

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The Effect of Continuous Care Model on Self-Efficacy and Adherence to Treatment in Patients Undergoing Coronary Bypass Graft

Protocol summary

Study aim

Determining the effect of continuous care model on self-efficacy and treatment compliance in patients undergoing coronary bypass graft

Design

Clinical trial with a control group, with parallel groups, without blinding, randomized, on 80 patients.

Settings and conduct

The two hospitals under the supervision of Shahid Beheshti University of Medical Sciences will be randomly selected, one to select the intervention group and the second control group, and further, random block sampling will be done in two intervention and control groups. After surgery, the intervention group of patients undergoing graft surgery can receive special care based on follow-up care model, and the control group can receive only routine care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 65 years old, not in critical or emergency conditions, 24 hours have passed since admission, no debilitating disease, able to communicate and not suffering from known physical and mental diseases, access to a smartphone with the ability to install a messenger. Exclusion criteria: not attending two sessions (or more) out of the total number of sessions, participating in another educational program, entering the acute phase of the disease and needing to be re-hospitalized, not answering all the questions.

Intervention groups

In the intervention group, patients will receive health care based on training based on the continuous care model, including four stages of familiarization, sensitization, control, and evaluation, but the control group will receive only common care.

Main outcome variables

-Self-efficacy in patients undergoing coronary bypass surgery -Adherence to Treatment in patients undergoing coronary bypass surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230924059499N1**

Registration date: **2023-10-31, 1402/08/09**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-31, 1402/08/09**

Update count: **0**

Registration date

2023-10-31, 1402/08/09

Registrant information

Name

Anis Kunani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3262 4715

Email address

aniskunani3611@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-17, 1402/07/25

Expected recruitment end date

2023-12-16, 1402/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Continuous Care Model on Self-Efficacy and Adherence to Treatment in Patients Undergoing Coronary Bypass Graft

Public title

The Effect of Continuous Care Model on Self-Efficacy and Adherence to Treatment in Patients Undergoing Coronary Bypass Graft

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 65 years Patients undergoing coronary bypass graft surgery for the first time Being alert Not being in dire and emergency situations 24 hours have passed since the patient was admitted No debilitating disease Not preventing speech, hearing and vision and able to establish communication and cooperation It is the absence of physical and mental diseases that affect the quality of life, such as dialysis or other mental problems, such as complications and problems that require medication or a special diet Access to a smartphone with the ability to install messenger

Exclusion criteria:

Do not attend two (or more) meetings out of the total number of meetings People who have participated in another educational program during the research People who enter the acute phase of the disease and need to be re-hospitalized Transfer from the desired research unit to another unit Withdrawal from participating in the study Failure to answer all questions in the questionnaire

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The sequence of random allocation and the list of blocks will be obtained with the help of R software. In this method, the number of people assigned to each group is almost equal. In this method, blocks are formed based on the variables in question. Block randomization works by randomizing participants into blocks, so that an equal number are assigned to each group. Equal numbers of participants are included in the intervention and control groups at consecutive but equal intervals. After each patient is hospitalized for coronary bypass graft surgery, according to the block of four prepared in the first stage, each patient will be randomly assigned to group A (intervention) or B (control group). For example, after randomly selecting a block such as ABAB block, patients are randomly placed in the intervention, control, intervention, and control groups, and the next patients are placed in the BBAA block as control, control, intervention, and intervention groups. After creating a

random sequence, sampling must be done by hiding the created sequence. In such a way that before assigning an individual, the assigned group is not specific for the samples. This can be done by putting a random sequence inside the envelope and choosing the non-transparent envelope by people. In this method, first a random sequence is created, then based on the size of the research sample, a number of envelopes are prepared and each of the created random sequences is recorded on a card and the cards are placed in the envelopes in order. . In order to preserve the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box in order. At the time of the registration of the participants, according to the order of entry of the eligible participants into the study, one of the letter envelopes is opened in order and the group The allocation of that participant is revealed. Each patient's code will be assigned. People are assigned to the desired group in the order of their entry into the study and randomly through randomized blocks

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 Shahid Beheshti University of Medical Sciences

Street address

Tehran, Vali Asr St., intersection of Ayat A... Hashemi Rafsanjani Highway, in front of Heart Hospital

City

Tehran

Province

Tehran

Postal code

1996835119

Approval date

2023-06-20, 1402/03/30

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.044

Health conditions studied

1

Description of health condition studied

Coronary artery bypass graft

ICD-10 code

I25.70

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris

Primary outcomes**1****Description**

Esteka's general self-efficacy

Timepoint

Measuring self-efficacy at the beginning of the study and 56 days after the start of the intervention

Method of measurement

Estaka General Self-Efficacy Questionnaire

2**Description**

Adherence to treatment

Timepoint

Measurement of adherence to treatment at the beginning of the study and 56 days after the start of the intervention

Method of measurement

Modanlo adherence to treatment Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group received training related to the continuous care model, which includes four stages of familiarization, sensitization, control and evaluation, in the form of individual and group training, one session before surgery and 3 sessions after surgery.

Category

Rehabilitation

2**Description**

The control group received routine ward care

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hossein Hospital

Full name of responsible person

Anis Kunani

Street address

No. 72, Shahid Shahbazi St

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2**Recruitment center****Name of recruitment center**

Shahid Modares Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Tehran-Shahid Chamran Highway - Yemen St. - Arabi St

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Anis Kunani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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