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

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Iran (Islamic Republic of)

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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

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29 Bahman Blvd., University of Tabriz

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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

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Name of organization / entity

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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

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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