

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Intervention program to promote local community readiness for childhood obesity prevention in late primary school children

Protocol summary

Study aim

Goal and objectives: Local community readiness promotion for childhood obesity prevention in late primary school children 1. Promotion of the community efforts 2. Raising awareness of the community about available efforts and childhood obesity issue 3. Increase the level of active participation of the community leaders 4. Strengthen the community climate for childhood obesity prevention 5. Promotion of the available resources for childhood obesity prevention

Design

Four schools with the same level of preparedness for obesity prevention programs are selected, and the appropriate intervention pattern is designed based on the level of readiness of these schools and runs for six months in these schools. Four schools are controls. Then the impact of the intervention on increasing the readiness level of the four intervention schools is evaluated and compared with the control schools.

Settings and conduct

A controlled community-based intervention program in elementary schools in districts 2 and 16 of Tehran

Participants/Inclusion and exclusion criteria

Eight public elementary schools in districts 2 and 16 of the Tehran Office of Education and related municipal neighborhood houses and public health care centers are the participants of this intervention

Intervention groups

Four elementary schools in districts 2 and 16 of the Office Education of Tehran constitute intervention groups. In intervention schools, 8 key strategies (Engagement, sensitization, Encouragement, Education, Informing, Create supportive environments, Modeling, and Incentive) are implemented by the School Food and Nutrition committee in the school environment. Four schools are also in the control group and no receive any intervention.

Main outcome variables

The number of local community programs and efforts,

the level of local community awareness, the involvement of local community leaders, the number of resources available

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191006044997N1**

Registration date: **2019-11-11, 1398/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-11, 1398/08/20**

Update count: **0**

Registration date

2019-11-11, 1398/08/20

Registrant information

Name

Mahdieh Niknam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 7483

Email address

ma_niknam@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-26, 1398/08/04

Expected recruitment end date

2020-04-23, 1399/02/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Intervention program to promote local community readiness for childhood obesity prevention in late primary school children

Public title
Promotion of local community readiness for childhood obesity prevention in late primary school children

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
All public primary schools in districts 2 and 16 of Tehran Office Education that have the second course (fourth, fifth and sixth grades)
Exclusion criteria:
School staff are reluctant to participate in the intervention Students are reluctant to participate in the intervention Parents are reluctant to participate in the intervention

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **8**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study, we have four intervention groups (four intervention schools) that receive the same interventions. Also, we have four control groups (4 control schools) that receive no intervention

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Nutrition and Food Technology Research Institute (NNFTRI) ethical committee

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2018-07-18, 1397/04/27

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1397.012

Health conditions studied

1

Description of health condition studied

Childhood obesity prevention

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

The number of local community's programs and efforts, the level of the local community's awareness, the involvement of local community leaders, the number of resources available

Timepoint

After determining the stage of local community readiness for childhood obesity prevention programs in selected primary schools in Tehran (before beginning the intervention), 6 months later, the stage of local community readiness for childhood obesity prevention programs is again reassessed.

Method of measurement

Semi-structured qualitative valid questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Four boys' and girls' elementary schools in districts 2 and 16 of Tehran with public health care center and municipal neighborhood house near the school constitute a local community that will be affected by 6 months intervention including 8 main strategies (Engagement, sensitization, Encouragement, Education, Informing, Create supportive environments, Modeling, and Incentive).

Category

Prevention

2

Description

Control group: Four schools (2 girls 'and boys' schools from each district) are in the control group and no receive any intervention. Then the impact of the intervention on increasing the readiness level of the four intervention schools is evaluated and compared with the control schools.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Elementary schools in districts 2 and 16 of Tehran Office of Education

Full name of responsible person

Mahdieh Niknam

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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

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Email

ma_niknam@sbm.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Morteza Abdollahi

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

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nutrition@sbm.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Zade Vakili

Street address

No. 24, Beginning of Parvaneh Ave., Yemen Street, Velenjak, Shaheed Chamran Highway

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+98 21 2241 6264

Email

info@endocrine.ac.ir

Web page address

http://endocrine.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mahdieh Niknam

Position
Student

Latest degree
Master

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The score of each school's readiness level (anonymously) will present at the beginning and end of the intervention

When the data will become available and for how long

Data access will begin 6 months after the publication of the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Only for systematic review and metaanalysis studies

From where data/document is obtainable

The corresponding author's email (ma-nikanam@sbmu.ac.ir) the corresponding author's phone (0098 09171393460)

What processes are involved for a request to access data/document

The data will be sent by email within a week after the

request

Comments