

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Effect of guided reflection on self-care and medical adherence in patients undergoing Coronary Artery Bypass Graft

Protocol summary

Study aim

this study will determine the effect of guided reflection on self-care and medical adherence in patients undergoing Coronary Artery Bypass Graft.

Design

One arm parallel group randomized trial with blinded postoperative care and outcome assessment on 94 patients. The 4-volume block method is used to generate a random allocation sequence.

Settings and conduct

In order to access and select the samples, The researcher refer to the CCU unit first and after entering the environment, while introducing oneself to patients undergoing coronary artery surgery who has the inclusion criteria, explaining the study objectives, importance, reason of performing the research, how to perform the research and Informed written consent will be obtained. Data collectors and data analyzer and clinical caregivers are blinded and will not be aware that how individuals are assigned to groups. the data collector will be a trained expert nurse who does not know how patients are allocated.

Participants/Inclusion and exclusion criteria

Inclusion criteria include no history of coronary artery bypass graft surgery, ability to communicate verbally, age range 30 to 75 years. Exclusion criteria is Patients with Cognitive impairment.

Intervention groups

Guided reflection, which includes several stages, will be explained to the patients in the exam group, and based on it and the questions that are asked in each stage, the person will discuss the situations and events that he/she has faced and his/her feelings. Express their positive and negative feelings about it and takes steps to better understanding and planing for A better performance in similar situations that are predicted in the future. In control group, they will have routine trainings of the clinic (Includes presentation of medication pamphlet and oral training by physician and nurse).

Main outcome variables

Self care: Medical adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200907048645N1**

Registration date: **2020-09-19, 1399/06/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-19, 1399/06/29**

Update count: **0**

Registration date

2020-09-19, 1399/06/29

Registrant information

Name

Elahe Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3323 2866

Email address

elahe2941@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-15, 1399/06/25

Expected recruitment end date

2020-11-15, 1399/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of guided reflection on self-care and medical adherence in patients undergoing Coronary Artery Bypass Graft

Public title

Effect of guided reflection on self-care and medical adherence

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

lack of experiencing CABG surgery before Ability to communicate verbally Between 20 to 60 years old

Exclusion criteria:

Patients with Cognitive impairment

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

The 4-volume block method is used to generate a random allocation sequence. Patients will be selected according to the criteria of the researcher and by sequential sampling method and will be randomly divided into two groups A and B. This means that a number of sealed envelopes are prepared, each containing an A or B code. The researcher takes the desired envelope in the specified order and acts according to the group registered in the envelope. It is determined in which group each patient will be placed.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, data collectors and data analyzer and clinical caregivers are blinded and will not be aware that how individuals are assigned to groups. In this way, the data collector will be a trained expert nurse who does not know how patients are allocated. Participants and researchers are not blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahrood University of Medical Sciences

Street address

Shahrood medical university, 7 tir Sq

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Approval date

2020-09-08, 1399/06/18

Ethics committee reference number

IR.SHMU.REC.1399.101

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**

Self care

Timepoint

Self-care will be measured at the beginning of the study, before the intervention, and six weeks after the intervention.

Method of measurement

Cardiac Patients' Self-Care Questionnaire Validated by Khodaminasab et al

2**Description**

Medical adherence

Timepoint

Medical adherence will be measured at the beginning of the study, before the intervention, and six weeks after the intervention.

Method of measurement

Morisky medical adherence questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Guided reflection, which includes several stages, will be explained to the patients in the experimental group, and based on it and the questions that are asked in each stage, the person will discuss the situations and events that he/she has faced And expresses his positive and negative feelings about it and Steps are taken to better understand and plan for better performance in similar situations that are predicted in the future.

Category

Rehabilitation

2

Description

Control group: related to the control group, they will have routine trainings in the clinic and ward (including providing medical pamphlets and oral training by a doctor and nurse).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh zahra hospital

Full name of responsible person

Elahe Mousavi

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Fatemeh Zahra hospital, Artesh Blvd, Emam hosein Sq

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Web page address

<https://fatemehzahrahospital.mazums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr Mohammad Hasan Emamian

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Web page address

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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

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Elahe Mousavi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

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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