

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of four weeks flaxseed supplementation and concurrent training on certain factors of cardiovascular disease and cortisol hormones in overweight women

Protocol summary

Study aim

The effect of four weeks concurrent training with flax seed supplementation on lipid profile (cholesterol and LDL, TG, HDL) and cortisol changes in overweight women.

Design

In this study, 36 healthy women overweight and eligible for entry into the study who are referred to university sports centers are selected. Participants were randomly divided into four homogeneous groups (supplementation: 9 people, exercise + supplementation: 9, exercise: 9, 9 controls), of which three groups were an intervention group and a control group, and each One participant is assigned a code.

Settings and conduct

The research on the treatment of overweight and it will be done randomly in University of Tabriz. The present study was carried out in a semi-experimental study.

Participants/Inclusion and exclusion criteria

Entry criteria: Female students of Tabriz University; Inactivity; Overweight; BMI between 25 and 29/9. Non-compliance criteria: Smoking; Cardiovascular disease and surgery; Having chronic illnesses; taking any type of fat supplement; having regular exercise.

Intervention groups

Intervention 1: Includes 9 supplementary with training
Intervention 2: Includes 9 concurrent training
Intervention 3: Includes 9 supplementation Flaxseed
Controls: Includes 9 people without any intervention

Main outcome variables

It is expected that four weeks of concurrent training, along with flaxseed supplementation, can have a positive effect on the lipid profiles (cholesterol, HDL-LDL-TG) and cortisol hormonal index.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171130037689N1**

Registration date: **2018-03-03, 1396/12/12**

Registration timing: **retrospective**

Last update: **2018-03-03, 1396/12/12**

Update count: **0**

Registration date

2018-03-03, 1396/12/12

Registrant information

Name

Fateme Halalkhor

Name of organization / entity

The University of Tabriz

Country

Iran (Islamic Republic of)

Phone

+98 41 4224 1099

Email address

m_nikkhesal@tabrizu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-20, 1396/09/29

Expected recruitment end date

2018-01-19, 1396/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of four weeks flaxseed supplementation and concurrent training on certain factors of cardiovascular disease and cortisol hormones in overweight women

Public title

Effect of flaxseed supplementation and concurrent training on overweight

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

women Students University of Tabriz Inactivity overweight BMI Between 25 and 29/9

Exclusion criteria:

Smoking Cardiovascular disease and surgery Chronic Diseases Consumption any kind of supplement fat burner Regularly have exercise activities

Age

From **20 years** old to **29 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, the university will be called upon to invite all women who are overweight to participate in the current study, and then from among the volunteers willing to participate in the study, 36 eligible people will study. The age range of 20 to 29 years will be selected. In order to homogenize the subjects, age, height, weight, fat percentage and some blood parameters of all subjects will be measured. Finally, considering these indices and using the Shapiro - Wilk test and ensuring the homogeneity of the data, 36 people will be randomly assigned to four homogeneous groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sport Sciences Research Institute of Iran

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2018-02-19, 1396/11/30

Ethics committee reference number

IR.SSRI.REC.1396.181

Health conditions studied

1

Description of health condition studied

Overweight

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

Weight

Timepoint

Before and after the exercise period

Method of measurement

Digital Weight Meter

2

Description

Body fat percentage

Timepoint

Before and after the exercise period

Method of measurement

Measuring subcutaneous fat with caliper

Secondary outcomes

1

Description

Cholesterol

Timepoint

Before and after the exercise period

Method of measurement

Colorimetric method using commercial kits

2

Description

High-density lipoprotein

Timepoint

Before and after the exercise period

Method of measurement

Colorimetric method using commercial kits

3

Description

Low density lipoprotein

Timepoint

Before and after the exercise period

Method of measurement

Colorimetric method using commercial kits

4

Description

Serum cortisol level

Timepoint

Before and after the exercise period

Method of measurement

It will be measured using the radioimmunoassay method.

5

Description

Malondialdehyde (MDA)

Timepoint

Before and after the exercise period

Method of measurement

Colorimetric method using Germany kit (BioCore)

6

Description

Total antioxidant capacity of the blood

Timepoint

Before and after the exercise period

Method of measurement

Spectrophotometry and ELISA

Intervention groups

1

Description

Intervention group1: flaxseed supplement (62.0 g / kg of body weight per day) in flaxseed supplementary group. Your flaxseed used in this study is from the Green Healing Faculty in Tabriz And was then ground and delivered as powder or broken and participated in a digital scale (0.62 grams per kilogram of body weight per day) in a pack containing three parts. Samples were asked to dissolve each package an hour before food, in three meals, and within 250 milligrams of water.

Category

Lifestyle

2

Description

Intervention group 2: concurrent training (endurance-

resistance) in the training group. concurrent training included aerobic exercises with an intensity of 65% of heart rate and resistance training with intensity of 60% 1RM

Category

Lifestyle

3

Description

Intervention group 3: concurrent training (endurance-resistance) and supplementation of flaxseed (62.0 g / kg of body weight per day) in the training group + flaxseed supplement

Category

Lifestyle

4

Description

Control group: They did not receive any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Tabriz

Full name of responsible person

Fateme HalalKhor

Street address

29 Bahman Blvd.,Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 41 4224 1099

Email

m_nikkhesal@tabrizu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Tabriz - Research Deputy

Full name of responsible person

Dr. Eskandar Fathi Azar

Street address

29 Bahman Blvd.,Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 41 3339 3635

Fax

+98 41 3334 4272

Email

e-fathiazar@tabrizu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of Tabriz - Research Deputy

Proportion provided by this source

100

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

University of Tabriz

Full name of responsible person

Fateme Halalkhor

Position

دانشجو

Latest degree

Master

Other areas of specialty/work

Physiology

Street address

29 Bahman Blvd.,Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 41 4224 1099

Fax

Email

m_nikkhesal@tabrizu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Tabriz

Full name of responsible person

Vahid Sari-Sarraf

Position

Associate Professor in Sport Physiology

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

29 Bahman Blvd.,Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5414646871

Phone

+98 41 3339 3251

Fax

Email

sarraf@tabrizu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

The University of Tabriz

Full name of responsible person

Fateme Halalkhor

Position

Student

Latest degree

Master

Other areas of specialty/work

Traditional Medicine

Street address

29 Bahman Blvd.,Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5414646871

Phone

+98 41 4224 1099

Fax

Email

m_nikkhesal@tabrizu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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