Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 2026

Effects of exercise training on depressive symptoms in patients with heart failure, reffered to Cardiac rehabilitation center of Shafa Hospital, Kerman University of Medical Science in 2016

Protocol summary

Summary

In this clinical trial study, 60 patients with heart failure who are referred to cardiac rehabilitation centers are randomly placed to the intervention group (n = 30) and control (n = 30) . After permission from the Ethics Committee and registered in the Ministry of Health clinical trial site, the study begins. All patients voluntarily provide written informed consent and they will assure that their information would remain confidential and they would have the authority to opt out from the experiment at any stage of the research. In the intervention group exercise 3 times a week for 8 weeks (maximum of 40 minutes per session) will be done. Each session includes 5-10 minutes warm-up, 20-40 minutes supervised training phase and 5-10 minutes of cooling and relaxing will be. During the supervised training phase, patients will exercise on a treadmill, stationary cycling and rowing Ergometer under Remote Monitoring, and will be done by trained personnel under the supervision of physicians specializing in sports medicine . The investigators will estimate the intensity level of participants using the HR reserve (HRR) method, beginning at 50% intensity (based on HR and feelings of exertion) and progressing to 70% intensity for a maximum of 40 minutes, 3 times per week. All exercise sessions of patients will be supervise by the physician and trained nurses and under ECG monitoring. Control group just follow up during the study and Will not participate in any exercise programs and will continue their own normal life activities. Data collection of demographic questionnaire and will be PHQ8 before and after the study period, both groups will be filled. The data was analyzed with SPSS version 21 .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201605107844N10**
Registration date: **2016-05-25, 1395/03/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-25, 1395/03/05

Registrant information

Name
Mansour Arab
Name of organization / entity
Kerman University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of exercise training on depressive symptoms in patients with heart failure, reffered to Cardiac rehabilitation center of Shafa Hospital, Kerman University of Medical Science in 2016

Public title

Effects of exercise training on depressive symptoms in patients with heart failure

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria were aged 40-75 years with a confirmed diagnosis of heart failure due to left ventricular systolic dysfunction (New York Heart Association functional classes II and III) and a history of symptoms and signs of heart failure at least 6 months, with left ventricular ejection fraction of 40% or less. Patients were excluded if they had acute myocardial infarction within 3 weeks; unstable angina pectoris; serious rhythm disturbance; symptomatic peripheral vascular disease; severe obstructive pulmonary disease, with a forced expiratory vital capacity 50% of expected as measured by spirometry; Acute systemic illness or fever ,Recent embolism , Acute pericarditis or myocarditis ,Supine resting HR >100bp ,Uncontrolled diabetes ,Decrease in SBP with exercise ,uncontrolled hypertension (resting blood pressure ≥160 mm Hg systolic or ≥90 mm Hg. Patients were also excluded due to an inability to exercise (e.g., severe musculoskeletal disorder,advanced valvular disease).

Age

From **40 years** old to **75 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)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Department of Kerman University of Medical Sciences

Street address

Kerman, crossroads T. Abad (S.), the first jihad Blvd., St. Ibn Sina, Vice Chancellor for Research and Technology Building, first floor, Physiology Research Center, Kerman

City

Kerman

Postal code

Approval date

2016-03-12, 1394/12/22

Ethics committee reference number

ir.kmu.rec.1394.652

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

I50

ICD-10 code description

I50.1,I50.9

Primary outcomes

1

Description

Symptoms of Depression

Timepoint

Immediately before and after intervention

Method of measurement

The Patient Health Questionnaire (PHQ)-8)

Secondary outcomes

empty

Intervention groups

1

Description

Patients randomized to the Intervention group first participated in exercise program, with a goal of 3 sessions per week for a total of 24 sessions in 2 months. Each session includes 5-10 minutes warm-up, 20-40 minutes supervised training phase and 5-10 minutes of cooling and relaxing will be. During the supervised training phase, patients will exercise on a treadmill, stationary cycling and rowing Ergometer under Remote Monitoring, and will be done by trained personnel under the supervision of physicians specializing in sports medicine . The investigators will estimate the intensity level of participants using the HR reserve (HRR) method, beginning at 50% intensity (based on HR and feelings of exertion) and progressing to 70% intensity for a maximum of 40 minutes, 3 times per week..

Category

Rehabilitation

2

Description
Control Group: No action
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Cardiac Rehabilitation Centerof Shafa Hospital
Full name of responsible person
Mazallahi Mahboobeh
Street address
Kerman highway Imam, campus Afzalipour Afzalipour Hospital
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kerman University of Medical Sciences
Full name of responsible person
Dr Pardakhti Abbas
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Kerman, Tahmasebabad Crossroads, the first jihad Blvd., St. Ibn Sina, Vice Chancellor for Research and Technology Building, first floor, Physiology Research Center, Kerman
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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
Vice chancellor for research, Kerman 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
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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