Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 class2, 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

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Iran (Islamic Republic of)

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+98 66 3343 4750

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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 conduced 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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Khyrabad, Shghayegh Square

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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

Street address

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

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Full name of responsible person

Marziyah Asadizaker

Position

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Person responsible for updating data

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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