

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Designing and evaluation of an educational program to promotion of weight management among 3-5 years children in Tehran based on PRECEDE PROCEED model

Protocol summary

Study aim

Designing and evaluation of an educational program to the promotion of weight management among preschoolers in Tehran based on PRECEDE-PROCEED model

Design

This study is a two-arm parallel randomized controlled trial with one blinded and 80 samples.

Settings and conduct

a quasi-experimental study in preschools of Tehran, one blinded in participants.

Participants/Inclusion and exclusion criteria

Preschools' mothers residing in Tehran, Illness child and taking drugs, Unwilling to participate in the study.

Intervention groups

To perform a designed educational program in the intervention group to promote weight management among children, Performing the usual program of preschool in the control group.

Main outcome variables

Weight changes among children; children's quality of life; nutrition and physical activity behaviors.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190413043257N1**
Registration date: **2019-04-23, 1398/02/03**
Registration timing: **prospective**

Last update: **2019-04-23, 1398/02/03**

Update count: **0**

Registration date

2019-04-23, 1398/02/03

Registrant information

Name

Najmeh Hamzavi Zarghani

Name of organization / entity

Tarbiat Modares University

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing and evaluation of an educational program to promotion of weight management among 3-5 years children in Tehran based on PRECEDE PROCEED model

Public title

education for promotion weight management among children based on PRECEDE PROCEED

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

preschools' mothers residing Tehran

Exclusion criteria:
illness child and taking drugs unwilling to participate in the study

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the random numbers table, the participants will be assigned in the control and intervention groups. This table contains a lot of numbers without a specific pattern. Initially, the researcher predetermined the direction of reading numbers (for example, left, right, up, or down). the second is to consider numbers for different groups, for example, even numbers for the intervention group and the odd numbers for the control group. Then the researcher points to one of the numbers and moves in one of the predicted directions and records the numbers and assigns them to different groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants won't be informed that they are in the intervention group or in the control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tarbiat Modares University

Street address

Tarbiat Modares University, Nasr, Jalal al ahmad street, Tehran.

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2018-06-27, 1397/04/06

Ethics committee reference number

IR.MODARES.REC.1397.034

Health conditions studied

1

Description of health condition studied

promotion of weight management

ICD-10 code

F90-F98

ICD-10 code description

Behavioural and emotional disorders with onset usually occurring in childhood and adolescence.

Primary outcomes

1

Description

weight changes

Timepoint

before intervention, Immediately and three months after intervention

Method of measurement

Measuring the weight of children by digital scales

Secondary outcomes

1

Description

Quality of life scores

Timepoint

Measurement of quality of life before intervention as well as immediately and 3 months after intervention.

Method of measurement

Using children's Quality of life questionnaire

2

Description

score of nutritional behaviors of children.

Timepoint

Measurement of nutritional behaviors of children before intervention as well as immediately and 3 months after intervention.

Method of measurement

Using nutritional behaviors questionnaire of children.

3

Description

score of physical activity behavior of children.

Timepoint

Measurement of physical activity behaviors of children before intervention as well as immediately and 3 months after intervention.

Method of measurement

Using physical activity behavior questionnaire of children.

Intervention groups

1

Description

Intervention group: Tehranian preschoolers' mothers in the intervention group will be received a designed educational program to manage the weight of children. This educational program will be based on the results from the qualitative phase of the study and PRECEDE / PROCEED model. This model is one of the most comprehensive and widely used of models in health education to assess social, epidemiological, behavioral and educational factors regarding behavioral modification. Training includes educational sessions in the form of questions and answers about the history of weight disorders in preschoolers and its complications in childhood and adolescence; as well as priority behaviors such as nutrition, physical activity. Appropriate training materials will be used to train them.

Category

Behavior

2

Description

Control group: Tehranian preschoolers' mothers in the control group will be received a usual program of preschool.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Medical Sciences, Tarbiat Modares University

Full name of responsible person

Fazlollah Ghofranipour

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Tarbiat Modarres University, Nasr, Jalal Al Ahmad, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Medical Sciences, Tarbiat Modares University

Full name of responsible person

Dr. Ya'qub Fathollahi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Faculty of Medical Sciences, Tarbiat Modares University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Medical Sciences, Tarbiat Modares University

Full name of responsible person

Fazlollah Ghofranipour

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

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Person responsible for updating data

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Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic characteristics are confidential, but information on the consequences of weight, quality of life, and behavior changes are shared.

When the data will become available and for how long

A week after receiving a request by email, write to the main investigator.

To whom data/document is available

The researchers in scientific institutions and university of non-communicable disease prevention unit in the Ministry of Health.

Under which criteria data/document could be used

Health departments of medical sciences universities

From where data/document is obtainable

Contact Dr. Fazlollah Ghobranpour by email address
GHOFRANF@modares.ac.ir

What processes are involved for a request to access data/document

A week after receiving a request by email to the main investigator.

Comments