

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Surrvey of educational exercise intervention efficiency based on social cognitive theory in patients empowerment diagnosed with heart failure

Protocol summary

Summary

The aim of this study is to evaluate educational exercise intervention efficiency based on social cognitive theory in patients empowerment diagnosed with heart failure. This study is parallel groups randomized clinical trial with pre/post design. All patients are recruited among patients diagnosed with cardiovascular disease who are referred to the cardiac rehabilitation in Isfahan Cardiovascular Research Center by a cardiologist. Of them 60 patients who meet the inclusion criteria (for example: EF less than 40% and NYHA Class II and Class III) recruited in the study. Participants are randomised to either intervention or control group through block randomisation using permuted blocks random numbers after baseline questionnaires and assessment are completed. At first, all patients are obtained informed consent form. Patients participate in cardiac rehabilitation program in both groups thrice for a week of eight weeks. For people in the intervention group, the research person also holds the weekly social cognitive theory-based educational sessions and face to face intervention during rehabilitation program. Content education covers self-management components, warning sign for heart failure, understanding risk for heart failure, what exercise you can do and how can you get your heart rate. Patient are ask to take walking, jogging, biking, calisthenics every week . The families are educated about their supportive role in patient exercise. Post rehabilitation assessment is done. Out come measures are conducted at one, three and six months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012113011616N1**

Registration date: **2013-01-03, 1391/10/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-03, 1391/10/14

Registrant information

Name

Fatemeh Rajati

Name of organization / entity

Isfahan University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Science

Expected recruitment start date

2012-03-08, 1390/12/18

Expected recruitment end date

2013-03-08, 1391/12/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Surrvey of educational exercise intervention efficiency based on social cognitive theory in patients empowerment diagnosed with heart failure

Public title

Effect of educational exercise intervention on heart failure

Purpose

Other

Inclusion/Exclusion criteria
 Inclusion criteria: (a) age 21 years or greater. (b) optimum medical therapy with no changes in medications within the past 30 days. (c) New York Heart Association (NYHA) Class II and Class III. (d) resting left ventricular ejection fraction < 40%. (e) able to speak and read Persian. (f) Willingness to participate in the study.
 Exclusion criteria: (a) clinical evidence of decompensated HF. (b) unstable angina pectoris. (c) orthopedic or neuromuscular disorders preventing participation in exercise and strength/resistance training.

Age
 From **30 years** old to **69 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **60**

Randomization (investigator's opinion)
 Randomized

Randomization description

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 Isfahan University of Medical Sciences

Street address

Medical university of Isfahan, Hezar jarib St. Isfahan, Iran

City

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Postal code

8174673461

Approval date

2012-03-05, 1390/12/15

Ethics committee reference number

391016

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

Physical activity

Timepoint

Before, after, one month, three months after intervention

Method of measurement

International Physical Activity Questionnaire (IPAQ)

2

Description

Quality of life

Timepoint

Before, after, one month, three months after intervention

Method of measurement

Minnesota Living with Heart Failure Questionnaire (MLHF)

Secondary outcomes

1

Description

Self-efficacy

Timepoint

before, after, one, and three months

Method of measurement

Cardiac Exercise Self-efficacy Questionnaire (CESE)

2

Description

Self-regulation

Timepoint

Before, after, one, and three months

Method of measurement

Exercise self-regulation questionnaire

3

Description

Outcome expectation

Timepoint

Before, after, one, and three months

Method of measurement

Exercise outcome expectation questionnaire

4

Description

Social support

Timepoint

Before, after, one, and three months
Method of measurement
Exercise social support questionnaire

5

Description

Ejection fraction

Timepoint

Before and after intervention

Method of measurement

Echocardiography

6

Description

Exercise tolerance

Timepoint

Before and after intervention

Method of measurement

Exercise tolerance test per METs

7

Description

Systolic blood pressure at rest

Timepoint

Before, after, one, and three months

Method of measurement

Per mm Hg using a mercury barometer

8

Description

Diastolic blood pressure at rest

Timepoint

Before and after intervention

Method of measurement

Per mm Hg using a mercury barometer

9

Description

Heart rate

Timepoint

Before, after, one, and three months

Method of measurement

Pulse rate in beats per minute

10

Description

Knowledge about for Heart Failure

Timepoint

Before, after, one, and three months

Method of measurement

The Patient Knowledge Questionnaire for Heart Failure Patients

Intervention groups

1

Description

Control group: Rehabilitation program for 8-week course of exercise (three 60-minute sessions per week). Frequency of steady state training is included 5-10 minutes sessions 3 times per week for more compromised patients; 20-30 minutes sessions 3 times per week for patients with good functional capacity. Intensity of training sessions is included initial phase that it is 40-50% peak VO₂, increasing duration from 5-15 minutes and in improvement phase that it is gradual increase to 60-80% peak VO₂, increasing duration to 15-20 minutes (up to 30 minutes as secondary goal). Patient work out in interval training by cycling and treadmill. Patients exercise in work phase of 30-120 seconds and recovery phase of 60-120 seconds at an intensity of 50% of maximum short term capacity (determined on exercise bike) by cycling. Heart failure patients work out with treadmill in work and recovery phases 60 seconds each. The cardiac rehabilitation is also included combination of nutritional counseling, medication follow-ups, stress management and depression counseling.

Category

Rehabilitation

2

Description

Intervention group: the intervention group are attended the weekly social cognitive theory-based educational sessions and face to face intervention during rehabilitation program. Content education covers self-management components, warning sign for heart failure, understanding risk for heart failure, what exercise you can do and how can you get your heart rate. Patients are encouraged to take walking, jogging, biking, calisthenics on nonrehabilitation days, because some patients who develop exhaustion after training may need a day of rest between sessions, these recommendations are offered by the specialist in sport medicine. The families are educated about their supportive role in patient exercise. Pamphlet, book, CD and other material about heart failure and exercise are provided for patients.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Cardiovascular Research Center

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr MOhammad Mahdi Amin

Street address

Isfahan, Hezar Jarib Str, Isfahan University of Medical Science

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Fatemeh Rajati

Position

phD candidate

Other areas of specialty/work

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PhD in communityHealth

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Person responsible for updating data

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Fatemeh Rajati

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PhD candidate

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty