

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Examining the mutual interactions of genetics, lifestyle and anthropometric measurements and assessment of influence of a health promotion intervention on anthropometric measurements and FTO and IRX3 genes expression among 12 to 18 years old boys

#### Protocol summary

##### Summary

The aim of this study was to examine the mutual interactions of genetics, lifestyle and anthropometric measurements and assessment of influence of a health promotion intervention on anthropometric measurements and FTO and IRX3 genes expression among 12 to 18 years old boys. This study is a field trial study. Inclusion Criteria: Age between 12 to 18 years, Completion the consent forms by student and his parents, Lack of diseases effective on weight and body composition, Lack of use of effective drugs on weight and body composition, Participating in educational, cultural and sportive programs Exclusion criteria: Get a weight affecting disease Interventions include Diet and physical activity changes. Main outcome measures include FTO and IRX3 gene expression changes and anthropometric indices.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016020925699N2**

Registration date: **2016-04-24, 1395/02/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-04-24, 1395/02/05

##### Registrant information

##### Name

Saeid Doaei

##### Name of organization / entity

National Nutrition and Food Technology Research Institute

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6643 6744

##### Email address

sdoaei@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

National Nutrition and Food Technology Research Institute and Health education and health promotion office

##### Expected recruitment start date

2016-03-01, 1394/12/11

##### Expected recruitment end date

2016-03-05, 1394/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Examining the mutual interactions of genetics, lifestyle and anthropometric measurements and assessment of influence of a health promotion intervention on anthropometric measurements and FTO and IRX3 genes expression among 12 to 18 years old boys

##### Public title

Examining the mutual interactions of Genetics, Lifestyle and Anthropometric measurements

##### Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion Criteria: Age between 12 to 18 years; Completion the consent forms by student and his parents; Lack of diseases effective on weight and body composition; Lack of use of effective drugs on weight and body composition; Participating in educational, cultural and sportive programs. Exclusion criteria: Get a weight affecting disease

## Age

From **12 years** old to **18 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **752**

## Randomization (investigator's opinion)

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

National Nutrition and Food Technology Research Institute

##### Street address

National Nutrition and Food Technology Research Institute, Faculty of Nutrition Sciences and Food Technology, Shahid Beheshti University of Medical Sciences

##### City

Tehran

##### Postal code

009821

##### Approval date

2016-02-29, 1394/12/10

##### Ethics committee reference number

lr.sbmu.nnftri.rec.1394.22

## Health conditions studied

### 1

#### Description of health condition studied

Obesity

#### ICD-10 code

E66.0

#### ICD-10 code description

Obesity due to excess calories

## Primary outcomes

### 1

#### Description

FTO gene expression

#### Timepoint

Baseline, 3 months after intervention

#### Method of measurement

Real time RT PCR

### 2

#### Description

IRX3 gene expression

#### Timepoint

Baseline, 3 months after intervention

#### Method of measurement

Real time RT PCR

### 3

#### Description

Lifestyle

#### Timepoint

Baseline, 3 months after intervention

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

BMI

#### Timepoint

Baseline, 3 month after intervention

#### Method of measurement

WHO standard charts

## Intervention groups

### 1

#### Description

Intervention group: 3 month lifestyle intervention based on Ottawa charter will be performed. The interventions include: healthy policy, create supportive environment, community action, development of personal skills, and health services reorientation.

#### Category

Lifestyle

### 2

#### Description

Control group: Observation  
**Category**  
N/A

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Shohadaye Entefazeh School  
**Full name of responsible person**  
Mr Ghadiri  
**Street address**  
Dehkade Olympik St.  
**City**  
Tehran

2

### Recruitment center

**Name of recruitment center**  
Matin School  
**Full name of responsible person**  
Mr Akbari  
**Street address**  
Dehkade olympik St.  
**City**  
Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Vice Chancellor for research of Shahid Beheshti  
University of Medical Sciences  
**Full name of responsible person**  
Mrs. Hoseini  
**Street address**  
Shahid Beheshti University of Medical Sciences,  
Velenjak, Tehran.  
**City**  
Tehran  
**Grant name**  
-  
**Grant code / Reference number**  
-  
**Is the source of funding the same sponsor  
organization/entity?**  
Yes  
**Title of funding source**  
Vice Chancellor for research of Shahid Beheshti  
University of Medical Sciences  
**Proportion provided by this source**  
**Public or private sector**  
*empty*  
**Domestic or foreign origin**  
*empty*  
**Category of foreign source of funding**  
*empty*

**Country of origin**  
**Type of organization providing the funding**  
*empty*

2

### Sponsor

**Name of organization / entity**  
Health education office of Health ministry  
**Full name of responsible person**  
Dr. Shahram rafiei far  
**Street address**  
Eivanak St., Ministry of Health, Health Education  
office of Ministry of Health  
**City**  
Tehran  
**Grant name**  
-  
**Grant code / Reference number**  
-  
**Is the source of funding the same sponsor  
organization/entity?**  
Yes  
**Title of funding source**  
Health education office of Health ministry  
**Proportion provided by this source**  
**Public or private sector**  
*empty*  
**Domestic or foreign origin**  
*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Saeid Doaei  
**Position**  
PhD of Nutrition sciences  
**Other areas of specialty/work**  
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Shahid Beheshti University of Medical Sciences,  
Tehran, IRAN.  
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**Phone**  
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**Email**  
sdoaei@sbmu.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Naser Kalantari

**Position**

Pediatrician

**Other areas of specialty/work****Street address**

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**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Saeid Doaei

**Position****Other areas of specialty/work****Street address**

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Tehran, IRAN.

**City**

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**Phone**

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*