Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Development, implementation and evaluation of an intervention to improve food and nutrition literacy among 10-12 years-old school children of Baneh using Intervention Mapping approach

Protocol summary

Study aim
Improve food and nutrition literacy among 10-12 years-old school children of Baneh using Intervention Mapping approach

Design
Randomised trial with control group ,without blinded, design for 300 students, Simple cluster randomization

Settings and conduct
This research has 3 phases, 4 sub-studies and 6 steps which on the students of the 4th, 5th and 6th grade of Baneh city in control and intervention groups will be done.The intervention phase of the study includes the allocation of the target group in two groups of intervention and control, which In the intervention group will be done the educational intervention.

Participants/Inclusion and exclusion criteria
Arrival conditions:1- Education at the 4th, 5th or 6th grade elementary level 2- Residents of Baneh City 3- Having consent from the participants and their parents Non-arrival conditions:1- Being over 12 years old and less than 10 years 2. Not having consent form

Intervention groups
The intervention group: Students from the 4th, 5th and 6th grade students studying and residing in Baneh, with the consent form to receive theoretical-based educational interventions to improve nutritional literacy. The control group:They have the same conditions as the intervention group

Main outcome variables
1- Promoting food and nutrition literacy (analytical, interactive, and functional) 2- Modify the weight of participants 3. Increased participants' height

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151208025431N5**
Registration date: **2018-07-14, 1397/04/23**
Registration timing: **prospective**

Last update: **2018-07-14, 1397/04/23**
Update count: **0**

Registration date
2018-07-14, 1397/04/23

Registrant information

Name
Elham Shakibazadeh

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 4293 3210

Email address
shakib@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2018-10-02, 1397/07/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Development, implementation and evaluation of an

intervention to improve food and nutrition literacy among 10-12 years-old school children of Baneh using Intervention Mapping approach

Public title
Improve food and nutrition literacy among 10-12 years-old school children of Baneh using Intervention Mapping approach

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
10-12 years-old elementary school children of Baneh City which schooling during the study course.

Exclusion criteria:
Elementary students over 12 years of age or under 10 years of age

Age
From **10 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple Random Cluster Lottery: Randomization is done using a simple random clustering method whose classes include four regions of the north, south, east and west of the city of Baneh and in each class each school is considered as a cluster, which these clusters, four schools (clusters) will be selected for each region which has two schools (one for boys and one for girls) for the intervention group and two schools (one for boys and one for girls) will also be for the control group. In each district there are 4 schools and in total in the whole city of Baneh, 16 schools will be selected. Given that the total number of non-profit primary schools is 4 schools whether or not they choose to influence the outcome of the study will not be effective, therefore to prevent their potential confounding effect, selection of the above schools abandoned and all elementary state schools that include 48 schools will be selected. excluded from the selection of these schools and all elementary state schools that include 48 School will be selected.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Designing a study based on intervention mapping approach which has six steps.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of tehran University of Medical Sciences

Street address
Poursina Street, Quds Ave, Keshavarz Boulevard, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2018-06-13, 1397/03/23

Ethics committee reference number
IR.TUMS.SPH.REC.1397.031

Health conditions studied

1

Description of health condition studied
Development, implementation and evaluation of an intervention to improve food and nutrition literacy among 10-12 years-old school children of Baneh using Intervention Mapping approach

ICD-10 code
Z55.8

ICD-10 code description
Other problems related to education and literacy
Inadequate teaching

Primary outcomes

1

Description
Improve food and nutrition literacy among 10-12 years-old school children of Baneh using Intervention Mapping approach

Timepoint
Measuring food and nutrition literacy at the beginning of the study ,3 and 6 months after the intervention .

Method of measurement
Standard questionnaire

2

Description
Weight

Timepoint
Measuring weight at the beginning of the study ,3 and 6 months after the intervention .

Method of measurement
Digital Sohenle Scale with 100g accuracy

3

Description
Height
Timepoint
Measuring height at the beginning of the study ,3 and 6 months after the intervention .
Method of measurement
Strip meter

Secondary outcomes

1

Description
Improve food and nutrition literacy among 10-12 years-old school children
Timepoint
0,3&6 Month
Method of measurement
Questionnaire

2

Description
Weight
Timepoint
0,3&6 Month
Method of measurement
Digital Sohenle Scale with 100g accuracy

3

Description
Height
Timepoint
0,3&6 Month
Method of measurement
Strip meter

Intervention groups

1

Description
Intervention group: Theory-based interventions based on SCT theory and the needs assessments that have been taken before the study begins and the level of food and nutrition literacy, weight and height before intervention and 3 and 6 months after the intervention.
Category
N/A

2

Description
Control group: The control group will not intervene and only level of food and nutrition Literacy , weight and height were measured baseline and 3, 6 months after the intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Elementary schools in Baneh city
Full name of responsible person
Mohammad Ahmadpour
Street address
No 76835,Taban Alley10,Shahid Motahari St
City
Baneh
Province
Kurdistan
Postal code
6691776835
Phone
+98 87 3426 6817
Fax
+98 21 4293 3072
Email
moahmadpour5885@gmail.com
Web page address
http://www.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeiyan
Street address
Poursina Street, Quds Ave, Keshavarz Boulevard, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
Fax
+98 21 8163 3623
Email
name@domian.com
Web page address
https://www.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source

School of Public Health, Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Ahmadpour

Position
Ph.D student

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

Street address
No 76835,Taban Alley10,Shahid Motahari St,Baneh, Kurdistan, Iran

City
Baneh

Province
Kurdistan

Postal code
6691776835

Phone
+98 87 3426 6817

Fax
+98 21 4293 3072

Email
moahmadpour5885@gmail.com

Web page address
http://www.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Elham Shakibazeh

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

Street address
School of Public Health, Poursina Street, Quds Ave, Keshavarz Boulevard, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1417613151

Phone
+98 21 4293 3333

Fax
+98 21 4293 3072

Email
shakibazadeh@sina.tums.ac.ir

Web page address
http://www.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Ahmadpour

Position
Ph.D Student

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

Street address
School of Public Health, Poursina Street, Quds Ave, Keshavarz Boulevard, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1417613151

Phone
+98 21 4293 3210

Fax
+98 21 4293 3072

Email
moahmadpour5885@gmail.com

Web page address
http://www.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

Analytic Code

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

Data Dictionary

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