# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 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)
**Phone**
+98 81 1838 0090
**Email address**
poorolajal@umsha.ac.ir

**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.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 1740

**Email**

samirayadollahi67@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

info.research@umsha.ac.ir

**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

**Street address**

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

samirayadollahi67@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Ali Akbari

**Position**

Master in Nursery

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

aakbari4973@gmail.com

## 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

**Street address**

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Email**

poorolajal@umsha.ac.ir

## 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