

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Assessing the effect of preoperative rehabilitation (prehab) program on physical function, balance and fear of fall of patients candidate for coronary artery bypass graft surgery

Protocol summary

Study aim

Determining the effect of preoperative rehabilitation program on physical function, balance and fear of falling in patients candidates for coronary artery bypass grafting (CABG)

Design

A clinical trial with a control group, with parallel groups without blinding, randomized on 92 patients, used the rand function of Excel software for randomization.

Settings and conduct

Research population: Elective heart surgery patients who refer to selected hospitals of Tehran University of Medical Sciences (Imam Khomeini Hospital and Tehran Heart Center). Otago exercise, leg exercise and breathing exercises in the first session in person for 45-60 minutes Provide videos and educational booklets to patients

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Adult patients at home (age over 60 years) On the waiting list for heart surgery for four weeks or more Heart surgery for the first time Ability to speak Persian Ability to use mobile and social networks Hemodynamically stable Willingness to participate in the study Inclusion criteria include cases of rehabilitation contraindications, such as cognitive impairment Inability to perform study steps Physical limitations prevent rehabilitation such as severely impaired patients.

Intervention groups

Preoperative rehabilitation program includes Otago exercise, stimulus spirometry use, coughing, and walking. Otago training protocol for four weeks, three sessions per week and the duration of each training session is 20 minutes Telephone interviews twice a week with patients to evaluate performance Upon completion of the study, postoperative care will be provided to members of the control group in order to comply with the

Otago sports ethics and training manual.

Main outcome variables

preoperative rehabilitation program Physical function, balance and fear of falling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220523054974N1**

Registration date: **2022-06-17, 1401/03/27**

Registration timing: **prospective**

Last update: **2022-06-17, 1401/03/27**

Update count: **0**

Registration date

2022-06-17, 1401/03/27

Registrant information

Name

Zoleikha Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessing the effect of preoperative rehabilitation (prehab) program on physical function, balance and fear of fall of patients candidate for coronary artery bypass graft surgery

Public title
Assessing the effect of preoperative rehabilitation (prehab) program on physical function, balance and fear of fall of patients candidate for coronary artery bypass graft surgery

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients at home (over the age of 60, according to the World Health Organization) waiting for coronary artery bypass graft surgery. Be on the waiting list for heart surgery for four weeks or more. Patients undergoing heart surgery for the first time. Be able to speak Persian and be literate. Be able to use mobile phones and social networks. Patients who are hemodynamically stable And tend to participate in the study.
Exclusion criteria:
Inclusion criteria include cases of rehabilitation contraindications, such as those with cognitive impairment and inability to complete the study process. Physical limitations that prevent rehabilitation, such as patients who are severely debilitated.

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description
Since the participants in this study gradually enter the study and in order not to create a balance in the number of participants in the two intervention and control groups, we will use random block allocation with square blocks. Using Excel 23 software, four blocks are defined, which in each block of houses are randomly divided between the control and intervention groups. Then, based on the order of the houses, the preparation cards are determined, which is the order of the 92 cards, which represent the group of each participant. Then each card is completely covered using a paper cover and the cards are coded in the previously specified order. With each person entering, an uncoated card is assigned and the

assigned group of each person is completely random and in full compliance. Blindness is responsible for random allocation.

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

Ethics committee of School of Nursing and Midwifery and School of Rehabilitation, Tehran University

Street address

Nosrat st., Tohid sq.

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Postal code

1419733171

Approval date

2022-05-21, 1401/02/31

Ethics committee reference number

IR.TUMS.FNM.REC.1401.021

Health conditions studied

1

Description of health condition studied

Patients undergoing coronary artery bypass graft surgery

ICD-10 code

I51.9

ICD-10 code description

Heart disease, unspecified

Primary outcomes

1

Description

Physical function, balance

Timepoint

12 months

Method of measurement

Patients' physical function (sppb), balance (berg), fear of falling (fes1) will be measured using designated instruments. The Short-Term Physical Function Assessment Questionnaire (SPPB) is a test designed to assess a patient's physical function. Balance in this study

is based on the Leaf Balance Test (BBS), which is used to measure the balance of the elderly.

Secondary outcomes

1

Description

Fear of falling

Timepoint

12 months

Method of measurement

International Fall Efficiency Scale Form: FES-1: This form has 10 items and the items in this questionnaire have four options (I am completely worried so I am not worried at all) (grades one to four) and each subject scores a total of 16 questions. Is (between 16 and 64); Each question measures the level of anxiety about falling when performing each of these activities on a 4-point scale (grades 1 to 4) and has 4 options (I am not worried about falling at all) to (I am completely worried about falling). Scores range from 16 to 64, with scores of 19-19 being the least worrying, scores of 20-27 being the average concern, and scores of 28-64 being the most worrying, with a higher score or score indicating concern or fear. more than

Intervention groups

1

Description

Intervention group: The members of the intervention group include people who will be randomly assigned to the intervention group based on the inclusion criteria. Consent to participate in the study will be taken from the group members. The use of the designated instrument in the form of practical tests based on performance will be completed by the researcher. The equipment required for these tests is a stopwatch, a chair and a meter. Then, preoperative rehabilitation program in the present study includes otago exercise, use of spirometer, cough and walking. Minutes will be taught. Intervention team members will be asked to practice the Otago Training Protocol for four weeks, three sessions per week, and each session lasts 20 minutes at home. The start of the Otago exercise program will include head movements, neck movements, torso extensions, torso movements and ankle movements, as well as balance exercises including bending the knee while standing, walking backwards, walking on heels and toes, standing on one foot. Changing posture from sitting to standing and walking up the stairs will also be included in the exercise program. Respiratory rehabilitation will also include diaphragmatic breathing and chest relaxation (10 attempts at deep breathing, deep nasal inhalation and exhalation), postural training (training in protective positions and cough movement, and use of respiratory spirometry with the patient. To provide the patient with self-care and correction of risk factors, nutritional care with the aim of providing energy to enable aerobic exercise, facilitate muscle repair and to adapt and help

cope with metabolic stress surgery and psychological interventions to reduce anxiety and emotional burden. Patients will be taught about surgery, a comprehensive training program will be provided to patients in the form of a booklet and a training video, and subsequent sessions include telephone interviews with patients twice a week to assess their performance in exercise, breathing, nutrition and correction of risk factors. , Talk of new concerns and clarify and correct any misconceptions about heart surgery.If you need to retrain the exercises, the necessary explanations will be given and finally after four weeks of intervention and ensure complete and correct performance Intervention the day before surgery for the second time and the fourth week After the surgery, for the third time, the study variables of physical function, balance and fear of falling will be measured and recorded based on the patient's performance using tools and practical tests.

Category

Behavior

2

Description

Control group: Includes people who will be randomly assigned to the control group based on inclusion criteria. Consent to participate in the study will be taken from the group members Demographic characteristics questionnaire and physical function questionnaire, balance and fear of falling using the tools determined as a test The practice-based practice will be completed by the researcher and the group members will be explained that no intervention will be performed on these patients but will be monitored during the study and if necessary ambiguities and questions will be answered and one month later From heart surgery, when they go to visit their surgeon, the researcher will complete the questionnaires of physical function, balance and fear of falling again using the designated tools as practical tests based on performance. After completing the study, in order to observe exercise ethics Otago and the postoperative care training booklet will be provided to members of the group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Zoleikha Abbasi

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Zoleikha Abbasi

Position

Master student of intensive care nursing

Latest degree

Bachelor

Other areas of specialty/work

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

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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

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