Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effects of aerobic exercises and low-calorie diet on inflammation and insulin resistance, a randomized clinical trial

Protocol summary

Study aim
Effects of aerobic exercise and low-calorie diet on inflammatory indices and insulin resistance in healthy middle-aged obese men without diabetes

Design
Controlled clinical trial with a parallel group design, single-blinded, randomized using block randomization method, including 90 participants (i.e. 45 in each group).

Settings and conduct
For subject selection, the physical education organization of the district under study (Fasa, town in sout east of fars province in Iran) submitted a recall. A total of 90 individuals entered the study, who were randomly assigned into two groups: one group (n=45) received diet therapy, while the other group (n=45) underwent exercise under the supervision of the study executor.

Participants/Inclusion and exclusion criteria
The inclusion criteria was signed informed consent, continuous inactivity, and having an BMI greater than 25. . Also, people with metabolic problems such as thyroid disease, cancer, lipid problems, blood glucose (diabetic maple), liver or kidney disease were excluded.

Intervention groups
The first group received a special diet that provides 500 calories less than the daily requirement calculated. The second group performed moderate intensity (60-75% of the maximum heart rate on the treadmill).

Main outcome variables
laboratory indicators including leptin, adiponectin, Chemerin, FBS, fasting insulin, insulin resistance index (HOMA-IR), hs CRP inflammatory index, interleukin 1β, and interleukin-6.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110811007297N6**
Registration date: **2020-01-17, 1398/10/27**
Registration timing: **retrospective**

Last update: **2020-01-17, 1398/10/27**
Update count: **0**

Registration date
2020-01-17, 1398/10/27

Registrant information

Name
Mojtaba Heydari

Name of organization / entity
Shiraz university of medical science

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-05, 1398/02/15

Expected recruitment end date
2019-08-06, 1398/05/15

Actual recruitment start date
2019-05-05, 1398/02/15

Actual recruitment end date
2019-08-06, 1398/05/15

Trial completion date
2019-08-15, 1398/05/24

Scientific title
Comparing the effects of aerobic exercises and low-calorie diet on inflammation and insulin resistance, a randomized clinical trial

Public title

Comparing the effects of aerobic exercises and low-calorie diet on insulin resistance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

no constant physical activity BMI above 25

Exclusion criteria:

those with metabolic problems and diseases including thyroid disease, cancer, lipid profile problems, blood sugar, blood pressure, liver and kidney diseases those who used any special diet or had changed their diet over the past six months

Age

From **35 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization for individuals (18 blocks with equal size of 5, non-stratified); randomization tool: table of random digits generated using Microsoft Excel software; allocation concealment: sequentially numbered sealed opaque envelopes which included groups' codes (according to the table of random digits). The secretary of ward will take an envelop (according to the sequence of referred patient). Then, patient's first name (to save patients' confidentiality) will be written on the envelop. Now, it will be opened and patient's group will be determined accordingly.

Blinding (investigator's opinion)

Single blinded

Blinding description

data collectors, outcome assessors, and bio-statistician

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Fasa University of Medical Sciences

Street address

Fasa University of Medical Sciences . Ethics department

City

Fasa

Province

Fars

Postal code

7135644144

Approval date

2019-07-10, 1398/04/19

Ethics committee reference number

IR.FUMS.REC.1398.072

Health conditions studied

1

Description of health condition studied

People with overweight and obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

leptin, adiponectin, Chemerin, FBS, fasting insulin, insulin resistance index (HOMA-IR), hs CRP inflammatory index, interleukin 1β, and interleukin-6.

Timepoint

Before the intervention and 12 weeks later

Method of measurement

Blood sample

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: special diet that provides 500 calories less than the TEE (including 50-50% carbohydrate, 15-20% protein and 30-25% fat), totally 3500 per week.

Category

Lifestyle

2

Description

Second intervention group: performed moderate exercise (60-75% of the maximum heart rate). Exercise for these people started at 90 minutes a week, was divided into three doses, and the heart rate was monitored through a monitor on the device. Duration of the session (10-15

minutes for each session) and the number of training sessions (started three times a week and reached seven sessions per week) was increased, at the end of intervention each person had an average of 200-300 minutes per week aerobic exercise in his program, equivalent to the 1400-2100 MET (3500 kcal/week)

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

The physical education organization of the district under study (Fasa, town in south east of Fars pr

Full name of responsible person

Seyed Reza Hojati

Street address

Fasa University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fasa University of Medical Sciences

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?

Yes

Title of funding source

Fasa 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

Fasa University of Medical Sciences

Full name of responsible person

Reza Homayounfar

Position

Associate Professor of Nutritional Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person
Seyed Reaza Hojati

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General Practitioner

Latest degree
Medical doctor

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General Practitioner

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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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be 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
All collected deidentified IPD

When the data will become available and for how long
Along with published article and for ever.

To whom data/document is available
People working in academic institutions

Under which criteria data/document could be used
There is no restriction on this matter. Requests will be reviewed by corresponding author.

From where data/document is obtainable
Professor Reza Homayounfar via his email: homayounfar@sbmu.ac.ir

What processes are involved for a request to access data/document
Researchers should email their request and their topic of researches. Response will be available within 7 working days.

Comments