

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effect of exercise training with different intensities on body composition and brown adipose tissue markers in obese and over weight women

Protocol summary

Study aim

Effect of a course of sport exercises with different intensities on body composition and brown fat indices in obese and overweight women.

Design

The 12-week training program in experimental groups 1 to 3 included heavy running from 77 to 93, a moderate intensity of 64 to 76, and a light intensity of 50 to 63 percent of heart rate at a maximum of three sessions per week. A sample of 50 people who were randomly (The method of tracking) assigned to 4 groups(experimental groups:13, control group:11).Before and after the training period, Irisine, FGF21 and Mayostatin serum samples were taken from all subjects in fasting state., Anthropometric measurements were also performed. clinical trial type: randomized clinical trial with control group

Settings and conduct

The training program is 12 weeks and three sessions a week.The place of the study is the sports hall in Bojnurd city.Subjects will be running in the designated range of heart rates by attending at the gym (5 o'clock).

Participants/Inclusion and exclusion criteria

50 volunteers (mean age: 40/2 ±3/25 years; weight 75/71± 5/71 kg; height 1/61 ± 0/05 m); age range of 35 to 45 years; non-inclusion criteria; Medication or change in diet, cardiovascular disease, having regular physical activity and the criteria for regular menstrual periods 12 months ago and having a body mass greater than 25 kg / m²

Intervention groups

Intervention group 1: interval training with heavy intensity,Intervention group 2: interval training with moderate intensity ,Intervention group 3: interval training with light intensity. control group:Untreated group

Main outcome variables

Irisin; Myostatin; FGF21

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180714040464N1**

Registration date: **2018-09-06, 1397/06/15**

Registration timing: **retrospective**

Last update: **2018-09-06, 1397/06/15**

Update count: **0**

Registration date

2018-09-06, 1397/06/15

Registrant information

Name

Zeynab Firozeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3228 7930

Email address

zfirozeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

2018-02-20, 1396/12/01

Actual recruitment end date

2018-05-21, 1397/02/31

Trial completion date

2018-08-22, 1397/05/31

Scientific title

The effect of exercise training with different intensities on body composition and brown adipose tissue markers in obese and over weight women

Public title

The effect of exercise training on body composition and brown adipose tissue markers

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

having regular menstruation 12 months ago having a body mass greater than 25 kg / m²

Exclusion criteria:

Menopause Sickness Tobacco use use of medication or change in diet having regular physical activity

Age

From **35 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random method. The method of tracking was used. Each name dropped out of the container in light, medium, heavy and control groups, respectively.

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**

National Ethics Committee in Biomedical Research of Hakim Sabzevari University

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Tohid shahr

City

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Province

Razavi Khorasan

Postal code

9617976487

Approval date

2018-05-12, 1397/02/22

Ethics committee reference number

IR.HSU.REC.1397.002

Health conditions studied**1****Description of health condition studied**

obesity , overweight

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes**1****Description**

Irisin

Timepoint

First and 12 weeks later

Method of measurement

ELISA laboratory method

2**Description**

Fibroblast growth factor 21(FGF21)

Timepoint

First and 12 weeks later

Method of measurement

ELISA laboratory method

3**Description**

Myostatin

Timepoint

First and 12 weeks later

Method of measurement

ELISA laboratory method

Secondary outcomes**1****Description**

maximal oxygen consumption(VO₂max)

Timepoint

First and 12 weeks later

Method of measurement

Rockport

2

Description

Body Mass Index(BMI)

Timepoint

First and 12 weeks later

Method of measurement

Digital scales and meters

3

Description

Waist-hip ratio (WHR)

Timepoint

First and 12 weeks later

Method of measurement

Meters

4

Description

Body fat percentage

Timepoint

First and 12 weeks later

Method of measurement

Caliper

Intervention groups

1

Description

Intervention group: heavy interval training-Three times a week - 12 weeks - with an intensity of 77-93% of maximum heart rate- Duration of activity from the beginning to the end of the protocol (25 to 65 minutes)

Category

Other

2

Description

Intervention group: medium interval training-Three times a week - 12 weeks - with an intensity of 64-76% of maximum heart rate- Duration of activity from the beginning to the end of the protocol (25 to 65 minutes)

Category

Other

3

Description

Intervention group: low interval training-Three times a week - 12 weeks - with an intensity of 50-63% of maximum heart rate- Duration of activity from the beginning to the end of the protocol (25 to 65 minutes)

Category

Other

4

Description

Control group: Lack of exercise within 12 weeks

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

bojnourd Amusement park

Full name of responsible person

Zeynab Firozeh

Street address

32meter Shohada

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2

Recruitment center

Name of recruitment center

afarinesh park

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hakim Sabzevari University

Full name of responsible person

Dr. Ahmed Farzaneh kord

Street address

Postbox 397, Hakim Sabzavari University, Tohidshahr, Sabzevar, Khorasan Razavi

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Email

afarzaneh@hsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hakim Sabzevari University

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

2

Sponsor

Name of organization / entity

Hakim sabzevari university

Full name of responsible person

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Street address

No 10, Qiam 1st, Bojnourd

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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

Personal

Proportion provided by this source

80

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

Hakim sabzevari university

Full name of responsible person

Zeynab Firozeh

Position

PHD student of exercise physiology

Latest degree

Master

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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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

Not applicable

Title and more details about the data/document

All data is shared after being unidentified

When the data will become available and for how long

One year after the publication of the results

To whom data/document is available

All people who need this data

Under which criteria data/document could be used

Lake of Plagiarism

From where data/document is obtainable

Saeid Ramezani rsaeid92@gmail.com

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

A week after sending a request to Gmail and an applicant's commitment to not use the data directly

Comments

The main concern of each researcher is the misuse of others by his research information. If this item is assured, all research information will be available.