

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of curcumin supplementation with High-intensity interval training on serum Irisin levels and lipid profile in non-active obese women: a randomized clinical trial "

Protocol summary

Study aim

Determining the effect of curcumin supplementation and intense interval training on serum aerosin levels and lipid profile of non-active obese women

Design

40 participants who met the inclusion criteria were selected. In the exercise group, intense intermittent exercises in the form of running and walking were used. The intensity of work was considered 80 to 100% of the reserve heart rate. The supplement-exercise group also performed the mentioned exercise program and consumed one 80 mg nanomicillin curcumin capsule daily. The curcumin supplement group took only one 80 mg nanomicillin curcumin capsule daily, and the placebo group took dextrose capsules before lunch.

Settings and conduct

The present study was a quasi-experimental study with a pretest and posttest design. The statistical population of the present study was obese women in Tabriz who were selected from sports clubs after being called and informed. The study site is Tabriz University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Entry requirements: lack of regular exercise in the last two years, lipid pattern disorder, not taking drugs and supplements
Exclusion criteria: Having thyroid, cardiovascular, respiratory, hypertension, diabetes, metabolic syndrome, pregnancy and lactation, as well as allergies to spices

Intervention groups

The subjects will be randomly divided into 4 groups of 10 people, including the control group, the exercise group + placebo, the exercise group + supplement and the supplement group.

Main outcome variables

serum aerosin levels and lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141004019397N2**

Registration date: **2021-09-10, 1400/06/19**

Registration timing: **retrospective**

Last update: **2021-09-10, 1400/06/19**

Update count: **0**

Registration date

2021-09-10, 1400/06/19

Registrant information

Name

Bahram Jamali Qarakhanlou

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 9696

Email address

jamalib@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-16, 1400/04/25

Expected recruitment end date

2021-08-16, 1400/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of curcumin supplementation with High-intensity interval training on serum Irisin levels and lipid profile in non-active obese women: a randomized clinical trial "

Public title

The effect of curcumin supplementation with High-intensity interval training on serum Irisin levels and lipid profile in non-active obese women "

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 30 to 35 years, obese (BMI greater or equal to 30), lack of regular exercise during the last two years, an impaired lipid profile, not taking drugs and supplements

Exclusion criteria:

Having thyroid, cardiovascular, respiratory, hypertension, diabetes, metabolic syndrome, pregnancy and lactation as well as allergies to spices unwillingness to cooperate

Age

From **30 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

Blood sampling before and after the protocol

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the number of subjects, We assign a number from 1 to 40 to each of them, then we enter the site <https://www.random.org/sequences>, and by entering the smallest and largest number as well as the number of groups, the site itself automatically divides people into 4 groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht St., Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165938634

Approval date

2021-07-05, 1400/04/14

Ethics committee reference number

IR.TBZMED.REC.1400.314

Health conditions studied

1

Description of health condition studied

obesity women

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

The rate of change in plasma aerosin

Timepoint

At baseline and two days after the last training session

Method of measurement

Sunlong Biotech kits will be used to measure aerosin

2

Description

Lipid profile changes

Timepoint

At baseline and two days after the last training session

Method of measurement

To measure lipid profile, it will be measured from Pars-Azmoon kits by ELISA method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The curcumin supplement group will take one 80 mg nanomicillin curcumin capsule daily for eight weeks before lunch with a glass of water.

Category

Other

2

Description

Intervention group: Exercise and curcumin supplementation group for eight weeks of intense interval training in the form of running and walking at 80 to 100% heart rate reserve and will take one 80 mg nanomicillin curcumin capsule daily before lunch with a glass of water.

Category

Other

3

Description

Intervention group: Exercise and placebo group in addition to daily exercise training protocol dextrose 80 mg capsules before lunch and a glass of water will be consumed.

Category

Placebo

4

Description

Control group: Dextrose 80 mg capsules once daily before lunch and a glass of water will be consumed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Call in educational and medical centers and clinics of Tabriz

Full name of responsible person

Solmaz Babaei Bonab

Street address

Third floor, No. 23, Eighth Alley, University neighborhood, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostadrahimi

Street address

Faculty of Nutrition Sciences, Tabriz University of Medical Sciences, Tabriz

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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

Tabriz University of Medical Sciences

Proportion provided by this source

50

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

Tabriz University of Medical Sciences

Full name of responsible person

Bahram Jamali

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Dept. of Basic Sciences, Paramedical School, Tabriz University of Medical Sciences, Tabriz, Iran

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Person responsible for scientific inquiries

Contact

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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

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

The results of the research will be shared after publication

When the data will become available and for how long

After printing the results

To whom data/document is available

Academic and scientific researchers

Under which criteria data/document could be used

research centers

From where data/document is obtainable

Via email and contact number

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

Immediately after printing

Comments