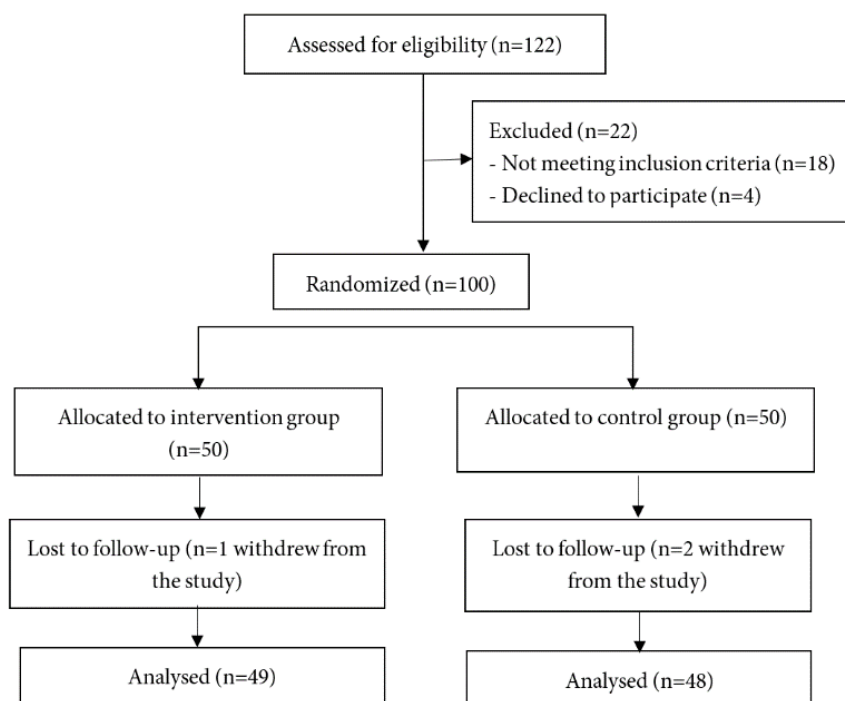
Before conducting the study, patients were fully informed about the purpose, procedures, possibility to withdraw from the study at any time, and the confidentiality of their personal data. Written informed consent was obtained from all participants, and all ethical principles were adhered to according to the Helsinki Declaration. At the end of the study, an educational booklet about caring for patients with HF was provided to the control group. This study was approved by the Ethics Committee of Hamadan University of Medical Sciences under the number IR.UMSHA.REC.1401.167 and registered in the Iranian Registry of Clinical Trials under the code IRCT20120215009014N426.

### Results

Of the 100 patients with HF, who were assigned to the intervention ( $n=50$ ) and control ( $n=50$ ) groups, 48 patients in the intervention group and 49 patients in the control group completed the study [Figure 1].

Most patients in both groups were women, married, housewives, and had basic reading and writing literacy. The mean age of patients in the control and intervention groups was 60.90 and 60.04 years, respectively. No significant difference was found between the two groups in terms of demographic and clinical characteristics ( $P>0.05$ ) [Table 1].

The independent-samples t-test showed that before the intervention, no significant differences were observed between the control and intervention groups in the mean self-care and QOL scores ( $P>0.05$ ). However, the mean posttest self-care score increased significantly in the intervention group ( $P<0.001$ ), whereas it did not change significantly in the control group ( $P=0.459$ ). Furthermore, the mean posttest QOL scores decreased significantly in the intervention groups ( $P < 0.001$ ), whereas all posttest QOL mean scores increased significantly in the control group ( $P<0.05$ ) [Table 2]. It should be noted that a lower QOL score indicates a higher QOL.



**Figure 1.** Study flow diagram

### Discussion

The results of the present study demonstrated a significant increase in the self-care of patients in the intervention group compared with the control group. This improvement can be attributed to the use of education based on Leventhal's model, which in turn corrected patients' distorted thoughts and inefficient self-care behaviors.<sup>[16]</sup> Misconceptions about disease can lead patients to become indifferent to self-care activities.

Patients react to diseases and self-care recommendations based on their perceived threat, which is influenced by their perceptions and beliefs about the disease,<sup>[22]</sup> personal experiences, prior information, and cultural factors.<sup>[25]</sup> Using Leventhal's model, we tried to identify patients' perceptions of the disease, pay attention to their signs and symptoms, sensitize patients about their health status, correct their misconceptions, make them more self-regulated, increase their compliance with the treatment

and care regimen, and eventually improve their self-care. However, researchers acknowledge that healthcare providers rarely inquire about patients' beliefs and perceptions during medical examinations, and that this aspect of patient education is often ignored in educational programs.<sup>[26]</sup> To address this gap, clinicians, including nurses, can use Leventhal's model to more effectively assess patients' perceptions of their illness and improve

their self-care. Consistent with our findings, previous studies have found that education based on Leventhal's model could improve self-care in patients with tuberculosis<sup>[21]</sup> and improve QOL,<sup>[10]</sup> and disease perception in diabetes.<sup>[19]</sup> Application of Leventhal's model could also improve treatment adherence in people with hypertension,<sup>[20]</sup> and reduce death anxiety in people with HF.<sup>[27]</sup>

**Table-1.** Comparison of the demographic data of the patients with heart failure in the intervention and control groups

Demographic characteristics	Intervention group n=48, n (%)	Control group n=49, n (%)	P-value
<b>Sex</b>			0.685 <sup>a</sup>
Female	25(52.1)	28(57.1)	
Male	23(47.9)	21(42.9)	
<b>Marital status</b>			0.723 <sup>b</sup>
Married	36(75.0)	40(81.6)	
Single	1(2.1)	1(2.1)	
Widowed	11(22.9)	8(16.3)	
<b>Occupation</b>			0.816 <sup>b</sup>
Household	19 (39.6)	22(44.9)	
Retired	4(8.3)	5(10.2)	
Self-employed job	12 (25)	13 (26.6)	
Employee	2(4.2)	0 (0)	
Farmer	5(10.4)	3(6.1)	
Unemployment	6(12.5)	6(12.2)	
<b>Education</b>			0.906 <sup>b</sup>
Reading and writing literacy	37(77.1)	38(77.6)	
Under diploma	4(8.3)	3(6.1)	
Diploma	4(8.3)	6(12.2)	
University degree	3(6.3)	2(4.1)	
<b>Income</b>			0.667 <sup>a</sup>
Sufficient	12(25.0)	9 (18.3)	
Partially sufficient	26 (54.2)	31(63.3)	
Insufficient	10(20.8)	9(18.4)	
<b>History of heart failure in the family</b>			0.572 <sup>a</sup>
Yes	14(29.2)	11(22.4)	
No	34(70.8)	38 (77.6)	
<b>Disease class</b>			0.354 <sup>a</sup>
2	34(70.8)	39(79.6)	
3	14(29.2)	10(20.4)	
<b>Medication use</b>			0.495 <sup>b</sup>
Yes	47(97.9)	49(100)	
No	1(2.1)	0(0)	
<b>Age (years)</b>	60.04±6.26	60.90±6.20	0.500 <sup>c</sup>
<b>Body mass index (kg/m<sup>2</sup>)</b>	25.67±4.40	26.14±2.09	0.504 <sup>c</sup>
<b>Duration of illness (months)</b>	20.29±14.02	19.92±14.84	0.900 <sup>c</sup>
<b>Hospitalization frequency</b>	3.54±2.52	3.37±2.58	0.737 <sup>c</sup>
<b>Ejection fraction (%)</b>	38.73±1.68	38.82±1.03	0.759 <sup>c</sup>

Data are presented as n (%) or Mean±SD, <sup>a</sup> Chi-square, <sup>b</sup> Fisher Exact test, <sup>c</sup> Independent t test



**Table-2.** Comparison of the mean scores of self-care, quality of life, and its subscales among the patients both groups

Variables	Time of evaluation	Intervention group n=48	Control group n=49	P-value <sup>a</sup>
<b>Self-care</b>				
	Before the intervention	33.02 ± 4.11	32.20±5.05	0.385
	After the intervention	37.79±5.60	31.55±4.64	< 0.001
	P-value <sup>b</sup>	< 0.001	0.459	
<b>Quality of life</b>				
<b>Physical</b>	Before the intervention	23.19±4.38	22.9±5.55	0.777
	After the intervention	21.00±3.63	23.45±5.44	0.011
	P-value <sup>b</sup>	0.001	0.026	
<b>Emotional</b>	Before the intervention	14.79±2.77	14.9±2.11	0.832
	After the intervention	13.6±2.33	15.59±2.10	<0.001
	P-value <sup>b</sup>	<0.001	0.003	
<b>Social</b>	Before the intervention	22.04±5.12	21.53±4.7	0.610
	After the intervention	20.21±3.78	22.35±4.61	0.014
	P-value <sup>b</sup>	<0.001	0.387	
<b>Total Quality of Life</b>	Before the intervention	60.02±7.47	59.33±8.27	0.666
	After the intervention	54.81±4.97	61.38±7.59	<0.001
	P-value <sup>b</sup>	<0.001	0.046	

Data are presented as Mean±SD, <sup>a</sup> Independent t test, <sup>b</sup> Paired t test

The four daily training sessions based on the Leventhal model was found to improve QOL in patients with HF. Signifying the association between disease perception and QOL, a study reported that education based on Leventhal's model improved disease perception and resulted in increased treatment adherence and QOL among patients with diabetes mellitus.<sup>[10]</sup> Patients with negative illness perceptions often believe that their disease is incurable, uncontrollable, chronic, severe, and has negative identity consequences.<sup>[25,27]</sup> These beliefs can worsen patients' experiences of fatigue, dyspnea, pulmonary edema, sleep disturbances, and loss of energy, ultimately resulting in poor QOL. However, as our results demonstrated, cognitive-behavioral interventions aimed at changing illness perceptions may be useful to improve QOL. This approach helps patients interpret their physical symptoms correctly, and gradually replaces internal controls with external controls, which consequently enhances patients' perception and self-care, and improves their QOL. However, Hwang et al. found no significant effect of the educational intervention on the QOL of patients with HF 3 and 12 months after the intervention.<sup>[18]</sup> The disparity may be attributed to differences in the evaluation time frame and the type of intervention.

Having a control group, the low level of sample attrition, and the random assignment of participants to groups increase the generalizability of our findings. However, the study participants were mostly literate; hence, the

generalization of the findings to illiterate individuals should be done with caution. Due to the Coronavirus disease 2019 (COVID-19) pandemic, the educational intervention was provided individually, but it may be beneficial to evaluate the effectiveness of group education as well. Another limitation of the study is the short duration of the outcome assessment period and the lack of blinding that should be addressed in future studies.

## Conclusions

The present study demonstrated that education based on Leventhal's self-regulation model could improve self-care and the QOL in patients with HF. Since this method is useful, easy, and cost-effective, nurses are suggested to use it to train patients with HF. Leventhal's model can assist patients change their perceptions through techniques such as cognitive restructuring. Our results can assist the nursing staff in first assessing the cognitive and emotional perception of patients regarding their illness, identifying potential misperceptions in patients, and attempting to correct their understanding of the disease. This could be an effective step to improve self-care and QOL for patients with HF.

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## Competing interests

The authors declare that they have no competing interests.

## Abbreviations

Heart failure: HF; American Heart Association: AHA; Coronavirus disease 2019: COVID-19; Quality of life: QOL; Leventhal's Self-Regulation Model: LSRM; European Heart Failure Self-care Behaviour Scale: EHFSBs; Minnesota Living with Heart Failure Quality of Life Questionnaire: MLHFQ;

## Authors' contributions

All authors read and approved the final manuscript. All authors take responsibility for the integrity of the data and the accuracy of the data analysis.

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## Role of the funding source

None.

## Availability of data and materials

The data used in this study are available from the corresponding author on request.

## Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki. This study was approved by the Ethics Committee of Hamadan University of Medical Sciences under the number IR.UMSHA.REC.1401.167 and registered in the Iranian Registry of Clinical Trials under the code IRCT20120215009014N426.

## Consent for publication

By submitting this document, the authors declare their consent for the final accepted version of the manuscript to be considered for publication.

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