

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Effects of an educational intervention based on the social cognitive theory on breakfast consumption behavior among female students in grades 7 and 8 attending middle schools

Protocol summary

Summary

Goal: To determine the effects of an educational intervention on theoretical constructs of the social cognitive model and breakfast consumption behavior in girl students of Kavar city. Study design: educational field trial with control group Study. Population: all the Kavar high school students in grades of 7 and 8. Inclusion criteria: signing an informed consent form of participation by students and their parents, behavioral defect in breakfast consumption; and being in a physical health status. Exclusion criteria: failure to attend training sessions and withdrawal of the study. Sample size: the results of a primary pilot study in the target population revealed that more than 90% of students had impaired behavior on eating breakfast. So using a census method, the total of 406 students will be studied in the format of control (one school) or intervention (two schools) groups. Intervention: The training group includes students who never have breakfast or use less than two food groups (bread and cereals or milk and dairy products) for breakfast or breakfast meal provides less than 20% of their daily required energy. They will be instructed based on six fundamental constructs of social learning theory of Bandura (self-efficacy, social support, self-regulation, outcome expectancy and observational learning) in two months. The efficacy of the intervention will be assessed by comparing calorie intake and main constructs of the social learning theory.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061028378N1**
Registration date: **2017-10-17, 1396/07/25**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-17, 1396/07/25

Registrant information

Name

Kambiz Karimzadeh Shirazi

Name of organization / entity

Social determinants of health research center, school of health, Yasuj University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Yasuj University of Medical Sciences

Expected recruitment start date

2017-11-09, 1396/08/18

Expected recruitment end date

2018-01-09, 1396/10/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of an educational intervention based on the social cognitive theory on breakfast consumption behavior among female students in grades 7 and 8 attending middle schools

Public title

Improving the consumption of breakfast in students

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: signing an informed consent form of participation by students and their parents, behavioural defect in breakfast consumption; and being in a physical health status. Exclusion criteria: failure to attend training sessions and withdrawal of the study.

Age

From **12 years** old to **14 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **406**

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**

Yasuj University of Medical Sciences

Street address

Staff building, school of health, Dastjerdi avenue,
Ostandari Square

City

Yasuj

Postal code**Approval date**

2016-02-06, 1394/11/17

Ethics committee reference number

IR.YUMS.Rec.1394.145

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

Behavioral defect in breakfast consumption

ICD-10 code

F98

ICD-10 code description

Other behavioural and emotional disorders with onset usually occurring in childhood and adolescence

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

Calorie intake from breakfast

Timepoint

One week before and two weeks after the intervention

Method of measurement

Questionnaire

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

Self-efficacy

Timepoint

One week before and two weeks after the intervention

Method of measurement

Questionnaire

2**Description**

Social support

Timepoint

One week before and two weeks after the intervention

Method of measurement

Questionnaire

3**Description**

Self-regulation

Timepoint

Before and 2 weeks after the intervention

Method of measurement

Questionnaire

4**Description**

Outcome expectancy

Timepoint

Before and 2 weeks after the intervention

Method of measurement

Questionnaire

5**Description**

Observational learning

Timepoint

Before and 2 weeks after the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: nutritional education for Proper consumption of the four food groups in breakfast, based on social cognitive theory constructs among students

Category

Behavior

2

Description

Control group: routine instructions for nutrition in schools

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Farhangian (Effat), Zeynab Kobra and Khadijeh Kobra middle schools

Full name of responsible person

Street address

City

Kavar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Hosein Mari Oriyad

Street address

Main building of Yasuj University of Medical Sciences, Shahid Motahari street

City

Yasuj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasuj 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

Social determinants of health research center, school of health, Yasuj University of Medical Science

Full name of responsible person

Kambiz Karimzadeh Shirazi

Position

Academic member, PhD

Other areas of specialty/work

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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