Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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+98 31 3577 3002
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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

Isfehan

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
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81661 73414
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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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81746-73461
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+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
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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