Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 scientific inquiries

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Latest degree

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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