# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

20 Sep 2026

## Comparison of three training interventions (aerobic interval, resistance and combination) on serum FAM19A5, arterial stiffness, glucose homeostasis and lipid and body composition indices in obese men

## Protocol summary

**Study aim**
Comparison of three training interventions (aerobic interval, resistance and combination) on serum FAM19A5, arterial stiffness, glucose homeostasis and lipid and body composition indices in obese men

**Design**
A randomized clinical trial with a control group, parallel groups, 100 patients. Randomization is performed simply and individually, and patients are grouped in groups 1, 2, 3, and 4, respectively.

**Settings and conduct**
Research subjects will participate in four groups for 12 weeks (three days a week). All measurements and exercises will be measured in Sabzevar.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Body mass index 30 to 35, Age 40 to 50 years. Exclusion criteria: having cardiovascular diseases, liver disease, kidney disease and having regular physical activity in at least the last six months

**Intervention groups**
Experimental groups: aerobic- interval, resistance, combined training groups will practice for 12 weeks (three sessions per week). The control group will be community based and without exercise.

**Main outcome variables**
FAM19A5، Arterial stiffness, Glucose, Insulin

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20151026024717N4**
Registration date: **2022-01-10, 1400/10/20**
Registration timing: **prospective**

Last update: **2022-01-10, 1400/10/20**
Update count: **0**

**Registration date**
2022-01-10, 1400/10/20

**Registrant information**

**Name**
Ehsan Mir

**Name of organization / entity**
Ferdowsi University of Mashhad

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-02-09, 1400/11/20

**Expected recruitment end date**
2022-05-10, 1401/02/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of three training interventions (aerobic interval, resistance and combination) on serum FAM19A5, arterial stiffness, glucose homeostasis and lipid and body composition indices in obese men

**Public title**
Comparison of three training interventions in obese men

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Confirmation of the health of the subjects, Body mass index between 30 and 35, Age 40 to 50 years

**Exclusion criteria:**

having cardiovascular diseases, musculoskeletal disorders, liver diseases, kidney diseases, thyroid dysfunction, having regular physical activity in at least the last six months

**Age**

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

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this research, subjects are selected simple randomization by random allocation rule. After determining the sample size, they will be equally divided into four groups (1- control, 2- aerobic interval training, 3- resistance training, 4- combined training). Using the lottery method, the names of the subjects are written on separate papers and placed in a container, then the names of the subjects are randomly taken out and placed in groups, respectively.

**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**

Baqiyatallah Al-Azam Educational and Medical Center

**Street address**

Baqiyatallah Al-Azam Hospital, Mulla Sadra Street, Vanak Square,

**City**

Tehran

**Province**

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**Postal code**

1435915371

**Approval date**

2021-09-18, 1400/06/27

**Ethics committee reference number**

IR.BMSU.BAQ.REC.1400.023

## Health conditions studied

### 1

**Description of health condition studied**

Obesity

**ICD-10 code**

E66

**ICD-10 code description**

Overweight and obesity

## Primary outcomes

### 1

**Description**

FAM19A5

**Timepoint**

Before the intervention and 48 hours after the end of intervention

**Method of measurement**

ELISA method

### 2

**Description**

Arterial stiffness

**Timepoint**

Before the intervention and 48 hours after the end of intervention

**Method of measurement**

Through the pulse pressure formula

### 3

**Description**

lipid indices

**Timepoint**

Before the intervention and 48 hours after the end of intervention

**Method of measurement**

ELISA method

### 4

**Description**

Body composition

**Timepoint**

Before the intervention and 48 hours after the end of intervention

**Method of measurement**

Body Composition Analyzer

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Aerobic interval training program including 10 minutes of warm-up with 40% of maximum heart rate (HRmax) and 40 minutes of cycling including eight cycles, each of which is 3 minutes with 80% of maximum heart rate (high intensity) and 2 minutes It will run at 50% of maximum heart rate (low intensity cycle) and 10 minutes of cooling with 40% of maximum heart rate.

**Category**
Prevention

### 2

**Description**
Intervention group: The resistance training program will include squats, chest presses, front thighs, back thighs, overhead wires, boat wires, forearms and back arms. During the first week, subjects perform 2 sets of 12-15 repetitions with an intensity of 40% 1RM. In the second week, the program includes 3 sets of 15-12 repetitions with an intensity of 50% 1RM. Between 3-5 weeks with the same number of sets, the number of repetitions will decrease to 8-12 and the intensity will increase to 55-60% of 1RM. From the sixth to the twelfth week, the number of repetitions of 8-12 is maintained. On the other hand, the intensity of training will increase to 80-65% of 1RM.

**Category**
Prevention

### 3

**Description**
Intervention group: The combined training program is such that the subjects of this group perform one session of aerobic periodic training (according to the program of aerobic periodic group), and the next session performs resistance training (according to the program of the resistance group) and This process will continue until the end of the 12-week program for this group.

**Category**
Prevention

### 4

**Description**
Control group: community-based and untrained.

**Category**
Prevention

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Sabzevar Center of Applied Science and Technology 2

**Full name of responsible person**
Arash Mohammadi

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Bagheiat-allah University of Medical Sciences

**Full name of responsible person**
Behzad Bazgir

**Street address**
Baqiyatallah University of Medical Sciences, MollaSadra street , Vanak Square

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**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Bagheiat-allah 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**
Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Behzad Bazgir
**Position**
Assistant Professor
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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**
Yes - There is 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**
Yes - There is a plan to make this available
**Title and more details about the data/document**
The whole data is potentially shared after unidentified individuals.
**When the data will become available and for how long**
The beginning of the data access period is 6 months after the publication of the articles.
**To whom data/document is available**
The data will be accessible only to researchers working in academic institutions.
**Under which criteria data/document could be used**
The data will be available as generally and non publication by the recipient.
**From where data/document is obtainable**
To receive research information, send an email to Ehsanmir1990@gmail.com
**What processes are involved for a request to access data/document**
Data will be sent after obtaining permission from the project manager.
**Comments**