Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 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)

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+98 28 3222 7951

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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'jop

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Person responsible for updating data

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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