

# 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.

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

Update count: **0**

#### Registration date

2020-12-12, 1399/09/22

#### Design

Randomised ,clinical parallel group trial with control group

#### Registrant information

##### Name

Vazgen Minasian

##### Name of organization / entity

University of Isfahan

##### Country

Iran (Islamic Republic of)

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##### Email address

vazgenmin@yahoo.com

#### 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.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### 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.

#### 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

#### Intervention groups

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

#### 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

#### 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**

## 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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

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**

University of Isfahan

**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 researcher

**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**