

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

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

Country

Iran (Islamic Republic of)

Phone

+98 34 1320 5179

Email address

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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, referred to Cardiac rehabilitation center of Shafa Hospital, Kerman University of Medical Science in 2016		Department of Kerman University of Medical Sciences	
Public title	Effects of exercise training on depressive symptoms in patients with heart failure	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
Purpose	Health service research	City	Kerman
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).	Postal code	
Age	From 40 years old to 75 years old	Approval date	2016-03-12, 1394/12/22
Gender	Both	Ethics committee reference number	ir.kmu.rec.1394.652
Phase	N/A	Health conditions studied	
Groups that have been masked	No information	1	
Sample size	Target sample size: 60	Description of health condition studied	
Randomization (investigator's opinion)	Randomized	Heart failure	
Randomization description		ICD-10 code	
Blinding (investigator's opinion)	Single blinded	I50	
Blinding description		ICD-10 code description	
Placebo	Not used	I50.1,I50.9	
Assignment	Parallel	Primary outcomes	
Other design features		1	
Secondary Ids		Description	
empty		Symptoms of Depression	
Ethics committees		Timepoint	
1		Immediately before and after intervention	
Ethics committee		Method of measurement	
Name of ethics committee		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	

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Description

Control Group: No action

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiac Rehabilitation Center of 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

Street address

Kerman, Tahmasebabad Crossroads, the first jihad Blvd., St. Ibn Sina, Vice Chancellor for Research and Technology Building, first floor, Physiology Research Center, Kerman

City

Kerman

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

Razi Nursing and Midwifery School, Kerman University of Medical Sciences

Full name of responsible person

Arab Mansoor

Position

MSN/ Lecturer of Nursing

Other areas of specialty/work

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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