Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

To determine the effect of two types of educational interventions including pamphlet and mobile application on traumatic dental injuries on the knowledge and self-reported performance of marital arts athletes aged 11-15 years

Protocol summary

Study aim
Evaluation of the changes in the knowledge, and self-reported practice of 11-15-year-old adolescent athletes' regarding prevention of traumatic dental injuries following to two interventions of educational pamphlet and mobile application

Design
Clinical trial without control group, with two parallel groups, without blinding, randomized, on 92 participants. Random number table and flipping a coin will be used for randomization.

Settings and conduct
Interventions will be performed on adolescent martial arts athletes in Tehran in three phases: baseline, intervention and final, which last for three months. A questionnaire will be used for gathering data on outcomes changes.

Participants/Inclusion and exclusion criteria
Participants are of both sexes. Participants are in age range 11-15. Participants are involved in martial arts. Participants have a smartphone with Android operating system

Intervention groups
Intervention 1:educational pamphlet; 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 pamphlet and an Android application. In both groups, 45 days after receiving the intervention, a reminder will be sent to the athletes (the same pamphlet in pamphlet group and sending a notification to mobile phones in application group).

Main outcome variables
Knowledge score changes; self-reported practice score changes

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130617013695N4**
Registration date: **2022-04-22, 1401/02/02**
Registration timing: **retrospective**

Last update: **2022-04-22, 1401/02/02**
Update count: **0**
Registration date
2022-04-22, 1401/02/02

Registrant information
Name
Samaneh Razeghi
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-08-22, 1399/06/01
Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To determine the effect of two types of educational interventions including pamphlet and mobile application on traumatic dental injuries on the knowledge and self-reported performance of marital arts athletes aged 11-15 years

Public title

Effect of education on prevention of traumatic dental injuries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The participant should practice in one of the martial arts The age of the athlete was between 11 - 15 years old The athlete or his/her parents have satisfied with participating in the study The athlete or his/her parents have a cellphone with Android system

Exclusion criteria:

Age

From **11 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

From the list of martial arts clubs provided by the Sports Medicine Federation, two clubs with athletes of both sexes will be randomly selected as clusters using a random number table. From the list of athletes in each club and based on the gender, two strata will be defined. Using a table of random numbers, 23 boys and 23 girls (46 people in total) will be selected. The allocation of intervention to these two clubs will be done randomly by flipping a coin; so that one club will receive an educational pamphlet and the other club will receive 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

Ethics Committee of School of Dentistry- Tehran University of Medical Sciences

Street address

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

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تهران

Province

Tehran

Postal code

1439955991

Approval date

2020-05-09, 1399/02/20

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1399.016

Health conditions studied

1

Description of health condition studied

Traumatic dental injuries

ICD-10 code

S02.5

ICD-10 code description

Fracture of tooth (traumatic)

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

Intervention group 1: An educational colorful pamphlet on prevention of Traumatic Dental Injuries (TDIs) will be designed based on on the latest evidence and scientific guidelines. This pamphlet provides information for athletes in two parts: 1- preventive measurements on TDIs in sports including mouth guard usage and different types of this appliance, and 2- proper TDIs' management after occurrence including soft tissue damage, crown fracture, tooth luxation, tooth avulsion, and alveolar bone damage. At baseline and after collecting filled out questionnaires by participants, the educational pamphlet will be distributed among participants in pamphlet group. The pamphlets will remain with the athletes. A month and a half after the first pamphlet, the same pamphlet 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 pamphlet, the application provides information for athletes in two parts: 1- preventive measurements on TDIs in sports including mouth guard usage and different types of this appliance, and 2- proper TDIs' management after occurrence including soft tissue damage, crown fracture, tooth luxation, tooth avulsion, and alveolar bone damage. 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 athletes via WhatsApp. Athletes 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 athletes 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, Ali Esmaeilpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Academic

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
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Other areas of specialty/work
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Person responsible for updating data

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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, 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; Athletes
Under which criteria data/document could be used
access to data and documents would be possible through sending 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