

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 81 1838 0090

##### Email address

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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**  
Arezo Seyrafi Dalir

**Street address**  
Farshchian Heart Hospital, Shahid Fahmideh Ave.

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arezo.seyrafidalir@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences

**Full name of responsible person**  
Dr. Reza Shokoohi

**Street address**  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

**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

**Full name of responsible person**  
Arezo Seyrafi Dalir

**Position**  
Student of Nursery

**Latest degree**  
Master

**Other areas of specialty/work**  
Nursery

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences

**Full name of responsible person**  
Dr. Azim Azizi

**Position**  
PhD in Nursery

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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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