

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Study of the Effect of Aerobic Continuous/Interval Training on Levels of Homeostasis Biomarkers in Overweight/Obese Girls

Protocol summary

Study aim

obese/overweight to investigate the continuous and interval aerobic training on the levels of energy homeostasis regulating biomarkers in obese/overweight girls 9-11 years old.

Design

Clinical trials with the control group, with parallel groups, one blind, randomized.

Settings and conduct

The study population will be composed of obese/overweight school girls in Babolsar city, which will be selected in accessible form and divided randomly into two groups of exercise intervention and one control group. Exercise Interventions will be conducted at the Sports Hall of the College of Sport Sciences of Mazandaran University.

Participants/Inclusion and exclusion criteria

The 9-11-year-old obese/overweight girls who are in the Tanner 2-3 will have the conditions for entry into the trial and those with menarche or those with diabetes, thyroid disorders, cardiovascular disease or any other disease requiring drug administration will not be included in the trial.

Intervention groups

36 obese/overweight girls 9-11 years old will be randomly assigned into in three homogeneous groups of 12 subjects, in which the intervention group 1 will perform interval aerobic training and the intervention group 2 will perform continuous aerobic training and the control group will not have any exercise program.

Main outcome variables

Energy homeostasis regulating biomarkers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180928041160N1**

Registration date: **2018-11-06, 1397/08/15**

Registration timing: **retrospective**

Last update: **2018-11-06, 1397/08/15**

Update count: **0**

Registration date

2018-11-06, 1397/08/15

Registrant information

Name

Rozita Fathi

Name of organization / entity

University of Mazandaran

Country

Iran (Islamic Republic of)

Phone

+98 11 3530 2201

Email address

r.fathi@umz.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-05, 1396/10/15

Expected recruitment end date

2018-01-13, 1396/10/23

Actual recruitment start date

2018-01-05, 1396/10/15

Actual recruitment end date

2018-01-13, 1396/10/23

Trial completion date

2018-03-16, 1396/12/25

Scientific title

Study of the Effect of Aerobic Continuous/Interval Training on Levels of Homeostasis Biomarkers in Overweight/Obese Girls

Public title

Effects of exercise training on energy homeostasis

Purpose
Basic science

Inclusion/Exclusion criteria
Inclusion criteria:
Overweight/Obese Girls Tanner Stage 2,3
Exclusion criteria:
The menarche has occurred Those with cardiovascular disease, diabetes and thyroid disorders

Age
From **9 years** old to **11 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **36**
Actual sample size reached: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Using random allocation software to generate random sequences, subjects are randomly assigned to one of the three study groups and received intervention from the same group.

Blinding (investigator's opinion)
Single blinded

Blinding description
It is planned in such a way that the participant does not understand which of the two training groups belongs.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of University of Mazandaran
Street address
beheshti Ave, Daneshgah Blvd, University of mazandaran
City
Babolsar
Province
Mazandaran
Postal code
13534 - 47416
Approval date
2018-08-15, 1397/05/24

Ethics committee reference number
IR.UMZ.REC.1397.015

Health conditions studied

1

Description of health condition studied
obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
spexin
Timepoint
Before the intervention and after 8 weeks of training
Method of measurement
Common Laboratory Kits

2

Description
Angiopoietin-like proteins
Timepoint
Before the intervention and after 8 weeks of training
Method of measurement
Common Laboratory Kits

3

Description
WNT1-inducible-signaling pathway protein 1 (WISP-1)
Timepoint
Before the intervention and after 8 weeks of training
Method of measurement
Common Laboratory Kits

4

Description
Dipeptidyl peptidase-4
Timepoint
Before the intervention and after 8 weeks of training
Method of measurement
Common Laboratory Kits

5

Description
Blood metabolic parameters such as lipid profile, glucose, insulin, and ...
Timepoint
Before the intervention and after 8 weeks of training
Method of measurement
Common Laboratory Kits

6

Description

Amino Acids

Timepoint

Before the intervention and after 8 weeks of training

Method of measurement

High-performance liquid chromatography

Secondary outcomes

1

Description

Anthropometric indices

Timepoint

Before the intervention and after 8 weeks of training

Method of measurement

Measurements of height, weight, waist circumference and subcutaneous fat

Intervention groups

1

Description

Intervention group: Perform Interval training for 8 weeks

Category

Prevention

2

Description

Intervention group: Perform continuous training for 8 weeks

Category

Prevention

3

Description

Control group: Not participate in any training programs

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Babolsar city schools

Full name of responsible person

Masoumeh Baghersalimi

Street address

Shahid kohan Ave, Abualisina school

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4783161936

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+98 11 4244 7258

Email

baghersalimi.m@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Mazandaran

Full name of responsible person

Elaheh Talebi Garakani

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talebi_umz@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Mazandaran

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

University of Mazandaran

Full name of responsible person

Masoumeh Baghersalimi

Position

PhD Student

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

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Person responsible for scientific inquiries

Contact

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University of Mazandaran
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Rozita Fathi
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Person responsible for updating data

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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

Information on the main outcome or the like can be shared.

When the data will become available and for how long

Start the access period at least one year after printing the results

To whom data/document is available

Data will only be available to researchers in academia

Under which criteria data/document could be used

The data analysis table will be available

From where data/document is obtainable

Email

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

Dr. Rozita Fathi will act discretion

Comments