

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effect of intervention based on the theory of planned behavior (TPB) on fruit and vegetable consumption rate in elementary school male students in Chaldoran 2012-2013

Protocol summary

Summary

The purpose of this study was to improve fruit and vegetable consumption in children. This study is an experimental intervention study. Participants are selected from the fourth, fifth and sixth grade students. The main inclusion criteria are: being school student in fourth, fifth and sixth grade; students and parents consent to participate in the study and Exclusion criteria are: consumption more than 5 units of the fruit and vegetables per day or lack of consent. Sample size for this study was 63 students for per group. Consider that a possibility loss of 20%, 76 samples chose for each group. After selecting the intervention and control groups, the data is collected in two stages: the first stage of data collection is before intervention and the second stage was two months after the intervention. Data gathered using a general questionnaire, a 24-hour recall questionnaire, a food frequency questionnaire and questionnaire designed based on the theory of planned behavior. Intervention includes a 1-hour educational session for parents, teachers and administrators and 4 educational sessions of 45 minutes for the students. The interested outcome of the study was the consumption rate of the fruit and vegetable before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307157352N8**

Registration date: **2013-09-15, 1392/06/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-09-15, 1392/06/24

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

center for community based participatory research, Tehran university of medical science

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intervention based on the theory of planned behavior (TPB) on fruit and vegetable consumption rate in elementary school male students in Chaldoran 2012-2013

Public title

Impact of education on fruit and vegetable consumption in children

Purpose

Prevention

Inclusion/Exclusion criteria

The main criteria of inclusion in the study are: School in fourth grade, fifth and sixth grade; students and parents consent to participate in the study . Exclusion criteria are: consumption more than 5 unite of fruit and vegetables a day; Lack of consent from study

Age

From **10 years** old to **12 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **152**

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

Tehran University of Medical Sciences

Street address

Sixth Floor, Central University, St. Ghods, Keshavarz Boulevard

City

Tehran

Postal code

Approval date

2013-08-04, 1392/05/13

Ethics committee reference number

896 /130/92/س

Health conditions studied

1

Description of health condition studied

Fruit and vegetable consumption

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fruit and vegetable consumption

Timepoint

Before and two months after the intervention

Method of measurement

Fruit and vegetable food frequency questionnaire and 24-hour recall 2-Cognitive- attitudinal Questionnaire

Secondary outcomes

1

Description

Behavioral intention, attitude, subjective norms, and perceived behavioral control

Timepoint

Before and two months after the intervention.

Method of measurement

Cognitive assessment questionnaire

Intervention groups

1

Description

Education was used as intervention in this study. Intervention included a 1-hour educational session for parents, teachers and administrators and 4 educational sessions of 45 minutes for the students. Stage of the intervention: 1- The first phase of the intervention was training parents about the importance and role of fruit and vegetable consumption in physical health. Also to support parents and to encourage students to eat fruits and vegetables. At the end, parents received an educational pamphlet about the importance of eating fruits and vegetables. 2- The second stage of intervention was to train teachers and school administrators. 3- The third stage of intervention was to teach students using the information obtained from questionnaires. To this end, the most important predictors of behavior (eating enough daily fruits and vegetables) were identified and were used to design a training program.

Category

Other

2

Description

The control group: We did not intervene in control group; however, control subjects received educational pamphlets at the end of the study.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Education

Full name of responsible person

Doctor Mohammad Hussein Taghdisi

Street address

The education of Chaldoran, Moallem Square,
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City

Chaldoran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

center for community based participatory research,
Tehran university of medical sciences

Full name of responsible person

Esmat Karimi

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Tehran, Ghods street, Tehran University of Medical
Sciences

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

Yes

Title of funding source

center for community based participatory research,
Tehran 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

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Full name of responsible person

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Position

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Towhid Babazadeh

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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