

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of twelve weeks of high-intensity functional training with spinach-derived thylakoid supplementation on some inflammatory and antioxidant markers, adipokines, myokines, and hepatokines in men with obesity

Protocol summary

Study aim

The effect of twelve weeks of high-intensity functional training with spinach-derived thylakoid supplementation on some inflammatory markers in men with obesity

Design

Clinical trial with parallel control group, randomized, single-center trial, Sample size 44 people, Blinding is not done.

Settings and conduct

Twelve weeks of high-intensity functional training with spinach-derived thylakoid supplementation for 44 obese men. Tehran health centers

Participants/Inclusion and exclusion criteria

Inclusion criteria: No addiction to drugs and alcohol; Not having a history of regular sports activity for at least 6 months; No history of disease; Not having any injury or physical problem; Body mass index equal to 30; Waist-to-height ratio greater than 0.5 Exclusion Criteria: Any psychological disorder; Use of psychiatric drugs before conducting study

Intervention groups

Intervention group1: In this group, according to the protocol, they will perform a high-intensity functional training program (HIFT) in 36 sessions of 60 minutes, in which CrossFit is used. Intervention group2: In this group, according to the protocol, they will perform a high-intensity functional training program (HIFT) in 36 sessions of 60 minutes. Daily, one bag containing 5 grams of thylakoid will be dissolved in a glass of water and given to the participants. Intervention group3: In this group, they will only do their daily exercises for 12 weeks. and daily, one bag containing 5 grams of thylakoid will be dissolved in a glass of water and given to the participants. Control group: In this group, they will only do their daily exercises for 12 weeks and will be prohibited from participating in regular activities. Daily,

one bag containing 5 grams of corn starch powder (placebo) will be dissolved in a glass of water and given to the participants.

Main outcome variables

Adipokines, Myokines, Hepatokines

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N77**

Registration date: **2023-04-26, 1402/02/06**

Registration timing: **prospective**

Last update: **2023-04-26, 1402/02/06**

Update count: **0**

Registration date

2023-04-26, 1402/02/06

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15
Expected recruitment end date
 2023-08-06, 1402/05/15
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 The effect of twelve weeks of high-intensity functional training with spinach-derived thylakoid supplementation on some inflammatory and antioxidant markers, adipokines, myokines, and hepatokines in men with obesity

Public title
 The effect of twelve weeks of high-intensity functional training with spinach-derived thylakoid supplementation on some inflammatory markers in men with obesity

Purpose
 Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
 No addiction to drugs and alcohol Not having a history of regular sports activity for at least 6 months No history of kidney, liver, cardiovascular disease and diabetes Not having any injury or physical problem Body mass index equal to 30 Waist-to-height ratio (WHtR) greater than 0.5
Exclusion criteria:
 Any psychological disorder to the individual's own report Use of psychiatric drugs before conducting study

Age
 From **23 years** old to **32 years** old

Gender
 Male

Phase
 2-3

Groups that have been masked
No information

Sample size
 Target sample size: **44**

Randomization (investigator's opinion)
 Randomized

Randomization description
 We will construct 6 blocks in AABB, BBAA, ABAB, BABA, ABBA, and BAAB using four blocks. We will assign 1 to 6 for each block. Then, using the random number table, based on the sample size, 11 units of 4 blocks will be selected so that we consider having 11 people in the group (A), 11 people in the group (B), 11 people in the group (C) and 11 people in the group (D). Therefore, we will do block randomization.

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Damghan branch

Street address

Islamic Azad University, Damghan branch; above Saadi square; Damghan.

City

Damghan

Province

Semnan

Postal code

3671637849

Approval date

2022-12-24, 1401/10/03

Ethics committee reference number

IR.IAU.DAMGHAN.REC.1401.034

Health conditions studied

1

Description of health condition studied

Obesity and overweight

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Body mass index

Timepoint

48 hours before the intervention and 48 hours after the twelve-week training period

Method of measurement

Weight with kilograms on a scale - Height with meters with the use of a rubber meter

Secondary outcomes

1

Description

Myokines

Timepoint

The first fasting blood sample 48 hours before and the second blood sample 48 hours after the twelve-week training period from the right arm

Method of measurement

They will be measured using laboratory kits and ELISA

devices

2

Description

Hepatokines

Timepoint

The first fasting blood sample 48 hours before and the second blood sample 48 hours after the twelve-week training period from the right arm

Method of measurement

They will be measured using laboratory kits and ELISA devices

3

Description

Adipokines

Timepoint

The first fasting blood sample 48 hours before and the second blood sample 48 hours after the twelve-week training period from the right arm

Method of measurement

They will be measured using laboratory kits and ELISA devices

Intervention groups

1

Description

Intervention group1: In this group, according to the protocol, they will perform a high-intensity functional training program (HIFT) in 36 sessions of 60 minutes, in which CrossFit is used.

Category

Treatment - Other

2

Description

Intervention group2: In this group, according to the protocol, they will perform a high-intensity functional training program (HIFT) in 36 sessions of 60 minutes, in which CrossFit is used. Daily, one bag containing 5 grams of thylakoid will be dissolved in a glass of water and given to the participants 30 minutes before lunch.

Category

Treatment - Other

3

Description

Intervention group3: In this group, no treatment will be given and they will only do their daily exercises for 12 weeks and will be prohibited from participating in regular activities. Daily, one bag containing 5 grams of thylakoid will be dissolved in a glass of water and given to the participants 30 minutes before lunch. It is only for comparison with intervention groups.

Category

Treatment - Other

4

Description

Control group: In this group, no treatment will be given and they will only do their daily exercises for 12 weeks and will be prohibited from participating in regular activities. Daily, one bag containing 5 grams of corn starch powder (placebo) will be dissolved in a glass of water and given to the participants 30 minutes before lunch. It is only for comparison with intervention groups.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran health centers

Full name of responsible person

Ayoub Saeidi

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Payandeh St., Iranmehr St., Tehran

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Tehran

Province

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1714956543

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Nemat Allah Nemati

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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
Islamic Azad University
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

Islamic Azad University, Damghan branch; above
Saadi square; Damghan.
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Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Ayoub Saeidi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physical education and sports sciences - sports
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Person responsible for updating data

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Latest degree
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are20935@gmail.com

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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