

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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

### 1

#### 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

### 1

#### Description of health condition studied

Consumption of healthy snacks in elementary students

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Stages of behavior change

#### Timepoint

Before the intervention, one months after the intervention

#### Method of measurement

Questionnaire

### 2

#### Description

The process of behavior change

#### Timepoint

Before the intervention, one months after the intervention

#### Method of measurement

Questionnaire

### 3

#### Description

Cognitive process

#### Timepoint

Before the intervention, one months after the intervention

#### Method of measurement

Questionnaire

### 4

#### 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

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##### 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

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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

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Qazvin University of Medical Sciences

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Dr. Hadi Morshidi

**Position**

PhD in Health Education

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

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**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