

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The Effect of Eight Weeks Aerobic Exercise and Sertraline Intake on Neurotrophic Factors, Inflammatory, Depressive, and Quality of Life of Patients after Coronary Artery Bypass Graft Surgery

#### Protocol summary

##### Study aim

Determining the effects of aerobic exercise and sertraline on neurotrophic, inflammatory, depressive and quality of life factors among the patients after coronary artery bypass graft surgery

##### Design

Double blind placebo controlled randomized clinical trial

##### Settings and conduct

The research method is quasi-experimental with pretest-post test design. The statistical population of this study consisted of men with the age of 40-60 years with coronary artery bypass graft referring to Fatemeh Zahra Hospital in Sari. The Sampling method was available. The groups were blinded by the participants in terms of participants and coded by the researcher. Finally, study hypotheses in the study groups were examined.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The patients who underwent CABG surgery for the first time. They ranged from 40 to 60 years in age. At least 2 to 6 months have elapsed since CABG surgery. Anxiety and depression scores are based on the HADS score of 8 or higher. Exclusion criteria: Having complicated ventricular arrhythmia, having a heart failure, having regular exercise history

##### Intervention groups

1- Aerobic training group, 2- Drug Intervention Group, 3- Drug-exercise group (Combined), 4- Control group. The intervention time for all 4 groups were 8 weeks. The drug group and the drug-exercise group took 25 to 50 mg once daily for 8 weeks. No intervention was performed on the control group and routine care was taken and placebo was given to them.

##### Main outcome variables

Health practitioners and physicians

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191125045496N1**

Registration date: **2020-04-17, 1399/01/29**

Registration timing: **retrospective**

Last update: **2020-04-17, 1399/01/29**

Update count: **0**

##### Registration date

2020-04-17, 1399/01/29

##### Registrant information

##### Name

Mostafa Behzad Khamislo

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3310 9230

##### Email address

mostafabehzadkh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-11, 1398/05/20

##### Expected recruitment end date

2019-10-12, 1398/07/20

##### Actual recruitment start date

2019-08-11, 1398/05/20

##### Actual recruitment end date

2019-11-16, 1398/08/25

##### Trial completion date

2020-01-30, 1398/11/10

## Scientific title

The Effect of Eight Weeks Aerobic Exercise and Sertraline Intake on Neurotrophic Factors, Inflammatory, Depressive, and Quality of Life of Patients after Coronary Artery Bypass Graft Surgery

## Public title

The effect of Aerobic Exercise with Sertraline On Patients after Coronary Artery Bypass Graft Surgery

## Purpose

Health service research

## Inclusion/Exclusion criteria

### Inclusion criteria:

The patients who underwent CABG surgery for the first time. They will range from 40 to 60 years in age. At least 2 to 6 months have elapsed since CABG surgery. Anxiety and depression scores based on the HADS score of 8 or higher.

### Exclusion criteria:

Having unstable angina pectoris and complicated ventricular arrhythmias Not having a heart failure Having regular exercise history Patient history of taking sertraline, or other antidepressant and anxiety medications

## Age

From **40 years** old to **60 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **60**

Actual sample size reached: **48**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Blind is done by the supervisor. Participants and researchers were blinded in this study.

## Placebo

Used

## Assignment

Factorial

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mazandaran University of

Medical Sciences

#### Street address

No. 3, Mahyar St., Maulam Blvd., Sari Town

#### City

Sari

#### Province

Mazandaran

#### Postal code

4817875816

#### Approval date

2019-12-18, 1398/09/27

#### Ethics committee reference number

IR.MAZUMS.REC.1398.1167

## Health conditions studied

### 1

#### Description of health condition studied

Patients after coronary artery bypass surgery(CABG)

#### ICD-10 code

I25.7

#### ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris

## Primary outcomes

### 1

#### Description

Depression and anxiety

#### Timepoint

At baseline (before intervention) and 8 weeks after intervention

#### Method of measurement

Hospital Anxiety and Depression Scale (HADS)

### 2

#### Description

Quality of Life

#### Timepoint

At baseline (before intervention) and 8 weeks after intervention

#### Method of measurement

Short Form Quality of Life Questionnaire (SF-36)

### 3

#### Description

Brain-derived neurotrophic factor

#### Timepoint

At baseline (before intervention) and 8 weeks after intervention

#### Method of measurement

By Eliza's research kit

### 4

#### Description

Interleukin-6

### Timepoint

At baseline (before intervention) and 8 weeks after intervention

### Method of measurement

By Eliza's research kit

## 5

### Description

C-Reactive Protein

### Timepoint

At baseline (before intervention) and 8 weeks after intervention

### Method of measurement

By Eliza's research kit

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention 1: Aerobic training group:Aerobic exercise for eight weeks (three sessions per week) consisted of 50-70% of maximal heart rate training for 20 to 40 minutes on the treadmill, under the control of a physician.

#### Category

Treatment - Other

### 2

#### Description

Intervention group:Drug Intervention Group: In addition to the usual care of the intervention groups (training-drug group and the drug group), the drug was administered by Hakim Darou Co, 25- 50 mg once daily for 8 weeks, according to the order of the treating physician.

#### Category

Treatment - Other

### 3

#### Description

Intervention group:Drug-exercise group (Combined):The group combined aerobic exercise with the mentioned intensity for 8 weeks as well as sertraline At a rate of 25- 50 mg once daily for 8 weeks.

#### Category

Treatment - Other

### 4

#### Description

Control group: No intervention was performed on the control group and routine care was taken and placebo was given.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Fatima Zahra Sari Heart Hospital

##### Full name of responsible person

Mstafa Behzad Khamlo

##### Street address

Fatima Zahra Heart Hospital., Army Boulevard., Sari Town

##### City

Sari

##### Province

Mazandaran

##### Postal code

4817875816

##### Phone

+98 11 3336 1700

##### Email

mostafabehzadkh@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr. Seyed Hamzeh Hosseini

##### Street address

Imam Khomeini Hospital., Amir Mazandaran St., Sari Town

##### City

Sari

##### Province

Mazandaran

##### Postal code

4817875816

##### Phone

+98 11 3336 1700

##### Email

hosseinish20@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Mazandaran University of Medical Sciences

#### Proportion provided by this source

10

#### 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

+98 11 3310 9230

**Fax**  
**Email**  
mostafabehzadkh@yahoo.com

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Seyed Hamzeh Hosseini  
**Position**  
Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Psychiatrics  
**Street address**  
Imam Khomeini Hospital., Amir Mazandaran St., Sari  
Town  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4817875816  
**Phone**  
+98 11 3310 9231  
**Email**  
hosseinish20@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Mostafa Behzad Khamslo  
**Position**  
Teaching  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Sport Medicine  
**Street address**  
No. 3, Mahyar St., Maulam Blvd., Sari Town  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4817875816  
**Phone**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Mostafa Behzad Khamslo  
**Position**  
Teaching  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Sport Medicine  
**Street address**  
No. 3, Mahyar St., Maulam Blvd., Sari Town  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4817875816  
**Phone**  
+98 11 3310 9230  
**Fax**  
**Email**  
mostafabehzadkh@yahoo.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

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

### Informed Consent Form

No - There is not 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