

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of aerobic, resistance and parallel exercise on lipid profiles, heart rate variability, inflammatory and biochemical indices in male smokers with metabolic syndrome.

Protocol summary

Study aim

Comparison of aerobic, resistance and parallel exercise on lipid profiles, heart rate variability, inflammatory and biochemical indices in male smokers with metabolic syndrome.

Design

Clinical trial with a control group, with parallel groups, randomized. The sample size is 10 people in each group. the randomization will be done using a random numbers table.

Settings and conduct

The current research method will be semi-experimental with a pre-test and post-test design. The statistical population will be all smokers suffering from metabolic syndrome volunteers (invitation) in Ardabil city. Cardiovascular test and blood sampling are done before and after the intervention (12 weeks of various sports exercises). The study was not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Smokers with a history of at least 3 years, suffering from metabolic syndrome, who have not participated in any regular exercise program for at least the last 3 months. Exclusion criteria: not suffering from kidney, heart, neurological diseases and no history of surgery, not using hormonal chemical drugs, especially steroids.

Intervention groups

1. Endurance training group: four training sessions per week for 12 weeks with endurance protocol 2. Resistance training group: four training sessions per week for 12 weeks with resistance protocol 3. Combined training group: two endurance training sessions and two strength training sessions per week for 12 weeks 4. Control group: no training

Main outcome variables

Lipid profile. Heart rate variability. Inflammatory index. Biochemical index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210815052187N1**

Registration date: **2024-03-08, 1402/12/18**

Registration timing: **retrospective**

Last update: **2024-03-08, 1402/12/18**

Update count: **0**

Registration date

2024-03-08, 1402/12/18

Registrant information

Name

Khashayar Alapour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2280 1336

Email address

khashalalpour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-01-30, 1402/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of aerobic, resistance and parallel exercise on lipid profiles, heart rate variability, inflammatory and biochemical indices in male smokers with metabolic syndrome.

Public title

Different exercises on lipid profile, heart rate and inflammatory indices

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Smokers with a history of at least 3 years Suffering from metabolic syndrome has not participated in any regular sports program for at least the last 3 months Waist circumference greater than or equal to 102 cm Triglyceride level greater than or equal to 150 mg/dL HDL less than 40 mg/dL, blood pressure 130/85 mmHg Fasting blood glucose greater than or equal to 110 mg/dL

Exclusion criteria:

Absence of kidney, heart, and nervous diseases No history of surgery Not using hormonal and steroid chemical drugs

Age

From **22 years** old to **32 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Limited randomization Random allocation law, which is one of the limited randomization methods, was used for randomization. This method represents a large block for the entire volume. For this purpose, based on the sample size, which will be 40 people. 10 people were randomly assigned to group A, 10 people to group B, 10 people to group C, and 10 people to group D. Then groups A, B, C and D were placed in a lottery container and then randomly the balls were removed from the container without replacement and the created sequence was recorded. Random tool It included table and ball, lottery container, sealed opaque envelopes. Block was the unit of individual randomization. Extension of random assignment In order to widen random allocation, sealed opaque envelopes with random sequence were used. In this method, based on the sample size of the research, a number of envelopes with aluminum wrappers (in order not to make the contents of the envelopes unclear) were prepared and each of the random sequences created was recorded on a card, and the cards inside the envelopes were in order were placed In order to preserve the random sequence, the outer surface of the envelopes is numbered. Finally, the lids of the envelopes are glued and placed in a box. At the time of registration of the eligible participants for the study, one of the envelopes

was opened and the assigned group of that participant was revealed. Implementation of random assignment process In this section, the supervisor created a random sequence, the student checked the participants based on the criteria for entering and exiting the study and enrolled them in the study, and the advisor divided the participants into 4 groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

islamic azad university of sari

Street address

farahabad road km 7, sari, mazandaran

City

sari

Province

Mazandaran

Postal code

48164194

Approval date

2023-12-05, 1402/09/14

Ethics committee reference number

IR.IAU.SARI.REC.1402.226

Health conditions studied

1

Description of health condition studied

Metabolic syndrome

ICD-10 code

E88.9

ICD-10 code description

Metabolic disorder, unspecified

Primary outcomes

1

Description

Lipid profile

Timepoint

Measuring the concentration level of lipid profiles at the beginning of the study (before the start of the intervention) and at the end after 12 weeks of the intervention.

Method of measurement

8 cc of blood will be taken from the subjects from the forearm vein. Measurement of the concentration level of lipid profiles by enzyme method (by Pars Azmoun company)

Secondary outcomes**1****Description**

Heart rate variability

Timepoint

Measurement of resting heart rate at the beginning of the study (before the start of the intervention) and at the end after 12 weeks of the intervention

Method of measurement

Holter monitoring device model VX3 of American DMS company along with Full Option software

2**Description**

Measurement of interleukin 6-8-10

Timepoint

Measuring the level of immunoglobulin A at the beginning of the study (before the start of the intervention) and at the end after 12 weeks of the intervention.

Method of measurement

Immunoglobulin A by ELISA method and using high sensitivity kits (0.11 pg) made in Italy

3**Description**

Tumor necrosis factor-alpha

Timepoint

Measurement of tumor necrosis factor-alpha at the beginning of the study (before the start of the intervention) and at the end after 12 weeks of the intervention.

Method of measurement

Using the ELISA kit made by Buster America

4**Description**

Measurement of cTnI and cTnT

Timepoint

Measurement of cTnI and cTnT at the beginning of the study (before the start of the intervention) and at the end after 12 weeks of the intervention.

Method of measurement

Done by using LIAISON device and advanced Chemiluminescence method

5**Description**

CK-MB measurement

Timepoint

CK-MB measurement at the beginning of the study

(before the start of the intervention) and at the end after 12 weeks of the intervention

Method of measurement

Using the Horiba kit in the colorimetry method

Intervention groups**1****Description**

Intervention group: Endurance training: Twelve weeks will be set as intervals. Four days a week, each session includes 10-15 minutes of warming up and cooling down, the first session is 5 repetitions of 3 minutes of running, with an intensity of 60% of the maximum heart rate with 1 minute of active rest along with stretching and relaxation movements (30-40% of the maximum heart rate)) will be done. Polar F11 heart rate monitor, made in Finland, will be used to control the intensity. Every week, a 3-minute period will be added to the training and intensity will be designed based on the wave curve to create the conditions and consistency of the effects created.

Category

Other

2**Description**

Intervention group: Resistance exercise: including 15-20 minutes of warm-up and cooling, 35-60 minutes of the main body of the exercise in seven stations, including the boat station, butterfly leg press, knee extension, knee bend, forearm bend (biceps), forearm extension to Shoulder side (triceps), in each station 3 sets, 8-12 repetitions, rest between sets 30 seconds and rest between repetitions 60-90 seconds, the intensity will be 60-80% of a maximum repetition, and this intensity will also be The waveform will be applied

Category

Other

3**Description**

Intervention group: Combined training: Two days a week, the endurance program similar to the endurance group and two days of the resistance program will be implemented alternately.

Category

Other

4**Description**

Control group: They participate in tests only before and after 12 weeks.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University

Full name of responsible person

Amin Farzaneh Hesari

Street address

Department of exercise physiology, Sari Branch,
Islamic Azad University, Farah abad road

City

Sari

Province

Mazandaran

Postal code

4816119318

Phone

+98 11 3317 5333

Email

af.hessari@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Sadegh Salmanpor

Street address

Office of Research and Technology, Sari Islamic Azad
University, Farah absd road

City

Sari

Province

Mazandaran

Postal code

4816119318

Phone

+98 11 3317 5333

Email

sadeghsalmanpour@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Islamic Azad University

Proportion provided by this source

1

Public or private sector

Private

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

Amin Farzaneh Hesari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

Department of Exercise Physiology, Sari Branch,
Islamic Azad University, Farah Abad road

City

sari

Province

Mazandaran

Postal code

4816119318

Phone

+98 11 3317 5333

Email

af.hessari@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Email

af.hessari@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Email

af.hessari@gmail.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

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

A piece of data that contains information about variables that can be shared.

When the data will become available and for how long

Available period from 2024

To whom data/document is available

Researchers

Under which criteria data/document could be used

Statistical analysis on the data is not allowed.

From where data/document is obtainable

Amin Farzaneh Hesari af.hessari@gmail.com

What processes are involved for a request to access data/document

The purposes and uses of the data should be clearly stated by the applicant.

Comments