

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of cardiac rehabilitation versus control group on improving the psychological characteristics of patients undergoing coronary artery bypass graft surgery: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of cardiac rehabilitation versus control group on improving the psychological characteristics of patients undergoing coronary artery bypass graft surgery

Design

This is a randomized clinical trial, phase II, in which 60 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients who are candidate for coronary artery bypass graft surgery referring to the Farshchian Heart Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 40 to 70 years, Candidate for undergoing coronary artery bypass graft surgery, Ability to read and enough understanding, Ability to perform sport exercise, Exclusion criteria: Limb defect, History of cardiac rehabilitation, History of previous cardiac surgery, Emergency cardiac surgery, Coronary artery bypass graft surgery with valve replacement, History of mental disorder, Taking sedatives or anti-anxiety drugs

Intervention groups

Intervention group: Routine care after coronary artery bypass graft surgery plus physical exercise and physiotherapy for cardiac rehabilitation in accordance with patient's cardiovascular status (including walking on a treadmill, stationary biking, walking, jogging, aerobics and stretching exercises) 60-minute sessions three times a week for one month. Control group: Just care after coronary artery bypass graft surgery

Main outcome variables

Primary outcome: Mean score of psychological indexes

General information

Reason for update

Due to increasing the number patients for improving the results

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N389**

Registration date: **2021-03-31, 1400/01/11**

Registration timing: **prospective**

Last update: **2023-08-01, 1402/05/10**

Update count: **1**

Registration date

2021-03-31, 1400/01/11

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of cardiac rehabilitation versus control group on improving the psychological characteristics of patients undergoing coronary artery bypass graft surgery: a randomized clinical trial

Public title

Effect of cardiac rehabilitation versus control group on improving the psychological characteristics of patients undergoing coronary artery bypass graft surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 40 to 70 years, Candidate for undergoing coronary artery bypass graft surgery, Ability to read and enough understanding, Ability to perform sport exercise,

Exclusion criteria:

Limb defect, History of cardiac rehabilitation, History of previous cardiac surgery, Emergency cardiac surgery, Coronary artery bypass graft surgery with valve replacement, History of mental disorder, Taking sedatives or anti-anxiety drugs

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2020-10-03, 1399/07/12

Ethics committee reference number

IR.UMSHA.REC.1399.564

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

Psychological characteristics

ICD-10 code

F89

ICD-10 code description

Unspecified disorder of psychological development

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

Mean score of psychological indexes (including physical complaints, obsession, sensitivity, depression, anxiety, aggression, phobia, paranoid thoughts and psychosis)

Timepoint

Before the intervention and 4 weeks later

Method of measurement

Using Symptom Checklist-90 (SCL90-R)

Secondary outcomes

empty

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

Intervention group: Routine care after coronary artery bypass graft surgery plus physical exercise and physiotherapy for cardiac rehabilitation in accordance with patient's cardiovascular status (including walking on a treadmill, stationary biking, walking, jogging, aerobics and stretching exercises) 60-minute sessions three times

a week for one month.

Category
Rehabilitation

2

Description
Control group: Just care after coronary artery bypass graft surgery

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Farshchian Heart Hospital in Hamadan city

Full name of responsible person
Samira Yadollahifar

Street address
Farshchian Heart Hospital, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Saeid Bashirian

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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

Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Samira Yadollahifar

Position
Master in Nursery

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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