

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

**City**

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**Province**

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**Postal code**

81661 73414

**Phone**

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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

**City**

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**Postal code**

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**Phone**

+98 31 3668 8138

**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

**City**

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**Province**

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**Postal code**

8164173375

**Phone**

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**Email**

fallah@mui.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

Ph.D. candidate

**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

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## 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