

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of two different high-intensity interval training on clinical status improvement after coronary artery bypass grafting in cardiac patients

#### Protocol summary

##### Study aim

Comparison of the effect of two different high-intensity interval training on clinical status improvement after coronary artery bypass grafting in cardiac patients

##### Design

A clinical trial with the control group, parallel groups, double-blind, block randomization, 99 patient as a sample size

##### Settings and conduct

The purpose of this study is to evaluate the efficacy of two types of high-intensity interval aerobic exercise on improving the clinical status of cardiac patients after coronary artery bypass surgery using a control group. The location is Farshchian Cardiovascular Hospital. The study is a double-blind in which participants, researchers, clinical caregivers, outcome assessors, and data analyzers were blinded. Clinical measurements will also be performed before and after the training period.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. The patient undergoes a coronary artery bypass grafting surgery 2. The age of the patient must be between 40-80 years old Exclusion criteria: 1. The patient should not undergo reconstructive heart valve injury 2. The patient should not have disabling movement disorders

##### Intervention groups

1. Control group that performs the routine exercise program of the hospital rehabilitation center 2. High-intensity interval training group with short-time active intervals 3. High-intensity interval training group with mid-time active intervals

##### Main outcome variables

Maximal aerobic power, Systolic and diastolic function of cardiac left ventricle, Heart rate variability, Quality of life, Lower extremity muscle strength

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200113046119N1**

Registration date: **2020-04-11, 1399/01/23**

Registration timing: **prospective**

Last update: **2020-04-11, 1399/01/23**

Update count: **0**

##### Registration date

2020-04-11, 1399/01/23

##### Registrant information

##### Name

Reza Ghahremani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3422 4042

##### Email address

ghahremani@webmail.guilan.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2020-12-21, 1399/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effect of two different high-intensity interval training on clinical status improvement after coronary artery bypass grafting in cardiac patients

## Public title

Investigation of the effect of exercise training on clinical status in infarction cardiac patients

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

The age of the subjects must be between 40-80 years old-age The subjects must undergo the coronary artery bypass grafting surgery

### Exclusion criteria:

There are disabling motor disorders in the patient The patient undergoes reconstructive valve surgery

## Age

From **40 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **99**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block randomization is used in the current study. The randomization unit is also considered individual. The random number table is also used as a randomization tool.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

This study is double-blinded that the subjects, clinical caregivers, researchers, outcome evaluators, and data analyzers are unaware of the allocation of study groups. Of course, The overall introduction of the study groups has been completely provided to the participants.

## 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

Shahid Fahmideh Ave

#### City

Hamadan

#### Province

Hamadan

#### Postal code

65178

### Approval date

2019-10-07, 1398/07/15

### Ethics committee reference number

IR.UMSHA.REC.1398.310

## Health conditions studied

## 1

### Description of health condition studied

Coronary artery disease

### ICD-10 code

I25

### ICD-10 code description

Chronic ischemic heart disease

## Primary outcomes

## 1

### Description

Maximal aerobic power

### Timepoint

Before and after the treatment

### Method of measurement

Bruce treadmill test

## 2

### Description

Heart rate variability

### Timepoint

Before and after the treatment

### Method of measurement

Electrocardiogram assessment of the patient

## 3

### Description

Quality of life

### Timepoint

Before and after the treatment

### Method of measurement

Heart disease patient's questionnaire

## 4

### Description

Lower extremity muscle strength

### **Timepoint**

Before and after the treatment

### **Method of measurement**

One repetition maximum test of the leg press

## **5**

### **Description**

Systolic and diastolic function of cardiac left ventricle

### **Timepoint**

Before and after the treatment

### **Method of measurement**

Echocardiography

## **Secondary outcomes**

## **1**

### **Description**

Resting heart rate of the patient

### **Timepoint**

Before and after the treatment

### **Method of measurement**

Polar heart rate monitoring

## **2**

### **Description**

Recovery heart rate of the patient

### **Timepoint**

Before and after the treatment

### **Method of measurement**

Polar heart rate monitoring

## **3**

### **Description**

Blood pressure

### **Timepoint**

Before and after the treatment

### **Method of measurement**

Mercury manometer

## **4**

### **Description**

Body composition of the patient

### **Timepoint**

Before and after the treatment

### **Method of measurement**

Body composition analyzer

## **Intervention groups**

## **1**

### **Description**

First intervention group: High-intensity interval training Group with Short Activity Interventions: This group will perform high-intensity interval training exercises with 15-second intervals on the treadmill for 12 weeks and 24 training sessions. Indeed, there will be two training

sessions in a week. The group's training program involves 15-second activity intervals with the intensity of 100% maximal aerobic power, with 15-second passive recovery among them. Each training session continues for 35 minutes.

### **Category**

Rehabilitation

## **2**

### **Description**

Control group: This group will participate in the routine rehabilitation program of the Hamadan Farshchian Hospital for 12 weeks and 24 training sessions. Indeed, there will be two training sessions in a week. Each training session continues for 35 minutes. The group's training program involves aerobic continuous moderate-intensity training on the treadmill.

### **Category**

Rehabilitation

## **3**

### **Description**

Second intervention group: High-intensity interval training Group with intermediate Activity Interventions: This group will perform high-intensity interval training exercises with 60-second intervals on the treadmill for 12 weeks and 24 training sessions. Indeed, there will be two training sessions in a week. The group's training program involves 60-second activity intervals with the intensity of 100% maximal aerobic power, with 60-second passive recovery among them. Each training session continues for 35 minutes.

### **Category**

Rehabilitation

## **Recruitment centers**

## **1**

### **Recruitment center**

#### **Name of recruitment center**

Farshchian hospital

#### **Full name of responsible person**

Lobat Majidi

#### **Street address**

Shahid Fahmideh Ave

#### **City**

Hamadan

#### **Province**

Hamadan

#### **Postal code**

6517839131

#### **Phone**

+98 81 3838 1740

#### **Email**

hcv@umsha.ac.ir

## **Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Saeed Bashirian

**Street address**

Shahid Fahmideh Ave

**City**

Hamadan

**Province**

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**Phone**

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**Email**

s\_bashrian@yahoo.com

**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**

Lobat Majidi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Lobat Majidi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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### Person responsible for updating data

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**Full name of responsible person**

Lobat Majidi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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**Email**

lobat.majidi@gmail.com

### 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**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable