

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effect of an educational intervention based on Health Belief Model on promotion of Osteoporosis preventive behaviors in students

#### Protocol summary

##### Summary

The purpose of current study is empower students against osteoporosis. This study is a Quasi-experimental study. Participants will be selected from first intermediate period students. The main inclusion criteria include schooling in first intermediate period, consent to participate in the study and lack of formal education about prevention of osteoporosis and exclusion criteria include refusal for participation in the study and absence of more than one session in the educational program. The sample size was obtained 73 persons for each group, of course considering probability of loss of patients around 10%; the sample size will be 88 persons for each group. After selecting the intervention and control groups, the data will be collected in two stages: the first phase of data collection will be before the intervention and the second stage 3 months after the intervention. Data will be collected using a questionnaire of based on the health belief model. In the stage before the intervention, the pre-test will be done in both intervention and control groups ,and after analyzing the data are identified resources, limitation, needs, and strengths and weaknesses in different fields and then type of content, teaching methods, time and the number of educational sessions are designed based on the health belief model structures. Outcome of the study is osteoporosis preventive behaviors in students, before and after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016021315422N6**

Registration date: **2016-03-02, 1394/12/12**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-03-02, 1394/12/12

##### Registrant information

###### Name

Towhid Babazadeh

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8877 9118

###### Email address

t-babazadeh@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical Science

##### Expected recruitment start date

2016-04-02, 1395/01/14

##### Expected recruitment end date

2016-12-20, 1395/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of an educational intervention based on Health Belief Model on promotion of Osteoporosis preventive behaviors in students

##### Public title

The Effect of Education on the Promotion of Osteoporosis Preventive Behaviors in Students

##### Purpose

Prevention

## Inclusion/Exclusion criteria

The main criteria of inclusion in the study are: schoolfellow in first intermediate period; consent to participate in the study ; lack of formal education about prevention of osteoporosis. Exclusion criteria are: the absence of more than one session in the training program; refusal for participation in the study

### Age

From **13 years** old to **15 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **176**

### Randomization (investigator's opinion)

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

Tehran University of Medical Sciences

##### Street address

Sixth Floor, Central University, St. Ghods, Keshavarz Boulevard

##### City

Tehran

##### Postal code

#### Approval date

2016-02-10, 1394/11/21

#### Ethics committee reference number

IR.TUMS.REC.1394.1939

## Health conditions studied

### 1

#### Description of health condition studied

Osteoporosis

#### ICD-10 code

M81

#### ICD-10 code description

Osteoporosis without pathological fracture

## Primary outcomes

### 1

#### Description

Preventive behaviors

#### Timepoint

Before the intervention and 3 months after intervention

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Perceived susceptibility toward osteoporosis

#### Timepoint

Before the intervention and 3 months after intervention

#### Method of measurement

Questionnaire

### 2

#### Description

Perceived severity of toward osteoporosis

#### Timepoint

Before the intervention and 3 months after intervention

#### Method of measurement

Questionnaire

### 3

#### Description

Perceived benefits toward osteoporosis

#### Timepoint

Before the intervention and 3 months after intervention

#### Method of measurement

Questionnaire

### 4

#### Description

Perceived barriers toward osteoporosis

#### Timepoint

Before the intervention and 3 months after intervention

#### Method of measurement

Questionnaire

### 5

#### Description

Self-efficacy toward osteoporosis

#### Timepoint

Before the intervention and 3 months after intervention

#### Method of measurement

Questionnaire

### 6

#### Description

Knowledge toward osteoporosis

#### Timepoint

Before the intervention and 3 months after intervention  
**Method of measurement**  
Questionnaire

## Intervention groups

### 1

#### Description

The Intervention group: in this study the intervention will be holding the training sessions. The intervention would be based on information obtained from the questionnaire.

#### Category

Behavior

### 2

#### Description

The control group: education in groups is not but after the end of data collection in the end of study, educational pamphlet and booklet will be given to the control group.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Education

##### Full name of responsible person

Towhid Babazadeh

##### Street address

West Azerbaijan, Chladoran, Moallem Square, The education of Chladoran

##### City

Chladoran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Vida Kardanmoghaddam

##### Street address

Tehran University of Medical Sciences, Ghods street, Tehran

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tehran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Soheila Ranjbaran

##### Position

Student

##### Other areas of specialty/work

##### Street address

Department of Health Education and Promotion, Faculty of Health, Tehran University of Medical Sciences, Ghods Street, Tehran

##### City

Tehran

##### Postal code

##### Phone

+98 21 8877 9118

##### Fax

##### Email

ranjbaran3637@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Towhid Babazadeh

##### Position

Student

##### Other areas of specialty/work

##### Street address

Department of Health Promotion and Education, Faculty of Health and Nutrition, Golgashte Street, Tabriz Tabriz

##### City

Tabriz

##### Postal code

##### Phone

+98 41 3335 7582

##### Fax

##### Email

towhid.babazadeh@gmail.com

##### Web page address

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Towhid Babazadeh

**Position**

PhD student

**Other areas of specialty/work****Street address**

Department of Health Promotion and Education,  
Faculty of Health and Nutrition, Golgashte Street,  
Tabriz

**City**

Tabriz

**Postal code****Phone**

+98 41 3335 7582

**Fax****Email**

towhid.babazadeh@gmail.com

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*