

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 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)

###### Phone

+98 46 1293 3210

###### Email address

nejadsadeghi\_e@razi.tums.ac.ir

##### 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

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

## 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

## 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

##### Street address

School of Public Health, Poursina Street, Tehran University of Medical Sciences

##### City

Tehran

##### Postal code

141556446

##### Phone

+98 21 4293 3210

##### Fax

##### Email

nejadsadeghi\_e@razi.tums.ac.ir

##### Web page address

## Person responsible for scientific 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****Street address**

School of Public Health, Street Poursina, Tehran  
university of medical science

**City**

Tehran

**Postal code**

141556466

**Phone**

+98 21 4293 3210

**Fax****Email**

nejadsadeghi\_e@razi.tums.ac.ir

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

School of Public Health,t Poursina Stree, Tehran  
University of Medical Sciences

**City**

Tehran

**Postal code**

141556446

**Phone**

+98 21 4293 3210

**Fax****Email**

nejadsadeghi\_e@razi.tums.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*

**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