Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Iran (Islamic Republic of)
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+98 21 6643 6744
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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
Examinig 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
Ir.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
Questionaire

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

Ḍehkade Olympik St.

City

Tehran

2

Recruitment center

Name of recruitment center

Matin School

Full name of responsible person

Mr Akbari

Street address

Ḍehkade 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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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Naser Kalantari

Position
Pediatrician

Other areas of specialty/work

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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)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty