

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Developing and evaluating of an interventional model to prevent and control childhood obesity in the fifth-graders. Tehran

#### Protocol summary

##### Summary

This study evaluates the effect of an interventional model for preventing and controlling overweight and obesity in male and female fifth-graders. First, based on WHO references obese (BMI-Z score  $\geq 2$ ) and overweight (BMI-Z score  $\geq 1$ ) students from 12 primary schools (randomly allocated to 6 intervention and 6 comparison) will be screened. Then from the screened students 30 students with the following inclusion criteria will be recruited: not metabolically ill, not on a weight losing diet and not professionally athlete. For selected students BMI-Z score as primary outcome will be calculated. Demographic data, as well as data on waist and hip circumference, triceps skin-fold thickness, food intake for 3 days (2 ordinary week days and 1 weekend) and physical activity will be collected at the beginning and at end of the 6-month intervention. The approach of the study will be Health Promoting Schools. The intervention includes three components, i.e., nutrition education (students and parents), increased physical activity, and changing environment (food items offered in schools' canteens). Nutrition education will be imparted (a 30-minute session per week) by health instructors; physical activity will be done under the supervision of the school coaches (2 one-hour sessions per week). Parents' education (a 1.5-hour session) will be monthly. Finally the efficacy of the intervention will be determined and reported.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013012412255N1**

Registration date: **2013-08-06, 1392/05/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-08-06, 1392/05/15

##### Registrant information

###### Name

Maryam Amini

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6640 2095

###### Email address

mamini@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Ministry of Health and Medical Education Tehran  
University of Medical Sciences

##### Expected recruitment start date

2012-11-06, 1391/08/16

##### Expected recruitment end date

2013-06-05, 1392/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Developing and evaluating of an interventional model to prevent and control childhood obesity in the fifth-graders. Tehran

##### Public title

prevention and control of obesity in primary school children in Tehran

##### Purpose

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: BMI-Z-Score > or =1(WHO), students in the fifth or sixth grades Exclusion criteria: metabolic disorders (hypo or hyperthyroidism), any disease which interfere with adherence to the intervention, intake of any appetite-reducing drug, doing professional sports, being on a weight reduction diet

### **Age**

From **9 years** old to **14 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **360**

### **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**

Tehran University of Medical Sciences

##### **Street address**

P.O.Box 14155-6446, Tehran

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2013-04-15, 1392/01/26

#### **Ethics committee reference number**

92,D,51,130

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

overweight/obesity

#### **ICD-10 code**

E66.0

#### **ICD-10 code description**

Obesity due to excess calories

## **Primary outcomes**

### **1**

#### **Description**

BMI

#### **Timepoint**

before and 6 month after the intervention

#### **Method of measurement**

weight by digital scale height by stadiometer

## **Secondary outcomes**

### **1**

#### **Description**

waist and hip circumferences

#### **Timepoint**

Before and 6 months after the intervention

#### **Method of measurement**

Tape meter

### **2**

#### **Description**

Triceps skinfold

#### **Timepoint**

Before and 6 months after the intervention

#### **Method of measurement**

Caliper

### **3**

#### **Description**

Physical activity

#### **Timepoint**

Before and 6 months after the intervention

#### **Method of measurement**

Standardized questionnaire

### **4**

#### **Description**

Energy intake

#### **Timepoint**

Before and 6 months after the intervention

#### **Method of measurement**

24 h food recall

### **5**

#### **Description**

Daily total fat intake

#### **Timepoint**

Before and 6 months after the intervention

#### **Method of measurement**

24-h food recall

### **6**

#### **Description**

Percentage of energy from fat

#### **Timepoint**

Before and 6 months after the intervention

**Method of measurement**

24-h food recall

**7**

**Description**

Total daily intake of carbohydrate

**Timepoint**

Before and 6 months after the intervention

**Method of measurement**

24-h food recall

**8**

**Description**

Percentage of energy from carbohydrate

**Timepoint**

Before and 6 months after the intervention

**Method of measurement**

24-h food recall

**Intervention groups**

**1**

**Description**

The approach of intervention is knowledge translation. The intervention will be multi-component including nutrition education (parents and students), increased physical activity, and changing of the schools, environment. The education will be monthly and weekly sessions for parents and students, respectively. The parents are taught about childhood obesity and its causes. They will also learn strategies to increase physical activity and vegetable and fruit consumption, as well as decrease consumption of high energy foods by their children. Nutrition education of the students will be done by health instructors of the schools who have been trained for this work. The content of the education will be mainly Iranian food pyramid, food groups, and energy value of the food groups. To increase physical activity of the students, weekly exercise sessions under supervision of their schools' coach will be done in schools. Finally, the school canteens will be supervised with particular attention to the type of foods (snacks, etc.) offered for sale.

**Category**

Lifestyle

**2**

**Description**

During the intervention period nothing will be done in comparison schools. At the end of intervention an educational session for parents (1.5 h) will be held for all comparison schools.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Primary schools of Tehransar area, Tehran

**Full name of responsible person**

Maryam Amini

**Street address**

Department of Nutrition & Biochemistry, School of Public Health, Poorsina Ave., Qods Ave.

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Akbar Fotoohi

**Street address**

Central building of Tehran University of Medical Sciences, Qods Ave., Keshavarz Blvd.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Ministry of Health and Medical Education

**Full name of responsible person**

Dr. Zahra Abdollahi

**Street address**

Department of Nutrition, Central building of Ministry of Health and Medical Education, Hafez intersection, Tehran, Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ministry of Health and Medical Education

**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**

Department of Community Nutrition, School of Nutrition & Dietetics, Tehran University of Medical Sci

**Full name of responsible person**

Maryam Amini

**Position**

PhD(Nutrition) candidate

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**Position**

Professor Emeritus

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**City**

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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*