

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 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)

##### Phone

+98 23 3345 1336

##### Email address

are20935@semums.ac.ir

##### 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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1714956543

##### **Phone**

+98 21 3379 1873

##### **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.

##### **City**

Damghan

##### **Province**

Semnan

##### **Postal code**

3671637849

##### **Phone**

+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

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Saadi square; Damghan.

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are20935@gmail.com

## 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  
**Street address**  
Islamic Azad University, Damghan branch; above  
Saadi square; Damghan.  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Ayoub Saeidi  
**Position**  
Assistant Professor  
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**Other areas of specialty/work**  
Physical education and sports sciences - sports  
physiology  
**Street address**

## Person responsible for updating data

### 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**  
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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