

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of Theory-based Intervention on Fruit & Vegetable Consumption among students of Ardabil City's high schools With SFS Approach

Protocol summary

Summary

The aim of this study is Effectiveness of Theory-based Intervention on Fruit & Vegetable Consumption among students of Ardabil City's high schools With SFS Approach. Inclusion criteria is having 15-13 years old, Informed consent and voluntary participation into the study and Exclusion criteria is not wanting to continue to participate in the study, moving, transfer or change of school. This research is Experimental Interventional study. In present study, 308 students randomly divided to intervention and control group. Data of three groups collected before, two and four months after educational intervention. For data gathering used questionnaires. Validity and reliability stages accomplished for the tools. Theory-based nutrition education performed for intervention group in 4 educational sessions during 4-week period for students and 2 educational sessions for parents and teachers. All students participated in this study voluntarily and with informed consent. In this research, educational interventions are made to change behavior and lifestyle changes

General information

Acronym

SFS - Student Family School

IRCT registration information

IRCT registration number: **IRCT2016051711371N2**

Registration date: **2017-03-27, 1396/01/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-27, 1396/01/07

Registrant information

Name

Bitra Shahbazzadegan

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1551 2007

Email address

b.shahbaz@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2016-10-06, 1395/07/15

Expected recruitment end date

2017-03-05, 1395/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Theory-based Intervention on Fruit & Vegetable Consumption among students of Ardabil City's high schools With SFS Approach

Public title

Theory-based Intervention on Fruit & Vegetable Consumption

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Having 15-13 years old; Informed consent and voluntary participation into the study

Exclusion criteria: Not wanting to continue to participate in the study, moving, transfer or change of school

Age
From **13 years** old to **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **308**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences

City

Tehran

Postal code

Approval date

2016-06-21, 1395/04/01

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.121

Health conditions studied

1

Description of health condition studied

Health

ICD-10 code

Z59.4

ICD-10 code description

Lack of adequate food

Primary outcomes

1

Description

Fruit consumption (Servings/day)

Timepoint

Before intervention, 2 months and 4 months after treatment

Method of measurement

Questionnaires

Secondary outcomes

1

Description

Behavioral capability

Timepoint

Before intervention, 2 months and 4 months after treatment

Method of measurement

Questionnaires

Intervention groups

1

Description

Intervention Group: Nutrition education based on social cognitive theory was implemented in a month for students, parents and teachers.

Category

Lifestyle

2

Description

Control group: Not receive intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Education and training Adebil province

Full name of responsible person

Ahmad Salimi

Street address

Education and training Adebil province

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences, Tehran

Full name of responsible person

Dr Abbas Rahimi

Street address

Shahid Beheshti University of Medical Sciences,
Tehran

City

Tehran

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, Tehran

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**

Ardabil University of Medical Sciences, Ardabil

Full name of responsible person

Bita Shahbazzadegan

Position

PhD Student

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

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bitashahbaz2004@yahoo.comb.shahbaz@arums.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