

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of partnership-based education on adherence to the treatment plans of patients undergoing open heart surgery

Protocol summary

Study aim

Determining the effect of partnership-based education on adherence to the treatment plans of patients undergoing open heart surgery

Design

A randomized, double blind, parallel group, controlled clinical trial on 86 patients. R software will be used for randomization.

Settings and conduct

The educational intervention (5 sessions for a week) is performed in the post-ICU of cardiac surgery of Imam Khomeini Hospital in Tehran, which has 13 beds. The collection of data are performed by a trained nurse outside the research team and analyst will not be aware of how individuals are assigned to the groups

Participants/Inclusion and exclusion criteria

Inclusion criteria are non-emergency surgery, performing heart surgery for the first time, ability to attend physically in educational sessions, have a minimum literacy rate, possibility of telephone access to follow up program. Exclusion criteria are previous experience of caring for a patient undergoing heart surgery, known mental illness.

Intervention groups

Intervention involves providing partnership-based education in which the patient and family member participate in educational sessions at the same time. The total number of sessions consists of 5 sessions for a week and the time of each session is between 20 to 40 minutes and includes two sessions of individual training with the presence of a patient and a family member and 3 sessions of group training including groups of 4 to 6 including patients and their family members. The content of the sessions includes the reason for the importance of following the medication regimen and the role of proper diet after surgery, as well as the time of starting chest physiotherapy, exercise and the time of starting sexual activity and the need to participate in cardiac rehabilitation program. The control group receives routine

ward care.

Main outcome variables

Adherence to dietary; physical activity and medication plan

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200714048104N2**

Registration date: **2020-08-29, 1399/06/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-29, 1399/06/08**

Update count: **0**

Registration date

2020-08-29, 1399/06/08

Registrant information

Name

Foroozan Atashzadeh-Shoorideh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2520

Email address

f_atashzadeh@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-04, 1399/04/14

Expected recruitment end date

2020-10-20, 1399/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of partnership-based education on adherence to the treatment plans of patients undergoing open heart surgery

Public title

partnership-based education and adherence to the treatment plans

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing non-emergency coronary artery bypass graft surgery and valve replacement surgery
Performing open heart surgery for the first time
Ability to read of educational booklet
Ability to attend physically in the educational sessions
Possibility of telephone access to follow up program
First-degree members of the patient who are in close contact with him / her and who are responsible for caring for the patient after discharge from the hospital
Have a minimum literacy rate

Exclusion criteria:

Previous experience of caring for a patient undergoing heart surgery for a family member known mental illness

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

The random assignment sequence and list of blocks will be obtained using R software. The block method is used for sampling. According to the total number of samples required for the study, which is 86 patients (43 patients in the intervention group (A) and 43 patients in the control group (B)), 21 blocks with a size of four includes two groups A and B will be randomly selected using the software, such as (ABAB). Then 86 pockets (43 pockets A and 43 pockets B) will be prepared. According to a list of blocks, a trained person outside the research team is responsible for randomly assigning patients. After admission of each patient to the intensive care unit, will be given a pocket and assigned to Group A (intervention) or B (control group), and the sample process will be performed sequentially until the end of completion of sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the nature of the study, it is not possible to blind participants and implement the intervention. But, the collection of demographic information and adherence of therapeutic plan assessment questionnaires (outcome assessment) are performed before and after the intervention by a trained nurse outside the research team and data analyst will not be aware of the assignment of individuals to groups.

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

Next to Ayatollah Taleghani Hospital, Shahid Arabi St, Yemen St, Shahid Chamran Highway, Tehran

City

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Province

Tehran

Postal code

1996835119

Approval date

2020-04-30, 1399/02/11

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.112

Health conditions studied**1****Description of health condition studied**

Cardiac disease

ICD-10 code

I51.6

ICD-10 code description

Cardiovascular disease, unspecified

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

adherence to dietary plan

Timepoint

Before intervention and 8 weeks after end of intervention

Method of measurement

questionnaire of adherence to dietary plan

2

Description

adherence to physical activity plan

Timepoint

Before intervention and 8 weeks after end of intervention

Method of measurement

questionnaire of adherence to physical activity plan

3

Description

adherence to medication plan

Timepoint

Before intervention and 8 weeks after end of intervention

Method of measurement

standard 8-item Morisky Medication Adherence scale (MMAS-8)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention includes education with partnership-based approach that will consist of 5 sessions including two sessions of individual training and three sessions of group training for (20 to 45) minutes. The first session includes individual training with the presence of the patient and the caregiver. The duration of the first session will be between 20 and 35 minutes, and information about the type of surgery, the necessary preparations before surgery, the reason for transfer to the ICU, the duration of hospitalization in the intensive care unit, the reason for using connections such as chest tubes and pacemakers, Will be given to them face to face with a focus on questions and answers. Then, three group training sessions (30 to 45 minutes) after transferring the patient to the post-ICU ward with the presence of patients and caregivers will be done in groups of 4 to 6 people. Group educations are speech-based with PowerPoint slides, group discussion, questions and answers and practical presentations. The content of the educations include the importance of medication regimen after surgery, the role of the proper diet after surgery, start time of the chest physiotherapy program, exercises, time to start sexual activity and the need to participate in a cardiac rehabilitation program. The last session is an individual training session (20 to 25 minutes) for each patient with the caregiver and the content of the education includes a description of the schedule of subsequent referrals after discharge and taking into account the warning signs and early and delayed complications after surgery, how to deal with these complications and referring to the hospital for a quick follow-up, necessary periodical tests, at the end, educational booklet and medication pamphlet were given to the participants.

Category

Other

2

Description

Control group: The control group uses routine hospital training and in order to observe ethics in research, the control group participants received a booklet and educational pamphlet

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Foroozan Atashzadeh-Shoorideh

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Imam Khomeini Hospital Complex, Dr. Gharib Street; at the end of Keshavarz Boulevard, Tehran

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Sponsors / Funding sources

1

Sponsor

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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
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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data analysis information

When the data will become available and for how long

After the publication of the article

To whom data/document is available

Nursing researchers and students

Under which criteria data/document could be used

It has not been decided yet

From where data/document is obtainable

Email to nedasanaie@sbmu.ac.ir

What processes are involved for a request to access

data/document

Email to nedasanaie@sbmu.ac.ir

Comments