

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparing the Effects of Gamification and Teach Back Training Methods on Treatment Regimen Adherence of Patients after Coronary Artery Bypass Graft Surgery

#### Protocol summary

##### Study aim

Comparing the effects of gamification and teach back training methods on adherence to treatment regimen of patients under Coronary Artery bypass Graft

##### Design

Randomized clinical trial with control group, triple block with sample size of 120 persons

##### Settings and conduct

The population of this study included all patients under CABG hospitalized in ICUs of hospitals affiliated to Tehran University of Medical Sciences who are trained with two approaches to adhering to a treatment regimen.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 18-60 years; Having an Android phone cell by a patient or main caregiver; Ability to understanding and speaking Persian; Willingness to participate in the study Exclusion criteria: Acute illness requiring emergency intervention

##### Intervention groups

After that patients are divided into three groups, they will complete the adherence to the therapeutic, physical activity and medication adherence questionnaires. Then in the first group (gamification) , the game is installed on the patient's or the primary caregiver's cellphone. This game is about physical activity, nutrition and adherence to the patient's medication. In the second group (teach back.) training will be provided in a simple and understandable language without the use of medical terms. At the end of each training session, the patient is asked to express what he or she understands in their own language. The control group received no intervention and the patient received routine care. Thirty days after the intervention, patients will receive the questionnaires again. It should be noted that the educational content of the two intervention groups is the same. After completion of the study, the educational content will be provided to the control group.

#### Main outcome variables

Adherence to treatment regimen

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111203008286N8**

Registration date: **2019-11-10, 1398/08/19**

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

Last update: **2019-11-10, 1398/08/19**

Update count: **0**

##### Registration date

2019-11-10, 1398/08/19

##### Registrant information

##### Name

Fatemeh Bahramnezhad

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6692 7171

##### Email address

fatemeh\_bahramnezhad@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-05, 1398/05/14

##### Expected recruitment end date

2020-03-04, 1398/12/14

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the Effects of Gamification and Teach Back Training Methods on Treatment Regimen Adherence of Patients after Coronary Artery Bypass Graft Surgery

**Public title**

Training patients with open heart surgery

**Purpose**

Education/Guidance

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

Patients with 18 and 60 years old Having an Android phone cell by a patient or main caregiver ability to speaking and understanding Farsi Willingness to participate in the study no hearing and speech impairment

**Exclusion criteria:**

patients' unwillingness to continue research in any part of the study The patient died

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **123**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples will be divided to 3 groups with block randomization. There are 9 possible ways to equally assign participants to block. Allocation proceeds by randomly selection by randomization.com after that will be recognized treatment assignment.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

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

empty

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

Ethics committee of Tehran University of Medical

Sciences

**Street address**

School of Nursing and Midwifery, Tohid Sq. Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Approval date**

2018-12-08, 1397/09/17

**Ethics committee reference number**

IR.TUMS.FNM.REC.1397.162

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

Treatment Regimen Adherence

**ICD-10 code**

I25.701

**ICD-10 code description**

Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm

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

Regimen adherence questionnaire score

**Timepoint**

Before and one month after the intervention

**Method of measurement**

Adherence to treatment regimen

**Secondary outcomes****1****Description**

Quality of life

**Timepoint**

2 months after intervention

**Method of measurement**

quality of life questioner

**Intervention groups****1****Description**

Intervention group: Before starting the test, the patient will complete informed consent form, demographic information questionnaire, dietary and movement regimen adherence questionnaire by Sanaie and colleagues, and Morisky Medication Adherence Scale. Then, the patient and the main caregiver in teach back

group receive simple and understandable instructions without medical terminology. At the end of each training section, the patient is asked to express what he or she has understood. For example, training for physical activity is as follows: (most of patients after surgery can walk for 3 to 10 minutes continuously without intolerance. Please focus on time, not speed. Choose smooth paths. Hills make you exhausted). After the training, information given to patients will be assessed. About the above subject, the patient will be told that if he wants to train one of his relatives, what will he state? After the explanations of the patient, if there is misunderstanding, the content will be revised and the patient and the main caregiver are asked to restate the content and this process continues until the patient has a correct understanding. But if the patient or the main caregiver did not understand the points, other sessions are taken into consideration. In the end, the presented information will be given to the patient in a form of a notebook to use it when needed. Thirty days after training, the questionnaire is completed again.

#### **Category**

Rehabilitation

### **2**

#### **Description**

Intervention group 2: For the patient and the main caregiver in the gamification group, the informed consent form and medication regimen adherence scale were completed and then, the training application is installed on the cellphone of the patient or the main caregiver after discharge and the methods to use the game will be explained by the researcher. After educational motions and its games, the android programming prepares all games and graphics for the user as an android application. The final application includes 3 sections of 5 to 10 minutes of animation about physical activity, medication regimen, dietary regimen, and game. Thirty days after intervention, the questionnaire is completed again. For the control group (recipient of regular care), before intervention, dietary regimen adherence questionnaire and demographic information scale will be completed and after 30 days, medication regimen adherence questionnaire is completed again

#### **Category**

Lifestyle

### **3**

#### **Description**

Control group: For the control group (receiving routine care), pre-intervention, demographic and adherence treatment questionnaires were completed and the questionnaires were completed again 30 days later. In this group, the patient doesn't receive any intervention.

#### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Dr. Shariati hospital

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

Fatemeh Bahramnezhad

##### **Street address**

Shariati hospital, Karegar St. Tehran, Iran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1419733171

##### **Phone**

+98 21 6105 4000

##### **Email**

bahramnezhad.f@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

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

Tehran University of Medical Sciences

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

Dr. Sahraian

##### **Street address**

Tehran University of Medical Sciences, Qodes street, Keshavarz Blvd.Tehran , Iran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1419733171

##### **Phone**

+98 21 8163 3698

##### **Email**

vcr@tums.ac.ir

##### **Web page address**

<http://www.tums.ac.ir>

#### **Grant name**

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

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

Yes

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

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Fatemeh Bahramnezhad

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Tohid Square, Dr. Mirkhani St. (East Nosrat)

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 21 6105 4000

**Email**

bahramnezhad.f@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Fatemeh Bahramnezhad

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Tohid Square, Dr. Mirkhani St. (East Nosrat)

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 21 6105 4000

**Email**

bahramnezhad.f@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Banafsheh Ghorbani

**Position**

Ms. student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

TehranTohid Square, Dr. Mirkhani St. (East Nosrat)

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 21 6105 4416

**Email**

banafshehghorbani@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**

Yes - There is 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**

No more information

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

No more information

**To whom data/document is available**

No more information

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

No more information

**From where data/document is obtainable**

No more information

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

No more information

**Comments**