

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of education using the interactive Avatar application on self-care, and the ability to identify and respond to the symptoms of heart attack in patients with acute coronary syndrome

Protocol summary

Study aim

Determining the effect of training using an interactive avatar application on self-care, and the ability to identify and respond to heart attack symptoms in patients with acute coronary syndrome.

Design

Clinical trial with intervention and control group, with parallel groups, without blinding, randomized, phase 3 on 70 patients, randomized time block method.

Settings and conduct

This study will be done in three stages: In the first stage, the content of the application will be collected and validated. In the second stage, the interactive avatar application will be designed and validated. The third phase of this study will include conducting a clinical trial in the CCU department of Imam Reza (a.s.) and Qaim (a.s.) hospitals in Mashhad.

Participants/Inclusion and exclusion criteria

1. Consent to participate in the study. 2. He has been hospitalized with acute coronary syndrome 3. Have stable clinical conditions 4. Be over 18 years old 5. To be fluent in Persian language to communicate and follow up the study. 6. The patient himself or his companion should have an Android mobile phone.

Intervention groups

The researcher will implement the intervention by giving a comprehensive explanation to the patients and obtaining an informed consent form from them. During the hospitalization of the patient, the interactive avatar application will be installed by the researcher on the patient's mobile phone (or the mobile phone of one of the patient's companions) and how to use the application will be taught to the patient by the researcher. Face and training will be applied using pamphlets. In both groups, the questionnaires will be completed before the intervention (in person) and one and three months after discharge (by phone and online).

Main outcome variables

Self -Care of coronary Heart Disease Inventory(SC-CHDI)
ACS Response Index Heart Attack Response questioner

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220920056001N1**

Registration date: **2023-01-03, 1401/10/13**

Registration timing: **prospective**

Last update: **2023-01-03, 1401/10/13**

Update count: **0**

Registration date

2023-01-03, 1401/10/13

Registrant information

Name

Nahid Keivanlou shahrestanaky

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education using the interactive Avatar application on self-care, and the ability to identify and respond to the symptoms of heart attack in patients with acute coronary syndrome

Public title

The effect of education using the interactive Avatar application on self-care, and the ability to identify and respond to the symptoms of heart attack in patients with acute coronary syndrome

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Consent to participate in the study Be hospitalized with the diagnosis of acute coronary syndrome Have a stable clinical condition Be over 18 years old To be fluent in Persian language to communicate and follow up the study The patient himself or his companion should have an Android mobile phone

Exclusion criteria:

Having cognitive impairment Having a hearing problem

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **70****Randomization (investigator's opinion)**

Randomized

Randomization description

The method of randomization is time block method. In this way, in order to prevent the dissemination of information, sampling in the intervention and control groups will be done in the middle of the week. In this way, the first group will be randomly selected by lottery, then the patients who meet the criteria for entering the study will be included in the intervention or control group in the middle of the week.

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 Faculty of Nursing and Midwifery- Mashhad University of Medical Sciences

Street address

Qureshi building, Near Hovaze Cinema , Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2022-09-18, 1401/06/27

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.062

Health conditions studied**1****Description of health condition studied**

Unstable angina

ICD-10 code

I20.0

ICD-10 code description

Unstable angina Angina:• crescendo• de novo effort• worsening effortIntermediate coronary syndromePre infarction syndrome

2**Description of health condition studied**

Acute myocardial infarction

ICD-10 code

I21

ICD-10 code description

Acute myocardial infarction: myocardial infarction specified as acute or with a stated duration of 4 weeks (28 days) or less from onset

Primary outcomes**1****Description**

Self-care score in self care coronary heart disease inventory

Timepoint

Self-care measurement at the beginning of the previous study (before the start of the intervention) and one month and three months after discharge from the hospital

Method of measurement

Self care of coronary heart disease inventory

2

Description

Identify the symptoms of a heart attack.

Timepoint

Measuring the ability to identify heart attack symptoms at the beginning of the previous study (before the start of the intervention) and one month and three months after discharge from the hospital.

Method of measurement

Acute coronary syndrome response index

3

Description

Response to heart attack symptoms

Timepoint

Measuring the response of heart attack symptoms at the beginning of the previous study (before the start of the intervention) and one month and three months after discharge from the hospital.

Method of measurement

Heart attack response questioner

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: installing the interactive avatar application on the mobile phone of the patient or one of their companions and teaching the patient how to use the application by the researcher to track the patients' use of the application during the follow-up period, the researcher will contact the research participants twice a week and in addition It will also answer their questions on reminding them to use the application.

Category

Other

2

Description

Control group: in the control group, the usual care that includes face-to-face training and training using pamphlets will be applied.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital (AS)

Full name of responsible person

Nayyereh Davoudi Hasanabad

Street address

Imam Reza (AS) Educational Research and Treatment Center, Imam Reza (AS) Hospital Square, Ibn Sina Street

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2

Recruitment center

Name of recruitment center

Ghaem Hospital (AJ).

Full name of responsible person

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Ghaem Hospital (AJ), Ahmedabad St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mobarhan

Street address

Research assistant, Qureshi building, Daneshgah street

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ghayourm@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source
Mashhad 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

four ways

City
Mashhad

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Person responsible for updating data

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Nahid Keivanlou

Position
Msc student in medical surgical nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
School of Nursing and Midwifery, Ibn Sina St, Doctoral four ways,

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Person responsible for scientific inquiries

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Position
Assistant Professor

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Other areas of specialty/work
Nursery

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School of Nursing and Midwifery, Ibn Sina St, Doctoral

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
It has no plans to publish

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available