Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of a home-based nutritional intervention program on anthropometric indices of preschool children with overweight and obesity

Protocol summary

Study aim

Determining the effect of home-based nutritional intervention program on anthropometric indices in obese and overweight preschool children of Urmia city

Design

A 6-month phase III cluster randomized parallel clinical trial on 260 overweight or obese preschool children

Settings and conduct

The present study is a community-based cluster randomized controlled trial in Urmia city, Iran. This study will be conducted among overweight and obese preschoolers. After receiving the code of ethics from Urmia University of Medical Sciences, sampling will be done from the health centers of Urmia city as clusters. The primary outcome of this study will be to find the effect of a 6-month home-based nutritional intervention program on improving the anthropometric indices of obese or overweight children and the constructs of the health belief model of mothers with obese and overweight children.

Participants/Inclusion and exclusion criteria

Inclusion criteria: overweight (body mass index z-score for age between +2 and +3) and obese (body mass index z-score for age above +3) preschoolers (2 to 5 years old) Exclusion criteria: preschool children with a known history of systemic diseases such as heart problems, kidney problems, cancer, etc., or parents who are absent in more than 20% of home visits

Intervention groups

Intervention group training: 1- Basic nutritional training based on the guidelines of the Ministry of Health 2- A nutritional pamphlet prepared for this study 3- Providing several low-calorie nutritious food recipes to mothers and 4- Behavioral training based on the health belief model to implement diet changes dietary for 6 months. This intervention will be provided in addition to regular services in health centers. Control group training: Routine training of health centers for 6 months

Main outcome variables

Body mass index, subcutaneous fat, waist circumference, health belief model structure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090124001580N8**
Registration date: **2023-11-08, 1402/08/17**
Registration timing: **prospective**

Last update: **2023-11-08, 1402/08/17**
Update count: **0**

Registration date

2023-11-08, 1402/08/17

Registrant information

Name

Shahsanam Gheibi

Name of organization / entity

Maternal and Childhood Obesity research Center, Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3222 6969

Email address

drgheibi@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2025-01-20, 1403/11/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of a home-based nutritional intervention program on anthropometric indices of preschool children with overweight and obesity

Public title
Effectiveness of a home-based nutritional intervention program on childhood obesity
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Overweight children (body mass index z-score for ages between +2 and +3) and obese children (body mass index z-score for ages above +3)
Exclusion criteria:
Preschool children with a known history of systemic diseases such as heart problems, kidney problems, cancer Children or parents who are absent in more than 20% of home visits Taking medicine or nutritional supplements affecting weight in children
Age
From **2 years** old to **5 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **260**
Randomization (investigator's opinion)
Randomized
Randomization description
This study will follow cluster randomization to assign subjects to intervention and control groups. Individuals in the same clusters will receive the same intervention. There are 63 health centers and 5 urban areas in Urmia city. The randomization strata will be based on urban areas so that subjects will be the same in terms of socioeconomic level between the two groups. Considering the average number of children registered in health centers and calculating the sample size, this study will require the selection of 10 health centers. In fact, 2 health centers from each urban area will be included in the study (each group = 5 clusters). These 2 centers will be randomly selected by lottery among all health centers in that area. Then 2 clusters selected from each strata will be divided into two intervention or control groups by simple randomization method and using coins.
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 committee of Urmia University of Medical Sciences
Street address
Orjhans Street, Resalat Blvd
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2023-11-07, 1402/08/16
Ethics committee reference number
IR.UMSU.REC.1402.220

Health conditions studied

1

Description of health condition studied
Obesity and overweight
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Body mass index
Timepoint
Before the start of the intervention, 3 and 6 months after the start of the intervention
Method of measurement
Formula

2

Description
Constructs of health belief model
Timepoint
Before the start of the intervention, 3 and 6 months after the start of the intervention
Method of measurement
Questionnaire

3

Description
Percentage of subcutaneous fat
Timepoint
Before the start of the intervention, 3 and 6 months after the start of the intervention
Method of measurement
Caliper device

4

Description
Waist circumference
Timepoint
Before the start of the intervention, 3 and 6 months after the start of the intervention
Method of measurement
Tape measure

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The trainings include 1- Basic nutritional training based on the guidelines of the Ministry of Health, 2- A nutritional pamphlet prepared for this study, 3- Providing several low-calorie nutritious food recipes to mothers, and 4- Behavioral training based on the health belief model to implement dietary changes for 6 months
Category
Lifestyle

2

Description
Control group: Routine training of health centers for 6 months
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia city health centers
Full name of responsible person
Amir Hossein Faghfouri
Street address
Orjhans Street, Resalat Blvd
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5714783734
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amir.nut89@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Shahsanam Gheibi
Street address
Orjhans Street, Resalat Blvd
City
Urmia
Province
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Postal code
571478334
Phone
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Email
gheibi1345sh@gmail.com
Grant name
Grant code / Reference number
12341
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Shahsanam Gheibi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

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Position
Assistant Professor
Latest degree
Ph.D.
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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Information about the main outcomes can be shared at the end of the study
When the data will become available and for how long
The access period will be 6 months after publication
To whom data/document is available
The data from this study will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
Six month after the publication of the articles obtained from the data of this project, the study data can be made available to the researchers upon request from the person in charge of the project and his/her approval
From where data/document is obtainable
Applicants can contact the corresponding author through the email or postal address below to receive the desired data. Postal address: Urmia University of Medical Sciences, Orjhans Street, Resalat Blvd. Contact number: 00984432234897. Email: gheibi1345sh@gmail.com
What processes are involved for a request to access data/document
Applicants will be able to access the data from the study by sending an email to the responsible author, at most after a week.
Comments