

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)

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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

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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.

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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

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Person responsible for scientific inquiries

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Other areas of specialty/work

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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

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