Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

The Combined effect of high-intensity functional training and terminalia chebula extract on liver enzymes, metabolic syndrome indices, and physical fitness factors in women with metabolic syndrome

Protocol summary

Study aim

The combined effect of high-intensity functional training and Terminalia chebula extract on improving liver enzymes, metabolic syndrome indices and physical fitness factors in women with metabolic syndrome

Design

The statistical population will include women with metabolic syndrome aged 35 to 45 years. 60 people will be selected by random sampling from among the population who volunteer to participate in the present study. The sample size was determined using G-power software.

Settings and conduct

The subjects were subjected to research interventions for 8 weeks, and after 8 weeks, the desired factors will be examined to obtain results. The research is being conducted in Farsh province, Eqlid city, Rastkar laboratory, and the workers' sports hall.

Participants/Inclusion and exclusion criteria

: blood triglycerides above 150 mg/dL, HDL less than 50 mg/dL, waist circumference more than 88 cm, fasting blood glucose above 100 mg/dL, and systolic blood pressure above 130 mmHg or diastolic blood pressure above 85 mmHg. Also, if the subjects have cardiovascular, respiratory, nephrotic, hepatic, and neurological disorders and consume alcohol and cigarettes, they will not be allowed to enter and participate in the present study.

Intervention groups

The training groups will perform HIFT exercises for eight weeks, three sessions per week, each session lasting 60 to 90 minutes. and the subjects in the supplement group will also take capsules containing black cumin extract at a dose of 500 mg twice daily (every 12 hours) with two glasses of water. The subjects in the control group will carry out daily activities for 8 weeks.

Main outcome variables

Improvement of liver enzymes, improvement of metabolic syndrome indicators (lipoprotein, abdominal obesity) and physical fitness factors

General information

Reason for update

Acronym

Mets. TC. HIFT.

IRCT registration information

IRCT registration number: **IRCT20251104067881N1**
Registration date: **2025-11-21, 1404/08/30**
Registration timing: **prospective**

Last update: **2025-11-21, 1404/08/30**
Update count: **0**

Registration date

2025-11-21, 1404/08/30

Registrant information

Name

Zahra Esmaeili

Name of organization / entity

Alzahra University Tehran

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-09, 1404/11/20

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 Combined effect of high-intensity functional training and terminalia chebula extract on liver enzymes, metabolic syndrome indices, and physical fitness factors in women with metabolic syndrome

Public title
Studying the effect of high-intensity functional training with terminalia chebula extract in women with metabolic syndrome
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Being 35-45 years old. blood triglycerides above 150 mg/dL, HDL below 50 mg/dL, waist circumference above 88 cm fasting blood glucose above 100 mg/dL, systolic blood pressure above 130 mmHg diastolic blood pressure above 85 mmHg.
Exclusion criteria:
If the subjects have cardiovascular, respiratory, nephrotic, hepatic, or neurological disorders, they will not be allowed to enter the present study. Also, if they consume alcohol or smoke, they will not be able to participate in the present study.
Age
From **35 years** old to **45 years** old
Gender
Male

Phase
2-3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, after initial recruitment and screening, eligible participants (women with metabolic syndrome) will enter the allocation phase. First, blood tests and measurements of required factors will be performed according to the protocol. Then, all eligible individuals, without any priority, precedence, or specific criteria for group entry, will be equally and with equal probability assigned to four research groups. The randomization process will be conducted using simple randomization. For this purpose, a computer-generated numerical list using Random Allocation Software will be used. This list will determine the allocation of individuals to one of the four groups (exercise, exercise + supplement, supplement, control). In this method, all individuals will have an equal chance of being placed in any of the groups, and no systematic differences in baseline characteristics will be created between the groups. Also, the data collector will not be informed of the randomization sequence to maintain at least a single-blind level.
Blinding (investigator's opinion)
Single blinded
Blinding description
Data collectors, such as the nurse who conducts blood tests, do not know who was in the control, exercise, supplement, and exercise groups.
Placebo
Not used
Assignment
Parallel
Other design features
In the present study, a new exercise program along with a herbal supplement that has no side effects is applied to people with metabolic syndrome.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Specialized Committee on Ethics in Biomedical Research, Alzahra University, Tehran
Street address
Al-Zahra University, Deh Vanak Street
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Province
Tehran
Postal code
1993891176
Approval date
2025-10-04, 1404/07/12
Ethics committee reference number
IR.ALZAHRA.REC.1404.076

Health conditions studied

1

Description of health condition studied
Women with metabolic syndrome
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Liver enzymes are unbalanced and elevated.
Timepoint
Measurements of all desired factors will be measured two days before and two days after the 8-week

intervention.

Method of measurement

Liver enzymes will be measured with blood tests and special kits.

2

Description

Metabolic syndrome indicators are unbalanced and tend to be high.

Timepoint

Measurements of all desired factors will be measured two days before and two days after the 8-week intervention.

Method of measurement

Lipid profile will be measured with blood tests and special kits.

3

Description

Metabolic syndrome indicators are unbalanced and tend to be high.

Timepoint

Measurements of all desired factors will be measured two days before and two days after the 8-week intervention.

Method of measurement

central obesity index (abdominal) will be measured with a tape measure with high accuracy.

4

Description

Physical fitness factors (muscular endurance) are weak.

Timepoint

Measurements of all desired factors will be measured two days before and two days after the 8-week intervention.

Method of measurement

muscular endurance will be measured by the number of repetitions of the sit-up and squat test.

5

Description

Physical fitness factors (muscular strength) are weak.

Timepoint

Measurements of all desired factors will be measured two days before and two days after the 8-week intervention.

Method of measurement

Muscular strength will be measured by a handgrip device.

Secondary outcomes

empty

Intervention groups

1

Description

The training groups will perform HIFT exercises for eight weeks, three sessions per week, each session lasting 60 to 90 minutes. HIFT exercises will be performed with a combination of resistance exercises (with body weight and free weights) and aerobic exercises in order to contribute to physical fitness factors related to health. The movements used in resistance and aerobic exercises will be functional (activities similar to daily life movements) and multi-joint. The first and last 10 minutes of each session will be dedicated to warming up and cooling down, and the main body of the exercise protocol will be accompanied by a gradual increase in intensity, duration, and repetition of exercises, according to the principle of overload. In the present study, exercise intensity control will be determined based on the rate of perceived exertion (RPE) scale. Examples of exercises that will be applied in the present study will include body weight exercises (such as burpees, Swedish push-ups, hip thrusts, various squats, lunges, crunches, etc.). Tools such as pull-ups and dumbbells will be used in the exercise sessions to increase exercise intensity (observing the principle of overload). Aerobic exercises will also be based on various aerobic movements. Subjects in the supplement group will take capsules containing black cumin extract at a dose of 500 mg twice daily (every 12 hours) with two glasses of water. Subjects in the control group will perform daily activities for 8 weeks.

Category

N/A

2

Description

Intervention group: Subjects in the supplement group will take capsules containing black cumin extract at a dose of 500 mg twice daily (every 12 hours) with two glasses of water.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rastegar Laboratory

Full name of responsible person

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Sponsors / Funding sources

1

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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
ندارم
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

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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