Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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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ostadrahimi@tbzmed.ac.ir
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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Assistant Professor

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Person responsible for updating data

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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