

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of morning-and-evening supervised Home-Based Cardiac Rehabilitation (HBCR) program on echo and Electrocardiographic indices, as well as general health among male patients with myocardium infraction, visiting Madani hospital of Khorramabad.

Protocol summary

Study aim

The purpose of the present study is effect of morning-and-evening supervised Home-Based Cardiac Rehabilitation (HBCR) program on echo and Electrocardiographic indices, as well as general health among male patients with myocardium infraction, visiting Madani hospital of Khorramabad.

Design

The subjects of this study are clinical trials with interventional and control groups, two blinds, randomized male population.

Settings and conduct

All patients with myocardial infarction (MI) referred to Shahid Madani heart hospital in khorramabad city. Following MI, in phase IV cardiac rehabilitation. sampling method is a randomized categorical method based on inclusion criteria and available criteria. The eligible individuals are divided into subgroups of morning and evening, and subjects under the floor are randomly assigned to four intervention and control groups Will take.

Participants/Inclusion and exclusion criteria

Inclusion criteria: History of angioplasty, coronary artery disease and/or angiography identification of moderate cardiovascular disorder. Exclusion criteria: Ejection fraction less than 40% and more than 55%, infectious diseases.

Intervention groups

The intervention groups received a feedback-based home cardiac rehabilitation, exercise program, and the necessity of continuing the program. The control groups, also performed the usual cardiac rehabilitation program without utilizing pedometer feedback.

Main outcome variables

Injection fraction, Diastolic function, Primary and final left ventricular , Cardiac and pulmonary valve deficiencies,

Cardiac and pulmonary valve stenosis, EKG changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181122041725N1**

Registration date: **2018-12-19, 1397/09/28**

Registration timing: **retrospective**

Last update: **2018-12-19, 1397/09/28**

Update count: **0**

Registration date

2018-12-19, 1397/09/28

Registrant information

Name

Mostafa Dehghani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-01, 1396/06/10

Expected recruitment end date

2017-12-01, 1396/09/10

Actual recruitment start date

2018-04-21, 1397/02/01

Actual recruitment end date

2018-05-22, 1397/03/01

Trial completion date

empty

Scientific title

Effect of morning-and-evening supervised Home-Based Cardiac Rehabilitation (HBCR) program on echo and Electrocardiographic indices, as well as general health among male patients with myocardium infraction, visiting Madani hospital of Khorramabad.

Public title

The effect of home-monitored cardiac rehabilitation in patients with myocardial infarction

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

1. History of angioplasty, known coronary artery disease, or angiography with moderate cardiovascular disease (mild CAD) Lack of regular physical activity during the three months prior to the intervention, so that their activity is less than 7,500 steps per day

Exclusion criteria:

Stabilized Blood Disorder Patients who have a history of using a pacemaker

Age

From **45 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients were assigned to the groups through the stratified randomization method. People were first divided into two strata of morning and evening. Then, the subjects were selected from the strata through the block randomization method and divided into the intervention and control groups according to the order of the selected block number and the internal arrangement of blocks. The selected block number by luck. It should be noted that to blind the person who performed the sampling and to prevent the prediction of allocation, the size of the blocks was not written in the protocol.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind clinical trial, which the patients were unaware of their allocation to the various groups Moreover, the researcher who was collecting various consequences of interventions will not be aware of group allocation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Lorestan University of Medical Sciences

Street address

Khorram Abad - Kamalundeh - Kilometer 4
Khorramabad Road, Boroujerd

City

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Province

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Postal code

6813833946

Approval date

2018-11-05, 1397/08/14

Ethics committee reference number

IR.LUMS.REC.1397.105

Health conditions studied**1****Description of health condition studied**

Effect of Home-based cardiac rehabilitation in myocardial infarction

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Echo and Electrocardiographic parameters

Timepoint

Before and after 8 weeks of cardiac rehabilitation

Method of measurement

Echo and Electrocardiography

2**Description**

General health

Timepoint

Before and after 8 weeks of cardiac rehabilitation

Method of measurement

GHQ questionnaire 28 questions

Secondary outcomes

1

Description

Ejection fraction

Timepoint

Before and after 8 weeks of cardiac rehabilitation

Method of measurement

Eco cardiography

2

Description

Left ventricular peak filling the initial and final

Timepoint

Before and after 8 weeks of cardiac rehabilitation

Method of measurement

Eco cardiography

3

Description

Heart rate rest

Timepoint

Before and after 8 weeks of cardiac rehabilitation

Method of measurement

Electrocardiogram

4

Description

Blood pressure

Timepoint

Before and after 8 weeks of cardiac rehabilitation

Method of measurement

Blood pressure device

5

Description

Mean arterial pressure (pressure Drift)

Timepoint

Before and after 8 weeks of cardiac rehabilitation

Method of measurement

Blood pressure device

Intervention groups

1

Description

Intervention group: The intervention groups (morning and evening) carried out the cardiac rehabilitation walking program using pedometers. The pedometer feedback- based home cardiac rehabilitation (PFHCR) program in this research included walking at home for almost 45-60 min (5-min warm-up, 40- min walking, and 5- min cool-down and stretching exercises).

Category

Rehabilitation

2

Description

Control group: The control groups (morning and evening) also performed the usual cardiac rehabilitation program without utilizing pedometer feedback. The control groups had the same cardiac rehabilitation exercise program but did not use the step counter feedback.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Madani city Khorramabad

Full name of responsible person

Mostafa Cheraghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Proportion provided by this source

100

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**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Mostafa Dehghani

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the data, such as the original outcome information

When the data will become available and for how long

2018

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

researchers

From where data/document is obtainable

telephone

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

, Phone numbers, or email addresses, along with the names and addresses of individuals

Comments

