

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effect of 8 weeks of functional training and chromium picolinate supplementation on leptin levels and body composition of overweight and obese women

#### Protocol summary

##### Study aim

Determining the effect of 8 weeks of functional training on blood leptin levels in overweight and obese women  
Determining the effect of 8 weeks of functional training on body composition (percentage of fat, fat mass and lean mass) overweight and obese women  
Determining the effect of 8 weeks of chromium picolinate supplementation on blood leptin levels in overweight and obese women  
Determining the effect of 8 weeks of chromium picolinate supplementation on body composition (fat percentage, fat mass and lean mass) of overweight and obese women

##### Design

Quasi-experimental study with control group, with cross design, without blinding, random blocking method with 4 blocks and using random number table of random sequence software.

##### Settings and conduct

The distal training protocol is performed under the supervision of an instructor and in a gym and will include six types of hopping that will be performed for eight weeks and three 31-minute sessions each week. The intensity of the exercises is applied progressively by adding movements every week.

##### Participants/Inclusion and exclusion criteria

Admission requirements: Women 25 to 35 years old with a body mass index of 25 and above. Conditions of non-entry: Women who have had a regular exercise program in the past year, or are allergic to chromium supplements, or by a doctor Sports activities are prohibited or no conscious consent.

##### Intervention groups

Group1: Daily intake of chromium picolinate supplement (two doses of 200 micrograms) for eight weeks  
Group2: Performing functional exercises for 8 weeks  
Group3: Performing functional exercises and daily consumption of chromium picolinate supplement (two doses of 200

micrograms) for 8 weeks  
Fourth group (control): not receiving intervention or treatment to reduce the main consequences

##### Main outcome variables

Serum leptin, fat percentage, fat mass, lean mass

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220604055076N1**

Registration date: **2022-06-13, 1401/03/23**

Registration timing: **prospective**

Last update: **2022-06-13, 1401/03/23**

Update count: **0**

##### Registration date

2022-06-13, 1401/03/23

##### Registrant information

##### Name

shaghayegh akramiyh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6691 2509

##### Email address

shaghayegh.painting@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-11, 1401/04/20

##### Expected recruitment end date

2022-08-01, 1401/05/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of 8 weeks of functional training and chromium picolinate supplementation on leptin levels and body composition of overweight and obese women

**Public title**

The effect of 8 weeks of functional training and chromium picolinate supplementation on leptin levels and body composition of overweight and obese women

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Overweight (body mass index 25 to 29.9) Obese (body mass index 30 and more) 25-35 years Female gender

**Exclusion criteria:**

Smoking Participate in regular sports activities for at least the past year Sensitivity to chromium supplementation Prohibition of exercise by a physician

**Age**

From **25 years** old to **35 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

40 participants are randomly divided into 4 groups using a table of random numbers. In the present study, the restricted randomization method was used, which will be performed in a block randomization method. The size of four blocks is equal and we will have four groups of 40 blocks (including 10 people participating in each group). Randomization tool also uses software random allocation software (Random allocation software). In addition to simple randomization, these random sequence generation software are able to generate random sequences by block generation method. For concealment, we use concealment allocation, so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed with random sequences (envelopes opaque, sealed, numbered sequentially), in which each random sequence is recorded on a card. And the cards are placed in the envelopes of the letter, respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible

participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

**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 Islamic Azad University, Science and Research Branch

**Street address**

Islamic Azad University, Science and Research Branch, shohada Hesarak Boulevard University Square, End of Shahid Sattari Highway, Tehran.

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۷۷۸۹۳۸۵۵

**Approval date**

2022-02-20, 1400/12/01

**Ethics committee reference number**

IR.IAU.SRB.REC.1400.299

**Health conditions studied****1****Description of health condition studied**

Serum leptin

**ICD-10 code****ICD-10 code description****2****Description of health condition studied**

Physical composition

**ICD-10 code****ICD-10 code description****3****Description of health condition studied**

Overweight and obesity

**ICD-10 code**

E66

**ICD-10 code description**

Overweight and obesity

## Primary outcomes

### 1

#### Description

Serum leptin levels

#### Timepoint

One week before the first session (pre-test) and 24 hours after the last training session (post-test) in the eighth week

#### Method of measurement

ELISA method using Leptin ELISA kit by Mercodia

### 2

#### Description

Physical composition

#### Timepoint

One week before the first session (pre-test) and 24 hours after the last training session (post-test) in the eighth week

#### Method of measurement

Bioelectric impedance analysis method by bioelectric impedance device (Model / IOI353)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group1: Daily intake of chromium picolinate supplement (two 200-microgram doses made by 21st Century USA after breakfast and dinner) for eight weeks

#### Category

Treatment - Other

### 2

#### Description

Intervention group2: Perform functional exercises for 8 weeks (including six types of hopping, which will last for eight weeks and three sessions of 31 minutes per week)

#### Category

Treatment - Other

### 3

#### Description

Intervention group3: Performing functional exercises and daily consumption of chromium picolinate supplement (two doses of 200 micrograms) for 8 weeks

#### Category

Treatment - Other

### 4

#### Description

Control group: not receiving intervention or treatment to reduce the main consequences

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sport Club

##### Full name of responsible person

Shaghayegh Akramiye

##### Street address

Islamic Azad University, Science and Research Branch, Shohada Hesarak Boulevard University Square, End of Shahid Sattari Highway.

##### City

Tehran

##### Province

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##### Phone

+98 21 4486 5179

##### Email

shaghayegh.painting@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Seyed babak Mozafari

##### Street address

End of Shahid Sattari Highway - University Square - Shohada Hesarak Boulevard - Islamic Azad University, Science and Research Branch

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##### Phone

+98 21 4486 5179

##### Email

Mozafari@srbiau.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

50

#### 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

**Province**  
Tehran  
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## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Shaghayegh Akramiye  
**Position**  
Student  
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## Person responsible for scientific inquiries

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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

Not applicable

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable