Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Implementing and Pilot Testing of a Customized Intervention to Increase Physical Activity and Healthy Eating among Preschool Children in Iran

Protocol summary

Summary

Objectives: Customizing and implementing Canadian health promotion program (Healthy Start), aligned with preschool bylaw in Iran and assessing the efficacy of this program on anthropometric parameters, quality of life, physical activity and healthy eating among preschoolers. Design: In a pilot-controlled trial, preschool girls and boys (aged 4-6) attending preschools are enrolled and the intervention is operated during six months. Due to the pilot design, sample size and randomization are not applicable. Setting and Conduct: Three preschools from three different socioeconomic status will be non-randomly selected for intervention and three preschools (from the same area) as controls and the intervention will be conducted during six months. Participants: preschool girls and boys (aged 4-6) attending preschools Intervention: A program containing five components: 1) promoting physical activity in preschoolers, 2) promoting healthy eating, 3) guiding educators for implementation, 4) active involvement of parents and 5) building partnership Main Outcome Measures: At baseline and after completion of intervention, anthropometric parameters, nutrition status, physical activity level and quality of life in children of both groups will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041927475N1**
Registration date: **2016-11-12, 1395/08/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-11-12, 1395/08/22

Registrant information

Name

Atieh Mehdizadeh Hakkak

Name of organization / entity

School of Medicine, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Research Chansllor of Mashhad University of Medical Sciences

Expected recruitment start date

2017-10-04, 1396/07/12

Expected recruitment end date

2018-05-06, 1397/02/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Implementing and Pilot Testing of a Customized Intervention to Increase Physical Activity and Healthy Eating among Preschool Children in Iran

Public title

Implementing and Pilot Testing of a Customized Intervention to Increase Physical Activity and Healthy Eating among Preschool Children in Iran

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Aged 4-6 years Attending preschool Signed informed consent of parents or guardian Exclusion criteria:Known cardiovascular, respiratory, endocrine or musculoskeletal problems (after physician inquiry) Having particular diet such as gluten-free or phenylalanine-free diets

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: **90**

Randomization (investigator's opinion)
N/A

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
Ethics Committee of Mashhad University of Medical Sciences

Street address
Ghoreishi Building, Daneshgah Street, Mashhad, Iran

City
Mashhad

Postal code

Approval date
2016-09-25, 1395/07/04

Ethics committee reference number
IR.MUMS.fm.REC.1395.208

Health conditions studied

1

Description of health condition studied
Unhealthy life style in terms of nutrition and physical activity

ICD-10 code
Z72.2

ICD-10 code description
Lack of physical exercise

2

Description of health condition studied
Unhealthy life style in terms of nutrition and physical activity

ICD-10 code
Z72.3

ICD-10 code description
Inappropriate diet and eating habits

Primary outcomes

1

Description
Height

Timepoint
Baseline and at the end (after 6 months)

Method of measurement
Stadiometer

2

Description
Nutrition status

Timepoint
Baseline and at the end (after 6 months)

Method of measurement
Questionnaire (NutriSTEP)

3

Description
Quality of life

Timepoint
Baseline and at the end (after 6 months)

Method of measurement
Questionnaire (PedsQL)

4

Description
Weight

Timepoint
Baseline and at the end (after 6 months)

Method of measurement
Digital scale

5

Description
Physical activity level

Timepoint
Baseline and at the end (after 6 months)

Method of measurement
Questionnaire (Physical Activity Assessment), Pedometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A program containing five components: 1) promoting physical activity in preschoolers (customized training material), 2) promting healthy eating (customized training material, healthy snacks and removing unhealthy buffets), 3) guiding educators for implementation, 4) active involvement of parents 5) building partnership
Category
Lifestyle

2

Description
Control group: Conventional nutrition and physical activity at preschoolers Conventional Nutrition: There is no snack protocol or nutrition recommendation in preschools. (open snack) Conventional physical activity: There is no guideline for duration and types of physical activity in preschools. Conventional physical activity:
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Three preschools non-randomly selected from three different socioeconomic status
Full name of responsible person
Atieh Mehdizadeh Hakkak
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Nematy
Street address
School of Medicine, Azadi Square, Mashhad, Iran
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Atieh Mehdizadeh
Position
PhD Candidate
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

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MD, PhD student

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