Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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

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

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)

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+98 11 3320 7545

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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
Isfehan

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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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

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

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

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Person responsible for scientific inquiries

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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