

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effect of empowerment program on self-care behaviors and re-admission of patients with heart failure

Protocol summary

Study aim

Evaluate of empowerment program effect on self care behaviors and readmission of patients with heart failure

Design

Randomized control trial with an empowerment program and outcome assessment

Settings and conduct

In this study, patients referred to the clinic of Masih Daneshvari Hospital in Tehran with heart failure will be identified and after obtaining informed consent, they were randomly assigned to a blocked intervention or control group. Then the level of self-care measures for both groups is evaluated. In this study for the intervention group carried out the empowerment plan includes a curriculum package and a face-to-face training along with telephone follow up but no action is taken in the control group. After 6 months, the level of self care measures and readmission is evaluated for both groups and the groups are compared

Participants/Inclusion and exclusion criteria

Ejection fraction below 40% Voluntary to participate in research Age older than 18 years Patients with heart failure grade 2, 3 or 4 according to American Heart Association criteria and cardiologist diagnosis Reading and writing skills Having a smartphone and the ability to use it himself or caregiver

Intervention groups

The patient with cardiac failure referred to clinic

Main outcome variables

The rate of self care measures and readmission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110704006946N2**

Registration date: **2018-08-07, 1397/05/16**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-07, 1397/05/16**

Update count: **0**

Registration date

2018-08-07, 1397/05/16

Registrant information

Name

mansour dianaty

Name of organization / entity

kashan university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 36 1557 8645

Email address

dianati_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2018-11-06, 1397/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of empowerment program on self-care behaviors and re-admission of patients with heart failure

Public title

"Effect of empowerment program on Self-care behaviors"

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Ejection fraction < 40% Inclination to participate in research Age older than 18 years Patients with heart failure grade 2, 3 or 4 according to American Heart Association criteria and cardiologist diagnosis Reading and writing skills Having a smartphone and the ability to use it himself or caregiver

Exclusion criteria:
Participating simultaneously in another similar study The presence of hearing and vision problems according to the biography contained in the case and the patient's or family's remarks

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, pezeshek Blvd.

City

Kashan

Province

Isfahan

Postal code

8715985131

Approval date

2018-02-03, 1396/11/14

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1396.32

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

150.0

ICD-10 code description

Congestive heart disease

Primary outcomes

1

Description

The score obtained from " Self Care Heart Failure Index" questionnaire and hospital readmission

Timepoint

At beginning of study and 6 month later of that

Method of measurement

Self Care Heart Failure Index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study for the intervention group carried out the empowerment plan includes a curriculum package and a face-to-face training along with telephone follow up.

Category

Other

2

Description

Control group: no action is taken in the control group but only evaluating of selfcare in two time.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

sara Rezaei

Street address

Masih Daneshvari Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Kashan 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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Position
Nurse
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Person responsible for updating data

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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