Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of education based Leventhal's self-regulation model versus control group on self-care and quality of life in patients with heart failure: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of education based Leventhal's self-regulation model versus control group on self-care and quality of life in patients with heart failure

Design
This is a randomized clinical trial with control group, in which eligible 102 patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct
This study will be performed in the Farshchian Heart Hospital in Hamadan city on 102 eligible patients. The patients will be randomly assigned to the intervention (routine care plus educational sessions) and control (just routine care) groups through the block randomization of four. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 25 to 70 years Heart failure Heart ejection fraction less than 50% Persian language Exclusion criteria: Hearing or vision impairment Medical education background

Intervention groups
Intervention group: Routine cardiac care plus training session using individual Leventhal's self-regulatory model and face to face for 60 minutes daily for 4 days (4 training sessions) including description of the nature of heart failure disease, its symptoms and related causes, consequences the disease, the disease course, and how to control and care for the disease. Control group: Just routine cardiac care

Main outcome variables
Primary outcome: Self-care, quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N426**
Registration date: **2022-05-17, 1401/02/27**
Registration timing: **prospective**

Last update: **2022-05-17, 1401/02/27**
Update count: **0**

Registration date
2022-05-17, 1401/02/27

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-31, 1401/03/10

Expected recruitment end date
2022-09-22, 1401/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of education based Leventhal's self-regulation model versus control group on self-care and quality of life in patients with heart failure: a randomized clinical trial

Public title
Effect of education based Leventhal's self-regulation model versus control group on self-care and quality of life in patients with heart failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 25 to 70 years Heart failure Heart ejection fraction less than 50% Persian language
Exclusion criteria:
Hearing or vision impairment Medical education background
Age
From **25 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **102**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2022-05-07, 1401/02/17
Ethics committee reference number
IR.UMSHA.REC.1401.167

Health conditions studied

1

Description of health condition studied
Heart failure
ICD-10 code
I50
ICD-10 code description
Heart failure

Primary outcomes

1

Description
Self-care
Timepoint
Before the intervention and 2 months after that
Method of measurement
Using the Jaarsma Questionnaire

2

Description
Quality of life
Timepoint
Before the intervention and 2 months after that
Method of measurement
Using the Minnesota Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine cardiac care plus training session using individual Leventhal's self-regulatory model and face to face for 60 minutes daily for 4 days (4 training sessions) including description of the nature of heart failure disease, its symptoms and related causes, consequences the disease, the disease course, and how to control and care for the disease.

Category
Treatment - Other

2

Description
Control group: Just routine cardiac care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Heart Hospital in Hamadan city
Full name of responsible person
Arezoo Seyrafi Dalir
Street address
Farshchian Heart Hospital, Shahid Fahmideh Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
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Arezoo Seyrafi Dalir
Position
Student of Nursery
Latest degree
Master
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Jalal Poorolajal

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Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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