

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effect of a combined exercise training program (MRT1 and HIIT2) with nutritional advice on lipid profile, obesity index and quality of life in obese and overweight children and teenagers

#### Protocol summary

##### Study aim

The propose of this research is to determine the effect of a combined exercise training program (MRT1 and HIIT2) and nutritional advice on lipid profile, obesity index and quality of life in obese and overweight children and teenagers. It is a randomized double-blind control trial. The samples size is consist of 120 children and teenagers between 10-19 years old randomized in 4 groups: 1. MRT group 2. HIIT group 3. Combination group 4. Control group. Before and after exercise they are checked with questionnaire kidscreen27, BMI and lipid profile. The research is conducted in 2017-2018 and research period per person would be 8 weeks.

##### Design

Randomized double-blinded controlled clinical trial

##### Settings and conduct

Isfahan

##### Participants/Inclusion and exclusion criteria

Children and adolescents in a range of 10-19 years old without any disease, no medications history and with body mass index > 1SD of ideal BMI for age and sex.

##### Intervention groups

Children and adolescents in a range of 10-19 years old

##### Main outcome variables

BMI-LDL-HDL-Cholesterol-Triglyceride-quality of life-age-sex-Arm circumference-waist

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150428021987N4**

Registration date: **2018-05-11, 1397/02/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-05-11, 1397/02/21**

Update count: **0**

##### Registration date

2018-05-11, 1397/02/21

##### Registrant information

###### Name

alireza ahmadi

###### Name of organization / entity

medical university of isfahan

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3668 3295

###### Email address

alirezaahmadi@med.mui.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

the cardiac reaserch institute of isfahan the reaserch institute of medical univercity of isfahan

##### Expected recruitment start date

2017-10-23, 1396/08/01

##### Expected recruitment end date

2018-10-23, 1397/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of a combined exercise training program (MRT1 and HIIT2) with nutritional advice on lipid profile, obesity index and quality of life in obese and overweight children and teenagers

##### Public title

Effect of exercise on obesity and lipid profile

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Children and adolescents in range of 10-19 years old without any disease, use no drugs with body mass index > 1SD of ideal BMI for age and sex

### Exclusion criteria:

Any diseases related to obesity or limiting strict exercise (diabetes, heart disease,...), drug intake, professional sports activities.

## Age

From **10 years** old to **19 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Double-blinded

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The participants and the nutritionists don't have information on investigated and controlled subjects.

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Research Institute of Isfahan University of Medical Sciences

##### Street address

Isfahan University of Medical Sciences, Hezarjarib street, Azadi square, Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

۷۳۴۶۱۸۱۷۴۶

#### Approval date

2017-08-14, 1396/05/23

## Ethics committee reference number

IR.MUI.REC.1396.446755

## Health conditions studied

### 1

#### Description of health condition studied

Obesity, Overweight

#### ICD-10 code

E66.0

#### ICD-10 code description

Obesity due to excess calories

## Primary outcomes

### 1

#### Description

Body Mass Index

#### Timepoint

In the beginning and 8 weeks later

#### Method of measurement

kg/m<sup>2</sup>

### 2

#### Description

Triglyceride

#### Timepoint

In the beginning and 8 weeks later

#### Method of measurement

gr/dL

### 3

#### Description

Cholesterol

#### Timepoint

In the beginning and 8 weeks later

#### Method of measurement

gr/dL

### 4

#### Description

HDL

#### Timepoint

In the beginning and 8 weeks later

#### Method of measurement

gr/dL

### 5

#### Description

LDL

#### Timepoint

In the beginning and 8 weeks later

#### Method of measurement

gr/dL

## 6

### **Description**

quality of life

### **Timepoint**

In the beginning and 8 weeks later

### **Method of measurement**

questionnaire kid screen 27

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

First group: High-Intensity Interval Training (HIIT) (After learning the practical steps and instructions in the rehabilitation center, they will exercise at home.)

#### **Category**

Lifestyle

### 2

#### **Description**

Second group: Metabolic Resistance Training (MRT)

#### **Category**

Lifestyle

### 3

#### **Description**

Third group: Combined exercises including Metabolic Resistance Training and High-Intensity Interval Training

#### **Category**

Lifestyle

### 4

#### **Description**

Fourth group: Control group which won't have any exercises

#### **Category**

Lifestyle

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Pediatric Cardiovascular Research Center

##### **Full name of responsible person**

Alireza Ahmadi

##### **Street address**

Pediatric Cardiovascular Research Center, Isfahan Cardiovascular Research Center, Close to Chamran Hospital, Moshtagh 3rd Blvd., Isfahan

##### **City**

Isfahan

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##### **Phone**

+98 31 3611 5313

##### **Email**

ahmadi\_cardio@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Pediatric Cardiovascular Research Center

##### **Full name of responsible person**

Alireza Ahmadi

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Pediatric Cardiovascular Research Center, Isfahan Cardiovascular Research Center, Close to Chamran Hospital, Moshtagh 3rd Blvd., Isfahan

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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**

Pediatric Cardiovascular Research Center

#### **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

### 2

#### **Sponsor**

##### **Name of organization / entity**

Isfahan University of Medical Sciences

##### **Full name of responsible person**

Dr Movahedian Attar

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Hezar jarib Ave., Azadi square, Isfahan

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**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
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**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**  
Pediatric Cardiovascular Research Center  
**Full name of responsible person**  
zohre navabi  
**Position**  
Masters degree  
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Master  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Undecided - It is not yet known if there will be a plan to  
make this available  
**Study Protocol**  
Undecided - It is not yet known if there will be a plan to

make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available