

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 ≥ 2) and overweight (BMI-Z score ≥ 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

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Email address

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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

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

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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