

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

The effectiveness of theory-based educational intervention on consumption of healthy snacks in elementary students

Protocol summary

Study aim

The aim of this study is to determine the effect of nutrition education on reducing the consumption of unhealthy snacks among primary school students.

Design

The current research is a randomized clinical trial that will be conducted by multi-stage random sampling method in primary school students in two test and control groups (120 samples) in schools.

Settings and conduct

The study population will include all students of the fourth, fifth and sixth grades of Elvand city. Two schools (n=60) will be assigned to the educational intervention group and two schools (n=60) will be assigned to the control group. Then, the educational intervention based on the structures of the stages of change is carried out during five sessions through face-to-face training, training through virtual space for the participants of the intervention group. Finally, the scores of the questions related to the meta-theoretical model before and after the training will be compared in two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having physical and mental readiness, and ability to participate in the study, studying in government schools. Exclusion criteria: Students who have a special disease that prevents them from participating properly in the study.

Intervention groups

The educational intervention includes four sessions (one session per week) for 60-90 minutes by the researcher. Also a training session for parents as secondary target group. The educational methods will include lectures, slides, video and photo shows, group discussions, brainstorming, and question and answer. The control group received routine training by a nutritionist during the intervention.

Main outcome variables

Awareness, behavior change process, cognitive process and reduction of consumption of unhealthy snacks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221211056776N1**

Registration date: **2023-06-13, 1402/03/23**

Registration timing: **retrospective**

Last update: **2023-06-13, 1402/03/23**

Update count: **0**

Registration date

2023-06-13, 1402/03/23

Registrant information

Name

Bahareh Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3222 7951

Email address

rataarya@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-17, 1402/01/28

Expected recruitment end date

2023-04-27, 1402/02/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of theory-based educational intervention on consumption of healthy snacks in elementary students	
Public title	The effect of nutritional education in the fourth, fifth and sixth grade of elementary school students to reduce the consumption of unhealthy snacks
Purpose	Prevention
Inclusion/Exclusion criteria	
Inclusion criteria:	Being students in the fourth, fifth and sixth grades of elementary school who live in the study area Willingness and satisfaction of students and their parents to participate in the study Being in the three stages of preparation for change, i.e. pre-thinking, thinking and preparation (according to the answers given to the algorithm of the stages of change) Having a smart mobile phone by the student or parents to send educational messages or virtual training if needed
Exclusion criteria:	Unwillingness to continue participating in the study Unavailability of the student when completing the post-test questionnaire (immigration during the research). Suffering from physical and mental disorders and diseases that somehow prevent proper participation in the study. (Certified by a physician).
Age	From 9 years old to 13 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 120
Randomization (investigator's opinion)	Randomized
Randomization description	Cluster randomization method will be used. In this way, 2 schools will be assigned as intervention and two schools will be assigned as control.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	Name of ethics committee Qazvin University of Medical Sciences Street address Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin, Iran City Qazvin Province Qazvin Postal code 3419759811 Approval date 2023-03-18, 1401/12/27 Ethics committee reference number IR.QUMS.REC.1401.370
Health conditions studied	
<u>1</u>	
Description of health condition studied	Consumption of healthy snacks in elementary students
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
Description	Stages of behavior change
Timepoint	Before the intervention, one months after the intervention
Method of measurement	Questionnaire
<u>2</u>	
Description	The process of behavior change
Timepoint	Before the intervention, one months after the intervention
Method of measurement	Questionnaire
<u>3</u>	
Description	Cognitive process
Timepoint	Before the intervention, one months after the intervention
Method of measurement	Questionnaire
<u>4</u>	
Description	Knowledge
Timepoint	

Before the intervention, one months after the intervention
Method of measurement
Questionnaire

5

Description
Dramatic relief
Timepoint
Before the intervention, one months after the intervention
Method of measurement
Questionnaire

6

Description
Timepoint
Method of measurement

7

Description
Social release
Timepoint
Before the intervention, one months after the intervention
Method of measurement
Questionnaire

8

Description
Reciprocal conditioning
Timepoint
Before the intervention, one months after the intervention
Method of measurement
Questionnaire

9

Description
Supportive relationships
Timepoint
Before the intervention, one months after the intervention
Method of measurement
Questionnaire

10

Description
Balance in decision making
Timepoint
Before the intervention, one months after the intervention
Method of measurement
Questionnaire

11

Description
Efficacy
Timepoint
Before the intervention, one months after the intervention
Method of measurement
Questionnaire

12

Description
Consumption of healthy snacks
Timepoint
Consumption of healthy snacks
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Parents' education
Timepoint
Before the intervention, one months after the intervention
Method of measurement
Questionnaire

2

Description
Parents' job
Timepoint
Before the intervention, one months after the intervention
Method of measurement
Questionnaire

3

Description
Age
Timepoint
Before the intervention, one months after the intervention
Method of measurement
Questionnaire

4

Description
sex
Timepoint
Before the intervention, one months after the intervention
Method of measurement
Questionnaire

5

Description

Student's weight

Timepoint

Before the intervention, one months after the intervention

Method of measurement

Questionnaire

6

Description

Number of household dimensions

Timepoint

Before the intervention, one months after the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Direct training with questions & answers in the intervention group for four weeks

Category

Behavior

2

Description

Control group: without action

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

School

Full name of responsible person

Dr. Hadi Morshedi

Street address

Department of Education, Malam Blvd, Alvand, Qazvin province, Iran

City

Alvand

Province

Qazvin

Postal code

3431878448

Phone

+98 28 3222 3334

Fax

Email

rataarya@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Hadi Morshidi

Street address

Shahid Bahonar Boulevard, Qazvin, Iran, Qazvin University of Medical Scincese

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3335 9504

Email

rataarya@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin University of Medical Sciences

Proportion provided by this source

100

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

Qazvin University of Medical Sciences

Full name of responsible person

bahareh amini

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

Street address

Shahid Bahonar Boulevard, Qazvin, Iran, Qazvin University of Medical Scincese

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3335 9504

Email

rataarya@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Hadi Morshidi

Position

PhD in Health Education

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Qazvin University of Medical Sciences, Shahid
Bahonar Boulevard, Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3335 9504

Email

hmorshedi@qums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Hadi Morshidi

Position

PhD in Health Education

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Shahid Bahonar Boulevard, Qazvin, Iran, Qazvin
University of Medical Sciences

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3335 9504

Email

hmorshedi@qums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable