Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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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

Ḍr. Shariati hospital

Full name of responsible person

Fatemeh Bahramnezhad

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Shariati hospital, Karegar St. Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

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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

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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