

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of 8 weeks of High intensity interval training and resistance training and consumption of flaxseed of grape seed extract on some parameters of oxidative stress (Tos and Ros) in women with type2 diabetes.

Protocol summary

Study aim

The effect of 8 weeks of High intensity interval training and resistance training and consumption of flaxseed of grape seed extract on some parameters of oxidative stress (Tos and Ros) in women with type2 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 grape seed extract. The control group is not subjected to any intervention.

Main outcome variables

diabetes, some antioxidant factors (total oxidant status, free oxygen species)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221120056548N7**

Registration date: **2023-05-18, 1402/02/28**

Registration timing: **prospective**

Last update: **2023-05-18, 1402/02/28**

Update count: **0**

Registration date

2023-05-18, 1402/02/28

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

2023-05-21, 1402/02/31

Expected recruitment end date

2023-05-31, 1402/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 8 weeks of High intensity interval training and resistance training and consumption of flaxseed of grape seed extract on some parameters of oxidative stress (Tos and Ros) in women with type2 diabetes.

Public title

The effect of exercise and grape seed extract on diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having diabetes being menopausal

Exclusion criteria:

History of cardiovascular disease

Age

From **50 years** old to **65 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) has been used, in which a number of intervention people and a number of comparison people are included in each block, and we have allocated 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

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Postal code

1474674646

Approval date

2023-04-19, 1402/01/30

Ethics committee reference number

IR.SSRC.REC.1402.028

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 oxidative stress parameters (Tos and Ros) has decreased.

Timepoint

Before and after interventions

Method of measurement

Using ELISA method and Zelbio kit made in Germany

Intervention groups**1****Description**

Intervention group: Intervention group: For aerobic exercise, the participants choose to exercise on a treadmill or ergometer bike. Aerobic training sessions start from 20 minutes and with an intensity of 60% of the maximum heart rate in the first and second week and increase to 30 minutes and up to 70% of the maximum heart rate in the 8th week. During the training, the heart rate is monitored by a Polar T31 oy pacemaker. Resistance training begins with one set of 15 repetitions for each movement in the first two weeks, and finally the intensity of the training is increased to two or three sets

of 10-120 repetitions. It increases in week 8. All resistance exercises are performed by means of gym machines and include chest press, leg press, cable underarm, cable front arm and cable back arm. The supplement group of grape seed extract is also consumed in the form of 200 mg capsules of grape seed extract of Vinicin Barrage essence for eight weeks and every day.

Category

Treatment - Other

2**Description**

Control group: This group is not subjected to any exercise intervention and supplement consumption.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Besat Hospital

Full name of responsible person

Saeid Shamlou Kazemi

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Shahid Beheshti Blvd

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6517838695

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Email

saeidshamlou9092@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice President of Research at 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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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice President of Research at 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****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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**Person responsible for updating data****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

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