

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of educational intervention on body mass index and thyroid function tests in children and adolescents with obesity or overweight

#### Protocol summary

##### Summary

Objectives: In the present study, the effect of healthy lifestyle intervention on body mass index and thyroid function tests in children and adolescents with obesity and overweight have been investigated. Design: The current interventional research included 126 overweight or obese children and adolescents with an age range of 7 to 18, from Birjand, who were divided into two groups of 63. Assignment of samples to the two groups (control and intervention) was non random. In the intervention group, education was conducted for 6 months. TSH, FT3, FT4 and BMI in both groups were measured and compared before and after the intervention. Participants including major eligibility criteria: Entry requirements include: the children and adolescents with non-syndromic overweight and obesity, with an age range of 7 to 18 years. Withdrawal conditions including: history of radioactive iodine treatment, thyroid hormone therapy, antithyroid drugs, and children with a known type of metabolic or endocrine disorders, and lack of the parental consent. Setting, conduct and interventions: In the intervention group, education was conducted to improve lifestyle and healthy nutrition for 6 months. In the control group, intervention was not performed. Main outcome measures (primary and secondary outcome variables): Changes in BMI and TSH, FT3, and FT4 hormones were the primary and secondary consequences of the present study.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2017081935772N1**

Registration date: **2017-11-12, 1396/08/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-12, 1396/08/21

##### Registrant information

###### Name

Neda Ebrahimi

###### Name of organization / entity

Birjand University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 56 3223 2895

###### Email address

neda.ebrahimi@bums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for research of Birjand University of Medical Sciences

##### Expected recruitment start date

2015-03-20, 1393/12/29

##### Expected recruitment end date

2016-03-19, 1394/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of educational intervention on body mass index and thyroid function tests in children and adolescents with obesity or overweight

##### Public title

The effect of educational intervention on BMI and thyroid function test

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: The children and adolescents with overweight and obesity (BMI above 85% percentile); Non-syndromic children and adolescents with an age range of 7 to 18 years; The parental informed consent.

Exclusion criteria: The children who had a medical history using radioactive iodine (radioiodine), thyroid hormones, and antithyroid drugs or any medication, that may affect thyroid; The children with a known type of endocrine or metabolic abnormalities; Students with lack of the parental consent.

## Age

From **7 years** old to **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **126**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

In this study, the areas in Birjand were initially arranged based on school distribution, later, the elementary levels, middle schools, and high schools in each area were classified and divided into clusters, then, the random samples of each cluster were systematically selected from obese children and adolescents who had health records in Atherosclerosis and Coronary Artery Research Center. Assignment of samples to the two groups (control and intervention) is non-random.

## Secondary Ids

### 1

#### Registry name

Birjand University of Medical Sciences

#### Secondary trial Id

884

#### Registration date

1394-02-01, 773/01/-46

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Sciences

#### Street address

Department of pediatrics, Faculty of Medicine, Birjand University of Medical Sciences (BUMS), Ghaffari avenue

#### City

Birjand

#### Postal code

9719113944

#### Approval date

2015-04-21, 1394/02/01

#### Ethics committee reference number

lr.BUMS.1394.298

## Health conditions studied

### 1

#### Description of health condition studied

Thyroid disorders

#### ICD-10 code

E00, E01,

#### ICD-10 code description

Disorders of thyroid gland

### 2

#### Description of health condition studied

Obesity and overweight

#### ICD-10 code

E66

#### ICD-10 code description

Overweight and obesity

## Primary outcomes

### 1

#### Description

Body mass Index (BMI)

#### Timepoint

6 months before and 6 months after of intervention

#### Method of measurement

Measuring of weight and height and calculate BMI according to a formula

## Secondary outcomes

### 1

#### Description

Thyroid function tests

#### Timepoint

6 months before and 6 months after of intervention

#### Method of measurement

Blood test

## Intervention groups

## 1

### Description

Intervention group: In the intervention group, the training was lectured with PowerPoint for parents, children, and adolescents in six meetings (every month, one meeting) which included the following subjects: obesity definition and its disadvantage in childhood and adulthood; the importance and benefits of weight control; recommendations and necessary actions for weight control, lifestyle modification, healthy diet, physical activity, and parental attitudes towards children. This intervention was 6 months.

### Category

Lifestyle

## 2

### Description

Control group: In the control group, educational intervention is not performed.

### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Vali-e-Asr hospital

##### Full name of responsible person

Dr.Neda Ebrahimi

##### Street address

Valiasr Hospital, Ghaffari Avenue, Birjand, Iran.

##### City

Birjand

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of Birjand University of Medical Sciences

##### Full name of responsible person

Dr. Fatemeh Taheri

##### Street address

Department of Pediatrics, Faculty of Medicine, Birjand University of Medical Sciences, Ghaffari Ave., Birjand, South khorassan, Iran

##### City

Birjand

##### 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 Birjand University of Medical Sciences

### Proportion provided by this source

100

### 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

Birjand University of Medical Sciences

#### Full name of responsible person

Dr. Neda Ebrahimi

#### Position

Student Research Committee, Resident of pediatrics

#### Other areas of specialty/work

#### Street address

Department of Pediatrics, Faculty of Medicine, Birjand University of Medical Sciences, Ghaffari Ave., Birjand, Iran

#### City

Birjand

#### Postal code

9717853577

#### Phone

+98 56 3223 2895

#### Fax

+98 56 3243 0076

#### Email

neda.ebrahimi@bums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Birjand University of Medical Sciences

#### Full name of responsible person

Dr.Neda Ebrahimi

#### Position

Student Research Committee, Resident of pediatrics

#### Other areas of specialty/work

#### Street address

Department of Pediatrics, Faculty of Medicine, Birjand University of Medical Sciences, Ghaffari Ave., Birjand, Iran

#### City

Birjand

#### Postal code

9717853577

#### Phone

+98 56 3223 2895

#### Fax

#### Email

neda.ebrahimi@bums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Dr. Neda Ebrahimi

**Position**

Student Research Committee, Resident of pediatrics

**Other areas of specialty/work**

**Street address**

Department of Pediatrics, Faculty of Medicine, Birjand  
University of Medical Sciences, Ghaffari Ave., Birjand,  
Iran

**City**

Birjand

**Postal code**

9717853577

**Phone**

+98 56 3223 2895

**Fax**

**Email**

neda.ebrahimi@bums.ac.ir

**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*