# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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**
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**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**
Isfehan
**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 Univercity

**Full name of responsible person**

Rasol Khaliltahmasebi

**Street address**

Hezar Jarib Isfaha Town

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Isfahan University of medical Sciences

**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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## Person responsible for updating data

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**Other areas of specialty/work**

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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**

-