

# 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 sirtuin1, eotaxin-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 sedentary women with body mass index between 25-29kg/m<sup>2</sup>, 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 criteria: Smoking, use of special drugs, use of any supplements.

##### Intervention groups

The training groups perform high intensity interval resistance (with an intensity of 70% of 1RM) and/or running (12x1-min running bouts at 80-90% HRmax) training 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

Sirtuin1, eotaxin-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)

##### Phone

+98 11 4224 1041

##### Email address

habibian.masoumeh@gmail.com

##### 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 on vitamin 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 / m<sup>2</sup> 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

**Street address**

Amirkola Belt, goalhaye12 street , Siavash Sports Club, Babol, Iran

**City**

Babol

**Province**

Mazandaran

**Postal code**

4715756135

**Phone**

+98 11 3239 3269

**Email**

akbarirohulah74@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Sari branch, Islamic Azad University

**Full name of responsible person**

Dr. Sadegh Salmanpour

**Street address**

km 7 of Darya Road, Islamic Azad University, Sari Branch, Sari, Iran.

**City**

Sari

**Province**

Mazandaran

**Postal code**

48161-19318

**Phone**

+98 11 2213 2891

**Fax**

**Email**

info@iausari.ac.ir

**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

**Street address**

7km Allameh Tabarasi street, Qaemshahr Branch, Islamic Azad University, Qaemshahr

**City**

Qaemshahr

**Province**

Mazandaran

**Postal code**

4765161964

**Phone**

+98 11 4224 1041

**Email**

habibian\_m@yahoo.com

## Person responsible for scientific 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

**Street address**

7 kilometers from Allameh Tabari Street, Islamic Azad University of Ghaemshahr Branch, Ghaemshahr, Iran.

**City**

Ghaemshahr

**Province**

Mazandaran

**Postal code**

4765161964

**Phone**

+98 11 4224 1041

**Email**

habibian\_m@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Qaemshahr branch, Islamic Azad University

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Masoumeh habibian

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**City**

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**Province**

Mazandaran

**Postal code**

4765161964

**Phone**

+98 11 4224 1041

**Email**

habibian\_m@yahoo.com

## 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