

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 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**

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

**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**