

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effectiveness of the national guideline on management of overweight and obesity with the routine services in the primary health care system on body mass index of school age children

Protocol summary

Summary

Aim of study: Determine the effectiveness of guideline for management of overweight and obesity in children through primary health care system design: not blinded controlled trial Intervention: training of health workers and then education of mothers by health workers during 2 months in 5 session to modify lifestyle Inclusion criteria: overweight or obese first grade children not using medicine affecting glucose hemoestasis not being diagnosed with hypothyroidism, diabetes, cardiovascular disease, epilepsy Not following a particular diet Exclusion criteria: having fracture during study Sample size: 89 child in each group main outcome measures: children body mass index

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013062213740N1**

Registration date: **2014-04-11, 1393/01/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-11, 1393/01/22

Registrant information

Name

Nasrin Omidvar

Name of organization / entity

Faculty of Nutrition Sciences and Food Technology,
National Nutrition and Food Technology Research I

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 7484

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Recruitment status

Recruitment complete

Funding source

UNICEF

Expected recruitment start date

2013-10-07, 1392/07/15

Expected recruitment end date

2014-03-06, 1392/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of the national guideline on management of overweight and obesity with the routine services in the primary health care system on body mass index of school age children

Public title

Comparing the effectiveness of the national guideline on management of overweight and obesity with the routine services in the primary health care system on body mass index of school age children

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: overweight or obese first grade children based on 2007 World Health Organization diagram; not using medicine affecting glucose and lipid profile hemoestasis and weight; not being diagnosed with hypothyroidism, diabetes, cardiovascular disease, epilepsy; not following a particular diet; not participate in

other trials: exclusion criteria: having fracture during study: migration

Age

From **6 years** old to **7 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **178**

Randomization (investigator's opinion)

Not 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

Ethics in research committee of National Nutrition and Food Technology Research Institute (NNFTRI) o

Street address

#7, Shahid Mahmoud Hafezi st, Shahid Farahzadi blvd.

City

Tehran

Postal code

1981619573

Approval date

2013-11-25, 1392/09/04

Ethics committee reference number

050521

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E65, E66,

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Body mass index

Timepoint

At the beginning of study, 3, 6 and 12 months after beginning

Method of measurement

kg/square meters by digital scale and walled stadiometer

Secondary outcomes

1

Description

Children calorie intake

Timepoint

At the beginning, 3, 6 and 12 months later

Method of measurement

1 day food diary

2

Description

Children physical activity

Timepoint

At the beginning of study, 3, 6 and 12 months later

Method of measurement

CASPIAN physical activity questionnaire

3

Description

Biochemical measures

Timepoint

At the beginning, 6 and 12 months after

Method of measurement

laboratory kits

4

Description

Self efficacy of mothers

Timepoint

At the beginning of study, 6 months later

Method of measurement

Questionnaire

5

Description

Providers knowledge, attitude and practice

Timepoint

At the beginning and 6 month later

Method of measurement

Questionnaire

Intervention groups

1

Description

In intervention group, educational intervention during 2 months in 5 sessions for mothers to understanding strategies for lifestyle modification

Category

Lifestyle

2

Description

In control group, routine care will be done. At the end of the study, educational booklet will be tendered to control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahra Homayoun urban health center

Full name of responsible person

Zahra Ghonche

Street address

Khaje Nasire Toosi st, before the Sepah square, Shariati st.

City

Tehran

2

Recruitment center

Name of recruitment center

Khaje Nezam urban health center

Full name of responsible person

Elham Badraghe

Street address

Sayyadi alley, Gouhari alley, at the end of Moallem st.

City

Tehran

3

Recruitment center

Name of recruitment center

Ahmadi urban health center

Full name of responsible person

Mahrokh Setavarz

Street address

At the first of Fatahnaii street, Damavand st.

City

Tehran

4

Recruitment center

Name of recruitment center

Dogmechi urban health center

Full name of responsible person

Elmira Pourmand

Street address

#96, Zarrin Ghobaii alley, Kermane Jonobi street, Resalat st.

City

Tehran

5

Recruitment center

Name of recruitment center

Samangan urban health center

Full name of responsible person

Mehrnaz Mahdipour

Street address

Shahid Baradarane Souri street, Samangan st, Narmak.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

UNICEF

Full name of responsible person

Amir Hossein Yarparvar

Street address

#7, Nezami st, Ghoba st, Shariati st.

City

Tehran

Grant name

sc109902

Grant code / Reference number

For health and nutrition work plan

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

Yes

Title of funding source

UNICEF

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

Faculty of Nutrition Sciences and Food Technology, National Nutrition and Food Technology Research I

Full name of responsible person

Nasrin Omidvar

Position

PhD in Nutrition/Associate professor

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

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Position

MSc student in Nutrition

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Full name of responsible person

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Position

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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