Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Comparative effectiveness of theory-based Educational intervention program and common education on anthropometric parameters, biochemical and blood pressure in obese adolescents.

Protocol summary

Summary

This study was carried out to evaluate the effectiveness of a focused nutrition education intervention to reduce the components of metabolic syndrome by using the Health Belief Model (HBM) among obese adolescents in Iran. In this Randomized controlled trial, an educational intervention program was conducted among 90 adolescents, living in Isfahan province of Iran. The inclusion criteria were as follows: age between 12–18 years, being overweight or obese. These participants were selected among obese adolescents who were referred from healthcare centers and schools to the Childhood Obesity Research Clinic of Pediatric Preventive Cardiology Department at Isfahan Cardiovascular Research Center. Participants were randomly assigned into intervention and control groups by simple randomization based on coin toss. The intervention group (n=46) participated in 12 educational sessions (one session/week) including educational lecture, group discussion, question-answer, pamphlet, booklet, power-point slide show on physical activity and its advantages, obesity and its consequences, susceptibility of obese people to cardiovascular disease and diabetes and healthy eating key-points based on the food guide pyramid. The control group (n=44) was assigned a usual program. Anthropometric, biochemical, dietary and blood pressure measurements were collected before the intervention at baseline (T0), at 3 months after the intervention (T1) and 3 months after the end of the intervention (T2) in order to evaluate the effectiveness of the nutrition education intervention program. All persons collecting information were unaware from the placement of adolescents in the case and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051017639N1**
Registration date: **2015-07-13, 1394/04/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-07-13, 1394/04/22

Registrant information

Name

MOJGAN NOURIAN

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 2671

Email address

nourian@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Self-funding

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2010-02-04, 1388/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effectiveness of theory-based Educational intervention program and common education on anthropometric parameters, biochemical and blood pressure in obese adolescents.

Public title
Nutrition education among obese adolescents
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria • Age between 12–18 years • Overweight or obese (BMI in the 85th–95th percentile or ≥95th percentile for age and sex) • Abdominal obesity (waist circumference ≥90th percentile for age and sex based on waist circumference cut-offs for Iranian children and adolescents) Exclusion criteria • History of diabetes and/or cardiovascular disease • Disease of the liver or any endocrine organ • Use of medication affecting serum lipids and serum glucose level • Following any prescribed diet and/or exercise program in the 6 months prior to the study
Age
From **12 years** old to **17 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
After screening the eligible participants were randomly assigned to the control group or the intervention group by simple randomization. In this case, all of the 100 participants numbered from 1 to 100 and divided in two groups based on odds and even numbers. Then, by coin toss the participants with odds number were considered as intervention group and the participants with even number were considered as control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of UPM university in Malaysia
Street address
UPM university in Malaysia
City
Selangor
Postal code
Approval date
2008-08-20, 1387/05/30
Ethics committee reference number
(UPM/FPSK/PADS/T7-MJKEticaPer/F01

Health conditions studied

1

Description of health condition studied
Obesity in adolescents
ICD-10 code
E66.0
ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Dietary intake-physical activity
Timepoint
Before the intervention, at 3 months after the intervention and 3 months after the end of the intervention
Method of measurement
Food record Questionnaire

Secondary outcomes

1

Description
Biochemical measurements, Blood Pressure, waist circumference
Timepoint
Before of the intervention, at 3 months after the intervention and 3 months after the end of the intervention
Method of measurement
Enzymatic method, kit (Parsazmoon), immunoturbidimetric method using Rondex commercially kit, Sphygmomanometer-Tape

Intervention groups

1

Description
Intervention1: Educational intervention based on education model (HBM) The intervention group (n=46) participated in 12 educational sessions (one session/week) including educational lecture, group discussion, question-answer, pamphlet, booklet, power-point slide show on physical activity and its advantages,

obesity and its consequences, susceptibility of obese people to cardiovascular disease and diabetes and healthy eating key-points based on the food guide pyramid.

Category

Behavior

2

Description

Intervention 2: The control group was assigned a usual program which included simple recommendations to reduce the intake of energy-dense foods such as fried foods, fast foods, cream, sugar and soft drinks in their diet and increasing the consumption of vegetables and fruits and doing more physical activity.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center in Isfahan university of medical science

Full name of responsible person

Street address

Hezar Jerib Avenue, Isfahan University of Medical Sciences

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Science

Full name of responsible person

Roya Kelishadi

Street address

Building No. 4, Hezar Jerib Avenue, Isfahan University of Medical Science, Isfahan

City

Isfahan

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, Isfahan University of Medical Science

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

Isfahan University of Medical Science/Nutrition Department

Full name of responsible person

Mojgan Nourian

Position

Ph.D / Lecturer

Other areas of specialty/work

Street address

Nutrition Department, Hezar Jerib Avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Postal code

Phone

+98 31 3792 2671

Fax

Email

nourian@hlth.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Science

Full name of responsible person

Mojgan Nourian

Position

PhD/lecture

Other areas of specialty/work

Street address

Nutrition Department, Hezar Jerib Avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Postal code

Phone

+98 31 3792 2671

Fax

Email

nourian@hlth.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Nutrition and Food Sciences

Full name of responsible person

Mojgan Nourian

Position

Ph.D/ Lecture
Other areas of specialty/work
Street address
Nutrition Department, Hezar Jerib Avenue, Isfahan University of Medical Sciences, Isfahan
City
Isfahan
Postal code
Phone
+98 31 3792 2671
Fax
Email
nourian@hlth.mui.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