

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of a period of exercise interventions on expression in MIR15b and MIR146b in overweight and obese boys adolescents

Protocol summary

Study aim

The overall purpose of this study is to investigate the effect of a period of intermittent exercise and motor skills on MIR15b and MIR146b expression and lipid profile in overweight and obese adolescents.

Design

This clinical trial has two experimental groups and a control group, which will be formed using cluster method. 225 students between 13 to 15 years old from schools in Lordegan city, after selection will be randomly matched based on body mass index in control and experimental groups. G power software will be used to divide people into groups based on body mass index.

Settings and conduct

The statistical population of this study will be obese and overweight students of the first secondary schools of Lordegan city with an age range of 13 to 15 years with body mass index higher than 85 percent. The research method of the present study will be semi -experimental with a pre-test-post-test experimental design with a control group that will be conducted in the field.

Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy adolescents; age range 13 to 15 years; body mass index above 85%; absence of any disease. Exclusion criteria: voluntary withdrawal of participants for any reason, disease or inability to exercise during the research period, injury during exercise and absence in more than three sessions during the training period.

Intervention groups

high intensity interval training (HIIT), selected school-based (SBE) and control groups

Main outcome variables

MIR146b, MIR15b levels, lipid profiles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200515047455N1**

Registration date: **2020-11-16, 1399/08/26**

Registration timing: **retrospective**

Last update: **2020-11-16, 1399/08/26**

Update count: **0**

Registration date

2020-11-16, 1399/08/26

Registrant information

Name

Rasol Khaliltahmasebi

Name of organization / entity

The University of Isfahan

Country

Iran (Islamic Republic of)

Phone

+98 38 3444 1733

Email address

r.tahmasebi110@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2019-01-20, 1397/10/30

Trial completion date

2019-12-21, 1398/09/30

Scientific title

The effect of a period of exercise interventions on expression in MIR15b and MIR146b in overweight and obese boys adolescents

Public title

The effect of a period of exercise interventions on expression of MIR15b and MIR146b

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy teens aged 13 to 15 years body mass index above 85% no any disease

Exclusion criteria:

Get sick Inability to perform exercises during the research period Injury during exercise Absence for more than three sessions

Age

From **11 years** old to **15 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Actual sample size reached: **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 Isfahan University

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

8891153311

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

IR.UI.REC.1399.054

Health conditions studied

1

Description of health condition studied

overweight and obesity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

MIR15b level

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

The MIR15b was extracted using a Real Time PCR system.

2

Description

MIR146b level

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

The MIR15b was extracted using a Real Time PCR system.

3

Description

Lipid profile

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Elayza methood

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: High intensity interval Ttraining include running a certain distance of 20 meters for 30 seconds and 30 seconds of active rest between activities. Participants perform a 20-meter reciprocating test to the point of fatigue to measure peak oxygen consumption and maximum aerobic velocity under the same environmental conditions. The distance that each person has to run in 30 seconds is calculated based on the maximum speed that he achieves in the 20-meter round trip test, and this distance increases every two

weeks according to the new record.

Category

Treatment - Other

2

Description

Intervention group: The program of the school-based training group includes a 20-meter round-robin test, basic futsal skills training, futsal games, and sit-ups

Category

Treatment - Other

3

Description

Control group: the control group did not participate in any specific training program during this period

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan University

Full name of responsible person

Rasol Khaliltahmasebi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Isfahan University of medical Sciences

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

Isfahan University of medical Sciences

Full name of responsible person

Rasol Khaliltahmasebi

Position

PhD Candidate, Faculty of Sport Sciences, University of Isfahan

Latest degree

Master

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

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Name of organization / entity

University of Isfahan

Full name of responsible person

Rasol Khaliltahmasebi

Position

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Latest degree

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Person responsible for updating data

Contact

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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

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments

-