

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of a Home-Designed Cardiac Rehabilitation program on blood pressure, heart rate, myocardial oxygen consumption indices and cardiovascular function in patients with coronary artery disease

#### Protocol summary

##### Study aim

Effect of a Home-Designed Cardiac Rehabilitation program on blood pressure, heart rate, myocardial oxygen consumption indices and cardiovascular function in patients with coronary artery disease, visiting to Shahid Rahimi hospital in Khorramabad

##### Design

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

##### Settings and conduct

All patients with coronary artery disease referred to Shahid Rahimi hospital in khorramabad city. Following percutaneous coronary angioplasty, 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. Exclusion criteria: At least eight weeks of myocardial infarction and two months of percutaneous coronary angioplasty

##### Intervention groups

The intervention group received a home cardiac rehabilitation, exercise program, and the necessity of continuing the program. The control groups, also performed the usual cardiac rehabilitation program without utilizing designed program.

##### Main outcome variables

Blood pressure, heart rate, myocardial oxygen consumption indices and cardiovascular function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181122041725N2**

Registration date: **2020-10-28, 1399/08/07**

Registration timing: **retrospective**

Last update: **2020-10-28, 1399/08/07**

Update count: **0**

##### Registration date

2020-10-28, 1399/08/07

##### Registrant information

##### Name

Mostafa Dehghani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 3263 0659

##### Email address

dehghani.m66@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-09, 1399/07/18

##### Expected recruitment end date

2020-10-21, 1399/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effect of a Home-Designed Cardiac Rehabilitation program on blood pressure, heart rate, myocardial oxygen consumption indices and cardiovascular function in patients with coronary artery disease

## Public title

The effect of home-designed cardiac rehabilitation in patients with coronary artery disease

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

History of angioplasty and angiography At least eight weeks of myocardial infarction and two months of percutaneous coronary angioplasty

### Exclusion criteria:

Intraventricular conduction disturbances Ischemic heart disease

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In order to control various factors influencing research outcomes, a set of conditions was considered to include subjects in the research. Eligible patients were assigned to the groups through the stratified randomization method. 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

No. 2, Lorestan University of Medical Sciences., Anooshirvan Rezaei Square

##### City

Korramabad

##### Province

Lorestan

##### Postal code

6813833946

#### Approval date

2020-10-07, 1399/07/16

#### Ethics committee reference number

IR.LUMS.REC.1397.105

## Health conditions studied

### 1

#### Description of health condition studied

Effect of program designed cardiac rehabilitation in percutaneous coronary angioplasty

#### ICD-10 code

I25.7

#### ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris

## Primary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

Before and after 8 weeks of cardiac rehabilitation

#### Method of measurement

Blood pressure device

### 2

#### Description

Heart rate

#### Timepoint

Before and after 8 weeks of cardiac rehabilitation

#### Method of measurement

Electrocardiogram

### 3

#### **Description**

Myocardial oxygen consumption

#### **Timepoint**

Before and after 8 weeks of cardiac rehabilitation

#### **Method of measurement**

Exercise test

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: The intervention group carried out the cardiac rehabilitation walking program using pedometers. The pedometer feedback- based home cardiac rehabilitation 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 group also performed the usual cardiac rehabilitation program without utilizing pedometer feedback. The control group 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**

Rahimi hospital city Khorramabad

##### **Full name of responsible person**

Mostafa dehghani

##### **Street address**

No. 1, Mojahedin Street., Azadi Square

##### **City**

Korramabad

##### **Province**

Lorestan

##### **Postal code**

6813833946

##### **Phone**

+98 66 3333 6150

##### **Email**

dehghani.m66@gmail.com

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Khoram-Abad University of Medical Sciences

##### **Full name of responsible person**

Ebrahim fallahi

##### **Street address**

No. 2, Lorestan University of Medical Sciences.,  
Anooshirvan Rezaei Square

##### **City**

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##### **Province**

Lorestan

##### **Postal code**

6814664535

##### **Phone**

+98 66 3333 6150

##### **Email**

dehghani.m66@gmail.com

#### **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**

Cardiology

##### **Street address**

No. 7, West Kakavand Street., Alavi Square

##### **City**

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##### **Province**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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**

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

**When the data will become available and for how long**

1399

**To whom data/document is available**

Researchers working in academia and scientific

**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**