

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Evaluating the effectiveness of Community-Based Cardiac Rehabilitation via an app with Gamification or Peer Support features on self-management and disease risk factors in PCI Patients: A Randomized Clinical Trial

Protocol summary

Study aim

To determine the effectiveness of a cardiac rehabilitation application with gamification or peer-support features in patients undergoing PCI.

Design

Randomized controlled trial, three parallel groups, no blinding. Block randomization (size 3). Sample size: 258 (86 per group). Phase: not applicable.

Settings and conduct

Post-PCI patients at Chamran Clinic will be randomly assigned to one of three groups. Data will be collected at baseline and six months later via questionnaires and examinations by a blinded assessor.

Participants/Inclusion and exclusion criteria

Patients aged 40–65 years with coronary artery disease, treated with PCI and discharged from Chamran Hospital within two weeks, classified as low-risk, preferring home-based rehabilitation, owning a smartphone, and providing consent. Exclusion: contraindications to exercise (untreated ventricular tachycardia, severe heart failure, LVEF <45%), uncontrolled hypertension, cognitive impairment, inability to use the app, or participation in another trial.

Intervention groups

Control group: Receives standard educational videos on disease, nutrition, physical activity, and self-management skills. Gamification app group: In addition to the videos, receives an application featuring points, badges, leaderboards, habit and symptom tracking, and daily reminders. Peer-support app group: In addition to the videos, receives an application with an internal social network for sharing experiences, viewing others' progress, sending messages, and participating in supervised peer groups.

Main outcome variables

Knowledge, attitude, and practice regarding self-

management; quality of life (SF-36); physical activity (IPAQ); depression/anxiety (PHQ-4); medication adherence (GMAS); biochemical markers; blood pressure; six-minute walk test; BMI and waist circumference.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250927067378N1**

Registration date: **2025-10-13, 1404/07/21**

Registration timing: **prospective**

Last update: **2025-10-13, 1404/07/21**

Update count: **0**

Registration date

2025-10-13, 1404/07/21

Registrant information

Name

Ehsan Shirvani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3611 5213

Email address

shirvani@med.mui.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-02-20, 1404/12/01

Expected recruitment end date

2027-02-20, 1405/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of Community-Based Cardiac Rehabilitation via an app with Gamification or Peer Support features on self-management and disease risk factors in PCI Patients: A Randomized Clinical Trial

Public title

App-Based Cardiac Rehabilitation With Gamification or Peer Support in PCI Patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 40 and 65 years Patients diagnosed with coronary artery disease who have undergone PCI and have been discharged from Chamran Hospital within two weeks prior to enrollment. Patients identified as low-risk by a cardiologist, eligible for home-based rehabilitation, and unwilling to participate in center-based programs. Possession of and ability to use a smartphone and the study application. Willingness to provide written informed consent and comply with the study protocol.

Exclusion criteria:

Patients with contraindications for exercise (such as untreated ventricular tachycardia, severe heart failure, left ventricular ejection fraction >45%, uncontrolled hypertension, or cognitive impairments preventing exercise). Inability to use the application due to physical or technological limitations. Concurrent participation in other clinical trials.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **258**

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining the ethical approval code from the Ethics Committee of Isfahan University of Medical Sciences, 258 eligible patient records of individuals who had undergone PCI will be randomly selected. A list of patient file numbers will be prepared in an Excel sheet, and 258 numbers will be chosen using a randomization formula based on a list of random numbers. Subsequently, two trained members of the research team will contact the patients, explain the importance of cardiac rehabilitation and the nature of the study, and invite them to participate. If they agree, they will be scheduled for a

visit at the Cardiac Rehabilitation Center of the Cardiovascular Research Institute in Isfahan to complete demographic data, medical history, and provide written informed consent. It should be noted that if any selected patient does not meet the inclusion criteria or declines to participate after being contacted, the case will be removed from the list and replaced with another eligible sample. Afterward, the patients will be randomly allocated in equal proportions (1:1:1) to one of the three study groups using block randomization with a block size of three. μ

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

Isfahan University of Medical Sciences - Alzahra Research Centers Complex (Research Ethics Committee)

Street address

Hezar Jarib St., Central Headquarters, Isfahan University of Medical Sciences and Health Services, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2025-08-13, 1404/05/22

Ethics committee reference number

IR.ARI.MUI.REC.1404.099

Health conditions studied

1

Description of health condition studied

Coronary Artery Disease, post-Percutaneous Coronary Intervention (PCI)

ICD-10 code

I25.10

ICD-10 code description

Atherosclerotic heart disease of native coronary artery without angina pectoris

2

Description of health condition studied

Ischemic Heart Disease

ICD-10 code

I25.9

ICD-10 code description

Chronic ischemic heart disease, unspecified

3

Description of health condition studied

Cardiac Rehabilitation

ICD-10 code

Z51.89

ICD-10 code description

Encounter for other specified aftercare

Primary outcomes

1

Description

Patients' knowledge, attitude, and practice towards self-management of heart disease

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

Knowledge, Attitude and Performance Questionnaire (CVD KAP 29 Checklist)

2

Description

Patients' quality of life score

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

SF-36 questionnaire

3

Description

Physical activity score of patients

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

International Physical Activity Questionnaire-short form: IPAQ- short form

4

Description

Patients' depression scores

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

Patient Health Questionnaire-4

5

Description

Patients' anxiety scores

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

Patient Health Questionnaire-4

6

Description

Patients' medication adherence score

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

General Medication Adherence Scale (GMAS)

7

Description

Total cholesterol level

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

In the laboratory using a diagnostic kit

8

Description

Patients' fasting blood sugar levels

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

In the laboratory using a diagnostic kit

9

Description

the HDL blood level of patients

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

In the laboratory using a diagnostic kit

10

Description

the LDL blood level of patients

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

In the laboratory using a diagnostic kit

11

Description

Patients' blood triglyceride levels

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

In the laboratory using a diagnostic kit

12

Description

Blood pressure levels in patients

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

A standard blood pressure monitor

13

Description

Patients' 6-minute walk test score (exercise and functional capacity)

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

The distance covered in 6 minutes by the patients, under the supervision of two trained nurses

14

Description

Body mass index level of patients

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

The patients' height and weight are calculated and recorded by two specialist nurses using a digital scale and a standard height gauge, without shoes and wearing light clothing

15

Description

Waist circumference of patients

Timepoint

Before the start of the intervention and 6 months after the start of the intervention

Method of measurement

Using a standard meter by two specialist nurses

Secondary outcomes

1

Description

Nutritional status of patients

Timepoint

Before the start of the intervention and six months after the start of the intervention

Method of measurement

Using the nutritional checklist used in the SIB system and primary health care centers

2

Description

Number of cigarettes smoked daily by patients

Timepoint

Before the start of the intervention and six months after the start of the intervention

Method of measurement

Number of cigarettes smoked by patients in a day

Intervention groups

1

Description

Application-Based Intervention Group (Gamification Group): After the initial contact, patients are invited to the cardiac rehabilitation center to complete baseline information and medical history, receive further explanations about the study, and provide written informed consent. Once all participants have completed their initial visit and baseline data have been collected, the research team will randomly assign them to one of three groups according to the described method. Participants will then be contacted again and scheduled for a follow-up in-person visit. During this session, questionnaires will be completed by two trained research team members. In addition, required tests and laboratory assessments will be performed. A sports medicine specialist will determine each patient's maximum heart rate and exercise intensity, while a nutritionist will provide a tailored dietary plan. Based on the group assignment, participants will either receive educational video clips or be guided to access the mobile application. Interventions in the Study Groups In accordance with standard components of cardiac rehabilitation, the research team will prepare short educational videos on the following topics: Understanding cardiovascular disease, warning signs, and treatment Nutritional principles for cardiac patients Smoking cessation and tobacco use management Self-management skills, including medication adherence, decision-making, and problem-solving Managing psychological issues such as stress, depression, and disease acceptance Principles of physical activity and home-based exercise for ischemic heart disease patients These videos will be the same for all three groups. Application-based groups: The same educational videos provided to the control group will be uploaded to the app. However, in these groups, physical activity training will be delivered as an interactive exercise program, including step-by-step guided movements, a stopwatch, and short instructional clips. Patients will progress through exercises interactively with the app, completing each movement with repetitions counted by the timer before moving to the next one. This contrasts with the control group, which only views exercise demonstration clips. Additionally, in all application-based intervention groups, the app includes features for recording medical information, medications, upcoming appointments, and results of home monitoring for comorbidities (such as blood pressure and blood glucose). Patients receive reminders through notifications to enter these data and regularly

measure and record their blood pressure or blood sugar (if they have hypertension or diabetes). The information is stored in the form of an electronic personal health record. Furthermore, daily notifications are sent to encourage patients to perform exercises, watch educational videos, and take their medications on time. In Gamification Group, participants will use an application redesigned with gamification features in addition to the general functions described above. Gamification here does not mean designing a game, but rather using game-related elements to increase motivation and adherence. These elements include points, badges, leaderboards, and progress tracking to enhance engagement and encourage physical activity and lifestyle changes. Moreover, in the educational and exercise sections, patients can post questions as comments and receive responses from support staff. This group also includes a habit tracker, symptom tracker, and reminder notifications to reinforce progress. Habit tracking: Patients can build motivation to adopt healthy habits and break unhealthy ones. For example, they can record daily avoidance of adding salt at the table or refraining from eating sweets. Each successful day strengthens their “progress chain,” and the app sends reminders to help maintain consistency. This chain motivates patients to preserve their progress and avoid breaking it. Symptom tracking: Patients can record symptoms (e.g., the timing and duration of angina). This allows monitoring of disease progression and worsening, and patients can share their records with their physician. Points and league features: Patients earn points (in the form of stars) for daily completion of exercises, viewing educational videos, recording and monitoring symptoms, or using the habit tracker. These points are visible to other participants, and patients are ranked in different leagues based on their scores. This feature creates a sense of competition that further motivates patients to adhere to self-management behaviors.

Category

Lifestyle

2

Description

Application-Based Intervention Group (Peer Support Group): After the initial contact, patients are invited to the cardiac rehabilitation center to complete baseline information and medical history, receive further explanations about the study, and provide written informed consent. Once all participants have completed their initial visit and baseline data have been collected, the research team will randomly assign them to one of three groups according to the described method. Participants will then be contacted again and scheduled for a follow-up in-person visit. During this session, questionnaires will be completed by two trained research team members. In addition, required tests and laboratory assessments will be performed. A sports medicine specialist will determine each patient’s maximum heart rate and exercise intensity, while a nutritionist will provide a tailored dietary plan. Based on the group assignment, participants will either receive educational video clips or be guided to access the mobile application.

Interventions in the Study Groups In accordance with standard components of cardiac rehabilitation, the research team will prepare short educational videos on the following topics: Understanding cardiovascular disease, warning signs, and treatment Nutritional principles for cardiac patients Smoking cessation and tobacco use management Self-management skills, including medication adherence, decision-making, and problem-solving Managing psychological issues such as stress, depression, and disease acceptance Principles of physical activity and home-based exercise for ischemic heart disease patients These videos will be the same for all three groups. Application-based groups: The same educational videos provided to the control group will be uploaded to the app. However, in these groups, physical activity training will be delivered as an interactive exercise program, including step-by-step guided movements, a stopwatch, and short instructional clips. Patients will progress through exercises interactively with the app, completing each movement with repetitions counted by the timer before moving to the next one. This contrasts with the control group, which only views exercise demonstration clips. Additionally, in all application-based intervention groups, the app includes features for recording medical information, medications, upcoming appointments, and results of home monitoring for comorbidities (such as blood pressure and blood glucose). Patients receive reminders through notifications to enter these data and regularly measure and record their blood pressure or blood sugar (if they have hypertension or diabetes). The information is stored in the form of an electronic personal health record. Furthermore, daily notifications are sent to encourage patients to perform exercises, watch educational videos, and take their medications on time. Participants in this group use an application that, in addition to the general features of an app-based intervention, has been redesigned with a peer support component. Peer support means the opportunity to interact and exchange ideas with patients who have had similar experiences. Participants in this group will have access to the in-app social network feature, which enables interaction, experience sharing, and receiving encouragement from peers who have undergone similar situations. Within this social network, each user can add other users as new friends (self-management companions). Users can view their companions’ self-management status and activities, as well as send reminder messages to them. In addition, activities that friends perform in the context of self-management (such as completing exercise sessions, engaging in educational tasks, etc.) are shared as posts, allowing peers to encourage and support one another through comments and likes. Moreover, a virtual group (chat room) tailored to the participants’ age and medical condition, and supervised by the medical support team, is created to facilitate conversations among peers. This connection with peers and observing their companionship in self-management helps foster motivation, while preventing feelings of loneliness or rejection in patients. Based on previous studies, such features are expected to contribute to the improvement of self-management. It is

worth noting that in the app-based rehabilitation groups, data on patients' activity within the app are extracted during the first week and then every two weeks, in order to monitor patient status and adherence to app usage. If any issues or lack of adherence are identified, the patient will be contacted. The purpose of this is to retain participants in the study; no new information is collected during these contacts, and these procedures are not considered study variables.

Category

Lifestyle

3

Description

Control group: Participants in this group will receive only the standard cardiac rehabilitation educational videos. These videos, developed by the research team based on the standard components of cardiac rehabilitation, cover topics such as understanding heart disease, warning signs and treatment, dietary recommendations for cardiac patients, smoking cessation and management, self-management skills (including medication adherence, decision-making, and problem-solving), psychological aspects such as stress and depression management, and safe home-based physical activity and exercise. The same educational videos will be provided to all study groups; however, participants in the control group will receive them via CD or a one-time file transfer through social media, based on their preference. They will not have access to the cardiac rehabilitation mobile application or its features (gamification or peer-support). During the first week and subsequently every two weeks, a brief follow-up phone call will be made to check the participants' status and encourage them to continue watching and practicing the educational materials. These calls are solely intended to maintain motivation and adherence and do not involve data collection.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Heart Educational, Medical and Research Center; Shahid Chamran Heart clinic

Full name of responsible person

Dr. Mohammadmehdi Hadavi

Street address

Isfahan Cardiovascular Clinic, Rahmani Alley, beside Shaheed Chamran Educational and Treatment Complex, after Pol-e Shahrestan, Moshtagh 3rd Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8158388994

Phone

+98 31 3611 5453

Email

mmhadavimd@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. gholamreza askari

Street address

No. 4 Building, Deputy of Research and Technology, Isfahan University of Medical Sciences, Hezar Jerib Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

askari@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

Dr. Ehsan Shirvani

Position

Assistant Professor of Cardiology

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Interventional Cardiology Research Center, Isfahan
Cardiovascular Research Institute, Shahid Rahmani
Alley, Moshtagh Sevom St., Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8158388994

Phone

+98 31 3611 5213

Email

shirvani_xs100@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Masoumeh Sadeghi

Position

Professor of Cardiology

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Isfahan Cardiovascular Research Center, Cardiac
Rehabilitation Research Center, Shaheed Chamran
Educational and Treatment Complex, Rahmani Alley,
after Pol-e Shahrestan, Moshtagh 3rd Street, Isfahan,
Iran

City

Isfahan

Province

Isfahan

Postal code

8158388994

Phone

+98 31 3611 5209

Email

sadeghimasoumeh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Sana Azizian

Position

Research Assistant

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Interventional Cardiology Research Center, Isfahan
Cardiovascular Research Institute, Shahid Rahmani
Alley, Moshtagh Sevom St., Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8158388994

Phone

+98 31 3611 5213

Email

sanaazizian98@gmail.com

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