Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 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
Street address
Payandeh St., Iranmehr St., Tehran
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Province
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1714956543
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Email
are20935@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Nemat Allah Nemati
Street address
Islamic Azad University, Damghan branch; above Saadi square; Damghan.
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3671637849
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+98 23 3522 5045
Email
info@damghaniau.ac.ir
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

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 physiology
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Person responsible for scientific inquiries

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Full name of responsible person
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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