Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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

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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 a ergometer or Treadmill will be done with 40 to 60% Vo2max 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
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Mr. Dr. Sasan Haghigi
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Sponsors / Funding sources

1

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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
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Full name of responsible person
Javad Najafi
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)
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