

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of a theory-based intervention on obesity-related behaviors, laboratory indices, body composition, body mass index and health-related quality of life in overweight adolescents

Protocol summary

Summary

Abstract Purposes: The theory of obesity-related behaviors in adolescents (TORBA) emerged from a qualitative study in Iran and presents a new approach to the weight-gain process during adolescence. This study aims at evaluating the effectiveness of a TORBA-based intervention on obese adolescents' weight reduction and its related factors. **Methods:** This is a randomized clinical trial conducted on 115 overweight adolescents (50% female) aged 12 to 17 years, and their parents will be recruited from healthcare centers located in district 13 of Tehran. All participants will attend a data collection, involving assessments of obesity-related behaviors, laboratory indices, body composition, body mass index and health-related quality of life, which will be conducted at baseline, after the intervention phase, and after maintenance phases (6 months and a year after intervention). Following completion of all pre intervention assessments, participants will be randomly assigned in to the intervention or control groups. The TORBA-based cognitive behavioral intervention, of this study, consists of face- to-face educational sessions for adolescents and their parents. A pilot study will establish the affordability of study educational packages. The study interventions involve improvement in diet, physical activity, and stress management which mainly implement through motivational interviews. Improvements in obesity-related behaviors, BMI, body composition are primary outcomes and secondary outcomes include improvement in laboratory indices and health-related quality of life. **Conclusion:** Data obtained in this study will provide valuable information about the effectiveness of a behavioral cognitive intervention, designed on a local-tailored theoretical framework and which could be used for designing future national strategies to prevent obesity in Iranian adolescents.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012235440N1**

Registration date: **2011-02-18, 1389/11/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-02-18, 1389/11/29

Registrant information

Name

Parisa Amiri

Name of organization / entity

Obesity research center

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Obesity research center, research Institute for endocrine Sciences, Shahid Beheshti University of medical sciences

Expected recruitment start date

2011-05-01, 1390/02/11

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of a theory-based intervention on obesity-related behaviors, laboratory indices, body composition, body mass index and health-related quality of life in overweight adolescents

Public title

Effectiveness of an educational program to adolescents' weight management

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. age 12-17 2. adolescents who were overweight or obese according to WHO cut off 3. living with a parent or adult caregiver who will prepare to participate in the study. Exclusion criteria: 1. they have a physical disability that prevent them to participate in the program

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: **115**

Randomization (investigator's opinion)

Randomized

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**

Research Institute for Endocrine Sciences

Street address

Obesity research center, research Institute for endocrine Sciences, Shahid Beheshti University of medical sciences

City

Tehran

Postal code**Approval date**

2005-10-09, 1384/07/17

Ethics committee reference number

750EC

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

overweight and obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

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

obesity-related behaviors

Timepoint

base line, 3, 6 and 12 months after intervention

Method of measurement

Obesity Predictors in Adolescents Questionnaire (OPAQ), FFQ, Physical activity questionnaire

2**Description**

laboratory indices

Timepoint

base line, 6 and 12 months after intervention

Method of measurement

measuring of FBS, Lipid profile and Insulin

3**Description**

BMI

Timepoint

base line, 3, 6 and 12 months after intervention

Method of measurement

Weight (Kg)/Height² (m)

4**Description**

Body composition

Timepoint

base line, 6 and 12 months after intervention

Method of measurement

Body composition analyzer

Secondary outcomes**1****Description**

health-related quality of life

Timepoint

baseline, a year after intervention

Method of measurement

Iranian version of pediatric quality of life inventory
PedsQL

Intervention groups**1****Description**

intervention group : The intervention program encompassed intensive and maintenance phases. The intensive phase consisted of 17 focus group discussions, twice a week and a 45 minute face-to-face session of nutritional counseling at the end of program. The maintenance programs included seven focus group discussions during six months. The study intervention involved improvement in diet, increase in the level of physical activity, and improvement of stress management which implemented through motivational interviews, group discussions, and educational publications

Category

Lifestyle

2**Description**

Control: conventional diet counseling

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Salavati and Alghadir health care center

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Institute for Endocrine Sciences

Full name of responsible person

Fereidoun Azizi

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Velenjak, Yaman Ave.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Institute for Endocrine 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**

Obesity research Center, Research Institute for Endocrine Sciences

Full name of responsible person

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Position

researcher/ Ph.D

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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