

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The effect of 4 weeks high-intensity interval training (HIIT) with Spirulina supplementation on serum total antioxidant capacity (TAC) and Malondialdehyde (MDA) in women with type 2 diabetes (T2D)

Protocol summary

Study aim

evaluate the effect of 4 weeks high-intensity interval training (HIIT) with Spirulina supplementation on serum total antioxidant capacity (TAC) and Malondialdehyde (MDA) in women with type 2 diabetes

Design

This study is a randomized, controlled clinical trial design with parallel group design.

Settings and conduct

The statistical population of this study is women with type 2 diabetes mellitus. 60 of these people are selected based on inclusion and exclusion criteria the research. After completion of the consent form, the anthropometric and blood glucose characteristics of the subjects were recorded and based on the blood glucose of the subjects, the subjects were divided into four groups: 1_ hiit + spirulina (15), 2_ hiit (15 subjects), 3_ supplements (15 people), 4_ controls (15 people). Blood sampling is performed in two steps, one day before the training sessions and 48 hours after the end of the training. Spirulina supplementation is 2 grams per day for supplemental groups. Research variables will be measured after 4 weeks of intervention. The results are analyzed using the appropriate statistical method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No Appearance and clinical signs of cardiovascular disease

Intervention groups

1. HIIT group : Three sessions per week for 4 weeks
2. Spirulina supplements: Take 2 grams of spirulina daily
3. Supplement and Exercise Group: Two grams of spirulina supplement per day and three sessions of exercise per week for 4 weeks
3. Control group: no exercise and supplement

Main outcome variables

serum levels of malondialdehyde and total antioxidant capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180711040425N1**

Registration date: **2018-10-10, 1397/07/18**

Registration timing: **retrospective**

Last update: **2018-10-10, 1397/07/18**

Update count: **0**

Registration date

2018-10-10, 1397/07/18

Registrant information

Name

Saeedeh Khodadadi

Name of organization / entity

Shahrood university of technology

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 2204

Email address

ss.kk1159@shahroodut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 4 weeks high-intensity interval training (HIIT) with Spirulina supplementation on serum total antioxidant capacity (TAC) and Malondialdehyde (MDA) in women with type 2 diabetes (T2D)

Public title

The effect of exercise intensity and supplementation on diabetes

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

T2D detection < 10 years ago Ages 40 to 65 years old No dependency to insulin The use of commonly used diabetes medications, such as metformin and glenabellamine

Exclusion criteria:

Cardiovascular disease Coronary artery disease Atrial fibrillation High blood pressure Congenital heart disease Retinopathy Neuropathy Body mass index 35 Ischemia in echocardiography Disability that causes difficulty in practice.

Age

From **40 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

To allocate participants to research groups, a computer inventory of random numbers using a computer software (Random Allocation Software 2.0) will first be created by one of the research colleagues. Allocate participants by one of the research team members that is not related to the participants is done by block randomization with 4 blocks within the experimental (training) and control groups. Participants will be classified into 4 groups using randomized block method, depending on their blood glucose variables. The limitation of this method is the prediction of final allocation, which is the solution of random use of blocks of different sizes. Assignment sequences are hidden by the envelopes encoded in the order numbered, and the letter envelopes are opened only after all the initial and initial evaluations of the participants have been made.

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 on Biomedical Research of Shahrood University of Medical Sciences.

Street address

Shahrood University of Technology, Haft-e-Tir Square

City

shahrood

Province

Semnan

Postal code

3619995161

Approval date

2018-07-02, 1397/04/11

Ethics committee reference number

IR.SHMU.REC.1397.069

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

serum levels of Malondialdehyde in women with type 2 diabetes

Timepoint

One day before the session begins and 48 hours after the end of the exercise

Method of measurement

The MDA level measurement will be performed by ELISA, using a commercially available chemical calorimetry laboratory kit (MDA test kit; ZellBio GmbH, Ulm, Germany).

2

Description

Serum Total Antioxidant Capacity in women with type 2 diabetes

Timepoint

One day before the session begins and 48 hours after the end of the exercise

Method of measurement

The serum level of antioxidant total capacity will be

measured by ELISA and using a commercial kit under the manufacturer's protocols (ZellBio GmbH, Germany).

Secondary outcomes

empty

Intervention groups

1

Description

first Intervention group: The training group consisted of three sessions per week of high intensity interval training for 4 weeks. Training sessions consisted of 45 minutes walk or running on a treadmill. Each session is divided into 10 minutes of warming up with an intensity 50-70% HRR, 10 minutes of cooling down with an intensity 50-70% HRR and 25 minutes of high intensity interval training (HIIT The training section consists of 4 4-minute sections, with an intensity of 85 to 95% HRR and 3-minute rest periods, with an intensity of 50-70% HRR).

Category

Other

2

Description

Spirulina 2 grams daily, including 4 pills 500 mg before meals, for 4 weeks. This supplement is made by Qeshm algae and contains spirulina pure green algae. spirulina is a blue-green wonder aglae. It is the most powerful food existing in nature with 60% protein content and 18 amino acids.

Category

Other

3

Description

Third intervention group: Exercise + supplement group consisting of three sessions per week of high intensity interval training for 4 weeks and 2 grams of supplementation of spirulina per day for 4 weeks

Category

Other

4

Description

fourth intervention group: control group, No Spirulina supplement and no exercise

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrood diabetes association

Full name of responsible person

Shahrood diabetes association

Street address

Imam street

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1355936735

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrood University of Technology

Full name of responsible person

Ali Hasani

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Shahrood University of Technology, Haft-e-Tir Square

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hassani_3@shahrood.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahrood University of Technology

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

Shahrood University of Technology

Full name of responsible person

saeedeh khodadadi

Position

Masters student

Latest degree

Master

Other areas of specialty/work

Others

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Latest degree

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahrood university of technology

Full name of responsible person

Saeedeh Khodadadi

Position

Student

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Shahrood University of Technology

Full name of responsible person

saeedeh khodadadi

Position

Student Master

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 more information.

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The informed consent form will be available to others without mentioning the names of the participants.

Details of the study process are also provided in detail in the file format.

When the data will become available and for how long

Start of the 6 month period after the research

To whom data/document is available

For university students and students in research related fields

Under which criteria data/document could be used

There are no specific conditions to provide such information.

From where data/document is obtainable

Saeedeh Khodadadi

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

Send message to the person responsible for providing the data

Comments