

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of a period of high-intensity interval training and a selected school-based exercises on plasma levels of has-miR125a-5p, CRP and lipid profile of adolescents with overweight and obesity

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The aim of this study is to compare the effectiveness of a period of high-intensity interval training, and selected school-based exercises on plasma level of has-miR125a-5p, CRP, and the lipid profile of children with overweight and obesity.

Design

Randomised ,clinical parallel group trial with control group

Settings and conduct

Forty-five male students aged 13-15 years from Lordegan city were selected and randomly divided based on age-related body mass index. Experimental groups participated in a 12-week and three sessions per week of exercise interventions, and the control group continued their daily activities without any exercise.

Participants/Inclusion and exclusion criteria

The participants of the study were obese/overweight boy adolescents, based on the Centers for Diseases Control and Prevention (CDC) classification. Inclusion criteria consisted of; no medication, no history of cardiovascular disease, no regular physical activity and any complications that may affect training outcomes.

Intervention groups

The intervention groups consist of (i) Control, (ii) High-intensity interval training, and (iii) school-based exercises.

Main outcome variables

has-miR125a-5p, CRP, lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190517043611N1**
Registration date: **2020-12-12, 1399/09/22**

Last update: **2020-12-12, 1399/09/22**

Update count: **0**

Registration date

2020-12-12, 1399/09/22

Registrant information

Name

Vazgen Minasian

Name of organization / entity

University of Isfahan

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Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a period of high-intensity interval training and a selected school-based exercises on plasma levels of has-miR125a-5p, CRP and lipid profile of adolescents with overweight and obesity

Public title

Effectiveness of high intensity interval training on inflammatory factors and level of lipids in adolescents with overweight and obesity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Adolescents Male Overweight and obese

Exclusion criteria:

Syndromic obesity Chronic diseases(asthma, diabetes and ...) Psychologic disease History of drug use

Age

From **13 years** old to **15 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Ethics committee of the University of Isfahan

Street address

University of Isfahan, Hezarjarib Ave., Isfahan, Isfahan, Iran

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8174673441

Approval date

2020-11-08, 1399/08/18

Ethics committee reference number

IR.UI.REC.1399.055

Health conditions studied

1

Description of health condition studied

Overweight and obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Inflammatory factors, has-miR125a-5p, CRP, and lipid profile

Timepoint

The study variables were measured before and after a 12-week exercise intervention.

Method of measurement

The has-miR125a-5p evaluated by quantitative real-time polymerase chain reaction (qRT-PCR), and the lipid profile and CPR by ELISA method.

Secondary outcomes

1

Description

Body mass index, Cardiorespiratory fitness, Body fat percentage.

Timepoint

These variables measured before and after a 12-week exercise intervention.

Method of measurement

The body mass index (BMI) was calculated by dividing the weight by the square of the height in meters. The participants performed the 20m shuttle run test to measure cardiorespiratory fitness (VO2max), and to estimate body fat percentage, assessment of skinfold thickness and the Jackson and Pollock's formula was used.

Intervention groups

1

Description

The school-based exercise group program consisted of 12 weeks/three sessions per week, execution of the 20m shuttle run test as the aerobic training mode, Futsal basic skills training, playing Futsal and sit-up exercises that started 30 minutes in the first week and lasted for about 55 minutes in the last session.

Category

Lifestyle

2

Description

The exercise program of high-intensity interval training group composed of running 30s a given distance at

85-100% of maximal speed, and 30s active recovery.

Category

Lifestyle

3

Description

The control group continued their daily activities without any exercise.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Isfahan

Full name of responsible person

Vazgen Minasian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Rasoul Rognizade

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Isfahan

Proportion provided by this source

50

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 Isfahan

Full name of responsible person

Vazgen Minasian

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data will be made available to relevant professionals with some conditions required.

When the data will become available and for how long

Approximately 3 months after acceptance and printing of the article.

To whom data/document is available

University Academic Specialists

Under which criteria data/document could be used

The analysis and use of the data is not permitted without the written permission of the researche

From where data/document is obtainable

Please refer to the corresponding author of the article.

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

The documentation request is received by the corresponding author's email and will be answered within 15 days.

Comments