Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Personalized Self-management Program on Self-Care and Rehospitalization of Inpatients with Heart Failure

Protocol summary

Study aim
Determination of the Effect of Personalized Self-management Program on Self-Care and Rehospitalization of Inpatients with Heart Failure

Design
A clinical trial, randomised, with control group, with a sample size of 84 patients with heart failure

Settings and conduct
The samples will be selected by convenience sampling based on the inclusion criteria from the patients hospitalized in educational hospitals of Shahrekord; Then they will be divided into 2 groups (intervention and control) according to random allocation rule.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Consent to participate in study, Confirmed medical diagnosis of heart failure, Ability to speak or write, Age: 18-60, Ejection fraction <55%; Exclusion criteria: Physical disability, Psycho-cognitive illness, Participation in similar training sessions, Decreased level of consciousness

Intervention groups
Intervention group: The educational sessions will be held for a total of 60 minutes (in 3 consecutive daily sessions). The first session will be face-to-face. During the next two sessions, a personalized pamphlet, tailored to each individual, will be reviewed with the patient. All developed educational materials will be derived from each patient's questionnaire. These trainings include adhering to recommended diets based on the patient's weight, regulating activities (based on age, gender, occupation, cardiac ejection fraction, and stage of the disease), adhering to the medication regimen and learning about their side effects, controlling smoking, identifying symptoms of the disease and adhering to training. About 60 days after the patients' discharge, a review of previous training and answering the patients' questions will be provided by the researchers. Control group: patients will only receive routine care and education.

Main outcome variables
Self-Care, Readmission Risk, Readmission

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250123064495N2**
Registration date: **2025-08-10, 1404/05/19**
Registration timing: **prospective**

Last update: **2025-08-10, 1404/05/19**
Update count: **0**

Registration date
2025-08-10, 1404/05/19

Registrant information
Name
Majid Heidary Farsani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 38 3322 2646
Email address
st-heidary@skums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-09-17, 1404/06/26
Expected recruitment end date
2025-11-17, 1404/08/26
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Personalized Self-management Program on Self-Care and Rehospitalization of Inpatients with Heart Failure

Public title
The effect of personalized self-management in patients with heart failure

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Consent to participate in study Confirmed medical diagnosis of heart failure Ability to speak or write Ability to speak in Persian Age: 18-60 Having a mobile or landline phone Ejection fraction <55% according to the result of the echocardiography report

Exclusion criteria:
Physical disability Psycho-cognitive illness Participate in similar training sessions Decreased level of consciousness

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
This study will be conducted in two university hospitals with 84 participants. The samples will be selected from inpatients in the cardiac and internal medicine departments of educational hospitals in Shahrekord using convenience sampling. Eligible patients will be divided into two groups using the block randomization method: intervention (A) and control (B). The randomized block procedure will be performed as follows: 1) All possible block states -created with the combination of AAABBB - labeling: AAABBB, ABBABA, BABABA, etc. will be written, 2) Written blocks will be provided in sealed envelopes, 3) One of the envelope will be be selected by a neutral person, and the six-letter combination will be noted down and then placed back in the box, 4) This process will be repeated 14 times to achieve a sequence of letters from 1 to 84, 5) Numbers from 1 to 84 will be assigned to each letter (A, B), and these numbers written on sealed envelopes. 6) At the beginning of sampling, the sealed envelopes will be opened and assigned to the patients. Participants will be randomly assigned to the intervention group or the control group according to the selected letters.

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 Shahrekord University of Medical Sciences

Street address
Shahrekord University of Medical Sciences Headquarters, Ayatollah Kashani Blvd

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Approval date
2025-05-20, 1404/02/30

Ethics committee reference number
IR.SKUMS.REC.1404.033

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, immediately and 3 months after intervention

Method of measurement
Self-Care of Heart Failure Index

2

Description
readmission risk

Timepoint
3 months after intervention

Method of measurement
Readmission risk questionnaire

3

Description
readmission
Timepoint
3 months after intervention
Method of measurement
Asking from patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After completing the questionnaires and reviewing their information, educational sessions will be held for a total of 60 minutes (in 3 consecutive daily sessions). The first session will be conducted face-to-face, with the patient's family member present, and the researchers will answer their questions. In the first session, only the contents of the general information booklet will be reviewed. In the next two sessions, which will be held virtually, in addition to reviewing the most important previous materials, a personalized pamphlet, tailored to each individual, will be reviewed with the patient. All developed educational materials will be derived from each patient's questionnaires, including adhering to recommended diet based on the patient's weight, regulation of activities (depending on age, gender, occupation, ejection fraction of the heart and stage of the disease), adherence to the medication regime and familiarisation with side effects, control of smoking based on individual habits, recognition of disease symptoms and adherence to training. If the patient is discharged during this period, the training will be conducted virtually by the researchers. To ensure that patients understand the material, all patients will receive an educational pamphlet, and researchers will receive regular feedback from patients during the training. Patients will also be asked to practically measure blood pressure and pulse rate, adjust the prescribed medication dosage, and monitor signs and symptoms. Finally, the researchers will correct their weaknesses. In the intervention group, 60 days after the patients are discharged, a review of the previous training will be held, and the researchers will answer the patients' questions. Then, depending on the patient's needs, the patient's or family's questions will be answered, and positive feedback will be given on their strengths.
Category
Behavior

2

Description
Control group: The control group will receive only routine care; No post-discharge education will be provided in this group.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Kashani Hospital
Full name of responsible person
Majid Heidary Farsani
Street address
Kashani Hospital, Parastar Avenue, Shahrekord
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr. Seyed Mohammad Omrani, Research Deputy of Shahrekord University of Medical Sciences
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Mostafa Roshanzadeh

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Name of organization / entity
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Position
Master student

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Nursery

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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