

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of educational package of family-centered behavioral modification on the child and family Dietary habits and BMI percentile of school-age obese girls

Protocol summary

Study aim

The effect of educational package of family-centered behavioral modification on the child and family Dietary habits and Body Mass Index(BMI) percentile of school-age obese girls

Design

Clinical trial with control group, with parallel groups, randomized

Settings and conduct

80 obese girls aged 7-12 years old with a BMI percentile of more than 85 will be selected from the 4 schools, which will be the research environment, by the available method. In the intervention group, Researcher-made training package "family-oriented behavioral reform" will be taught in 7 sessions of 45 minutes, then the BMI percentile, child and family behavior and eating habits and anthropometric indicators will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with a BMI percentile greater than 85%(WHO definition of childhood overweight and obesity), Age between 7- 12 years, Mother's attendance at the training sessions, Parent's ability to read and write, Informed consent to participate in the study, Living with both parents. Exclusion criteria: Participating in another weight control program, Having psychiatric disorder, heart disease or shortness of breath during exercise, Medical status or use of medications for weight loss, Reaching puberty

Intervention groups

In the intervention group, the child and mother will be taught the family- centered behavioral modification educational package, and at the end, they will be given the educational package, and the follow-up will continue for 3 months by weekly telephone call. In the control group, information about obesity and its complications will be given and at the end of the research, they will be given an educational package.

Main outcome variables

Child and family eating behaviors and habits , BMI percentile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191203045584N1**

Registration date: **2020-08-29, 1399/06/08**

Registration timing: **prospective**

Last update: **2020-08-29, 1399/06/08**

Update count: **0**

Registration date

2020-08-29, 1399/06/08

Registrant information

Name

Hadiseh Asadabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 8511

Email address

asadabadih961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-15, 1399/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational package of family-centered behavioral modification on the child and family Dietary habits and BMI percentile of school-age obese girls

Public title

Effect of Family-centered behavioral Modification training on Dietary habits and BMI of obese children

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Children with a BMI percentile greater than 85%(WHO definition of childhood overweight and obesity) Age between 7- 12 years Mother's attendance at the training sessions Parent's ability to read and write Informed consent to participate in the study Living with both parents

Exclusion criteria:

participating in another weight control program Having a psychiatric disorder Exercise heart disease or shortness of breath during exercise Medical status or use of medications for weight loss Reaching puberty

Age

From **7 years** old to **12 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The research population will be selected by simple randomization method without alternatives using envelopes, so that out of ten schools in one of the middle areas of Mashhad city, 2 schools will be selected as the intervention group and 2 schools as the control group. It is necessary to explain that the first and third choices will be the intervention group and the second and fourth choices will be the control group. Randomization on samples is not possible due to their inclusion in the study with special features. 80 obese girls aged 7-12 years old with a BMI percentile of more than 85 will be selected from the above 4 schools, which will be the research environment, by the available method.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical sciences

Street address

Mashhad Nursing And Midwifery Schole, Ebne Sina St

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2019-12-14, 1398/09/23

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.075

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

Dietary counselling and surveillance

ICD-10 code

Z71.3

ICD-10 code description

Dietary counseling and surveillance

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

The rate of change in child and family eating behavior and habits

Timepoint

The first training session and at the end of the third month

Method of measurement

Child Eating Behavior Questionnaire and Duch Eating Behavior Questionnaire and Child and Family Dietary Habits Questionnaire

2**Description**

BMI percentile percentage

Timepoint

First meeting and at the end of each month for 3 months

Method of measurement

Meters and scales

3

Description

Skin thickness

Timepoint

Before the intervention and at the end of the intervention

Method of measurement

Caliper

4

Description

Arm circumference

Timepoint

Before the intervention and at the end of the intervention

Method of measurement

Non-stretch calibrated tape

5

Description

Height

Timepoint

First meeting and at the end of each month for 3 months

Method of measurement

Meter

6

Description

Weight

Timepoint

First meeting and at the end of each month for 3 months

Method of measurement

Scales

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Family-centered behavioral modification educational package (contains information on obesity, motivation and skills development that is extracted from articles, book and program of Iran Eco and approved by the professors of Mashhad School of Nursing and Midwifery and nutritionist) in 7 sessions of 45 minutes will be taught for child and mother (mother presence is required in half of the sessions), at the end of the educational sessions, the educational package will be given to them and the follow-up will continue for 3 months by weekly phone call.

Category

N/A

2

Description

Control group: information about obesity and its complications will be given and at the end of the research, they will be given an educational package.

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Selected Primary Schools of Nursing Education in Mashhad City

Full name of responsible person

Dr. Tahereh Sadeghi

Street address

Ayatollah Behjat St

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Email

Sadeghit@mums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Robabeh Latifnezhad

Street address

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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

Mashhad University of Medical Sciences

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**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Tahereh Sadeghi

Position

Academic staff

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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

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Full name of responsible person

Hadiseh Asadabadi

Position

Master of Pediatric Nursing Student

Latest degree

Bachelor

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All potential data can be shared after unidentifiable people

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

For researchers working only in academic and scientific institutions

Under which criteria data/document could be used

School Health

From where data/document is obtainable

Mashhad School of Nursing and Midwifery

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

Immediately by visiting the library of Mashhad School of Nursing and Midwifery

Comments