Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Evaluation and comparison of the effectiveness of a 12-session center-based cardiac rehabilitation course with a hybrid form of cardiac rehabilitation course on changes in myocardial function indices, risk factors and quality of life in patients with ischemic heart disease

Protocol summary

Study aim
Assessment and comparison of changes in myocardial functional indices, risk factors, and quality of life in patients with ischemic heart disease after 12-session cardiac rehabilitation in two groups: center-based group and hybrid group (combination of center-based and home-based)

Design
Clinical trial with two parallel groups (center-based and hybrid) with 63 participants in each group, single-blinded and randomized using random numbers table.

Settings and conduct
Study Location: Isfahan Cardiovascular Rehabilitation Center; study population: patients with ischemic heart disease; type of blinding: single-blind (researcher and analyzer); blinding method: Patients will be assigned to two groups, intervention, and control, by the clinical observer. However, the clinical observer will provide the collected data to the researcher and analyzer after anonymizing the intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: the patient has been treated for ischemic heart disease; at least two weeks have passed since undergoing PCI (percutaneous coronary intervention) or four weeks have passed since CABG (coronary artery bypass grafting); being at the age of 30-80 years old. Non-inclusion criteria: contraindications for cardiac rehabilitation; physician's non-consent for patient's participation in the study; patient who do not consent to participate in the study.

Intervention groups
Intervention group: hybrid; In this group, cardiac rehabilitation is conducted with 6 in-person sessions at the cardiac rehabilitation center and 6 virtual sessions at the individual's home. Control group: center-based; In this group, cardiac rehabilitation is conducted in person at the cardiac rehabilitation center over 12 sessions.

Main outcome variables
Average functional capacity (METs) of patient based on exercise test.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230705058678N1**
Registration date: **2023-08-27, 1402/06/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-27, 1402/06/05**
Update count: **0**

Registration date
2023-08-27, 1402/06/05

Registrant information

Name
Sina Rouhani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3254 6962

Email address
sn.rouhani@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the effectiveness of a 12-session center-based cardiac rehabilitation course with a hybrid form of cardiac rehabilitation course on changes in myocardial function indices, risk factors and quality of life in patients with ischemic heart disease

Public title

Comparison of hybrid and center-based cardiac rehabilitation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The patient has been treated for ischemic heart disease in one of the hospitals in Isfahan City At least two weeks have passed since PCI or 4 weeks since CABG The minimum age for participation in the study is 30 years, and the maximum age is 80 years

Exclusion criteria:

Contraindications for cardiac rehabilitation Patients who do not consent to participate in the study Physician's non-consent for patient's participation in the study.

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be conducted through tables of random numbers and by computers that generate numbers randomly. The table of random numbers to be used is produced by the RAND Corporation (www.rand.org). These tables have random numbers in both row and column directions. First, all patients' names will be numbered. Then, the researcher selects a random number from the table of random numbers for selecting individuals in the intervention group. After selecting one number randomly, the researcher moves either in the row or column direction and sequentially chooses the next individuals until the last person in the intervention group is determined. The remaining individuals will be assigned to the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are randomly assigned to two groups, hybrid and center-based, and the clinical observer records the relevant information after conducting the intervention. Then, without specifying the name of each group (as A and B), this information is provided to the researcher and analyzer in a file. The analyzer and researcher remain unaware of which group the data corresponds to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Biomedical Ethics Research Committee of School of Medicine - Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar jarib ave.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2021-04-05, 1400/01/16

Ethics committee reference number

IR.MUI.MED.REC.1400.006

Health conditions studied

1

Description of health condition studied

Cardiac rehabilitation

ICD-10 code

I20.9

ICD-10 code description

Angina pectoris, unspecified

Primary outcomes

1

Description

Average functional capacity (METs) of patients based on exercise test

Timepoint

At the beginning of the study (prior to intervention) and at the end of the study after 12 rehabilitation sessions

Method of measurement
Exercise test

Secondary outcomes

1

Description
Quality of life score based on MacNew questionnaire
Timepoint
At the beginning of the study (prior to intervention) and at the end of the study after 12 rehabilitation sessions
Method of measurement
MacNew questionnaire

2

Description
Anxiety score in Spielberger questionnaire
Timepoint
At the beginning of the study (prior to intervention) and at the end of the study after 12 rehabilitation sessions
Method of measurement
Spielberger questionnaire

3

Description
Depression score in Beck questionnaire
Timepoint
At the beginning of the study (prior to intervention) and at the end of the study after 12 rehabilitation sessions
Method of measurement
Beck questionnaire

4

Description
The amount of physical activity based on the IPAQ questionnaire
Timepoint
At the beginning of the study (prior to intervention) and at the end of the study after 12 rehabilitation sessions
Method of measurement
IPAQ questionnaire

5

Description
Smoking
Timepoint
At the beginning of the study (prior to intervention) and at the end of the study after 12 rehabilitation sessions
Method of measurement
Questionnaire

6

Description
Serum level of Triglyceride
Timepoint
At the beginning of the study (prior to intervention) and at the end of the study after 12 rehabilitation sessions
Method of measurement
Testing the patient blood sample

7

Description
The changes in systolic blood pressure
Timepoint
At the beginning of the study (prior to intervention) and at the end of the study after 12 rehabilitation sessions
Method of measurement
Sphygmomanometer

8

Description
The changes in body mass index (BMI)
Timepoint
At the beginning of the study (prior to intervention) and at the end of the study after 12 rehabilitation sessions
Method of measurement
Body mass index formula

9

Description
Fasting blood sugar level
Timepoint
At the beginning of the study (prior to intervention) and at the end of the study after 12 rehabilitation sessions
Method of measurement
Testing the patient blood sample

10

Description
The changes in diastolic blood pressure
Timepoint
At the beginning of the study (prior to intervention) and at the end of the study after 12 rehabilitation sessions
Method of measurement
Sphygmomanometer

11

Description
Serum level of cholesterol
Timepoint
At the beginning of the study (prior to intervention) and at the end of the study after 12 rehabilitation sessions
Method of measurement
Testing the patient blood sample

Intervention groups

1

Description
Intervention group: In this group, cardiac rehabilitation will be conducted through 6 sessions at the center and another 6 sessions at home. Each cardiac rehabilitation exercise session at the center will last for 60 minutes and will include stretching and low-intensity exercises for

warming up, lasting 5 to 10 minutes. Then, the main exercise regimen for the patient will be performed using exercise equipment such as ergometers and treadmills, followed by 5 to 10 minutes of cool-down exercises for recovery. During the 6-session rehabilitation course conducted at home, participants will receive educational instructions on healthy nutrition, risk factor control, as well as engage in physical activities provided through instructional CDs. Participants' walking will be recorded using a pedometer, and their daily physical activity duration, intensity, and distance covered will be noted and evaluated using a daily physical activity log table.

Category
Rehabilitation

2

Description
Control group: In this group, 12 sessions of rehabilitation will be conducted at the center. Each cardiac rehabilitation exercise session at the center will last for 60 minutes and will include stretching and low-intensity exercises for warming up, lasting 5 to 10 minutes. Then, the main exercise regimen for the patient will be performed using exercise equipment such as ergometers and treadmills, followed by 5 to 10 minutes of cool-down exercises for recovery.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Chamran Hospital

Full name of responsible person
Mitra Naderi

Street address
Cardiac Rehabilitation Research Center, Isfahan Cardiovascular Research Institute, Shahid Rahmani Alley, next to Shahid Chamran Hospital, Mushtaq 3rd St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahan Cardiovascular Research Institute

Full name of responsible person
Nazal Sarrafzadegan

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crc@mui.ac.ir

Web page address
https://icri.mui.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Isfahan Cardiovascular Research Institute

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
Esfahan University of Medical Sciences

Full name of responsible person
Sina Rouhani

Position
Researcher

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Cardiac Rehabilitation Research Center, Isfahan Cardiovascular Research Institute, Shahid Rahmani Alley, next to Shahid Chamran Hospital, Mushtaq 3rd St.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Professor

Latest degree

Specialist

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Person responsible for updating data

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After completing the study, the results comparing the intervention and control groups for each variable are published in an article and made available to the public. The individual participants' data files will be made available to researchers through a virtual server in a secure research environment (SRE). Researchers can access the raw data files in this environment after anonymizing the individuals and performing their analysis on them.

When the data will become available and for how long

The results of the study are accessible after the article is published. Access to the individual participants' data file will be possible for researchers 6 months after the publication of the article.

To whom data/document is available

The results of the study will be made available to the public in the form of an article. The raw data file will only be provided to researchers from reputable academic and scientific institutions.

Under which criteria data/document could be used

These data will be made available to researchers for relevant studies or to complement previous research. Adherence to research ethics principles and the preservation of intellectual property rights are necessary for accessing the information. Researchers can access and observe the raw data of the participants in a secure research environment (SRE) after anonymizing them, and they can perform statistical analysis on the data or generate reports based on it.

From where data/document is obtainable

To access the data, researchers can contact the Cardiovascular Research Institute of Isfahan University of Medical Sciences. Email: crc@mui.ac.ir Phone number: 00983136115310 Address: Isfahan Cardiovascular Research Institute, Rahmani Alley, next to Chamran Cardiac Educational and Treatment Center, Moshtagh 3rd Street, Isfahan. Website: icri.mui.ac.ir

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

1. Submitting a request by the researcher to the Research Deputy of the Cardiovascular Research

Institute. 2. Approval of the request and signing a memorandum of understanding. 3. Setting up the SRE environment for the researcher. 4. Uploading the data and dictionary for observation and analysis. 5. Sending the final report and output to the researcher after the approval of the Research Deputy.

Comments