Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Orem-based self-care education on self-management and readmission in elderly patients with Chronic Heart Failure, Fasa 1403

Protocol summary

Study aim
Determining the effect of training based on the Orem self-care model on self-management ability and readmission in elderly people with heart failure in Fasa city, 2014

Design
A randomized, single-blind clinical trial with two intervention groups and a control group. 60 elderly patients with heart failure. Simple random assignment of the sample to the intervention and control groups.

Settings and conduct
CCU and post-CCCU departments of Hazrat Vali Asr (A.T.) Medical Education Center, Fasa University of Medical Sciences. In the intervention group, in addition to the usual ward care, a self-care educational program was provided in the form of 4 sessions, each session lasting 10-60 minutes. The study was single-blind (participants).

Participants/Inclusion and exclusion criteria
. Exclusion criteria included the occurrence of specific mental and physical disorders, patient death, failure to participate in educational sessions, incomplete questionnaires, and unwillingness to continue cooperation.

Intervention groups
In the intervention group, in addition to the usual ward care, a self-care educational program will be held in the form of 4 sessions, each session lasting 10-60 minutes, in the morning/afternoon shift, for as long as the patient is hospitalized in the hospital. In the control group, no intervention will be performed during the hospitalization period and they will be under the usual ward care and education.

Main outcome variables
Self-management and readmission

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250713066477N1**
Registration date: **2025-09-28, 1404/07/06**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-28, 1404/07/06**
Update count: **0**

Registration date
2025-09-28, 1404/07/06

Registrant information

Name
Zahra Rahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 917 264 8225

Email address
rahimizahra318@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-21, 1404/05/30

Expected recruitment end date
2025-12-21, 1404/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Orem-based self-care education on self-management and readmission in elderly patients with Chronic Heart Failure, Fasa 1403

Public title
The effect of education based on the Orem self-care model on self-management ability and readmission in elderly patients with heart failure.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a diagnosis of heart failure according to the New York Age 60 years and older Residence in the city of Fasa Minimum literacy Full patient consent No history of participating in previous documented educational programs in the field of the current disease No surgery in the past semester No chronic diseases in the final stages (chronic liver, kidney and lung diseases and cancer), and no mental, cognitive and psychological disorders
Exclusion criteria:
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The sample allocation to the intervention and control groups is simple randomization, such that in an envelope, there are... cards with the letters A written on one card and B written on the other. Patients who met the criteria for entry into the intervention are asked to pick one card, patients who pick card A will be placed in the intervention group, and patients who pick card B will be placed in the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants do not know they are in the intervention/control group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Fasa University of Medical Sciences
Street address
Ibn Sina Square
City
Fasa
Province
Fars
Postal code
7461686688
Approval date
2025-04-14, 1404/01/25
Ethics committee reference number
IR.FUMS.REC.1404.015

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-management
Timepoint
Before the intervention/immediately and three months later
Method of measurement
Questionnaire

2

Description
Readmission
Timepoint
Before the intervention/immediately and three months later
Method of measurement
Checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, in addition to the usual ward care, a self-care educational program will be held in the form of 4 sessions, each session lasting 10-60 minutes, in the morning/afternoon shift, as long as the patient is hospitalized. The education will be conducted face-to-face, with lectures and answers to

possible questions for the patient and the patient's caregiver. The sessions will be interactive and based on self-care behavior and individual needs assessment regarding self-care and self-management of the disease through examining barriers and problem solving in the presence of the patient and caregiver.

Category
N/A

2

Description
Control group: In the control group, no intervention will be performed during hospitalization and they will be subject to routine ward care and education.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr Hospital

Full name of responsible person
Mostafa Bijani

Street address
Ibn Sina Square

City
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Province
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Postal code
7461686688

Phone
+98 917 330 8451

Email
bizhani_mostafa@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Fasa University of Medical Sciences

Full name of responsible person
Mojtaba Farjam

Street address
Ibn Sina Square

City
Fasa

Province
Fars

Postal code
7461686688

Phone
+98 917 710 4789

Email
farjam@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Fasa 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
Fasa University of Medical Sciences

Full name of responsible person
Mostafa Bijani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Ibn Sina Square

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bizhani_mostafa@yahoo.con

Person responsible for scientific inquiries

Contact

Name of organization / entity
Fasa University of Medical Sciences

Full name of responsible person
Mostafa Bijani

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Mostafa Bijani
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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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
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All the questionnaires used in this study as well as the content of the training program will be provided to the applicants.
When the data will become available and for how long
The time period for accessing the data is after the publication of the article extracted from the study and there is no time limit.
To whom data/document is available
Researchers, nursing managers and hospital management can send their request to use the results of this research to the responsible author Mostafa Bijani in writing. Tell: 09173308451
Email:bizhani_mostafa@yahoo.com
Under which criteria data/document could be used
Nursing managers can use the results of this research to develop training programs for patients and patients' families
From where data/document is obtainable
Researchers can send their request to use the results of this research to the responsible author Mostafa Bijani in writing. Tell: 09173308451
Email:bizhani_mostafa@yahoo.com
What processes are involved for a request to access data/document
Sending the request for the use of research documents and results to the responsible author and sending the results by the responsible author to the requesting person Tell: 09173308451
Email:bizhani_mostafa@yahoo.com
Comments