Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

The effect of 12 weeks of aerobic training on serum levels of galectin3, GDF15 and some inflammatory markers in elderly women with metabolic syndrome

Protocol summary

Study aim
The effect of twelve weeks of aerobic exercise on serum levels of galectin 3, GDF15 and some inflammatory markers in elderly women with metabolic syndrome

Design
The clinical trial will consist of two groups of control and aerobic exercise intervention that will be randomly assigned to one of two groups.The sample size will be 24 individuals that and serum sampling and measurement of other variables will be done in two stages of pre-test and post-test.

Settings and conduct
This clinical trial is an aerobic training program in which 24 individuals will be randomly divided into two groups of aerobic training and control. The research variables will be measured in two stages before and after the intervention. Aerobic training intervention will be conducted in the Kahrizak Charity Center in Karaj.

Participants/Inclusion and exclusion criteria
Inclusion criteria: female sex, age 54–78 years, nonsmokers, no special diet and having MS. Exclusion criteria: Individuals with chronic diseases such as T2D, hypertension and cardiovascular disease, and those participating in regular physical activity (for a minimum of 6 months prior to the study) or unable to increase their level of physical activity for any reason.

Intervention groups
Control group; aerobic training group

Main outcome variables
Improve body composition, improve insulin resistance, improve cardio-metabolic risk factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170725035302N1**
Registration date: **2020-01-21, 1398/11/01**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-21, 1398/11/01**
Update count: **0**

Registration date
2020-01-21, 1398/11/01

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 914 584 3996

Email address
mousa.khalafi@ut.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-11, 1398/10/21

Expected recruitment end date
2021-02-16, 1399/11/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of 12 weeks of aerobic training on serum levels of galectin3, GDF15 and some inflammatory markers in elderly women with metabolic syndrome

Public title

The effect of exercise training on inflammatory factors in metabolic syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria were: female sex, age 54–78 years, nonsmokers, no special diet (i.e., low-carbohydrate diet, low fat, and vegetarian, etc.) and having MS, according to the indicators that included waist circumference of greater than 88 cm, fasting plasma glucose of greater than 88 mg/dl, HDL levels of less than 50 mg/dl, triglycerides levels of greater than 150 mg/dl and blood pressure greater than 130/85 mmHg.

Exclusion criteria:

Individuals with chronic diseases such as T2D, hypertension and cardiovascular disease, and those participating in regular physical activity (for a minimum of 6 months prior to the study) or unable to increase their level of physical activity for any reason

Age

From **54 years** old to **78 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Twenty-four volunteer subjects eligible to participate in the study will be randomly assigned to either aerobic training (AT, n=12) or control (CON, n=12). For this purpose, a simple randomization method will be used. All names will be placed in the bag and will be randomly selected and placed in either of the aerobic training intervention or control groups.

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

Research Ethics Committee of Sport Sciences Research Institute

Street address

Mir Emad st.

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2641-02-23, 2019/12/04

Ethics committee reference number

IR.SSRI.REC.1398.623

Health conditions studied

1

Description of health condition studied

metabolic syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

reduction of cardiovascular risk factors

Timepoint

2 steps. One week before the intervention and 48 hours after the last training session

Method of measurement

Using blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: aerobic training. The aerobic training protocol will be a walking and slow-running program that will run for 12 weeks, 3 sessions per week, and each session will run from 30 to 60 minutes, with low to moderate intensity. Also, each training session will include a five-minute warm-up and cool down program that will use stretching and walking for this purpose.

Category

Lifestyle

2

Description

Control group: control. The control group will not receive any treatment

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Kahrizak Charity
Full name of responsible person
Afshin Vejdani
Street address
Saheb Zaman Street
City
Karaj
Province
Alborz
Postal code
1575633411
Phone
+98 26 8832 3253
Email
info@kahrizak.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Alireza Ramazani
Street address
Shahid Sadoughi Street
City
Karaj
Province
Alborz
Postal code
۳۳۶۱۶۵۹۹۱۳
Phone
+98 26 4421 0165
Email
ar50ramezani@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University

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
Islamic Azad University
Full name of responsible person
Kamilia Moghadami
Position
Assistant Professor of Islamic Azad University
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
Street address
Shahid Sadoughi Street
City
Karaj
Province
Alborz
Postal code
۳۳۶۱۶۵۹۹۱۳
Phone
+98 936 194 5408
Email
kamilia58@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
kamilia Moghadami
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
Street address
Shahid Sadoughi Street
City
Karaj
Province
Alborz
Postal code
۳۳۶۱۶۵۹۹۱۳
Phone
+98 936 194 5408
Email
kamilia58@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Kamilia Moghadami
Position
Assistant Professor

Latest degree
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Sport Medicine
Street address
Shahid Sadoughi Street
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۳۳۶۱۶۵۹۹۱۳
Phone
+98 936 194 5408
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kamilia58@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The results of the data analysis, including the results of inflammatory factors and body composition changes after the aerobic exercise, will be published in the paper intervention.
When the data will become available and for how long
3-6 month
To whom data/document is available
Colleague: Mousa Khalafi
Under which criteria data/document could be used
Statistical analysis on serum data.
From where data/document is obtainable
Kamilia Moghadami, Mousa Khalafi
What processes are involved for a request to access data/document
Data will only be available in the research article.
Comments