

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

AgeFrom **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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

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Person responsible for general 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