

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

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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,
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Full name of responsible person

Hassan Okatialiabad

Position

PhD, Assistant Professor

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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