

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The effect of 8 weeks of high-intensity interval training (HIIT) with and without vitamin D supplementation on some muscle atrophy indexes in older men

#### Protocol summary

##### Study aim

Determining the effect of eight weeks of high-intensity interval training (HIIT), vitamin D supplementation and their combination on serum levels of GDF8, IGF-1, miRNA-1, miRNA-133a and miRNA-206 in inactive elderly men

##### Design

A controlled clinical trial with randomized parallel groups was performed on 40 inactive elderly men

##### Settings and conduct

For this purpose, in a quasi-experimental research project, 40 elderly people (60 to 75 years old) were considered as a research sample. Subjects will be randomly divided into four groups of 10: control, HIIT, HIIT + vitamin D exercise, and vitamin D group. The training protocol is performed three days a week for eight weeks. Vitamin D supplementation in the vitamin D group and the HIIT + vitamin D exercise group is estimated at 2000 International Units (IU) per day. Blood samples and functional tests are taken at rest 48 hours before the start of training and 48 hours after the last training session.

##### Participants/Inclusion and exclusion criteria

- Age range: 75-60 years
- inactive (less than 90 minutes of regular exercise per week)
- Do not use drugs and anabolic supplements, blood pressure, anti-inflammatory and antioxidants

##### Intervention groups

Subjects are divided into four groups. 1 - Control group that follow their daily schedule and diet. 2- Vitamin D group: which consumes 2000 international units of vitamin D per day and perform daily activities 3-high-intensity interval training group that performs these exercises three days a week for 8 weeks 4-high-intensity interval training group + vitamin D intake, this group 3 days a week of high-intensity interval training in addition to consuming 2000 international units of vitamins

##### Main outcome variables

vitamin D: IGF-1: GDF-8: miRNA-1: miRNA-133a: miRNA-206

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190917044797N2**

Registration date: **2022-02-05, 1400/11/16**

Registration timing: **prospective**

Last update: **2022-02-05, 1400/11/16**

Update count: **0**

##### Registration date

2022-02-05, 1400/11/16

##### Registrant information

##### Name

Javad Vakili

##### Name of organization / entity

The University of Tabriz

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3339 3251

##### Email address

vakili@tabrizu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-09, 1400/11/20

##### Expected recruitment end date

2022-04-09, 1401/01/20

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
The effect of 8 weeks of high-intensity interval training (HIIT) with and without vitamin D supplementation on some muscle atrophy indexes in older men

**Public title**  
The effect of high-intensity interval training (HIIT) and vitamin D supplementation on older men

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age range 60 to 75 years inactive (less than 90 minutes of regular exercise per week) Do not use drugs and anabolic supplements, blood pressure, anti-inflammatory and antioxidants  
**Exclusion criteria:**  
The elderly are injured Metabolic and cardiovascular diseases

**Age**  
From **60 years** old to **75 years** old

**Gender**  
Male

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
At first, the subjects will be selected using a simple random method. Then, using a table of random numbers, they are divided into four groups: control, exercise, vitamin D and exercise + vitamin D. Therefore, each candidate will be assigned a two-digit number from 01.02.000 to 40. Starting from a point on the table of random numbers in the direction of the desired row or column, the same number of digits is determined for the selection of individuals (five-digit numbers whose last two digits are similar to the existing codes) that are randomly assigned to one of the groups It will be given. This will continue until the number of people in each group is completed. Therefore, the researcher will not have the option to change the status of the assignment or predict it. Random hiding will be done by a third party who does not participate in other stages of the intervention.

**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 tabriz University  
**Street address**  
29 Bahman Blvd., University of Tabriz  
**City**  
tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5166616471  
**Approval date**  
2022-01-02, 1400/10/12  
**Ethics committee reference number**  
IR.TABRIZU.REC.1400.059

## Health conditions studied

### 1

**Description of health condition studied**  
Sarcopenia  
**ICD-10 code**  
M62.5  
**ICD-10 code description**  
Muscle wasting and atrophy, not elsewhere classified

## Primary outcomes

### 1

**Description**  
Serum levels of vitamin D  
**Timepoint**  
48 hours before and after 8 weeks of exercise training  
**Method of measurement**  
Using the ELISA method

### 2

**Description**  
Serum levels of Insulin-like hormone 1  
**Timepoint**  
48 hours before and after 8 weeks of exercise training  
**Method of measurement**  
Using the ELISA method

### 3

**Description**  
Serum levels of myostatin hormone  
**Timepoint**

48 hours before and after 8 weeks of exercise training

**Method of measurement**

Using the ELISA method

**4**

**Description**

miRNA-1

**Timepoint**

48 hours before and after 8 weeks of exercise training

**Method of measurement**

Real Time PCR technique

**5**

**Description**

miRNA-133a

**Timepoint**

48 hours before and after 8 weeks of exercise training

**Method of measurement**

Real Time PCR technique

**6**

**Description**

miRNA-206

**Timepoint**

48 hours before and after 8 weeks of exercise training

**Method of measurement**

Real Time PCR technique

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Control group: without receiving supplements and exercise program

**Category**

Other

**2**

**Description**

Intervention group: The daily intake of 2000 international units of vitamin D per day will be done for eight weeks.

**Category**

Other

**3**

**Description**

Intervention group: Group three (high-intensity interval training ): Subjects in the high-intensity interval training group will participate 3 days a week for 8 weeks of high-intensity interval training with an intensity of more than 75% of the reserve heart rate. Blood samples are taken at rest 48 hours before the start of training and 48 hours after the last training session.

**Category**

Other

**4**

**Description**

Intervention group: Group four (High-intensity interval training +Vitamin D group): Subjects in the high-intensity interval training group will take vitamin D, 3 days a week, for 8 weeks of high-intensity interval training with an intensity of more than 75% of the reserve heart rate. During this period, 2,000 international units of vitamin D will be consumed every day. Blood samples are taken at rest 48 hours before the start of training and 48 hours after the last training session.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

The University of Tabriz

**Full name of responsible person**

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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**

The University of tabriz

**Proportion provided by this source**

20

**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**

The University of tabriz

**Full name of responsible person**

Kaveh Baturak

**Position**

P.hd student

**Latest degree**

Master

**Other areas of specialty/work**

Sport Physiology

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**Position**

Associate professor

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Physiology

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## Person responsible for updating data

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

No - There is not 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