Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Development and Evaluation of a Deep Learning-Based Patient Assistant Model after Coronary Artery Bypass Graft Surgery: A Multi-Method Study

Protocol summary

Study aim
Design and evaluation of a combined care package after Coronary Artery Bypass Graft (CABG) Design and evaluation of the performance of a patient assistant model for identifying surgical site infection and performing incentive spirometry based on deep learning after CABG Determine and compare the effectiveness of a combined care package on pulmonary and motor function of patients after CABG in the experimental and control groups Determine and compare the effectiveness of a combined care package on the incidence of surgical site infection in the experimental and control groups

Design
Randomized clinical trial, with control group, with parallel groups, without blinding, randomization in a 1:1 ratio with a computer-generated random number sequence and using a block of four

Settings and conduct
Patients undergoing CABG at Jamaran Hospital will be randomly assigned to the intervention group, who will receive in-person and video training and use a deep learning-based patient assistant model, while the control group will receive only standard postoperative care.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Access and ability to use a deep learning-based model; Willingness and consent to participate in the study; Elective surgery patients; Patients with EF≥ 30% Exclusion criteria: Postoperative complications; infection before discharge; Patients requiring re-surgery or other medical intervention; Kidney failure requiring alternative treatment; Cognitive disorders; Hearing and vision disorders; Severe respiratory disorders; Long-term hospitalization after surgery

Intervention groups
The intervention group uses a deep learning-based patient assistant model and receives in-person and video training, and the control group receives standard post-coronary artery bypass grafting care protocols.

Main outcome variables
6-minute walk test results and incidence of surgical site infection

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221231056998N4**
Registration date: **2026-01-27, 1404/11/07**
Registration timing: **prospective**

Last update: **2026-01-27, 1404/11/07**
Update count: **0**

Registration date
2026-01-27, 1404/11/07

Registrant information
Name
Malihe Sadat Moayed
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-03-03, 1404/12/12
Expected recruitment end date
2027-02-01, 1405/11/12
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development and Evaluation of a Deep Learning-Based Patient Assistant Model after Coronary Artery Bypass Graft Surgery: A Multi-Method Study

Public title

valuation of a Deep Learning-Based Patient Assistant Model after Coronary Artery Bypass Graft Surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Access and ability to use a deep learning-based model Willingness and consent to participate in the study Age over 18 Elective surgery patients Patients with EF ≥ 30%

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned in a 1:1 ratio to one of the experimental (B) and control (A) groups using a computer-generated random number sequence using a block of four. Given the block size of four, there will be a total of six blocks as AABB, ABAB, ABBA, BBAA, BABA, BAAB. After the blocks are numbered, each block is used for four patients. In this case, if block number one is randomly selected, the first patient will be in group A, the second patient in group A, the third patient in group B, and the fourth patient in group B. For the fifth patient, one of the blocks is randomly selected again, and the fifth to eighth patients will be assigned to group A or B, respectively. This method will continue until the desired sample size is reached.

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

Research Ethics Committees of Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences, Sheikh Bahai street, Vanak Square

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Tehran

Province

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Postal code

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Approval date

2026-01-12, 1404/10/22

Ethics committee reference number

IR.BMSU.REC.1404.176

Health conditions studied

1

Description of health condition studied

Patients undergoing coronary artery bypass graft surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Effectiveness of the combined care package after coronary artery bypass graft surgery by measuring the outcomes of blood oxygen saturation, heart rate, distance traveled by the patient to assess pulmonary and motor function measured using the 6-minute walk test and the outcome of the incidence of surgical site infection checked with the SSI checklist recommended by CDC

Timepoint

The 6MWT will be used to evaluate the effect of the combined care package on the patients' pulmonary and motor function. After 30 days, the researcher will be present at the doctor's visit at the clinic and will perform a 6-minute walk test for both intervention and control groups. In this test, patients must walk along a specified 30-meter corridor. Before starting the test, the instructions for the test are explained to the patients, and the heart rate and oxygen saturation percentage of the patients are measured by the researcher with a pulse oximeter. Patients can rest if necessary, but they will start walking again as soon as they are able. Then, after 6 minutes, the distance covered by the patient, heart rate, and oxygen saturation percentage will be recorded. Finally, the results of the 6MWT will be compared in the two groups. The evaluation of the effect of the combined care package on the incidence of infection will be

performed using the SSI checklist recommended by the CDC. At the patient's first visit (approximately two weeks after surgery), the researcher will examine and judge the wound status through a checklist that includes items such as local pain or tenderness, local swelling in the wound area, redness or warmth in the wound area, purulent drainage, spontaneous separation of the wound edges, opening or aspiration as determined by the surgeon, and microbial growth in the culture sample if requested by the physician. The results of the wound examination in the two groups will be compared.

Method of measurement

Before and after the 6-minute walk test, the heart rate and oxygen saturation of the patients will be measured by the researcher with a pulse oximetry device. The distance traveled will be measured using a meter and corridor markings. The incidence of infection will be assessed using the SSI checklist recommended by the CDC.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Recipient of standard post-coronary artery bypass grafting care protocols

Category

Rehabilitation

2

Description

Intervention group: User of the deep learning-based patient assistant model and recipient of in-person and video training

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Jamaran hospital

Full name of responsible person

Malihe Sadat Moayed

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Malihe Sadat Moayed

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)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is 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
Not applicable

Title and more details about the data/document
De-identified patient demographic information, limited images of categories used in designing the de-identified deep learning model, de-identified study outcome information

When the data will become available and for how long
Accessible after results are printed.

To whom data/document is available
For researchers at academic institutions

Under which criteria data/document could be used
No decision has been made yet.

From where data/document is obtainable
No decision has been made yet.

What processes are involved for a request to access data/document
No decision has been made yet.

Comments