

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Effect of a 12-week combined exercise training program on lipid peroxidation, total antioxidant capacity, high-sensitivity C-reactive protein, body composition, physical function, and lipid profile in women with subclinical hypothyroidism

#### Protocol summary

##### Study aim

Investigating the effect of combined exercises on lipid peroxidation, total antioxidant capacity, high-sensitivity C-reactive protein, body composition, physical performance, and lipid profile.

##### Design

The clinical trial has a control group and an exercise group, each group has a sample of 22 people. After completing all the initial evaluations, the subjects will be divided into the training group and the control group using two block randomization in order to balance the number of samples allocated. Also, due to the importance of concealing the random allocation, a sealed envelope is used. It is intended to perform random blocking based on age and one of the body composition indicators such as body mass index or fat percentage.

##### Settings and conduct

- Location of the project: Isfahan city - Intervention: combined exercise training (resistance and aerobic exercises)

##### Participants/Inclusion and exclusion criteria

- TSH between 5 and 10 mu/l
- No special disease and no medication
- Same body mass index
- No pregnant
- No regular exercise training for at least six months
- No smoking
- No alcohol consumption
- Not using food supplements containing zinc, magnesium and vitamin A during the last 3 months

##### Intervention groups

The control group does not receive any exercise The intervention group receives two types of resistance training with elastic bands and aerobic training, which is resistance training with 60 to 75% of a maximum repetition in the range of 12 to 14 repetitions and aerobic exercise with an intensity of 40 to 60% of Vo2max is performed on a bicycle or treadmill ergometer

##### Main outcome variables

Malondialdehyde High-sensitivity C-reactive protein TC TG LDL-C HDL-C Total antioxidant capacity Body fat percentage Waist to hip ratio (WHR) Body mass index (BMI) "The result of the 30-second test of getting up from the chair" "The result of the 30-second arm curl test"

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220809055643N1**

Registration date: **2022-08-16, 1401/05/25**

Registration timing: **prospective**

Last update: **2022-08-16, 1401/05/25**

Update count: **0**

##### Registration date

2022-08-16, 1401/05/25

##### Registrant information

##### Name

Javad Najafi

##### Name of organization / entity

The university of Shahrekord

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3260 5668

##### Email address

javad.najafi1526@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-06, 1401/06/15  
**Expected recruitment end date**  
2022-10-07, 1401/07/15  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Effect of a 12-week combined exercise training program on lipid peroxidation, total antioxidant capacity, high-sensitivity C-reactive protein, body composition, physical function, and lipid profile in women with subclinical hypothyroidism

**Public title**  
Effect of combined exercise training on subclinical hypothyroidism variables

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

TSH between 5 and 10 mu/l No special disease and no medication Same body mass index No pregnant no regular exercise training for at least six months before participating in this study No smoking No alcohol consumption Not using food supplements containing zinc, magnesium and vitamin A during the last 3 months

**Exclusion criteria:**

Diagnosis of the attending physician regarding the need to withdraw from the study Personal desire to withdraw from the study Getting other diseases

**Age**  
From **35 years** old to **49 years** old

**Gender**  
Female

**Phase**  
N/A

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

**Sample size**  
Target sample size: **54**

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

**Randomization description**  
After completing all the initial evaluations, the subjects will be divided into the training group and the control group using two block randomization in order to balance the number of samples allocated. Also, due to the importance of concealing the random allocation, a sealed envelope is used. It is intended to perform random blocking based on age and one of the body composition indicators such as body mass index or fat percentage.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

A new and safe training system, as well as exploring variables that have been less explored.

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Research Ethics Committee in Shahrekord University

**Street address**

Shahrekord University, Blvd Rahbar, Shahrekord

**City**

Shahre kord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8818634141

**Approval date**

2022-07-26, 1401/05/04

**Ethics committee reference number**

IR.SKU.REC.1401.26

**Health conditions studied**

1

**Description of health condition studied**

Subclinical hypothyroidism

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Lipid peroxidation

**Timepoint**

24 hours before the beginning of the interventions - 48 hours after the end of the interventions

**Method of measurement**

Measurement of malondialdehyde through blood sample taken by valid laboratory kits

2

**Description**

Total antioxidant capacity

**Timepoint**

24 hours before the beginning of the interventions - 48 hours after the end of the interventions

**Method of measurement**

Measurement of antioxidant capacity through blood samples taken by valid laboratory kits

### 3

#### **Description**

C-reactive protein with high sensitivity

#### **Timepoint**

24 hours before the beginning of the interventions - 48 hours after the end of the interventions

#### **Method of measurement**

Measurement of C-reactive protein level in blood sample by valid laboratory kits

### 4

#### **Description**

Blood lipid profile

#### **Timepoint**

24 hours before the beginning of the interventions - 48 hours after the end of the interventions

#### **Method of measurement**

Measuring the level of lipid profile in the blood sample by valid laboratory kits

### 5

#### **Description**

Body fat percentage

#### **Timepoint**

24 hours before the beginning of the interventions - 48 hours after the end of the interventions

#### **Method of measurement**

Measurement of the thickness of subcutaneous fat (triceps brachialis, Supraspinatus and thigh) using calipers and formula calculations.

### 6

#### **Description**

Waist to hip ratio

#### **Timepoint**

24 hours before the beginning of the interventions - 48 hours after the end of the interventions

#### **Method of measurement**

Measure waist circumference at the narrowest point divided by hip circumference at the widest point

### 7

#### **Description**

Body mass index

#### **Timepoint**

24 hours before the beginning of the interventions - 48 hours after the end of the interventions

#### **Method of measurement**

Measure weight in kilograms by height in meters to the power of two

## **Secondary outcomes**

### 1

#### **Description**

Lipid peroxidation

#### **Timepoint**

48 hours after the last training session

#### **Method of measurement**

Malondialdehyde measurement through a blood sample taken by a valid laboratory kit

### 2

#### **Description**

Total antioxidant capacity

#### **Timepoint**

48 hours after the last training session

#### **Method of measurement**

Measuring the antioxidant capacity of blood by valid laboratory kits

### 3

#### **Description**

C-reactive protein with high sensitivity

#### **Timepoint**

48 hours after the last training session

#### **Method of measurement**

Measurement of C-reactive protein level in blood by valid laboratory kits

### 4

#### **Description**

Lipid profile

#### **Timepoint**

48 hours after the last training session

#### **Method of measurement**

Measurement of lipid profile components in blood by valid laboratory kits

### 5

#### **Description**

Body fat percentage

#### **Timepoint**

48 hours after the last training session

#### **Method of measurement**

Measurement of the thickness of subcutaneous fat (triceps brachialis, Supraspinatus and thigh) using calipers and formula calculations.

### 6

#### **Description**

Waist to hip ratio

#### **Timepoint**

48 hours after the last training session

#### **Method of measurement**

Waist circumference at the lowest point divided by hip circumference at the widest part

### 7

#### **Description**

Body mass index

#### **Timepoint**

48 hours after the last training session

#### **Method of measurement**

Weight in kilograms divided by height in meters to the power of two

## Intervention groups

### 1

#### Description

Intervention group: receiving a resistance exercise program with an elastic band and performing an aerobic program on a treadmill or an exercise bike.

#### Category

N/A

### 2

#### Description

Intervention group: Subjects in the intervention group receive two types of exercises for 12 weeks. At the beginning of each session, 10 minutes of warm-up exercises, then 5 minutes of stretching exercises - after that, 20 minutes of resistance exercises using an elastic band with an intensity of 60 to 75%, a maximum repetition in the range of 12 to 14 repetitions, and then aerobic exercises on an ergometer or Treadmill will be done with 40 to 60% Vo<sub>2</sub>max for 30 minutes, and at the end stretching movements will be done to cool down the body.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan Endocrine and Metabolism Research Center

##### Full name of responsible person

Mr. Dr. Sasan Haghigi

##### Street address

Khoram Ave, Republic Square

##### City

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##### Province

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8187698191

##### Phone

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##### Fax

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahrekord University

##### Full name of responsible person

Mr. Dr. Ahmed Kiwani

#### Street address

Shahrekord University, Rahbar Blvd

#### City

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#### Province

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#### Postal code

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#### Phone

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#### Email

Intl\_ofic@cha.sku.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Payment of financial resources by the researcher

#### 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

Persons

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Shahrekord University

##### Full name of responsible person

Javad Najafi

##### Position

Masters student

##### Latest degree

Master

##### Other areas of specialty/work

Exercise physiology

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##### Province

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##### Postal code

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##### Phone

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##### Email

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## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Shahrekord University

**Full name of responsible person**

Akbar Azamian Jazi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise physiology

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

The University of Shahrekord

**Full name of responsible person**

Javad Najafi

**Position**

Masters student

**Latest degree**

Master

**Other areas of specialty/work**

Sport physiology

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No.238, Lale Sharghi Blvd. Bhzhrche Ave,2 Moshtaghe Ave

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**Email**

javad.najafi1526@gmail.com

## **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**

After the relevant article is printed

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

Access starts 3 months after results are published

**To whom data/document is available**

Everyone and public

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

Prevention and treatment

**From where data/document is obtainable**

Internet

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

search

**Comments**