Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 8 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 of40-60 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 Khamslo

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 Khamslo

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

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Mazandaran

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4817875816

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+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

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

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

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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

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Latest degree

Master

Other areas of specialty/work

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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

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