

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of the effect of individually designed energy conservation training on self-care empowerment and quality of life of patients with heart failure

Protocol summary

Study aim

Determining the impact of the individually designed energy conservation training program on empowering self-care and quality of life in heart failure patients

Design

Clinical trial with control group, with parallel, uncorrected, randomized block of 4 on 66 patients

Settings and conduct

The training program for the test group will be designed and implemented based on the results of the analysis of the findings and individual interview with the patient and a member of the patient's family. In the heart clinic, heart ward and CCU ward of Khorramabad Ashayer and Madani Hospital

Participants/Inclusion and exclusion criteria

Having heart failure with class 2, 3 and 4 2. Patients over 18 years old 3. Ejection fraction below 45% 4. Familiarity with Persian language 5. Full alertness and awareness of time and place 6. Having a moderate to poor self-care score. 7. Having a quality of life score higher than 24

Intervention groups

For patients in the intervention group, 4 face-to-face training sessions of 30 minutes per person will be performed every 3 weeks. Patients in the control group will receive routine nursing training after discharge or routine clinic training.

Main outcome variables

Increasing the level of awareness of patients with heart failure, improving self-care, improving the quality of life, increasing the independence of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220612055150N1**

Registration date: **2022-07-06, 1401/04/15**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-06, 1401/04/15**

Update count: **0**

Registration date

2022-07-06, 1401/04/15

Registrant information

Name

Maryam Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3343 4750

Email address

mari01taheri06@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-28, 1401/04/07

Expected recruitment end date

2022-07-18, 1401/04/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of individually designed energy conservation training on self-care empowerment and quality of life of patients with heart failure

Public title

Evaluation of the effect of individually designed education on empowerment of heart failure patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having heart failure with class 3, 2 and 4 according to the classification of the New York Heart Association with the diagnosis and confirmation of the relevant doctor. Patients over 18 years old Ejection fraction below 45% Familiarity with Persian language Full alertness and awareness of time and place Having a self-care score of 29 to 60 which is moderate to poor self-care (32) Having a quality of life score higher than 24 which is average and poor quality of life (34)

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization of 4 pieces, we have 6 blocks of 4 pieces, which according to the sample size, we randomly select 17 times from these 6 blocks. In the 4 pieces blocks, A is the intervention group and B is the control group.

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 Jundishapur Ahvaz University of Medical Sciences

Street address

Unit 4, Faraz Building, Shokoofeh St., Imam Square

City

Khoramabad

Province

Lorestan

Postal code

6813918975

Approval date

2022-05-28, 1401/03/07

Ethics committee reference number

IR.AJUMS.REC.1401.079

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

Quality of life score and self-care score of heart failure patients

Timepoint

The beginning of the study and 12 weeks later

Method of measurement

European Heart Failure Self-Care Behavior Questionnaire and Minnesota Quality of Life Questionnaire with Heart Failure

Secondary outcomes

1

Description

Quality of life score

Timepoint

At the beginning of the study and 12 weeks after the study

Method of measurement

Minnesota Heart Failure Quality of life Questionnaire with 21 questions

Intervention groups

1

Description

Intervention group: For patients in the intervention group, 4 face-to-face training sessions of 30 minutes will be conducted for each person every 3 weeks. (The first session, The third week, The six week and the ninth week will be in the CCU, cardiology department or outpatient cardiology clinics). In the first session, prioritized trainings will be provided for each patient based on the needs assessment obtained from the information of the questionnaires in the form of face-to-face training and questions and answers. At the end of the first session, patients are emphasized on registering edema in the lower extremities, number of times sitting during the

day, recording posture after doing housework, walking, climbing stairs, sleeping position, performing daily activities, recording shortness of breath, anxiety And depression in the notebook and present it to the next session or send via SMS to the researcher. In this case, the patient is encouraged to perform self-monitoring actions and doing these things becomes a daily routine for the patient and his family. In the second, third and fourth sessions, according to the patient's records of his condition, the trainings will be repeated in the areas required by the patient and the patient's possible questions will be answered.

Category

Other

2**Description**

Control group: Patients of the control group will receive routine nursing training after discharge or routine clinic training.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ashayer Hospital and Madani Hospital

Full name of responsible person

Maryam Taheri

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnosh zakerkish

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Ground floor, Vice Chancellor for Research and Technology, Ahvaz University of Medical Sciences, University City, Golestan Blvd.

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Maryam Taheri

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Marziyah Asadizaker

Position

professor

Latest degree

Ph.D.

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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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Individual data of participants, information on the main outcome

When the data will become available and for how long

Start data access 3 months after printing results

To whom data/document is available

Researchers and students in academic institutions

Under which criteria data/document could be used

Use documentation in an article or dissertation

From where data/document is obtainable

By e-mail address

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

Apply by e-mail and it will be sent within 15 days

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Maryam Taheri

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

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