

# 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)

##### Phone

+98 21 7644 3892

##### Email address

abbasi-z@razi.tums.ac.ir

##### 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.  
**City**  
Tehran  
**Province**  
Tehran  
**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

##### **Street address**

North Kargar St., Tehran, Iran

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**2**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Hospital Complex

**Full name of responsible person**

Zoleikha Abbasi

**Street address**

Tohid Square, Tehran, Iran

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Akbar Fotouhi

**Street address**

corner of Quds St., Keshavarz Blvd.

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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**

Nursery

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Elham Navab

**Position**

Associate Professor, School of Nursing & Midwifery,  
Tehran University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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

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**Full name of responsible person**

Zoleikha Abbasi

**Position**

Master student of nursing intensive care

**Latest degree**

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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