

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of 8 weeks HIIT and resistance exercises and consumption of flaxseed oil on some parameters of oxidative stress (cat and sod) in women with diabetes

Protocol summary

Study aim

Determining the effect of 8 weeks of HIIT and resistance exercises and consumption of flaxseed oil on some parameters of oxidative stress (cat and sod) in women with diabetes

Design

Clinical trial with control group, with parallel groups, randomized, on 60 patients. Randomization by the method of equal blocks (15 blocks of 4) in which a number of intervention people and a number of comparison people are included in each block.

Settings and conduct

By referring to Hamedan Ba'ath Hospital, eligible people were identified and placed in the intervention groups using equal blocks randomization (15 blocks of 4). Then, people will go to the sports club for training intervention and perform exercises and supplements for 8 weeks. And before and 24 hours after exercise interventions, blood samples are taken from people to be measured in the laboratory.

Participants/Inclusion and exclusion criteria

Entry requirements: suffering from diabetes
Conditions of non-entry: inability to practice

Intervention groups

Exercises and supplements group: In the exercises group, the samples are subjected to high-intensity and resistance intermittent exercises, and the supplement group consumes flaxseed oil. The control group is not subjected to any intervention.

Main outcome variables

diabetes, some antioxidant factors (catalase and superoxide dismutase)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221120056548N3**

Registration date: **2023-02-25, 1401/12/06**

Registration timing: **prospective**

Last update: **2023-02-25, 1401/12/06**

Update count: **0**

Registration date

2023-02-25, 1401/12/06

Registrant information

Name

Saeid Shamlou kazemi

Name of organization / entity

Bu-Ali Sina university

Country

Iran (Islamic Republic of)

Phone

+98 912 859 7297

Email address

saeidshamlou9092@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-28, 1401/12/09

Expected recruitment end date

2023-03-05, 1401/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 8 weeks HIIT and resistance exercises and

consumption of flaxseed oil on some parameters of oxidative stress (cat and sod) in women with diabetes

Public title
The effect of exercise and consumption of flaxseed oil on diabetes

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Having diabetes
Exclusion criteria:
History of cardiovascular disease

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this randomization, the method of equal blocks (15 blocks of 4) was used, in which a number of intervention people and a number of comparison people are included in each block, and we assigned them to different groups. The method and tool of block random sequence generation has been done using <https://www.sealedenvelope.com/simple-randomiser/v1/lits>.

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

Ethics Committee of Sport Sciences Research Institute

Street address

Fifth Alley, Mir Emad Ave., Ostad Motahari Ave

City

Tehran

Province

Tehran

Postal code

1474674646

Approval date

2022-12-31, 1401/10/10

Ethics committee reference number

IR.SSRI.REC.1401.1870

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

The percentage of people whose blood sugar levels have decreased.

Timepoint

Blood sugar measurement before and after the intervention

Method of measurement

By measuring blood sugar in the laboratory

Secondary outcomes

1

Description

The percentage of people in whom the level of antioxidants catalase and superoxide dismutase increased.

Timepoint

Before and after interventions

Method of measurement

Using ELISA method and Zelbio kit made in Germany

Intervention groups

1

Description

Intervention group: Resistance training includes: resistance training by ballistic method and three sessions are held every week for 8 weeks. Each session started with a 15-minute warm-up including soft running, stretching and 3 sets of 5 repetitions of squat jumps without weights and jumping up and forwards without weights. Each session lasted approximately 30 to 40 minutes. 2 minutes rest between each set and 4 minutes rest between each movement. Movements include 10 throws of a medicine ball of 3 kg from the front of the chest, double leg jump from a bent position with a pause between each movement while carrying a weight of one kilogram in each hand, jumping up from a bent position

with a pause between each movement and carrying the weight. One kilogram in each hand would be 10 repetitions of plantar flexion at 30% maximal effort and 10 jump squats, starting with the knee bent at 90 degrees at 30% maximal effort. HIIT training includes: The training program of the HIIT group will include periods of 60 seconds of maximal running (85-95% heart rate reserve (HRR)) followed by 60 seconds of low-intensity running (55-60% HRR). Subjects first week 6 times, 8 times in the second week, 10 times in the third to eighth week. Flaxseed oil consumption: in the herbal supplement group, Barij flaxseed oil capsules were used and each subject was given one capsule daily. It can be consumed before lunch. The consumption period is eight weeks and every day.

Category

Treatment - Other

2

Description

Control group: This group is not subject to any exercise intervention or supplement consumption.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

saeid shamlou kazemi

Street address

Shahid Beheshti Blvd

City

Hamadan

Province

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6517838695

Phone

+98 81 3264 0020

Email

saeidshamlou9092@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Danesh Alborz University

Full name of responsible person

Saeid Shamlou Kazemi

Street address

Bu-Ali Sina University, Shahid Mostafa Ahmadi Roshan Street, Hamedan

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saeidshamlou9092@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Danesh Alborz University

Proportion provided by this source

10

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Bu-Ali Sina University

Full name of responsible person

Saeid shamlou kazemi

Position

Student

Latest degree

Master

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

If the intellectual rights are preserved, the data can be sent to the researchers.

From where data/document is obtainable

Email address: saeidshamlou9092@gmail.com

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

Submission of a written request (one week)

Comments