Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of tailored education of energy conservation on Fatigue level and hospitalization times in patients with heart failure

Protocol summary

Study aim
Determination of the Effect of a Designed Energy Conservation Program on Fatigue and Frequency Admission in Patients with Heart Failure

Design
The present study is a clinical trial with a control group with parallel random groups of 48 people. The intervention is done by random assignment method using randomized permutable blocks with size 6 block (using a random permutation table).

Settings and conduct
This study is a randomized controlled clinical trial study. Which will be conducted in the CCU sections of the educational hospitals and outpatient clinics of the educational hospitals, which will be evaluated for 48 patients with heart failure. The fatigue measurement scale will be used in the pre-test to determine the fatigue level with both groups. After collecting pre-test data, the educational program is designed and implemented based on the results of the analysis of the findings and the individual interview with the patient and one of the family members of the patient. After the intervention, the severity of fatigue and the frequency of hospitalization of the patients were recorded and Checked out.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1 - Sustained heart failure with Classes 2, 3 and 4 according to the classification of the New York Heart Association with the diagnosis and approval of the relevant physician. 2. Ejection fraction below 45% 3. Having heart failure for at least 6 weeks 4. Having fatigue more than 18 (moderate and severe) Exclusion criteria Missing more than one training session

Intervention groups
The intervention group receive 12 weeks of appropriate educational support programs, including five face-to-face training sessions of 45 minutes per person. The control group will receive routine training and will not receive new training.

Main outcome variables
Energy conservation in patients

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20171203037737N3**
Registration date: **2019-04-08, 1398/01/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-08, 1398/01/19**
Update count: **0**

Registration date
2019-04-08, 1398/01/19

Registrant information
Name
sedighe ghobadian
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 3320 9717
Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-03-06, 1397/12/15
Expected recruitment end date
2019-05-22, 1398/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of tailored education of energy conservation on Fatigue level and hospitalization times in patients with heart failure

Public title
Effect of education on Fatigue level and hospitalization times in patients with heart failure

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Sustained heart failure with grades 2, 3 and 4 based on the classification of the New York Heart Association with the diagnosis and approval of the relevant physician. Ejection fraction below 45% Heart failure for at least 6 weeks Familiarity with Farsi Having a fatigue score of 18 (moderate and severe) Complete vigilance and awareness of time and place

Exclusion criteria:
Sustained heart failure with grades 2, 3 and 4 based on the classification of the New York Heart Association with the diagnosis and approval of the relevant physician. Ejection fraction below 45% Having a fatigue score of 18 (moderate and severe)

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method will be run by randomized block method, which will be executed using block size 6 (using a random permutation table).

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz jundishapur University of Medical Sciences

Street address
Ahvaz.Golestan.

City
Ahvaz

Province
Khouzestan

Postal code
15794-61357

Approval date
2019-02-16, 1397/11/27

Ethics committee reference number
IR.AJUMS.REC.1397.871

Health conditions studied

1

Description of health condition studied
Heart failure

ICD-10 code
I50.2

ICD-10 code description
Systolic (congestive) heart failure

Primary outcomes

1

Description
Fatigue Score in the Crap Questionnaire

Timepoint
At regular intervals from the time of pretest (before the intervention) up to 3 months after the pretest

Method of measurement
Krupp Fatigue Severity Scale

2

Description
hospitalization times

Timepoint
In two separate periods of 1.5 months and 3 months

Method of measurement
Quantitative and according to the frequency of admission to the follow-up period

Secondary outcomes

1

Description
The ability to maintain energy

Timepoint
At regular intervals from the time pre-test (before intervention) up to three months after pre-test

Method of measurement
Krupp Fatigue Severity Scale

Intervention groups

1

Description
Intervention group: Patients in the intervention group will receive 12 weeks of appropriate educational support program that will be tailored to each individual patient's situation, including five 45-minute face-to-face training sessions for each person. (First visit, and every three weeks a training session after the first visit and for the first 12 weeks of the first visit, the third week, the sixth week, the ninth week and the twelfth week in the ccu section or the outpatient clinics of the heart and the vascular)
Category
Rehabilitation

2

Description
Control group: The control group received routine training, including oral instructions from the department or clinic for heart failure, and will receive no new training.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
CCU departments and outpatient clinics in Ahvaz educational hospitals
Full name of responsible person
Marzieh Asadizaker
Street address
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marziyehasadizaker@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Marzieh Asadizaker
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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
50
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
Leila Haghighii
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Position
Assistant Professor

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Person responsible for updating data

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Full name of responsible person
simin Jahani

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Assistant Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Information about patients will be confidential.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
No - There is not 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
Data on the main outcome of the study will be published in the article.

When the data will become available and for how long
Two months after the completion of the research

To whom data/document is available
Professors, researchers and students

Under which criteria data/document could be used
research

From where data/document is obtainable
Magazine site

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