

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 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**

rasht

**Province**

Guilan

**Postal code**

4185733411

**Phone**

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**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**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

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**Email**

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**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

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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**