

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparing the effect of high intensity interval training and Mediterranean diet without caloric restriction on inflammatory factors and body composition in over weight and obese woman

Protocol summary

Study aim

Investigating and comparing the effect of 8 weeks of high intensity interval training and Mediterranean diet without caloric restriction on inflammatory factors and body composition in over weight and obese woman

Design

Clinical trial, with parallel arms including 3 intervention groups with 45 subjects and one control group. Subjects will be voluntarily divided to intervention or control groups.

Settings and conduct

Overweight or obese women referring to a diet therapy center who are able and willing to participate in our study groups.

Participants/Inclusion and exclusion criteria

Age between 18-50, having a Body mass index over 25, not being pregnant or lactating

Intervention groups

Intervention groups will take part in a high intensity interval training program, or Mediterranean diet program, or will receive both interventions for 8 weeks

Main outcome variables

Body Mass Index, Fat Mass, Waist Hip Ratio, Interleukin-6, Leptin, Adiponectin, Tumor Necrosis Factor alpha, C-Reactive Protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130424013107N4**

Registration date: **2022-12-03, 1401/09/12**

Registration timing: **retrospective**

Last update: **2022-12-03, 1401/09/12**

Update count: **0**

Registration date

2022-12-03, 1401/09/12

Registrant information

Name

Maryam Koushkie Jahrimi

Name of organization / entity

Shiraz University

Country

Iran (Islamic Republic of)

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mkoushki@rose.shirazu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-08-01, 1401/05/10

Actual recruitment start date

2022-07-30, 1401/05/08

Actual recruitment end date

2022-08-11, 1401/05/20

Trial completion date

2022-10-13, 1401/07/21

Scientific title

Comparing the effect of high intensity interval training and Mediterranean diet without caloric restriction on inflammatory factors and body composition in over weight and obese woman

Public title

Comparing the effect of high intensity interval training and Mediterranean diet on inflammatory factors and body composition

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18-50 years old BMI over 25

Exclusion criteria:

pregnant or lactating women

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Actual sample size reached: **47**

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Research Ethics Committees of Shiraz University

Street address

Eram sq.

City

Shiraz

Province

Fars

Postal code

۸۴۳۳۴ - ۷۱۹۴۶

Approval date

2022-07-15, 1401/04/24

Ethics committee reference number

IR.US.REC.1401.009

Health conditions studied**1****Description of health condition studied**

overweight and obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes**1****Description**

Body Mass Index

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

body analyzer and stadiometer

2**Description**

Fat Mass

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

body analyzer

3**Description**

Waist Hip Ratio

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

tape

4**Description**

Interleukin-6

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

laboratory kit

5**Description**

Leptin

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

laboratory kit

6**Description**

Adiponectin

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

laboratory kit

7**Description**

Tumor Necrosis Factor alpha

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

laboratory kit

8

Description

C reactive protein

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: High intensity interval training. In this group, subjects would exercise on a stationary bike, 3 sessions a week for 8 weeks (24 sessions). Each session would last 20 minutes which consists of 5 minutes warm-up, 6 bouts of 1-min efforts at 90-95% of peak heart rate (HRpeak) interspersed with 1 min of active recovery at 50-60% of HRpeak, and 3-min cooling down stretches.

Category

Lifestyle

2

Description

Intervention group 2: Mediterranean diet group. The participants will follow the principal aspects of Mediterranean diet without calorie restriction for 8 weeks.

Category

Lifestyle

3

Description

Intervention group 3: This group will receive a combination of Mediterranean diet and high intensity interval training program

Category

Lifestyle

4

Description

Control group: This group will not receive any intervention programs.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehr Nutrition Center

Full name of responsible person

Mohamadreza Rabiee

Street address

No. 16, 4th Floor, Unique Apartment, 9th Alley, Shariati Blvd.

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mohamadreza.rb@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University

Full name of responsible person

Mohamad Hadi Sadeghi

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Physical Education and Sport Science Department, Shiraz University, Eram Sq.

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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

Shiraz University

Proportion provided by this source

30

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

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University

Full name of responsible person
Mohamadreza Rabiee

Position
PhD Student

Latest degree
Master

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All details will be published.

When the data will become available and for how long

Probably 6 months after data collection

To whom data/document is available

All interested people

Under which criteria data/document could be used

application-research

From where data/document is obtainable

Shiraz University

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

Thesis will be available in university laboratory

Comments