Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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)

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+98 21 2280 1336

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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 scienece

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

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Province
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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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.

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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
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