

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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

##### Email address

keivanlousn992@mums.ac.ir

##### 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

**Age**

From **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**

120.0

**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**

121

**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

##### **City**

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9137913316

##### **Phone**

+98 51 3854 3031

##### **Email**

DavoudiN@mums.ac.ir

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Ghaem Hospital (AJ).

##### **Full name of responsible person**

Nayyereh Davoudi Hasanabad

##### **Street address**

Ghaem Hospital (AJ), Ahmmedabad 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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##### **Fax**

##### **Email**

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

## 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  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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Assistant Professor  
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## Person responsible for updating data

### 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**  
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**Other areas of specialty/work**  
Nursery  
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Keivanlousn992@mums.ac.ir

## 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