

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Development and evaluation of intervention based on enabling mothers for prevention of obesity in 4 to 6 years old children

Protocol summary

Summary

This study aimed to design and evaluation based intervention aimed at enabling mothers to prevent obesity in 6-4 years old children will be conducted in kindergartens in Behbahan city. This study is a randomized trial. Before random assignment to intervention and control groups, mothers of children complete the questionnaires (pre -test). After division, the intervention group (mothers) will receive educational intervention. Educational intervention based on social cognitive theory and the theory of family system (skills and parenting practices). control group will not receive any intervention. (Control group after completion of the study, held training sessions on healthy life style.) mothers (intervention and control groups), 3 and 6 months post-intervention respond to questionnaires again . (after the test). Then the data is analyzed and the results will be extracted.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012626078N2**

Registration date: **2016-02-12, 1394/11/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-12, 1394/11/23

Registrant information

Name

Elham NejadSadeghi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Education of Tehran University of Medical Sciences

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development and evaluation of intervention based on enabling mothers for prevention of obesity in 4 to 6 years old children

Public title

Prevention of obesity in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Lack of consent to participate in the study; Mother with at least one child 4-6 years old. Exclusion criteria:Unwillingness to continue to participate in the study; Pregnant women; Mothers of child out age 6-4 years old; Children who are 6-4 years old but suffered a physical disability that are activities Physical moderate to severe disorder imported;A child with a weight-related medical problem; Child who has participated in other weight management programs.

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Tehran University of Medical Sciences, 16 Azar Street

City

Tehran

Postal code**Approval date**

2016-01-05, 1394/10/15

Ethics committee reference number

IR.TUMS.REC.1394.1557

Health conditions studied**1****Description of health condition studied**

obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes**1****Description**

Preventive behaviors of obesity in children (daily: 2 hours of physical activity, eating five portions of fruit and

vegetables, eating sugar-free drinks and watching less than two hours of TV)

Timepoint

Before the intervention, 3 and 6 months after intervention

Method of measurement

questionnaire

Secondary outcomes**1****Description**

Child eating behavior (response to the food, the answer to satiety , low dining emotional, emotional overeating, an interest in wine, enjoy a meal, eat slowly and excuses food)

Timepoint

Before, 3 and 6 months after the intervention.

Method of measurement

Questionnaire

2**Description**

Skills (communication skills , monitoring, problem solving, encourage good behavior, bad behavior management)

Timepoint

Before, 3 and 6 months after the intervention.

Method of measurement

Questionnaire

3**Description**

How to feed the baby by the mother (the child's freedom of action, the regulation of emotions Children with food, encourage children to respect the balance and diversity in eating, control of food available to children, using food as a reward, the participation of children in meal planning, food consumption modeling, monitoring snack, Forced to eat, with the aim of limiting the child's health, weight control and nutrition training with the aim of limiting the child-to-child)

Timepoint

Before, 3 and 6 months after the intervention.

Method of measurement

Questionnaire

4**Description**

Constructs of social cognitive theory (environmental factors, expected outcomes, emotional adjustment, self-control and self-efficacy)

Timepoint

Before, 3 and 6 months after the intervention.

Method of measurement

Questionnaire

5

Description

Procedures parenting (authoritarian practices, arbitrary manner ,lax procedures)

Timepoint

Before, 3 and 6 months after the intervention.

Method of measurement

Questionnaire

6

Description

Body Mass Index

Timepoint

Before, 6 months after the intervention.

Method of measurement

(Weight in kilograms) divided by (height in meters squared 2)

Intervention groups

1

Description

The intervention group (mothers), educational intervention (training classes) will be received. Educational intervention will be based on social cognitive theory and the theory of family systems (parenting skills and practices). Content, methods and number of training sessions will be according to the analysis of the results of pre - test.

Category

Prevention

2

Description

Control group will not receive any intervention . (For control group after completion of study, training sessions are held based on a healthy lifestyle)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kindergarten dependent on the well-being organization of Behbahan city

Full name of responsible person

Mohammad Rezaei Asl

Street address

Well-being organization of Behbahan city, next to the park Sharifnia, Shahid Nikpour avenue, Edalat Blvd.

City

Behbahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Education of Tehran University of Medical Sciences

Full name of responsible person

Doctor Mohammad Jalili

Street address

Tehran University of Medical Sciences, 16 Azar Street

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 Education of Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Elham NejadSadeghi

Position

PhD student health education and health promotion

Other areas of specialty/work

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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

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Elham Nejadsadeghi

Position

PhD student health education and health promotion