Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

The effect of high intensity interval resistance training and vitamin D intake on the levels of Sirtuin1, Eotaxin-1 and some anti inflammatory-oxidative markers in overweight women with low vitamin D status.

Protocol summary

Study aim

Evaluate the effect of intense interval resistance and running training with vitaminD intake on the levels of sirtoin1, eutoxin-1 and some anti-inflammatory-oxidative markers in overweight women with low vitaminD status.

Design

This study is a quasi-experimental one-blind clinical trial that will be performed using a pre-post test design with a control group for 8 weeks. Subjects were randomly divided into six groups: control, vitaminD, resistance interval, running interval, resistance interval+vitaminD and running interval+vitaminD. Exercise or combinations with vitaminD groups perform the prescribed exercises. VitaminD and exercise+vitaminD groups will receive 50,000IU of VitaminD weekly.

Settings and conduct

The statistical population includes sedentry women with body mass index between 25-29kg/m2, referred to Babol sports clubs. High intensity interval resistance and/or running training are performed three sessions per week for 8 weeks at the Paya Sports Club in Babol. Subjects in the vitaminD or combination groups, and the exercises or control groups, will take supplement and placebo, respectively.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being overweight, being a non-athlete, having levels of 25-hydroxyvitaminD less than 30ng/ml .Exclusion critiaer: Smoking, use of special drugs, use of any supplements.

Intervention groups

The training groups performs high intensity interval resistance (with an intensity of 70% of 1RM) and/or running (12x1-min running bouts at 80-90% HRmax) trainig for 8 weeks.The supplement group will take 50,000IU of vitaminD capsules weekly for 8 weeks .Supplemental+training groups, in addition to performing the desired exercises, similar to the supplement group, take vitaminD. The control group does not undergo intervention.

Main outcome variables

Siirtoin1, eutoxin-1,Inflammatory and anti-inflammatory markers, antioxidant markers

General information

Reason for update

Add study on the effect of high-intensity interval running exercises, in addition to studying the effect of high-intensity resistance training exercises and comparing the effect of these two types of exercises on the studied variables(Due to the commonality of control and Supplement groups)

Acronym

IRCT registration information

IRCT registration number: **IRCT20190831044650N3**
Registration date: **2021-08-22, 1400/05/31**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-12, 1401/08/21**
Update count: **2**

Registration date

2021-08-22, 1400/05/31

Registrant information

Name

Masoumeh Habibian

Name of organization / entity

Qaemshahar Branch, Islamic Azad University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-08-21, 1400/05/30

Expected recruitment end date
2021-09-21, 1400/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of high intensity interval resistance training and vitamin D intake on the levels of Sirtuin1, Eotaxin-1 and some anti inflammatory-oxidative markers in overweight women with low vitamin D status.

Public title
The effect of high intensity interval resistance training and vitamin D intake onvitamin D th and anti inflammatory-oxidative status in overweight women

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having a body mass index between 25 to 29 kg / m2 Not participating in regular sports activities for the past six months Not having cardiovascular disease Not having hypertension Not having Inflammatory diseases Serum levels of 25-hydroxyvitamin D less than 30 ng / ml

Exclusion criteria:
Use any specific medications or supplements Pregnancy Smoking

Age
From **23 years** old to **29 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **78**

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 six groups: control, resistance interval, running interval, vitamin D, resistance interval+vitamin D and running interval+ vitamin D. Therefore, each of the candidates will be assigned a two-digit number from 01, 02, ..., 10, 11, ..., to 52. The same number of digits is determined for the selection of individuals by starting a hand movement from a point in the table of random numbers in the direction of the desired row or column (five-digit numbers whose last two digits are similar to the existing codes) and each is randomly assigned to One of the groups. 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 disguise will be done by a third party who does not participate in other stages of the intervention.

Blinding (investigator's opinion)
Single blinded

Blinding description
Analysts will be blind. The researcher will administer vitamin D capsules (50,000 units) to vitamin D, resistance interval+ vitamin D, running interval+ vitamin D individuals as well as placebo to control and exercise groups

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Sari branch, Islamic Azad University

Street address
7 km Darya Road, Sari, Islamic Azad University, Sari Branch, Iran

City
Sari

Province
Mazandaran

Postal code
48181-19318

Approval date
2021-04-27, 1400/02/07

Ethics committee reference number
IR.IAU.SARI.REC.1400.004

Health conditions studied

1

Description of health condition studied
Overweight

ICD-10 code
E66.0

ICD-10 code description
Obesity due to excess calories

2

Description of health condition studied
Vitamin D deficiency

ICD-10 code

E50.5

ICD-10 code description

Vitamin D deficiency

Primary outcomes

1

Description

Eotaxin-1

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Using the ELISA method

2

Description

Sirtuin1

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Using the ELISA method

3

Description

interlukin10

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Using the ELISA method

4

Description

25- hydroxy vitamin D

Timepoint

Before and after interventions

Method of measurement

Using the ELISA method

5

Description

Brain-Derived Neurotrophic Factor

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Using the ELISA method

6

Description

Superoxide dismutase

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Laboratory methods

7

Description

Tumor necrosis factor alpha

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Using the ELISA method

8

Description

Monocyte Chemoattractant Protein 1

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Using the ELISA method

9

Description

Malondialdehyde

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

spectrophotometrically

10

Description

Homocysteine

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Using the ELISA method

11

Description

Total Antioxidant Capacity

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Ferric Reducing/Antioxidant Power

12

Description

Transforming growth factor-beta 1 (TGF-beta1)

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Using the ELISA method

13

Description
Vascular endothelial growth factor (VEGF)
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Using the ELISA method

14

Description
C-Reactive Protein (CRP)
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Using the ELISA method

15

Description
Adiponectin
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Using the ELISA method

16

Description
Thyroid stimulating hormone
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Using the ELISA method

Secondary outcomes

1

Description
Sleep quality
Timepoint
Before and after interventions
Method of measurement
Sleep quality questionnaire

2

Description
Quality of Life
Timepoint
Before the intervention and 2 weeks after the intervention
Method of measurement
Quality of Life Questionnaire

Intervention groups

1

Description
Control group: There is no intervention in the control group and they are given placebo in a single blind manner
Category
Placebo

2

Description
Intervention group 1: Vitamin D group, who take 50,000 IU of vitamin D capsules once a week for 8 weeks.
Category
Treatment - Other

3

Description
Intervention group 2: resistance interval group will perform 8 weeks and three times a week of high intensity interval resistance training consisting of three sets of 6 repetitions at 70% of 1repetition maximum (RM) and then 20 seconds of rest between repetitions until exhaustion repeated for 3 times with 2 .30” rest between sets. They will also take a placebo capsule containing oral paraffin weekly
Category
Treatment - Other

4

Description
Intervention group 3: Subjects in this group will have 8 weeks of high intensity interval resistance training similar to the interval resistance group and will consume 50,000 IU of vitamin D capsules once a week.
Category
Treatment - Other

5

Description
Intervention group 3: running interval group will perform 8 weeks and three times a week of high intensity interval running training consisting of 12 x 1-min running bouts at 80-90% HRmax interspersed with 1-min active recovery at 50%HRmax. They will also take a placebo capsule containing oral paraffin weekly.
Category
Treatment - Other

6

Description
Intervention group 5: Subjects in this group will have 8 weeks of high intensity interval running training similar to the interval running group and will consume 50,000 IU of vitamin D capsules once a week.
Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Paya Sports Siavash

Full name of responsible person
Ruhollah Akbari

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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
Sari branch, Islamic Azad University

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Qaemshahr branch, Islamic Azad University

Full name of responsible person
Masoumeh habibian

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

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

Data Dictionary
No - There is not a plan to make this available