Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Impact of prehabilitation program on discharge readiness and surgery outcomes in patients going on a coronoray artery bypass Graft

Protocol summary

Study aim
Assessing effect of the prehabilitation program on discharge readiness and post-surgery outcomes in patients undergoing CABG surgery

Design
This study is a randomised clinical trial with a control group, with parallel groups, blinded outcome assesment on 60 patients. After checking the inclusion and exclusion criteria, the eligible patients will be assigned to two groups using a random 4 blocks method.

Settings and conduct
Participants will be randomly divided into intervention and control groups. The control group will receive standard care, while patients in the intervention group will receive the nurse-led prehabilitation program including respiratory muscle strengthening exercises, preoperative nutritional guidance, and stress management techniques. In this study, data analysts are blinded to the placement of patients in the intervention or control group.

Participants/Inclusion and exclusion criteria
Inclusion criatria are having an on-pump coronary bypass surgery, being on the elective coronary artery bypass surgery list, experiencing Heart surgery for the first time, ability to speak and understand Persian, not having diagnosed with anxiety or other psychological disorders (self-report), non-concurrency of CABG surgery with other surgeries. Exclusion criterias are History of cerebrovascular disease and/or stroke, Previous heart or lung surgery or disesases, Presence of neuromuscular disorder, and Patients with cognitive disorders and/or Alzheimer's disease

Intervention groups
The patients with a diagnosis of coronary artery disesase referred to IKHC cardiac surgery clinic will be screened for the eligibility criteria.

Main outcome variables
The patients' discharge readiness assessed by nurse and the patient, anxiety and depression before surgery and before discharge, length of stay in the hospital and intensive care unit, duration of intubation.

General information

Reason for update
Updating the publication schedule for printing the protocol study article.

Acronym
PreCABG

IRCT registration information
IRCT registration number: **IRCT20231019059768N1**
Registration date: **2024-05-23, 1403/03/03**
Registration timing: **prospective**

Last update: **2025-04-02, 1404/01/13**
Update count: **1**

Registration date
2024-05-23, 1403/03/03

Registrant information

Name
Pouya Dolat Abadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-30, 1403/03/10

Expected recruitment end date
2024-07-21, 1403/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of prehabilitation program on discharge readiness and surgery outcomes in patients going on a coronoray artery bypass Graft

Public title

prehabilitation in patients going on a coronoray artery bypass Graft

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having an on-pump coronary bypass surgery Being on the elective coronary artery bypass surgery list Experiencing Heart surgery for the first time Ability to speak and understand Persian Not having diagnosed with anxiety or other psychological disorders (self-report) Non-concurrency of CABG surgery with valve replacement or other surgeries

Exclusion criteria:

Emergency surgery History of cerebrovascular disease and/or stroke Previous heart or lung surgery Presence of neuromuscular disorder Previous COPD disease Vulvar diseases Patients with cognitive disorders and/or Alzheimer's disease

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be selected by continuous sampling and the patients will be placed in two groups of control and case by Block Balanced Randomization (BBR). By using the free website http://www.randomization.com/, the assignment sequence will take place. In such a way that the number of subjects in each block will be set to 6, for the control group letter A and for the case group, the letter B will be considered, and finally, by approving the Randomization Sequence in the system for 10 blocks, The assignment sequence will be created for the 60 samples by combining the letters A and B. Finally, the cards containing the blocks will be placed inside the standard envelope, and as a result, allocation concealment will be considered and observed. Based on qualified samples, a Shuffling Envelope will be taken by the researcher accidentally. Finally, the random allocation method will be determined by the research samples.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, data analysts are blinded to the placement of patients in the intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Research of Imam Khomeini Hospital Complex (RA)

Street address

Imam Khomeini Hospital Complex, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

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Approval date

2023-10-10, 1402/07/18

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.287

Health conditions studied

1

Description of health condition studied

Ischemic heart disease

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

Primary outcomes

1

Description

Score of patients' Discharge readiness assessed by Nurse

Timepoint

Immediately after making discision to discharge the patient

Method of measurement

According to readiness for hospital discharge scale RN assessment short form

2

Description
Score of patients' Discharge readiness by patient
Timepoint
Immediately after making discision to discharge the patient
Method of measurement
According to readiness for hospital discharge scale short form

3

Description
Anxiety score in hospital anxiety and depression scale (HADS)
Timepoint
At the beginning of the study (before the start of the intervention), and the night before the surgery, and immediately after making discision to discharge the patient.
Method of measurement
Hospital anxiety and depression scale (HADS)

4

Description
Depression score in hospital anxiety and depression scale (HADS)
Timepoint
At the beginning of the study (before the start of the intervention), and the night before the surgery, and immediately after making discision to discharge the patient.
Method of measurement
Hospital anxiety and depression scale (HADS)

5

Description
Duration of stay in the hospital
Timepoint
After patient's dicharge
Method of measurement
Based on the duration of hospitalization documented in the patient's files

6

Description
Duration of stay in intensive care unit
Timepoint
After patient's dicharge
Method of measurement
Based on the duration of stay in the intensive care unit documented in the patient's files

7

Description
Duration of intubation time
Timepoint
After patient's dicharge
Method of measurement
Based on the duration of intubation time documented in the patient's files

Secondary outcomes

empty

Intervention groups

1

Description
This intervention includes 1) communication between the researcher nurse and the patient 2) a general explanation about the surgical procedure in a way that does not cause anxiety 3) encouraging the patient to talk about his/her concerns and their causes and correcting the patient's inappropriate thoughts 4) introduction Stress management methods that include progressive muscle relaxation, deep breathing, and guided imagery and then teaching and practicing the preferred method to the patient. 5) Providing recommendations related to the type of nutrition before the operation, including consuming fewer carbohydrates, and consuming more foods containing protein, vitamins, and micronutrients. 6) Advising to quit smoking if needed and teaching exercises related to strengthening the respiratory muscles, such as using the pursed-lip breathing method to the patient and practicing these methods until the exercises are performed correctly by the patient. In this way, the eligible samples in the heart surgery clinic will be selected, and after obtaining informed consent; a demographic information questionnaire, hospital anxiety and depression scale, and Duke physical activity scale will be completed by volunteers. In the case of the test group, considering that heart surgery patients enter the study about 7 days before the surgery, the researcher starts his intervention one week before the surgery. In the first session, face-to-face training will take place in the heart surgery clinic, and at the same time, a complete Prehabilitation booklet will be provided to the patient. The second and third sessions will be held in the afternoon (between 16:00 and 18:00) in the patient's heart surgery department. In the second and third sessions of the intervention, while reviewing the teachings discussed in the first session, the patient is encouraged to raise issues that occupy his mind, the researcher answers the patient's questions, and then the patient's preferred stress management method and breathing exercises are performed. Each session lasts about 45 to 60 minutes based on the patient's needs. In the case of both control and test groups, routine care including drug therapy and hemodynamic control of the patient is performed. On the day of surgery, the hospital anxiety and depression scale questionnaire will be filled again by the patient. On the morning of the discharge, the hospital anxiety and depression scale and the discharge readiness questionnaire are filled by the patient. Also, the discharge readiness questionnaire from the nurse's point of view is completed by his/her direct nurse. The checklist including the length of stay in the ICU, the length of intubation, the length of stay in the

hospital, the approximate time of the patient's mobility, and the observation of atelectasis (according to the doctor's diagnosis) will be completed by the researcher. Also, after 30 days, the patient will be contacted and asked about re-hospitalization and the patient will be asked to complete Duke's physical activity questionnaire that was given to him on the day of discharge and send it to the researcher through messengers.

Category

Rehabilitation

2

Description

The control group will receive routine care including drug therapy and hemodynamic monitoring. The eligible samples in the heart surgery clinic will be selected, and after obtaining informed consent; a demographic information questionnaire, hospital anxiety and depression scale, and Duke physical activity scale will be completed. On the day of surgery, the hospital anxiety and depression scale questionnaire will be filled again by the patient. On the morning of the discharge, the hospital anxiety and depression scale and the discharge readiness questionnaire are filled by the patient. Also, the discharge readiness questionnaire from the nurse's point of view is completed by his/her direct nurse. The checklist including the length of stay in the ICU, the length of intubation, the length of stay in the hospital, the approximate time of the patient's mobility, and the observation of atelectasis (according to the doctor's diagnosis) will be completed by the researcher. Also, after 30 days, the patient will be contacted and asked about re-hospitalization and the patient will be asked to complete Duke's physical activity questionnaire that was given to him on the day of discharge and send it to the researcher through messengers.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital Complex

Full name of responsible person
Pouya Dolat Abadi

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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
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
Pouya Dolat Abadi

Position
Master of Sciences Studnet

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The data includes demographic information (such as age and gender), discharge readiness, duration of intubation, ICU stay, occurrence of atelectasis, onset of mobility, hospital stay, and levels of anxiety and depression. Additionally, data related to the 30-day readmission rate have been collected. All individual participant data will be processed through anonymization prior to sharing to ensure the privacy of individuals is protected. However, due to the sensitivity of the data and ethical considerations, only a portion of the data, particularly information related to primary outcomes (such as discharge readiness), will be available for public sharing. More sensitive data, such as detailed demographic information or specific clinical details, will only be provided to authorized researchers for specific research purposes with official permission.
When the data will become available and for how long
Access period begins after results are printed.
To whom data/document is available
We have a rigorous process in place to ensure that only qualified researchers who are affiliated with academic or research institutions and who can demonstrate their qualifications and data protection measures are given access. This access is exclusively for research purposes, safeguarding the integrity and security of our data.
Under which criteria data/document could be used
Data access is limited to research matching the study's goals and ethics. Researchers must sign an agreement banning re-identification and detailing non-commercial use. Analyses may need approval; publications require pre-approval for data integrity. Documents are restricted to related research per the agreement.
From where data/document is obtainable
Data can be accessed by contacting the corresponding author via provided email.
What processes are involved for a request to access data/document
Data can be accessed by contacting the corresponding author via provided email. The response is expected to

be provided within two weeks.

Comments