

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Aug 2026

### The effect of combined training with and without consuming the flaxseed , on the estrogen hormone, also on the Lipid profile and insulin resistance of postmenopausal women

#### Protocol summary

##### Study aim

The purpose of this study would be studying the effect of the combined training on the estrogen hormone, the lipid profile and the insulin resistance, with and without using the flax seed, in the menopause women inactive.

##### Design

A clinical trial with a pre-test, post-test, community-based approach with two randomized groups

##### Settings and conduct

Location: City of Torbat Heydarieh Collecting samples from people referring to health centers. Semi-experimental research with two groups of combined exercises and combined exercise group with flaxseed

##### Participants/Inclusion and exclusion criteria

1.Inactive postmenopausal women 2.One year since the last menstruation 3.non-use of hormone therapy 4.having a BMI between 25 and 30 5.having a fat percentage of over 25 6.and having no regular exercise in the last 6 months

##### Intervention groups

Combined exercise group, Combined exercise group plus flaxseed supplement

##### Main outcome variables

Lipid Indices (LDL, HDL, TG, COL) Estrogen Insulin resistance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171031037142N2**

Registration date: **2018-02-12, 1396/11/23**

Registration timing: **retrospective**

Last update: **2018-02-12, 1396/11/23**

Update count: **0**

##### Registration date

2018-02-12, 1396/11/23

##### Registrant information

###### Name

**Name of organization / entity**

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 5229 9300

###### Email address

jahanshiri.nasrin@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-02-29, 1394/12/10

##### Expected recruitment end date

2016-04-08, 1395/01/20

##### Actual recruitment start date

2016-03-05, 1394/12/15

##### Actual recruitment end date

2016-04-08, 1395/01/20

##### Trial completion date

empty

##### Scientific title

The effect of combined training with and without consuming the flaxseed , on the estrogen hormone, also on the Lipid profile and insulin resistance of postmenopausal women

##### Public title

The effect of combination training and flax on menopausal complications

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

One year since the last menstruation, having a body mass index of 25-30 kg / m<sup>2</sup>, having a fat percentage of over 25%,

**Exclusion criteria:**

not using hormone therapy and not having regular exercise in the last 6 months

**Age**

From **50 years** old to **60 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **30**

Actual sample size reached: **27**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

To determine the subjects in the training group and the exercise group with supplementation, from 1 to 30, it was written on small sheets and placed inside the box. Individuals extracted a number from the inside of the box before the first training session, if the desired number was paired, the person in the training group and, if the number was the one, the person was supplemented in the training group

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Mashhad Ferdowsi University

**Street address**

Azadi Square, Ferdowsi University of Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9117948974

**Approval date**

2017-12-03, 1396/09/12

**Ethics committee reference number**

IR.MUM.FUM.REC.1396.05

**Health conditions studied****1****Description of health condition studied**

In this study, the disease has not been studied and the subjects are healthy

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Estrogen is a collection of female sex hormones that consists of three main types of 17 beta-estradiol, estradiol and sterile, and is the main cause of female secondary sex traits. In this study, estradiol levels, the most important type of estrogen, were measured by blood sampling

**Timepoint**

Blood samples were collected for measuring estrogen 24 hours before and 48 hours after the last exercise session.

**Method of measurement**

To measure estrogen, the Japanese Toseh Kit was used

**2****Description**

Insulin resistance is called insulin resistance, because of the inability of the body to produce enough insulin or the inability to use insulin effectively. Insulin resistance was measured using the Homa formula.

**Timepoint**

Blood samples were collected for measuring insulin resistance 24 hours before and 48 hours after the last exercise session.

**Method of measurement**

In order to measure insulin and glucose, a kit of Pars tazmon was used in Iran

**3****Description**

Fat Profile: Blood lipids that appear in the form of triglycerides of cholesterol and lipoprotein (HDL, LDL).

**Timepoint**

Blood samples were collected for measuring fat profile, 24 hours before and 48 hours after the last exercise session.

**Method of measurement**

To determine the fat profile, the Pars azmon kits of Iran were used

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: combined training (The aerobic exercise was preformed with the intensity of 60 to 80 percent of the maximal heart rate and the resistance exercise with 4moves bench presses, wide grip last pull down, leg extension and lying leg curls with the intensity of 60 to 80 percent of a maximal repetition)

### Category

Other

## 2

### Description

Intervention group: combined training(The aerobic exercise was preformed with the intensity of 60 to 80 percent of the maximal heart rate and the resistance exercise with 4moves bench presses, wide grip last pull down, leg extension and lying leg curls with the intensity of 60 to 80 percent of a maximal repetition)plus flaxseed (using 25 grams of the milled flaxseed )

### Category

Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Health Centers

#### Full name of responsible person

Heydarbeygi Mina

#### Street address

Valiasr Township, Daneshahr Crossroads

#### City

Torbat Heidariyeh

#### Province

Razavi Khorasan

#### Postal code

9516143440

#### Phone

+98 51 5229 2584

#### Email

jahanshiri.nasrin@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mashhad Ferdowsi University

#### Full name of responsible person

Ahmad Reza Bahrami

#### Street address

Freedom Square, Ferdowsi University of Mashhad

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9177948974

#### Phone

+98 51 3880 5000

#### Email

pr@um.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad Ferdowsi University

#### Proportion provided by this source

75

#### 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

Mashhad Ferdowsi University

#### Full name of responsible person

Jahanshiri Nasrin

#### Position

Physical Education Instructor

#### Latest degree

Master

#### Other areas of specialty/work

Physical Education / Exercise Physiology

#### Street address

Valiasr Township, Laleh 2, No. 12

#### City

Torbat Heidarieh

#### Province

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#### Postal code

9516143459

#### Phone

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#### Email

jahanshiri.nasrin@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad Ferdowsi University

#### Full name of responsible person

Jahanshiri Nasrin

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Physical Education Instructor

#### Latest degree

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad Ferdowsi University

**Full name of responsible person**

Jahanshiri Nasrin

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**Email**

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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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All individual data of the participants in this study can be subscribed to after being unidentifiable

**When the data will become available and for how long**

Start the access period 3 months after printing the results

**To whom data/document is available**

Researchers working in academic institutions and health centers

**Under which criteria data/document could be used**

Use data and research results to help the community and conduct further research

**From where data/document is obtainable**

Email jahanshiri.nasrin@yahoo.com

**What processes are involved for a request to access data/document**

After receiving the email and ensuring that the reason for the request is one month

**Comments**

No specific explanation