

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of smartphone educational application on disease perception self-care behavior, and self-efficacy in patients undergoing percutaneous coronary intervention

Protocol summary

Study aim

Investigating the effect of smartphone educational applications on disease perception self-care behavior, and self-efficacy in patients undergoing percutaneous coronary intervention.

Design

A randomized, controlled with a control group, parallel groups, single-blind, randomized. we will use the block random allocation method for randomization.

Settings and conduct

By referring to the angioplasty department of Shahid Rajaei Hospital affiliated to Alborz Medical Sciences, patients are randomly assigned to intervention and control groups. The educational content application will be delivered to the patients in the intervention group, a smartphone follow-up. In the control group, patients receive only the usual medical intervention during this period. Four weeks after the intervention, the questionnaires will be completed.

Participants/Inclusion and exclusion criteria

Age between 18 and 60 years old. Ability to read and understand the Persian language. Having healthy senses of hearing and sight. Having access to a smartphone and being able to use them. Having access to and the ability to use a smartphone. Do not participate in another study at the same time. For the first time, percutaneous coronary interventions have been performed. Suffering from any disease that cannot continue participating in the study. Failure to continue accessing the smartphone for any reason.

Intervention groups

The Intervention group: In addition to routine training after discharge, people will receive educational content based on mobile health through an application that can be installed on a smartphone. The application will contain educational materials based on the Leventhal self-regulatory model. The patients in the control group

receive only the usual medical intervention, routine rehabilitation training, and practice during this period.

Main outcome variables

perception of self-care behavior, and self-efficacy

General information

Reason for update

change from double-blinded to single-blinded.

Acronym

IRCT registration information

IRCT registration number: **IRCT20110912007529N27**

Registration date: **2023-01-21, 1401/11/01**

Registration timing: **retrospective**

Last update: **2025-03-01, 1403/12/11**

Update count: **1**

Registration date

2023-01-21, 1401/11/01

Registrant information

Name

Nahid Rejeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 3071

Email address

reje@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-03, 1401/01/14

Expected recruitment end date

2022-07-11, 1401/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of smartphone educational application on disease perception self-care behavior, and self-efficacy in patients undergoing percutaneous coronary intervention

Public title

The effect of smartphone educational application on patients undergoing percutaneous coronary intervention

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 60 years old. Able to read and write in Persian Having sensory health of hearing and sight Access to smart phones and being able to use smart phones (patient/ his or her care giver) No simultaneous participation in research or other intervention Not having a history of known psychological disorders

Exclusion criteria:

Having any disease, which is not able to continue participating in the study lack of mobile phone access

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be randomly assigned into 2 groups using permuted block randomization with an allocation ratio of 2:2. Random allocation sequence will be determined using a computerized program (www.sealedenvelope.com).

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analyser won't have any information about the assigned group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran. Iran

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2022-11-28, 1401/09/07

Ethics committee reference number

Shahed.REC.1401.102

Health conditions studied

1

Description of health condition studied

angioplasty

ICD-10 code

Z95.5

ICD-10 code description

Presence of coronary angioplasty implant and graft

Primary outcomes

1

Description

Disease perception

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Brief illness perception questionnaire (BIPQ)

Secondary outcomes

1

Description

Self-care behavior

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Self-Care Miller Scale

2

Description

Self-efficacy

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Self-efficacy Sullivan scale

Intervention groups

1

Description

Intervention group: After discharge remote learning through phone calls will be made for this group. Interventions include assessment of patient care, and providing advice and training necessary to perform self-care behavior, the application will contain educational materials based on the Leventhal self-regulatory model.

Category

Rehabilitation

2

Description

Control group: patients who receive only the usual medical intervention, routine rehabilitation training, and practice during this period.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Martyr Rajaei Hospital

Full name of responsible person

Khatereh Salavati

Street address

Martyr Rajaei Hospital, Martyr Rajaei Avenue, Martyr Beheshti Avenue, Hesarak, Karaj, Alborz

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Rajaei@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Shahriar Bijani

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Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran, Iran

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bijani@shahed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

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

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Web page address**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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some of the statistical data is available after being unidentifiable

When the data will become available and for how long

The access period is up to after the publication of the results.

To whom data/document is available

Data is available to academic researchers.

Under which criteria data/document could be used

The use of information for academic research projects is allowed

From where data/document is obtainable

Requests for specific information should be sent by Nahid Rejeh (email: nrejah@yahoo.com)

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

Requests for specific information should be sent by Nahid Rejeh (email: nrejah@yahoo.com)

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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