

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

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Ahvaz.Golestan.

City

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Province

Khuzestan

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 Asadzaker

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz 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

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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Habib Haybar

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Specialist

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Person responsible for updating data

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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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Comments

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