

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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

Country

Iran (Islamic Republic of)

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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
Tehran

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

Street address

No. 137, Northern Side of the Mother square

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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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Email

Ehanmir1990@gmail.com

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

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

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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