

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation and designing a home-based cardiac rehabilitation in myocardial infarction patient based on health action process approach

Protocol summary

Study aim

Determining the effectiveness of cardiac rehabilitation program at home based on the "health action process approach" in patients with myocardial infarction

Design

A randomized controlled clinical trial on 136 patients

Settings and conduct

The intervention group receives a home-based cardiac rehabilitation program under the Android application based on the "health action process approach" for 8 weeks, and the control group receives the usual cardiac rehabilitation programs in the center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with myocardial infarction with any diagnosis and treatment. exclusion criteria: not being satisfied with the program

Intervention groups

Intervention group: Home-based cardiac rehabilitation group
Control group: usual cardiac rehabilitation program in the center

Main outcome variables

Physical activity score, functional capacity score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210509051235N1**

Registration date: **2021-11-06, 1400/08/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-06, 1400/08/15**

Update count: **0**

Registration date

2021-11-06, 1400/08/15

Registrant information

Name

Zahra Fallah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3577 3002

Email address

zfallah88@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-03-19, 1400/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and designing a home-based cardiac rehabilitation in myocardial infarction patient based on health action process approach

Public title

Evaluation a home based cardiac rehabilitation in myocardial infarction patient

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with myocardial infarction with any diagnosis and treatment
High risk people with a doctor's diagnosis
Having a license from your doctor to participate in a cardiac rehabilitation program at home
Having a mobile phone or tablet (Android) to receive the application

(patient or a family member living with her) Willingness to participate in the study Have a minimum literacy

Exclusion criteria:
Mental dysfunction Musculoskeletal Disorder Lack of application and discontinue programs in the educational process

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **165**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization unit is individual and patients are randomly assigned to one of the two intervention and control groups by permutation blocks (each block with a volume of 2).

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Hezar Jerib St., East Door of Isfahan University, Isfahan University of Medical Sciences

City
Isfahan

Province
Isfahan

Postal code
81746-73461

Approval date
2021-02-28, 1399/12/10

Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.755

Health conditions studied

1

Description of health condition studied

Myocardial infarction

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description

Physical activity score in IPAQ

Timepoint

Before, 3 and 6 months after the intervention

Method of measurement

IPAQ Physical Activity Questionnaire

2

Description

Functional capacity score

Timepoint

Before and 6 months after the intervention

Method of measurement

6 minute walk test

3

Description

Endothelial function of the heart

Timepoint

Before and 6 months after the intervention

Method of measurement

Flow mediated dilation

Secondary outcomes

1

Description

Anxiety and depression score

Timepoint

Before and 6 after the intervention

Method of measurement

Standard Anxiety and Depression Inventory (HADS)

Intervention groups

1

Description

Intervention group: This group receives a home-based cardiac rehabilitation program under the Android application based on the health action process approach for 8 weeks.

Category

Rehabilitation

2

Description

Control group: This group receives usual cardiac rehabilitation programs at the hospital.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Hospital, Isfahan

Full name of responsible person

Masoumeh Sadeghi

Street address

3rd Moshtagh St

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81661 73414

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Email

fallah@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology

Street address

Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Building No. 4, Vice Chancellor for Research and Technology

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Phone

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Email

research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Fallah

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Health Promotion

Street address

Shahid Ardestani St., Shahid Babaei Air Base

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Fallah

Position

Ph.D. candidate

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Fax

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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