

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Investigating the effect of educational intervention based on mobile phone application on self-care behaviors of patients after Coronary artery bypass surgery

#### Protocol summary

##### Study aim

General purpose of the study Determining the effect of educational intervention through a mobile phone application on self-care behaviors after coronary heart transplant surgery in patients undergoing coronary heart transplant surgery.

##### Design

Clinical trial with a control group, without blinding, randomized, 3 study phases on 86 patients, consecutive sampling

##### Settings and conduct

In the first phase of this study, the educational content needed to design a mobile phone-based application for self-care of patients who have undergone coronary artery bypass surgery will be discussed. The data collected in this phase will be used as educational content of the educational application in the second phase of the study. Evaluation will be done in the third phase of the study. which will include the technical evaluation of the mobile application and the evaluation of the educational intervention through the mobile application on self-care behaviors after coronary heart transplant surgery in patients undergoing coronary heart transplant surgery in patients referred to the heart surgery center in Sanandaj.

##### Participants/Inclusion and exclusion criteria

The conditions for entering the study include the willingness and ability to participate in the study, having a smart mobile phone and the ability to work with mobile software and perform coronary artery bypass surgery. The conditions for not entering the study include having a neurological or cognitive disorder that cannot use a mobile phone, emergency coronary artery bypass surgery, and previous elective coronary artery surgery.

##### Intervention groups

Patients referred to heart surgery center in Sanandaj who are Electively undergoing coronary artery bypass

surgery

##### Main outcome variables

Adherence to drug therapy; Wound care; Diet; Physical activity; Return visit and follow-up by the Doctor

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230722058876N1**

Registration date: **2023-12-11, 1402/09/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-12-11, 1402/09/20**

Update count: **0**

##### Registration date

2023-12-11, 1402/09/20

##### Registrant information

##### Name

Saeed Yarahmadi

##### Name of organization / entity

Tarbiat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8288 4547

##### Email address

saeed.yarahmadi@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2024-06-20, 1403/03/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of educational intervention based on mobile phone application on self-care behaviors of patients after Coronary artery bypass surgery

**Public title**

Investigating the effect of educational intervention based on mobile phone application on self-care behaviors of patients after Coronary artery bypass surgery

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Willingness and ability to continue participating in research Having a smartphone and the ability to install software and use it Living in Sanandaj city within 6 months from the time of entering the study Coronary artery bypass surgery and discharge from the hospital Ability to provide informed consent

**Exclusion criteria:**

Participant suffering from a specific disease that makes it impossible for her to participate in the research Patients undergoing emergency surgery Patients who have neurological or cognitive impairments such as vision, hearing or cognitive impairment that impair their ability to use a digital device. Receive training before entering the study

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 86

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

From the list of participants who meet the entry criteria and based on the determined sample size, the test and control groups will be selected randomly from among the participating patients. Sampling method will be available in this study in such a way that the patients referred for elective coronary artery bypass surgery in the open heart surgery center of Sanandaj city, who have the conditions to enter, will be included in the study and in order to make the research conditions uniform. For two intervention and control groups, it will be using sequential sampling method.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Tarbit Modares University

**Street address**

Faculty of Medicine, Tarbiat Modares University, Jalal Al-Ahmad St., Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

331-14115

**Approval date**

2023-11-25, 1402/09/04

**Ethics committee reference number**

IR.MODARES.REC.1402.124

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

Coronary Artery Bypass surgery

**ICD-10 code**

Z95.1

**ICD-10 code description**

Presence of aortocoronary bypass graft

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

Self-care behaviors after coronary artery bypass graft surgery

**Timepoint**

Before discharge, 1 and 3 months after surgery

**Method of measurement**

Questionnaire of knowledge, attitude and application of self-care in patients undergoing coronary artery bypass surgery

**2****Description**

Knowledge of self-care behaviors after coronary artery bypass graft surgery

**Timepoint**

Before discharge, 1 and 3 months after surgery

#### **Method of measurement**

Questionnaire of knowledge, attitude and application of self-care in patients undergoing coronary artery bypass surgery

### **3**

#### **Description**

Attitudes towards self-care behaviors after coronary artery bypass surgery

#### **Timepoint**

Before discharge, 1 and 3 months after surgery

#### **Method of measurement**

Questionnaire of knowledge, attitude and application of self-care in patients undergoing coronary artery bypass surgery

## **Secondary outcomes**

### **1**

#### **Description**

Rehospitalization due to heart disease

#### **Timepoint**

After discharge, one and three months after surgery

#### **Method of measurement**

Number of hospital readmissions due to heart disease

### **2**

#### **Description**

Mortality due to heart disease

#### **Timepoint**

One year after surgery

#### **Method of measurement**

Death rate from heart disease

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Self-care educational content in the form of a mobile application in different ways (videos, text, images) and in different formats (tests, Lightner reminder box, gamification, reminders, alarms, progress monitoring, control of vital signs) which includes medication reminders (recognition Medicine, side effects of each medicine, amount and time of taking each medicine), how to care for the wound, diet control, reminder of physical activity, amount of physical activity, use of gamification and reminder of when to visit the doctor, will be in the right hand of these patients.

#### **Category**

Rehabilitation

### **2**

#### **Description**

Control group: Patients referred to the heart surgery center who underwent elective surgery and need

emergency surgery. If they want to participate in the study and meet the entry criteria, after providing explanations and receiving informed consent, they will be randomly placed in the control group and will receive the routine training of the department.

#### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Cardiac Surgery Center of Tohid Sanandaj Hospital

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

Saeed Yar Ahmadi

##### **Street address**

Sanandaj, Griashan Street, Tawheed Hospital

##### **City**

Sanandaj

##### **Province**

Kurdistan

##### **Postal code**

6616813131

##### **Phone**

+98 87 3328 6112

##### **Fax**

+98 87 3322 7118

##### **Email**

saeed.yarahmady@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tarbiat Modares University

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

Amir Abdulzadeh

##### **Street address**

Faculty of Medicine, Tarbiat Modares University, Jalal Al-Ahmad St., Tehran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

33114115

##### **Phone**

+98 21 8285 3590

##### **Email**

med@modares.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Tarbiat Modares University

#### **Proportion provided by this source**

**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

**2****Sponsor****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Omid Zarei

**Street address**Kurdistan University of Medical Sciences, Sanandaj,  
Pasdaran Blvd**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617913446

**Phone**

+98 87 3366 4645

**Email**

journal@muk.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Tarbiat Modares University

**Proportion provided by this source**

1

**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**

Tarbiat Modares University

**Full name of responsible person**

Saeed Yarahmadi

**Position**

PhD student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Tehran Jalal AleAhmad Nasr

**City**

Tehran

**Province**

Tehran

**Postal code**

33114115

**Phone**

+98 21 8288 4547

**Fax****Email**

saeed.yarahmadi@modares.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Saeed Yarahmadi

**Position**

PhD student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Tehran Jalal AleAhmad Nasr

**City**

Tehran

**Province**

Tehran

**Postal code**

333114115

**Phone**

+98 21 8288 4547

**Fax****Email**

saeed.yarahmadi@modares.ac.ir

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

Tarbiat Modares University

**Full name of responsible person**

Saeed Yarahmadi

**Position**

PhD student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Tehran Jalal AleAhmad Nasr

**City**

Tehran

**Province**

Tehran

**Postal code**

33114115

**Phone**

+98 21 8288 4547

**Fax****Email**

saeed.yarahmadi@modares.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

**Title and more details about the data/document**

Part of the data (information about the main outcome and secondary outcomes) can be shared.

**When the data will become available and for how long**

The access period starts 6 months after the results are published

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

By citing the source, the use of documents is allowed.

**From where data/document is obtainable**

Saeed Yarahmady, email: saeed.yarahmady@gmail.com, contact number 09188789172

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

Sending an email or calling the researcher's phone number and fully explaining the process through which the information of this research is going to be used.

**Comments**