

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of self-management promotion model on quality of life and self-efficacy of patients with chronic heart failure.

Protocol summary

Quality of life and self-efficacy of patients with chronic heart failure

Study aim

The effect of self-management promotion model on quality of life and self-efficacy of patients with chronic heart failure discharged from Kashan Shahid Beheshti Hospital.

Design

A controlled, non-blinding, randomized clinical trial will be performed on 56 patients with chronic heart failure. A random number table will be used for randomization.

Settings and conduct

This study will be performed on patients with chronic heart failure discharged from Kashan Shahid Beheshti Hospital. In the intervention group, the self-management promotion model will be implemented. This model is in 6 steps. The intervention will be held in eight sessions (two sessions per week, each session for 20 minutes in one month). Data will be collected using a three-part questionnaire including demographic characteristics, minnesota living with heart failure questionnaire (MLHFQ), and the sullivan cardiac self-efficacy questionnaire at three-time intervals (before, immediately, and one month after intervention).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) consent to participate in the present study, 2) age 18 to 65 years, 3) a definitive diagnosis of heart failure at discharge (Class 2 (EF=30% to 45%) and 3 (EF <30%) Heart failure), 4) classes 2 and 3 based on the New York Heart Failure Criterion, 5) having a medical sphygmomanometer and scales, 6) ability to call and follow up
Non-inclusion criteria: 1) patients with underlying diseases such as chronic renal failure, liver cirrhosis in the past month, and cancer, 2) have mental illness, 3) inability to self-care, and 4) participate in another study at the same time.

Intervention groups

Conventional care will be performed in the control group. In the intervention group, the self-management promotion model will be implemented.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201018049059N1**

Registration date: **2021-05-31, 1400/03/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-31, 1400/03/10**

Update count: **0**

Registration date

2021-05-31, 1400/03/10

Registrant information

Name

Mohammad Javad Ghazanfari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3320 7545

Email address

javad.ghazanfari12@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-08-06, 1400/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-management promotion model on quality of life and self-efficacy of patients with chronic heart failure.

Public title

The effect of self-management promotion model on quality of life and self-efficacy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the present study Age 18 to 65 years A definitive diagnosis of heart failure at discharge (Class 2 (EF=30% to 45%) and 3 (EF <30%) Heart failure) Classes 2 and 3 based on the New York Heart Failure Criterion Having a medical sphygmomanometer and scales Ability to call and follow up

Exclusion criteria:

Patients with underlying diseases such as chronic renal failure, liver cirrhosis in the past month, and cancer. Have mental illness. Inability to self-care. Participate in another study at the same time.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by permuted block randomization method. First, 6 blocks of 4 consisting of two letters A and B will be prepared and we will assign a number from 1 to 6 to each of them. Then, using the random number table, the numbers 1 to 6 are selected (15 numbers). Finally, a sequence of 60 letters A and B will be obtained. Each sample will have a number from 1 to 60 if they include the present study, and each person will receive an A or B code based on the number in the list. Also, blinding will not be done due to face-to-face training.

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 Kashan University of Medical Sciences

Street address

Isfahan, Kashan, Ghotb Ravandi Blvd., Hekmat 56, Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

87159-73474

Approval date

2021-01-11, 1399/10/22

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1399.079

Health conditions studied

1

Description of health condition studied

Chronic Heart Failure Patients

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

Quality of life

Timepoint

In three time periods (before, immediately, and one month after the intervention)

Method of measurement

Minnesota Living with Heart Failure Questionnaire

2

Description

Self-efficacy

Timepoint

In three time periods (before, immediately, and one month after the intervention)

Method of measurement

Sullivan Cardiac Self-Efficacy Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The self-management promotion model will be implemented in the intervention group. This model includes steps 1) case selection, 2) identifying patients' problems, 3) formulating a care plan, 4) implementing the intervention, 5) evaluation and 6) continuous monitoring of the patient's condition. The intervention will be held in eight sessions (two sessions per week, each session for 20 minutes in one month). Data will be collected using a three-part questionnaire including demographic characteristics, Minnesota Living with Heart Failure Questionnaire (MLHFQ), and Sullivan Cardiac Self-Efficacy Questionnaire at three time periods (before, immediately, and one month after the intervention). Educational content will be provided to participants using pamphlets, booklets, and educational videos.

Category

Rehabilitation

2

Description

Control group: Eligible participants in the control group will receive conventional care. Conventional care includes in-hospital and discharges training according to Brunner & Suddarth's Medical-Surgical Nursing 14th Ed (2018) in relation to disease-related care such as diet, nutrition, fluid intake, possible complications of the disease. In the present study, these trainings are provided by the researcher. Patients will complete the questionnaires in person before providing routine care. The researcher will also follow up on participants' quality of life and self-efficacy in the eighth week by asking questions via telephone.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Kashan

Full name of responsible person

Mohammad Javad Ghazanfari

Street address

Qotb-e Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

87159 88111

Phone

+98 31 5554 0026

Email

javad.ghazanfari12@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Reza Afazel

Street address

Qutb Ravandi Boulevard

City

Kashan

Province

Isfahan

Postal code

87159-73474

Phone

+98 31 5544 3022

Email

mohammadrezaafazel1338@gmail.com

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

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Javad Ghazanfari

Position

Student Research Committee

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Isfahan Province, Kashan, Qutb Ravandi Blvd, hekmat 56, Kashan University of Medical Sciences and Health Services

City

Kashan

Province

Isfahan

Postal code

87159-73474

Phone

+98 11 3320 7545

Fax

Email

Javad.ghazanfari12@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Javad Ghazanfari

Position

Student Research Committee

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Isfahan Province, Kashan, Qutb Ravandi Blvd, hekmat 56, Kashan University of Medical Sciences and Health Services

City

Kashan

Province

Isfahan

Postal code

87159-73474

Phone

+98 11 3320 7545

Fax

Email

Javad.ghazanfari12@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Javad Ghazanfari

Position

Student Research Committee

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Isfahan Province, Kashan, Qutb Ravandi Blvd, hekmat 56, Kashan University of Medical Sciences and Health Services

City

Kashan

Province

Isfahan

Postal code

87159-73474

Phone

+98 11 3320 7545

Fax

Email

Javad.ghazanfari12@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers in the field of hemodialysis on request

From where data/document is obtainable

Contact the authors of the present study via email of the corresponding author. Email:

Javad.ghazanfari12@gmail.com.

What processes are involved for a request to access data/document

Contact the authors of the present study via email of the corresponding author. Email:

Javad.ghazanfari12@gmail.com.

Comments