

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, Eqid 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

Iran (Islamic Republic of)

Phone

+98 71 4434 0448

Email address

zahraesmaeili931@gmail.com

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 science

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

City

Tehran

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	Zahra Esmaeili
Street address	Eqlid County. Valiasr Street
City	Eqlid
Province	Fars
Postal code	1111111111
Phone	+98 71 4434 0448

Email
zahraesmaeili931@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Alzahra University, Tehran
Full name of responsible person
Dr. Nahid Atghia
Street address
Deh Vanak Street
City
Tehran
Province
Tehran
Postal code
1993891176
Phone
+98 71 4434 0448
Email
zahraesmaeili931@gmail.com

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

Contact

Name of organization / entity
Alzahra University, Tehran
Full name of responsible person
Zahra Esmaeili
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Sport Medicine
Street address
Deh Vanak Street
City
Tehran
Province
Tehran

Postal code
1993891176
Phone
+98 71 4434 0448
Email
zahraesmaeili931@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Alzahra University, Tehran
Full name of responsible person
Zahra Esmaeili
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Sport Medicine
Street address
Deh Vanak Street
City
Tehran
Province
Tehran
Postal code
1993891176
Phone
+98 71 4434 0448
Email
zahraesmaeili931@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Alzahra University, Tehran
Full name of responsible person
Zahra Esmaeili
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Sport Medicine
Street address
deh vanak srteet
City
Tehran
Province
Tehran
Postal code
1993891176
Phone
+98 71 4434 0448
Email
zahraesmaeili931@gmail.com

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