

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### The effect of two educational interventions on the knowledge and self-reported practice of 10-13-year-old elementary school students towards traumatic dental injuries

#### Protocol summary

##### Study aim

Evaluation of the effect of two educational intervention methods (flashcard and application) in relation to traumatic dental injuries on the awareness and self-expression performance of 10-13-year-old elementary school students.

##### Design

Clinical trial without a control group, with two parallel groups, without blinding, randomized, on 280 participants. Random number table and flipping a coin will be used for randomization.

##### Settings and conduct

Interventions will be performed on adolescent students in Tehran in three phases: baseline, intervention, and final, which last for three months. A questionnaire will be used for gathering data on outcome changes.

##### Participants/Inclusion and exclusion criteria

Entry condition: the age of the student is between 10-13 years old, the parents or the student have consented to participate in the study, and the student or his parents have a smartphone with Android operating system. Exclusion condition: the student does not have the ability to understand the questions in the questionnaire, the parents or the student do not want to participate in the study, and the student does not have access to a smartphone.

##### Intervention groups

Intervention 1: educational flash cards; Intervention 2: educational application in Android mobile phone. The educational content of both interventions will be similar to each other on the importance of preventing dental injuries and appropriate action when dental injuries occur which will be prepared with colorful pictures and based on the latest scientific evidence. The interventions will be presented to two groups of participants: an educational flashcard package and an Android application. In both groups, 45 days after receiving the intervention, a

reminder will be sent to the students.

##### Main outcome variables

Knowledge score changes; self-reported practice score changes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130617013695N5**

Registration date: **2022-11-28, 1401/09/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-11-28, 1401/09/07**

Update count: **0**

##### Registration date

2022-11-28, 1401/09/07

##### Registrant information

##### Name

Samaneh Razeghi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8801 5960

##### Email address

s-razeghi@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-06, 1401/08/15

##### Expected recruitment end date

2023-02-04, 1401/11/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of two educational interventions on the knowledge and self-reported practice of 10-13-year-old elementary school students towards traumatic dental injuries

**Public title**

Effect of education on prevention of traumatic dental injuries

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

The age of the student was between 11 - 15 years old  
The student or his/her parents have satisfied with participating in the study  
The student or his/her parents have a cellphone with Android system

**Exclusion criteria:**

The student does not have the ability to understand the questionnaire questions  
Parents or students do not want to participate in the study  
The student does not have access to a smartphone

**Age**

From **10 years** old to **13 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **280**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A list of girls' and boys' elementary schools covered by the Tehran University of Medical Sciences in Tehran will be prepared. From this list, two girls' primary schools and two boys' primary schools will be randomly selected as strata. Again, from the fourth to the sixth grades of each primary school, two classes will be defined as a cluster. Allocation of the intervention to these four primary schools will be done randomly and by a coin toss: in two primary schools (one for girls and one for boys) it will be in the form of educational flash cards and in the other two primary schools (one for girls and one for boys) it will be in the form of an educational application.

**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 Committees of School of Dentistry-  
Tehran University of Medical Sciences

**Street address**

School of Dentistry, Tehran University of Medical  
Sciences, North Kargar Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1439955991

**Approval date**

2022-05-28, 1401/03/07

**Ethics committee reference number**

IR.TUMS.DENTISTRY.REC.1401.030

**Health conditions studied****1****Description of health condition studied**

Traumatic dental injuries

**ICD-10 code**

S02.5

**ICD-10 code description**

Fracture of tooth

**Primary outcomes****1****Description**

changes in knowledge score gained by questionnaire

**Timepoint**

Measuring knowledge score at the baseline (before  
intervention) and three months after intervention

**Method of measurement**

Based on scores obtained from knowledge questions in  
the standardized questionnaire for assessing athletes'  
knowledge about traumatic dental injuries

**2****Description**

changes in self-reported practice score gained by  
questionnaire

**Timepoint**

Measuring self-reported practice score at the baseline  
(before intervention) and three months after intervention

**Method of measurement**

Based on scores obtained from self-reported practice  
questions in the standardized questionnaire for assessing

athletes' self-reported practice about traumatic dental injuries

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first intervention group: a package containing educational flash cards with color pictures regarding the prevention of dental injuries is prepared based on the latest evidence and scientific guidelines. This package has information for students in two parts: 1- Proper management of dental injuries after they occur, including soft tissue damage, crown fracture, tooth loss, dental avulsion, and alveolar bone fracture, and 2- Methods of preventing dental injuries in teenagers, including the use of mouth guard and its types. At baseline and after collecting filled-out questionnaires by participants, the educational flash cards will be distributed among participants in the flash card group. The flash cards will remain with the students. A month and a half after the flash cards distribution, a reminder will be sent again to the athletes as a reminder.

#### Category

Prevention

### 2

#### Description

Intervention group 2: An educational application on prevention of Traumatic Dental Injuries (TDIs) in Android operating system, will be designed based on on the latest evidence and scientific guidelines with similar content to the pamphlet. As same as flash cards, the application provides information for students in two parts: 1- proper TDIs' management after occurrence including soft tissue damage, crown fracture, tooth luxation, tooth avulsion, and alveolar bone damage, and 2- preventive measurements on TDIs in sports including mouth guard usage and different types of this appliance. At baseline, after collecting filled out questionnaire by participants, the link to access the application in Miket, the Iranian application market, will be sent to the students or thier parents via SMS. Students will be asked to contact one of the study researchers if they have problems in installing or using the app. A month and a half after sending the link, a notification designed in the app will be sent to students as a reminder .

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

School of Dentistry, Tehran University of Medical Sciences

#### Full name of responsible person

Samaneh Razeghi

#### Street address

North Kargar St.

#### City

Tehran

#### Province

Tehran

#### Postal code

1439955991

#### Phone

+98 21 8801 5960

#### Fax

+98 21 8801 5961

#### Email

s-razeghi@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Akbar Fotoohi

##### Street address

Vice Chancellor for Research and Technology, sixth floor, University Central Building, corner of Quds Str., Keshavarz Blvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

1439955991

##### Phone

+98 21 8163 3685

##### Fax

+98 21 8898 9664

##### Email

pajoheshi-ece@sina.tums.ac.ir

##### Web page address

##### 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

Public

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Samaneh Razeghi

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

School of Dentistry, Tehran University of Medical Sciences, North Kargar Str.

**City**

Tehran

**Province**

Tehran

**Postal code**

1439955991

**Phone**

+98 21 8801 5960

**Fax**

+98 21 8801 5961

**Email**

s-razeghi@tums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Samaneh Razeghi

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

School of Dentistry, Tehran University of Medical Sciences, North Kargar Str.

**City**

Tehran

**Province**

Tehran

**Postal code**

1439955991

**Phone**

+98 21 8801 5960

**Fax**

+98 21 8801 5961

**Email**

s-razeghi@tums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Samaneh Razeghi

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

School of Dentistry, Tehran University of Medical Sciences, North Kargar Str.

**City**

Tehran

**Province**

Tehran

**Postal code**

1439955991

**Phone**

+98 21 8801 5960

**Fax**

+98 21 8801 5961

**Email**

s-razeghi@tums.ac.ir

## 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**

Undecided - It is not yet known if there will be 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**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

After making people unrecognizable, the study protocol, information on the main outcomes (Knowledge and practice), informed consent form, and report of the study will be shareable.

**When the data will become available and for how long**

Initiation of access: from the publication of the manuscript

**To whom data/document is available**

Researchers in academic and scientific organizations; Education departments; Parents and students

**Under which criteria data/document could be used**

Access to data and documents would be possible by sending a request email to the main researcher.

**From where data/document is obtainable**

Sending email to Dr. Samaneh Razeghi (s-razeghi@tums.ac.ir)

**What processes are involved for a request to access data/document**

Sending email to Dr. Samaneh Razeghi (s-razeghi@tums.ac.ir)

**Comments**