Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of an intervention based on Leventhal's self-regulation model on the level of health literacy and adherence in heart failure patients

Protocol summary

Study aim
Determining the effect of an intervention based on Leventhal's self-regulation model on the level of health literacy and adherence in heart failure patients

Design
In this study, 92 patients with heart failure who were hospitalized in Social Security Organization hospitals were selected through a convenience sampling method. Subsequently, participants were randomly assigned to intervention and control groups using a randomized block design with blocks of four. After obtaining written informed consent from the patients, the researcher completed demographic information questionnaires, the Heart Failure Health Literacy Questionnaire, and the Heart Failure Adherence Questionnaire for both groups. The control group received only routine ward care, while the intervention group, in addition to routine care, underwent an educational intervention based on Leventhal's self-regulation model. This intervention was conducted individually and in person during three sessions of 30 to 40 minutes each during the hospitalization period. The questionnaires were re-administered one month and three months after the intervention

Settings and conduct
A total of 92 patients with heart failure hospitalized in the Social Security Organization hospitals of Qazvin will be selected using a convenience sampling method.

Participants/Inclusion and exclusion criteria
confirmed heart failure diagnosis by a cardiologist, informed consent, no known psychiatric disorder, and no participation in similar educational programs in the past 6 months Exit criterion: unwillingness to continue, severe disability or death, new acute debilitating illness, or missing any educational session

Intervention groups
The intervention group will receive training based on Leventhal's self-regulation model.

Main outcome variables
Health literacy – adherence in patients with heart failure

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20250713066474N1**
Registration date: **2025-07-24, 1404/05/02**
Registration timing: **prospective**

Last update: **2025-07-24, 1404/05/02**
Update count: **0**

Registration date
2025-07-24, 1404/05/02

Registrant information

Name
Atefeh علیزاده ریسنی

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3333 6001

Email address
atefehalizaddeh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-21, 1404/06/30

Expected recruitment end date
2026-01-10, 1404/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of an intervention based on Leventhal's self-regulation model on the level of health literacy and adherence in heart failure patients

Public title

Investigating the effect of Leventhal's self-regulation model on health literacy and adherence in heart failure

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of heart failure by a cardiologist Informed consent to participate in the study No known psychiatric disorders No participation in a similar educational program in the past 6 months

Exclusion criteria:

Unwillingness to continue participation at any stage Occurrence of severe disability or death Development of a new debilitating acute illness Absence from at least one educational session

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with blocks of four will be used for allocation. To determine the allocation sequence using block randomization, the online randomization tool available at https://www.sealedenvelope.com/simple-randomiser/v1/lists will be utilized. Randomization will be performed by an independent individual.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

In this study, 92 patients with heart failure who are hospitalized in Social Security Hospital of Qazvin and meet the inclusion criteria (confirmed diagnosis of heart failure by a cardiologist and willingness to participate in the study) will be selected using a convenience sampling method. The patients will then be randomly assigned to intervention and control groups using a four-block randomization method. After obtaining written informed consent from the patients, demographic information, the Heart Failure Health Literacy Questionnaire, and the Heart Failure Adherence Questionnaire will be completed by the researcher in both groups. The control group will receive only routine care, while the intervention group, in addition to routine care, will receive an educational intervention based on Leventhal's self-regulation model, delivered individually and face-to-face during three sessions of 30 to 40 minutes each during hospitalizationEducational Sessions:Session 1:The content focuses on enhancing patients' understanding of the disease, including explanations about the nature of heart failure, symptoms (shortness of breath, limb swelling, weakness, fatigue), causes (hypertension, coronary artery disease, valvular disease), disease progression, short- and long-term consequences (frequent hospitalizations, functional limitations), and the possibility of disease control through appropriate treatment. Misconceptions held by patients will also be identified and corrected. Techniques such as feedback provision, concrete examples, sharing experiences of successful patients, and short-term goal setting (e.g., weight loss, blood pressure control) will be employed.Session 2:After reviewing the content of the first session, this session emphasizes self-care aspects including adherence to an appropriate diet (reducing salt and fat intake), correct medication use, physical activity suitable to cardiac status, and stress management. Training in effective communication skills, managing negative emotions, and correcting negative disease-related thoughts (such as "my disease is incurable") will also be conducted. This session will also include a Q&A addressing patients' uncertainties and daily experiences in disease management.Session 3:This session will review previous sessions and assess patients' understanding of the disease and behavioral changes. Education on coping strategies for stress, anxiety, and depressive symptoms, psychological consequences of the disease, the importance of continuous medication adherence, and regular medical follow-up will be provided. Barriers and challenges to treatment adherence and self-care will be identified and practical solutions offered. At the end of this session, a comprehensive educational brochure containing information about the disease, diet, exercise, medication, warning signs, stressors, and their management will be given to the intervention group patients. To uphold ethical principles, this brochure will also be provided to the control group patients after the study is completed.Follow-up:Patients will be evaluated at three time points: immediately after hospital discharge, one month after discharge, and three months after discharge through telephone calls and in-person visits at the clinic. The health literacy and treatment adherence questionnaires will be re-administered at each stage.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of qazvin University of Medical Sciences

Street address
Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin

City
qazvin

Province
Qazvin

Postal code
15315-34199

Approval date
2025-07-08, 1404/04/17

Ethics committee reference number
IR.QUMS.REC.1404.115

Health conditions studied

1

Description of health condition studied
Patients with heart failure

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Health literacy

Timepoint
"Before the intervention, one month after the intervention, three months after the intervention."

Method of measurement
Health literacy questionnaire

2

Description
Adherence

Timepoint
"Before the intervention, one month after the intervention, three months after the intervention."

Method of measurement
Heart Failure Adherence Questionnaire

Secondary outcomes

1

Description
Illness perception

Timepoint
"Before the intervention, one month after the intervention, three months after the intervention."

Method of measurement
Illness perception questionnaire

Intervention groups

1

Description
Intervention group: , in addition to routine care, will receive an educational intervention based on Leventhal's self-regulation model, delivered individually and face-to-face during three sessions of 30 to 40 minutes each during hospitalizationEducational Sessions:Session 1:The content focuses on enhancing patients' understanding of the disease, including explanations about the nature of heart failure, symptoms (shortness of breath, limb swelling, weakness, fatigue), causes (hypertension, coronary artery disease, valvular disease), disease progression, short- and long-term consequences (frequent hospitalizations, functional limitations), and the possibility of disease control through appropriate treatment. Misconceptions held by patients will also be identified and corrected. Techniques such as feedback provision, concrete examples, sharing experiences of successful patients, and short-term goal setting (e.g., weight loss, blood pressure control) will be employed.Session 2:After reviewing the content of the first session, this session emphasizes self-care aspects including adherence to an appropriate diet (reducing salt and fat intake), correct medication use, physical activity suitable to cardiac status, and stress management. Training in effective communication skills, managing negative emotions, and correcting negative disease-related thoughts (such as "my disease is incurable") will also be conducted. This session will also include a Q&A addressing patients' uncertainties and daily experiences in disease management.Session 3:This session will review previous sessions and assess patients' understanding of the disease and behavioral changes. Education on coping strategies for stress, anxiety, and depressive symptoms, psychological consequences of the disease, the importance of continuous medication adherence, and regular medical follow-up will be provided. Barriers and challenges to treatment adherence and self-care will be identified and practical solutions offered. At the end of this session, a comprehensive educational brochure containing information about the disease, diet, exercise, medication, warning signs, stressors, and their management will be given to the intervention group patients. To uphold ethical principles, this brochure will also be provided to the control group patients after the study is completed.

Category
Behavior

2

Description
Control group: receive routine care training

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Social Security Hospitals of Qazvin
Full name of responsible person
Atefeh Alizadeh risani
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+98 28 3366 5009
Email
info@qazvin.tamin.ir
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Mohammad Ali Soleimani
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Phone
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Email
info@qums.ac.ir
Web page address
http://www.qums.ac.ir/

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
Atefeh Alizadeh risani
Position
student
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Position
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Latest degree
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Other areas of specialty/work
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atefehalizaddeh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Complete data are shareable after proper anonymization procedures.

When the data will become available and for how long
Following the publication of the main study results

To whom data/document is available
Academic and research institution scholars

Under which criteria data/document could be used
-

From where data/document is obtainable
Atefeh Alizadeh risani email: atefehalizaddeh@yahoo.com

What processes are involved for a request to access data/document
Request via email - Typically responded to within approximately 10 days.

Comments
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