

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of eight weeks of aerobic training with orange juice in body composition and lipid profiles and antioxidant capacity and inflammatory factors in overweight middle - aged women

Protocol summary

Study aim

The aim of this study was to evaluate the effect of eight weeks of aerobic exercise with orange juice on body composition and lipid profiles and antioxidant capacity and inflammatory factors of overweight middle-aged women.

Design

Clinical trial, with control group, randomized, on 60 people

Settings and conduct

The statistical population of this study is overweight middle-aged women aged 30 to 59 years who participated in aerobic exercise sessions with orange juice supplementation, which were purposefully selected as a statistical sample after fully explaining the purpose and research method and obtaining consent. The duration of aerobic exercise was 8 weeks (3 days per week). Samples were selected from those who referred to the Kan Health Center, which is located in the training sessions of the Shahid Shaban Ali Sports Complex in the Kan region.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with a BMI above 28 who were in perfect physical and mental health.

Intervention groups

The number of samples in this study is 60 overweight women with a body mass above 28. Which were selected voluntarily and randomly divided into 4 control groups (n = 15), orange juice supplement (n = 15), exercise group (n = 15) and exercise group + orange juice supplement (n = 15).

Main outcome variables

hsCRP: MDA: body composition: lipid profile: TAC

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210103049934N1**
Registration date: **2021-01-05, 1399/10/16**
Registration timing: **retrospective**

Last update: **2021-01-05, 1399/10/16**

Update count: **0**

Registration date

2021-01-05, 1399/10/16

Registrant information

Name

samira ghalishourani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4460 6448

Email address

samira8810@yahoo.co.uk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

2018-07-11, 1397/04/20

Actual recruitment end date

2018-10-17, 1397/07/25

Trial completion date

2018-10-17, 1397/07/25

Scientific title

The effect of eight weeks of aerobic training with orange

juice in body composition and lipid profiles and antioxidant capacity and inflammatory factors in overweight middle - aged women

Public title

The effect of eight weeks of aerobic training with orange juice in body composition and lipid profiles and antioxidant capacity and inflammatory factors in women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women had a body mass index above 28 who had a general level of physical and mental health.

Exclusion criteria:**Age**

From **30 years** old to **59 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

N/A

Randomization description**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**

Committee of Sport Sciences Research Institute

Street address

NO3, 5th st, miremad st, motahari ave

City

tehran

Province

Tehran

Postal code

1587958711

Approval date

2018-07-03, 1397/04/12

Ethics committee reference number

IR.SSRI.REC.1397.183

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

Overweight middle-aged women

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Inflammatory factors and overweight in middle-aged women

Timepoint

Before and after 8 weeks of aerobic exercise

Method of measurement

Pars Company test kit

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

lipid profile

Timepoint

Before and after 8 weeks of aerobic exercise

Method of measurement

Pars Company test kit

2**Description**

body composition

Timepoint

Before and after 8 weeks of aerobic exercise

Method of measurement

Pars Company test kit

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

Interventions group: Orange Juice Supplement / Aerobic Exercise / Aerobic Exercise + Orange Juice Supplement

Category

Treatment - Other

2**Description**

Control group: control

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kan Health Center

Full name of responsible person

samira sadat ghalishourani

Street address

Shahran - Koohsar St. - facing the first Shahran St. -
Shahid Adhami St.

City

tehran

Province

Tehran

Postal code

1469696334

Phone

+98 21 4460 6448

Email

samira8810@yahoo.co.uk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

hossein abed natanzi

Street address

End of Shahid Sattari Highway - University Square -
Shohada Hesarak Boulevard - Islamic Azad University,
Science and Research Branch

City

tehran

Province

Tehran

Postal code

۱۴۷۷۸۹۳۸۵۵

Phone

+98 21 4486 9442

Email

h-abednatanzy@srbiau.ac.ir

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

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**

Other

Person responsible for general inquiries

Contact**Name of organization / entity**

Islamic Azad University

Full name of responsible person

samira sadat ghalishourani

Position

nutritionist in health care

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Punak Square, Hamila Blvd., Ostad Nazari Sharghi St.,
Golha Complex, No. 13, Unit One

City

tehran

Province

Tehran

Postal code

1469696334

Phone

+98 21 4460 6448

Email

samira8810@yahoo.uk.co

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Islamic Azad University

Full name of responsible person

samira sadat ghalishourani

Position

nutritionist in health care

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Punak Square, Hamila Blvd., Ostad Nazari Sharghi St.,
Golha Complex, No. 13, Unit One

City

tehran

Province

Tehran

Postal code

1469696334

Phone

+98 21 4460 6448

Email

samira8810@yahoo.uk.co

Person responsible for updating data

Contact**Name of organization / entity**

Islamic Azad University

Full name of responsible person

samira sadat ghalishourani

Position

nutritionist in health care

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Punak Square, Hamila Blvd., Ostad Nazari Sharghi St.,
Golha Complex, No. 13, Unit One

City

tehran

Province

Tehran

Postal code

1469696334

Phone

+98 21 4460 6448

Email

samira8810@yahoo.uk.co

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

Only the main consequences of the study can be shared.

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

It will be available to everyone.

Under which criteria data/document could be used

It will be available to everyone.

From where data/document is obtainable

To published articles

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

One year after the full publication of the results

Comments