

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of an educational intervention based on the TransTheoretical Model on dairy consumption of girl students of 10th and 11th grade

Protocol summary

Study aim

Determining the effect of educational intervention based on transtheoretical model on dairy consumption of 10th and 11th grade female students in Sowmehsara public schools

Design

A clinical trial with a control and intervention group, with parallel, non-randomized groups of 49 people in each group and due to the limited number of selected clusters, random allocation is not possible.

Settings and conduct

The place of study is the city of Sowmehsara. The city of Soomehsara has 2 public girls' schools in the second grade of high school. Two classes from Narjes School for control (49 people) and 2 classes from Afaf School for intervention group (49 people). The students of the intervention group are divided into 4 groups of 12-12 people. The educational content of each session will include general and specific trainings. One month after the educational intervention, the questionnaires are completed again by the students of the intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: employment in the tenth and eleventh grade, having the consent to participate in the study
Exclusion criteria: Having a special diet related to the consumption of dairy products prescribed by a specialist according to the student statement

Intervention groups

Intervention group: Educational intervention in 4 sessions that will be about all structures according to the need and low scores directly and using the lecture method, participatory methods such as question and answer activation, group discussion and brainstorming.
Control group: During the intervention and one month of follow-up, the control group will not receive training and after completing the study, educational booklets will be provided to them.

Main outcome variables

Dairy consumption status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200718048132N1**

Registration date: **2020-11-04, 1399/08/14**

Registration timing: **retrospective**

Last update: **2020-11-04, 1399/08/14**

Update count: **0**

Registration date

2020-11-04, 1399/08/14

Registrant information

Name

Nooshin Rouhani tonkaboni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3384 9411

Email address

nrouhani@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-05, 1399/06/15

Expected recruitment end date

2020-09-12, 1399/06/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of an educational intervention based on the TransTheoretical Model on dairy consumption of girl students of 10th and 11th grade

Public title
The effect of an educational intervention based on the TransTheoretical Model on dairy consumption of girl students

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Study in the tenth and eleventh grades Having the consent to participate in the study
Exclusion criteria:
Having a special diet related to the consumption of dairy products prescribed by a specialist, according to the student statement

Age
From **15 years** old to **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Not 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
Research Ethics Committee of Guilan University of Medical Sciences
Street address
Former building of the Azad University - Rasht School of Health (new building)- Behind of the building of the Radio and Television Organization-- Resalat St- Rasht-Islamic Republic of Iran.
City
rasht

Province
Guilan
Postal code
4185733411
Approval date
2020-07-01, 1399/04/11
Ethics committee reference number
IR.GUMS.REC.1399.132

Health conditions studied

1

Description of health condition studied
The effect of an educational intervention based on the TransTheoretical Model on dairy consumption of students
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Dairy consumption status
Timepoint
Before the intervention and one month after the intervention
Method of measurement
questionnaire

Secondary outcomes

1

Description
Student Awareness Score
Timepoint
Before the intervention and one month after the intervention
Method of measurement
Using a researcher-made questionnaire (12 questions)

2

Description
Student change process score
Timepoint
Before the intervention and one month after the intervention
Method of measurement
Using a researcher-made questionnaire (20 questions)

3

Description
Student decision balance score
Timepoint
Before the intervention and one month after the intervention
Method of measurement
Using a researcher-made questionnaire (17 questions)

4

Description

Students' self-efficacy score

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Using a researcher-made questionnaire (10 questions)

Intervention groups

1

Description

Intervention group: In the case of educational intervention, the training program will be held once a week for 30-45 minutes. In this intervention, all of the constructs, based on the research requirements and low scores regarding them, will be taught directly through employing lecture method, appropriate participatory methods such as question and answer activation, group discussion. The educational content of each session will include general and specific training according to the stages of students' change in dairy consumption. General training strategies in the program include: Drawing attention to the program through informing participants regarding the recommended amount of milk and its products, the importance of its consumption during adolescence and the side effects resulting from lack of its consumption. Specific training is based on improving the constructs of trans-theoretical model regarding self-efficacy, change processes (cognitive and behavioral) and decisional balance (perceived barriers and benefits), and the stages of subjects' change. General topics of educational materials include: The importance of nutrition during adolescence, the food pyramid and the role of each group in body health, the importance and role of milk and its products in body health, the role of calcium in the body, the side effects of insufficient calcium intake, the role of dairy in preventing osteoporosis, diseases related to low consumption of dairy products, benefits of dairy consumption on body health, perceived barriers regarding dairy consumption, ways of overcoming barriers considering dairy consumption and increasing self-awareness, environmental reevaluation, self-reappraisal, self-liberation, counterconditioning, reinforcement management, stimulus control, helping relationships, social liberation, and perceived ways to enhance perceived self-efficacy for increasing dairy consumption.

Category

Behavior

2

Description

Control group: During the intervention and one month of follow-up, the control group will not receive training and after the intervention, educational booklets will be provided to them.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Efaf High School

Full name of responsible person

Shahla Fazel Toulami

Street address

Broshnavard St., Hosseini Panah St.

City

sowmesara

Province

Guilan

Postal code

4361957674

Phone

+98 13 4432 8599

Email

shahlafa2013@gmail.com

2

Recruitment center

Name of recruitment center

Narjes High School

Full name of responsible person

Leila Faizi Khakiani

Street address

Jafari Street, in front of Mosalla

City

sowmesara

Province

Guilan

Postal code

4331666419

Phone

+98 13 4432 3150

Email

h.nejadhoseini@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Reza Naghipour

Street address

Vice Chancellor for Research and Technology-
Opposite to 17 Shahrivar Hospital - Old Building of the
Faculty of Health -Shahid Siadati St-Namjoo St

City

rasht

Province

Guilan

Postal code

4193713111

Phone

+98 13 3333 5821

Fax

+98 13 3333 6395

Email

research@gums.ac.ir

Web page address

http://www.gums.ac.ir/research/default.aspx?tabid=303

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

30

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 scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Noushin Rouhani Tonekaboni

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Former building of Azad University - Rasht School of Health (new building)-Behind the building of the Radio and Television Organization-Resalat St

City

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Guilan

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4185733411

Phone

+98 13 3384 9411

Email

nrouhani@gums.ac.ir

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Noushin Rouhani Tonekaboni

Position

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nrouhani@gums.ac.ir

Web page address

http://www.gums.ac.ir/healthschool/default.aspx?tabid=381

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Noushin Rouhani Tonekaboni

Position

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Latest degree

Ph.D.

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information on the frequency distribution of students in
the stages of changing dairy consumption, student

awareness, change process, decision balance and self-
efficacy
**When the data will become available and for how
long**
6 months after printing the results
To whom data/document is available
University professors and students
Under which criteria data/document could be used
For similar studies
From where data/document is obtainable
By contacting the email nrouhani@gums.ac.ir
**What processes are involved for a request to access
data/document**
By contacting the email nrouhani@gums.ac.ir
Comments