

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Sep 2026

### The effect of 8 weeks interval training with vitamin D supplementation on appetite -depended hormones in overweight men

#### Protocol summary

##### Study aim

Evaluation of weight and appetite changes caused by regular exercise and vitamin D supplementation

##### Design

The present study is a randomized clinical trial and the subjects are assigned in the pretest-posttest design with the control group. Subjects randomly are divided into four groups including: training group with vitamin D supplementation (n=12), training group with placebo(n=12),supplementation group(n=12) and control group(n=12).experimental groups were given 3 sessions per week during 8 weeks .

##### Settings and conduct

This study is the semi- experimental and double-blind (neither the researcher nor participants are aware of which placebo or supplement group they receive) will be conducted in the Javanroud. The experimental group will perform training in Imam Khomeini cloub and blood sampling from each of the two groups will perform in the Hazrat Rasoul hospital laboratories in Javanrud.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria:14>Age>30;Over weight (a body mass index above 25kg/m2);Having an informed consent for participation in the study Non-inclusion criteria: Gender(Women); having desaese and taking drugs and supplements; drug and alcohol addiction; having regular exercise in recent 6 months

##### Intervention groups

Intervention group1: were given 3 sessions per week (85 to 95% max heart rate) during 8 weeks Intervention group2: In addition to given 3 sessions per week ( 85 to 95% ax heart rate) during 8 weeks,take daily 2000 IU of vitamin D3 supplementation . Intervention group3:Only take daily 2000 IU of vitamin D3 supplementation. Control group:The control will have no supplement and regular exercise program during this time and will only participate in pre-test and post-test measurements.

##### Main outcome variables

Weight; BMI; appetite related hormones change includes:

Acylated Ghrelin; PYY; Orexin and Insulin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180708040392N2**

Registration date: **2019-09-13, 1398/06/22**

Registration timing: **prospective**

Last update: **2019-09-13, 1398/06/22**

Update count: **0**

##### Registration date

2019-09-13, 1398/06/22

##### Registrant information

##### Name

Naser Rostamzadeh

##### Name of organization / entity

The University of Kurdistan

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3371 1530

##### Email address

n.rostamzadeh@hum.uok.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2019-10-23, 1398/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of 8 weeks interval training with vitamin D supplementation on appetite –depended hormones in overweight men

**Public title**

The effect of interval training with vitamin D supplementation on appetite –depended hormones

**Purpose**

Prevention

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

Being at the age of 14-30 years old BMI>25 kg/m2  
Informed consent

**Exclusion criteria:**

Gender (Women can not be selected as a sample) People who have a certain disease and take medication Having a regular sports activity during recent 6 months Having drug and smoking addiction

**Age**

From **14 years** old to **30 years** old

**Gender**

Male

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization by simple drawing method:The researcher devote a number to each of the samples, then they are being selected by using the random number table or the computer model and randomly assigned to one of the groups

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Both participants and the researcher were kept blind in this study

**Placebo**

Used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Kurdistan University

**Street address**

Kurdistan University , Pasdaran Blvd.

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

۶۶۱۷۷-۱۵۱۷۵

**Approval date**

2019-07-06, 1398/04/15

**Ethics committee reference number**

IR.UOK.REC.1398.024

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

Obesity

**ICD-10 code**

E66.9

**ICD-10 code description**

Obesity, unspecified

**Primary outcomes****1****Description**

Obesity

**Timepoint**

Before starting the protocol and again after 8 weeks training

**Method of measurement**

Measure of Body Mass Index ( BMI )

**2****Description**

Accylated Ghrelin

**Timepoint**

Before starting the protocol and again after 8 weeks training

**Method of measurement**

Serum ELISA Kit

**3****Description**

PYY

**Timepoint**

Before starting the protocol and again after 8 weeks training

**Method of measurement**

Serum ELISA Kit

#### 4

**Description**

Orexin

**Timepoint**

Before starting the protocol and again after 8 weeks training

**Method of measurement**

Serum ELISA Kit

#### 5

**Description**

Insulin

**Timepoint**

Before starting the protocol and again after 8 weeks training

**Method of measurement**

Serum ELISA Kit

### Secondary outcomes

#### 1

**Description**

The amount of calorie intake

**Timepoint**

before starting the intervention and after a 8 weeks training

**Method of measurement**

By remember food intake form

### Intervention groups

#### 1

**Description**

Intervention group: do interval training for 8 weeks and taken 2000 IU of vitamin D3 supplement per day

**Category**

Lifestyle

#### 2

**Description**

Control group: This group does not receive any intervention and only participates in measurements

**Category**

Lifestyle

#### 3

**Description**

Intervention group: do interval training for 8 weeks and taken placebo per day

**Category**

Placebo

#### 4

**Description**

Intervention group: taken 2000 IU vitamin D per day

**Category**

Lifestyle

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

University of Kurdistan

**Full name of responsible person**

Naser Rostamzadeh

**Street address**

No.1, Zibashahr Ave., Baharan Town

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617883357

**Phone**

+98 87 3371 1530

**Email**

n.rostamzadeh@hum.uok.ac.ir

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

The University of Kurdistan

**Full name of responsible person**

Mehrdad Khamforoush

**Street address**

University of Kurdistan, Pasdaran, Sanandaj

**City**

Sansndaj

**Province**

Kurdistan

**Postal code**

6617715175

**Phone**

+98 87 3366 4600

**Email**

m.khamforoush@uok.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

The University of Kurdistan

**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**

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

The University of Kurdistan

**Full name of responsible person**

Naser Rostamzadeh

**Position**

Student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Physiology

**Street address**

No.1, Zibashahr Ave., Baharan Town

**City**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Part of the data, such as average age, gender, the average of the body mass index and results of the outcome have the possibility of sharing

**When the data will become available and for how long**

6 months after the report of results

**To whom data/document is available**

Researchers in Academic and scientific institutions

**Under which criteria data/document could be used**

Only for compare with similar research using the documentation permitted

**From where data/document is obtainable**

By email

**What processes are involved for a request to access data/document**

After sending the request via e-mail, lasts for 2 months

**Comments**