

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study on the Effect of Nutrition Education and Physical Activity intervention using Social Cognitive Theory for Overweight and Obese Student Girls of Middle School of Shahinshahr.

Protocol summary

Summary

This study aimed to correct two important criteria of lifestyle, nutrition and physical activity, and ultimately reduce the prevalence of overweight and obesity and promoting level of health among adolescents, will be implemented among girl students by using nutrition and physical activity education according to SCT. For this study, a total 150 students who are 12 to 16 years old and do not received and followed any diet for losing weight before study, and do not have any metabolic diseases, will be randomly selected and then will be randomly divided into two groups (intervention and control, each group comprise 75 students). In the intervention group, students and their parents will be taught about nutrition and physical activity with participating in theory and practical seminars, conferences and workshops. Other parts of education are, sending messages for students and their parents, educational CD and holding practical exercise classes. Students in both groups before the study will complete questionnaires about their nutritional and physical activity behaviors. In addition, they will complete questionnaires about self-efficacy, perceived social support and perceived outcome expectation in nutrition and physical activity. After six month intervention questionnaires will be completed again. Weight, height and waist circumference of students, will be measured and recorded before and after study. Finally, data will be analyzed.

General information

Acronym

SCT: Social cognitive theory

IRCT registration information

IRCT registration number: **IRCT2013103115211N1**

Registration date: **2013-11-27, 1392/09/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-11-27, 1392/09/06

Registrant information

Name

Mohammad Bagherniya

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3183

Email address

m_bagherniya@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences, Shhinshahr city department of education

Expected recruitment start date

2013-12-01, 1392/09/10

Expected recruitment end date

2014-05-31, 1393/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study on the Effect of Nutrition Education and Physical Activity intervention using Social Cognitive Theory for Overweight and Obese Student Girls of Middle School of

Shahinshahr.

Public title

The effect of of nutrition and physical activity education on nutrition and exercise behaviors weight in overweight and obese adolescents.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Second and third grade female students in middle schools who according to the WHO 2007 Tables have Body Math Index above the 85th percentile; Student's age are between 12 to 16 years; Students do not have any of the exclusion criteria.

Exclusion criteria: Using drugs which associated with overweight and obesity, such as nerve drugs, corticosteroids and so on; Received and followed any diet by students for losing weight before the study; Students who have any Metabolic diseases such as endocrine disorders, thyroid disease, diabetes and so on.

Age

From **12 years** old to **16 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

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

Vice-Chancellor for Research, Tehran University of Medical Sciences

Street address

4th fl, Main Organization of Tehran University of Medical Sciences, Qods corner, Keshavarz Blv, Tehran

City

Tehran

Postal code

Approval date

2013-11-19, 1392/08/28

Ethics committee reference number

92-02-161-23509-98943

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

weight

Timepoint

Before intervention, three months after starting intervention, at the end, after intervention

Method of measurement

digital scale

2

Description

height

Timepoint

Before intervention, three months after starting intervention, at the end, after intervention

Method of measurement

height gauge

3

Description

Body Math Index

Timepoint

Before intervention, three months after starting intervention, at the end, after intervention

Method of measurement

wieght/height2

4

Description

waist circumference

Timepoint

Before intervention, three months after starting intervention, at the end, after intervention

Method of measurement

non-elastic flexible tape

5

Description

nutritional behavior

Timepoint

Before intervention and after intervention

Method of measurement

questionnaire

6**Description**

physical activity behavior

Timepoint

Before intervention and after intervention

Method of measurement

questionnaire

7**Description**

nutrition self efficacy

Timepoint

Before intervention and after intervention

Method of measurement

questionnaire

8**Description**

physical activity self efficacy

Timepoint

Before intervention and after intervention

Method of measurement

questionnaire

9**Description**

perceived social support in nutrition

Timepoint

Before intervention and after intervention

Method of measurement

questionnaire

10**Description**

perceived social support in physical activity

Timepoint

Before intervention and after intervention

Method of measurement

questionnaire

11**Description**

outcome expectation in nutrition

Timepoint

Before intervention and after intervention

Method of measurement

questionnaire

12**Description**

outcome expectation in physical activity

Timepoint

Before intervention and after intervention

Method of measurement

questionnaire

Secondary outcomes

empty

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

intervention group: students and their parents will be taught about nutrition and physical activity with participating in theory and practical seminars, conferences and workshops (12 sessions and each session 60 minutes). In addition, 6 sessions will be held for Individual Counseling about nutrition and physical activity for students (each session 60 minutes). Other parts of education are comprised from sending 48 messages for students and their parents, educational CD and holding practical exercise classes for students (40 sessions and each session 90 minutes). All interventions will be done in 6 months.

Category

Behavior

2**Description**

Control group: During study no intervention will be done in control group. but after that, four education sessions will be held in control group for students and their parents. (each session will be 90 minutes)

Category

Behavior

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

Health Network of Shahinshahr and meime city

Full name of responsible person

Ramesh Allipour Birgani

Street address

9 west street, Taleghani Boulevard, Shahinshahr city

City

Shahinshahr

2**Recruitment center****Name of recruitment center**

Department of Education of Shahinshahr city

Full name of responsible person

Sadegh Shenavaie

Street address

Next to the Fatemieh square, Imam Khomeini Boulevard

City

Shahinshahr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice-chancellor for research, Dr Masoud Younesian

Street address

4th fl, Main Organization of Tehran University of
Medical Sciences, Qods corner, Keshavarz Blv, Tehran

City

Tehran

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source**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

2

Sponsor

Name of organization / entity

Department of Education of Shahinshahr city

Full name of responsible person

Sadegh Shenavaie

Street address

Next to the Fatemieh square, Imam Khomeini
Boulevard

City

Shahinshahr

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

Yes

Title of funding source

Department of Education of Shahinshahr city

Proportion provided by this source**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

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Bagherniya

Position

MSc student of public health in nutrition

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences

Full name of responsible person

Seyed Ali Keshavarz

Position

PhD/ full Professor of Nutrition

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Bagherniya

Position

MSc student of public health in nutrition

Other areas of specialty/work**Street address**

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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