

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 Jul 2026

### A study on the effectiveness of a comprehensive home based cardiac rehabilitation intervention on the health promotion of patient with coronary heart disease

#### Protocol summary

##### Summary

The aim of this study is to determine the effect of a comprehensive home-based cardiac rehabilitation intervention on health promotion of coronary heart disease patients. This study is a single blinded, randomized trial in which 240 patients with coronary heart disease will be enrolled in the Phase III cardiac rehabilitation. Exclusion criteria included unstable angina, dementia, and cardiac arrhythmia. Patients will be randomly allocated into two groups based on permuted blocks method. After the initial evaluation, the intervention group will receive consultation on physical activity, healthy diet, stress management, and smoking cessation by related specialists. Additionally, patients will be visited at the baseline, 10 days, one month, and three months after intervention by a cardiologist. Moreover, trained nurses will visit patients' at home at the baseline, sixth and twelfth weeks after intervention. Participants will be also given a telephone number to share their possible problems with specialists. In contrast, control group will receive routine training before discharging from hospital. Primary outcomes (quality of life, psychological and smoking status, BMI, blood pressure, blood cholesterol level, and physical activity) will be measured 6 months after intervention. Secondary outcomes (CVD events and death rates due to cardiovascular reasons) will be measured a year after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016022926820N1**

Registration date: **2016-08-09, 1395/05/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-08-09, 1395/05/19

##### Registrant information

###### Name

Alireza Ansari Moghaddam

###### Name of organization / entity

Zahedan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 3329 5884

###### Email address

ar.ansarimoghadam@zaums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

National Institute for Medical Research Development (NIMAD)

##### Expected recruitment start date

2016-07-09, 1395/04/19

##### Expected recruitment end date

2017-01-08, 1395/10/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A study on the effectiveness of a comprehensive home based cardiac rehabilitation intervention on the health promotion of patient with coronary heart disease

##### Public title

Home based cardiac rehabilitation

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
Inclusion criteria: having coronary heart disease.  
Exclusion criteria: dementia; unstable angina; cardiac arrhythmia's

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **240**

**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

National Institute for Medical Research Development (NIMAD)

##### Street address

National Institute for Medical Research Development (NIMAD) Between Gharib and Eskandari Ave., Azadi St., Tehran, Iran.

##### City

Tehran

##### Postal code

#### Approval date

2016-03-05, 1394/12/15

#### Ethics committee reference number

IR.NIMAD.REC. 1394.019

## Health conditions studied

### 1

#### Description of health condition studied

Coronary heart disease

#### ICD-10 code

I21

#### ICD-10 code description

Acute myocardial infarction

## Primary outcomes

### 1

#### Description

Quality of life

#### Timepoint

Before and 6 months after intervention

#### Method of measurement

Quality of life questionnaire for cardiac patients

### 2

#### Description

Depression

#### Timepoint

Before and 6 months after intervention

#### Method of measurement

Beck Depression Inventory

### 3

#### Description

Physical activity

#### Timepoint

Before and 6 months after intervention

#### Method of measurement

Godin Leisure Time Physical Activity Questionnaire

### 4

#### Description

Blood pressure

#### Timepoint

Before and 6 months after intervention

#### Method of measurement

Using mercury sphygmomanometer on millimeters of mercury scale

### 5

#### Description

BMI

#### Timepoint

Before and 6 months after intervention

#### Method of measurement

The person's weight in kilograms divided by the square of height in meters

### 6

#### Description

Lipid profile

#### Timepoint

Before and 6 months after intervention

#### Method of measurement

Using related laboratory kits

## Secondary outcomes

### 1

#### Description

Recurrent cardiovascular events

#### Timepoint

A year after the intervention

#### Method of measurement

Individual medical records

### 2

#### Description

Mortality due to cardiovascular disease

#### Timepoint

A year after the intervention

#### Method of measurement

Individual medical records

## Intervention groups

### 1

#### Description

Intervention group will be given three sessions of educational program (for half an hour each) on physical activity. Comparably, control group will receive routine training before discharge.

#### Category

Lifestyle

### 2

#### Description

Intervention group will be given three sessions of educational program (for half an hour each) on stress management. Comparably, control group will receive routine training before discharge.

#### Category

Lifestyle

### 3

#### Description

Intervention group will be given three sessions of educational program (for half an hour each) on healthy diet. Comparably, control group will receive routine training before discharge.

#### Category

Lifestyle

### 4

#### Description

Intervention group will be given three sessions of educational program (for half an hour each) on smoking cessation for current smokers. Comparably, control group will receive routine training before discharge.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khatam al-Anbia Hospital

##### Full name of responsible person

Mahmood Barahooi (Nurse)

##### Street address

Khatam al-Anbia Hospital, Jam-e Jam Blvd, Zahedan, Iran.

##### City

Zahedan

### 2

#### Recruitment center

##### Name of recruitment center

Ali Ebne Abitaleb Hospital

##### Full name of responsible person

Shahrzad Saraband (Nurse)

##### Street address

Ali Ebne Abitaleb Hospital, Khalij-e-Fars Highway, Zahedan, Iran.

##### City

Zahedan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

National Institute for Medical Research Development (NIMAD)

##### Full name of responsible person

Sayena Rafizadeh (Proposal Evaluation)

##### Street address

National Institute for Medical Research Development (NIMAD) Between Gharib and Eskandari Ave., Azadi St., Tehran, Iran

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

National Institute for Medical Research Development (NIMAD)

#### 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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Hassan Okatialiabad

**Position**

PhD, Assistant Professor

**Other areas of specialty/work****Street address**

Zahedan University of Medical Sciences, Jannat Blvd,  
Prof. Hesabi Sq, Zahedan, Iran.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

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PhD, Assistant Professor

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

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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