Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of High-Intensity Functional Training Combined with Terminalia chebula Supplementation on Nitric Oxide, C-Reactive Protein, Insulin Resistance, and Cardiometabolic Risk in Women with Metabolic Syndrome

Protocol summary

Study aim

The effect of high-intensity functional training combined with black cumin supplement on improving nitric oxide, C-reactive protein, insulin resistance, and cardiometabolic risk in women with metabolic syndrome.

Design

Simple random sampling was performed with a sample size of 60 women with metabolic syndrome using G Power software. The subjects were aged 35 to 45 and divided into 4 groups (supplement, exercise, control, supplement and exercise).

Settings and conduct

The subjects will be under research interventions for 8 weeks. Before and after 8 weeks, the desired factors will be measured to obtain results. The research will be conducted in Fars Province, Eghlid City, Rastegar Laboratory and Kargan Sports Hall.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the present study were waist circumference greater than 88 cm, blood triglyceride level greater than 150 mg/dL, HDL level less than 50 mg/dL, systolic blood pressure greater than 130 mmHg or diastolic blood pressure greater than 85 mmHg, and blood glucose level greater than 100 mg/dL. Inactivity, non-smoking, and alcohol consumption were other inclusion criteria for the present study.Also, if the subjects have cardiovascular, respiratory, renal, or neurological disorders, they will not be allowed to enter the research.

Intervention groups

Terminalia chebula supplementation in two groups (supplement and exercise and supplement) High-intensity functional training (exercise, supplement and exercise)

Main outcome variables

on Nitric Oxide, C-Reactive Protein, Insulin Resistance, and Cardiometabolic Risk

General information

Reason for update

Acronym

TC. HIFT. Mets

IRCT registration information

IRCT registration number: **IRCT20251104067880N1**
Registration date: **2025-11-14, 1404/08/23**
Registration timing: **prospective**

Last update: **2025-11-14, 1404/08/23**
Update count: **0**

Registration date

2025-11-14, 1404/08/23

Registrant information

Name

Fatemeh Esmaeili

Name of organization / entity

Al-zahra University, Tehran

Country

Iran (Islamic Republic of)

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faatemeh.esmaeili2024@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-10, 1404/10/20

Expected recruitment end date

2026-03-11, 1404/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of High-Intensity Functional Training Combined with Terminalia chebula Supplementation on Nitric Oxide, C-Reactive Protein, Insulin Resistance, and Cardiometabolic Risk in Women with Metabolic Syndrome

Public title
Investigating the effect of high-intensity functional training combined with Terminalia chebula supplementation in women with metabolic syndrome.

Purpose
Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:
The inclusion criteria for the present study were waist circumference greater than 88 cm, blood triglyceride level greater than 150 mg/dL, HDL level less than 50 mg/dL, systolic blood pressure greater than 130 mmHg or diastolic blood pressure greater than 85 mmHg, and blood glucose level greater than 100 mg/dL. Failure to attend more than three training sessions, unwillingness to continue participating in the study, failure to take supplements regularly, and physical injury were exclusion criteria.

Exclusion criteria:
Subjects will not be included in the study if they have the following conditions: smoking and alcohol consumption, history of or suffering from any heart, lung, kidney, liver or neurological disease.

Age
From **35 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization. According to the call for volunteers to participate in the study (women with metabolic syndrome), blood tests and the desired factors were measured. We placed the people in 4 groups of 15 people without regard to specific criteria and with completely equal chances. (That is, the people in the exercise or supplemental exercise or mock or control group are no different from each other.)

Blinding (investigator's opinion)
Single blinded

Blinding description
those responsible for data collection, such as the nurse responsible for blood tests, do not know who is in the control, exercise, supplement, and supplement and exercise groups.

Placebo
Not used

Assignment
Factorial

Other design features
The current study includes exercise and herbal supplementation to improve metabolic health in people with metabolic syndrome.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کمیته تخصصی اخلاق در پژوهش های زیست پزشکی

Street address
Alzahra University Deh Vanek St.

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Province
Tehran

Postal code
1993891176

Approval date
2025-10-04, 1404/07/12

Ethics committee reference number
IR.ALZAHRA.REC.1404.075

Health conditions studied

1

Description of health condition studied
Women with metabolic syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Nitric oxide, C-reactive protein, insulin resistance, and cardiometabolic risk are not balanced and optimal.

Timepoint
Measurements of all factors considered are measured on two days (the first day for blood factors and the second day for physical performance) before and after 8 weeks.

Method of measurement
Nitric oxide, C-reactive protein, and insulin resistance are measured with blood tests, and cardiometabolic risk is measured using blood pressure measurements, waist circumference to height, and the Cooper test to measure aerobic capacity.

Secondary outcomes

empty

Intervention groups

1

Description
Exercise group. Supplement group. Exercise and supplement group. Control group. Interventions are applied to the first three groups for 8 weeks. 3 training sessions per week and 500 mg supplement capsules are taken twice a day for 8 weeks.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
آزمایشگاه رستگار
Full name of responsible person
Fatemeh Esmaeili
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
do not have
Proportion provided by this source
1
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
Alzahra University, Tehran
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No further information available.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available