

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Designing, implementing and evaluating a virtual educational program to promote the oral health of 12-year-old students

#### Protocol summary

##### Study aim

Designing, implementing and evaluating a virtual educational program to promote the oral health of 12-year-old students.

##### Design

A clinical trial with a control group, multi-stage cluster sampling, un-blinded and randomized on 168 students

##### Settings and conduct

After obtaining the necessary permits from the education authorities, the list of girls' and boys' primary schools in Hamadan's education areas will be received first. Then three girls' schools and three boys' schools will be randomly selected for study. In the next step, schools will be randomly divided into intervention and control groups. Then, referring to the selected schools, one class will be randomly selected from among the sixth grade classes of each school.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 12 years old, eruption of all permanent teeth, willingness to participate in the study. Exclusion criteria: Having an orthodontic appliance, having Oral Mucous lesions, needing any emergency dental treatment and having movement restriction

##### Intervention groups

Intervention group 1: Using the designed mobile application  
Intervention group 2: face to face training  
Control group: no training

##### Main outcome variables

Knowledge: Knowledge in the field of oral health.  
Behavior: Self-care behaviors in the field of oral health.  
Community Periodontal Index: Evaluation of periodontal condition based on presence of calculus, gingival bleeding and presence of periodontal pocket. Simplified Oral Hygiene Index: Evaluation of dental debris and calculus based on the involved surfaces of index teeth  
Plaque index: Evaluation of plaque on dental surfaces

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230313057708N1**

Registration date: **2023-04-25, 1402/02/05**

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

Last update: **2023-04-25, 1402/02/05**

Update count: **0**

##### Registration date

2023-04-25, 1402/02/05

##### Registrant information

##### Name

Zeinab Mosayebi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 1059

##### Email address

zm.mosayebi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-25, 1402/02/05

##### Expected recruitment end date

2023-09-22, 1402/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Designing, implementing and evaluating a virtual educational program to promote the oral health of 12-year-old students

#### Public title

Effect of application in promotion of oral health

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

12 years old Eruption of all permanent teeth Having an android phone or tablet Willingness to participate in study Parental consent

##### Exclusion criteria:

Having an orthodontic appliance Having Oral Mucous Lesions Needing any emergency dental treatment Having movement restriction

#### Age

From **12 years** old to **12 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **168**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The sampling method in this study is a multi-stage cluster. Sampling will be done using a table of random number. For this purpose, the list of all primary schools for girls and boys will be received from education department of Hamadan city and each school will be given a two-digit code (code 01 to 57 for boy's schools and code 01 to 68 for girl's schools). To select girl's schools, refer to the table of random numbers and the starting point will be selected. The starting point will be done by closing the eyes and placing a finger or the tip of the pen on the table. Then, based on adjacent two-digit numbers, it will move in the direction of the line. In this path, two types of numbers are encountered, one of which is smaller than the total number of girl's schools and the other is larger than the number of schools. Only smaller numbers will be selected for sampling. The selected number is actually the school code that is selected as a sample. The first number will be considered as intervention school 1, the second number will be intervention school 2 and the third number will be considered as control school. After completing the sampling of girl's schools, the same will be repeated for the selection of boy's schools. In order to select the classes, one class will be selected from the list of sixth grade classes in each school using a table of random numbers (like the method of choosing schools) and all students of that class will enter the study based on having the inclusion and exclusion criteria.

#### 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 Hamadan University of Medical Sciences

##### Street address

4th floor, Headquarters of the University of Medical Sciences, Shahid Fahmideh St., Pajuhesh square

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838636

#### Approval date

2023-03-04, 1401/12/13

#### Ethics committee reference number

IR.UMSHA.REC.1401.1041

## Health conditions studied

### 1

#### Description of health condition studied

Oral Health

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Knowledge: Having knowledge in the field of oral and dental health

#### Timepoint

At the beginning of the study and 12 weeks later

#### Method of measurement

Knowledge standard questionnaire

### 2

#### Description

Percentage of people who brushed twice a day with a toothpaste containing fluoride

#### Timepoint

At the beginning of the study and 12 weeks later

#### Method of measurement

Behavior standard questionnaire

### 3

#### **Description**

Use dental floss at least once a day

#### **Timepoint**

At the beginning of the study and 12 weeks later

#### **Method of measurement**

Behavior standard questionnaire

### 4

#### **Description**

Mouthwash use

#### **Timepoint**

At the beginning of the study and 12 weeks later

#### **Method of measurement**

Behavior standard questionnaire

## **Secondary outcomes**

### 1

#### **Description**

The percentage of dental plaque in each person

#### **Timepoint**

At the beginning of the study and 12 weeks later

#### **Method of measurement**

Clinical examination by a dentist

### 2

#### **Description**

Determining the rate of periodontal tissue health of each person

#### **Timepoint**

At the beginning of the study and 12 weeks later

#### **Method of measurement**

Clinical examination by a dentist

### 3

#### **Description**

Determining the rate of dental debris and calculus in each person

#### **Timepoint**

At the beginning of the study and 12 weeks later

#### **Method of measurement**

Clinical examination by a dentist

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: The educational program in this group will be using the mobile application. Application design sessions will be held face-to-face and virtually with the participation of dental professors and student, software engineers and a number of 12-year-old students. In this application, 10 educational programs will be placed and students can use its contents during one month. Students will be trained in the following topics: the importance of oral hygiene, familiarity with

tooth structure and periodontal structure, awareness of oral and dental diseases (decay and periodontal diseases) and their causes, ways to prevent oral and dental diseases. Also, in this application, students will be able to ask their questions about oral and dental health issues and they will be answered. Also, a brochure will be prepared for mothers, which will provide tips on the importance of oral hygiene and its role in public health, and the goals and implementation of the intervention program.

#### **Category**

Prevention

### 2

#### **Description**

Intervention group 2: The educational program in this group will include 6 face-to-face training sessions for students during a month. Also, a brochure will be prepared for mothers, which will provide tips on the importance of oral hygiene and its role in public health, and the goals and implementation of the intervention program. Interventions in students will be done with 10 educational videos. Students will be trained in the following topics: the importance of oral hygiene, familiarity with tooth structure and periodontal structure, awareness of oral and dental diseases (decay and periodontal diseases) and their causes, ways to prevent oral and dental diseases. A group called "Oral Health" will be created in Rubika messenger and the members of this group will consist of students, their families, teachers and principals of each school, professor of social dentistry and dental student. In this group, member's questions about oral health issues will be answered.

#### **Category**

Prevention

### 3

#### **Description**

Control group: Receive routine programs and training in school.

#### **Category**

Prevention

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Sabrian Ranjbar Primary School

##### **Full name of responsible person**

Masoume Ebrahimi Hajir

##### **Street address**

Hakim St., Ostadan

##### **City**

Hamadan

##### **Province**

Hamadan

##### **Postal code**

6513817433

**Phone**

+98 81 3822 1277

**Email**

prm@medu.ir

**2**

**Recruitment center**

**Name of recruitment center**

Shahid Ahmed Karmi Primary School

**Full name of responsible person**

Azize Malmir

**Street address**

18 meters away from Sadeghieh, Dr. Chamran Blvd.,

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6513817433

**Phone**

+98 81 3823 9300

**Email**

prm@medu.ir

**3**

**Recruitment center**

**Name of recruitment center**

Shahid Oshtad Primary School

**Full name of responsible person**

Fahima Mohammadi Ezzati

**Street address**

Azadi St., Dr. Chamran Town

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6010738448

**Phone**

+98 81 3835 5227

**Email**

prm@medu.ir

**4**

**Recruitment center**

**5**

**Recruitment center**

**Name of recruitment center**

Attar primary school

**Full name of responsible person**

Sefat-o-allah Attar

**Street address**

Roodkhane Alley, Rokni Entrance, Besat Square

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6516795835

**Phone**

+98 81 3822 0490

**Email**

prm@medu.ir

**6**

**Recruitment center**

**Name of recruitment center**

Hor Riyahi primary school

**Full name of responsible person**

Iraj Torabian

**Street address**

Mohamadieh St., Saeidieh

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6516948331

**Phone**

+98 81 3822 4191

**Email**

prm@medu.ir

**7**

**Recruitment center**

**Name of recruitment center**

Mino primary school

**Full name of responsible person**

Alireza Aliverdi

**Street address**

Tohid St., 600 dastgah

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6518733333

**Phone**

+98 81 3424 7151

**Email**

prm@medu.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Reza Shokoohi

**Street address**

4th floor, Headquarters of Hamadan University of medical science, Shahid Fahmideh Boulevards

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**Phone**  
+98 81 3131 4058  
**Email**  
Fanavari@umsha.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Hamedan 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**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Zeinab Mosayebi  
**Position**  
Student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
School of Dentistry, Hamedan University of Medical Science, Shahid Fahmide Blvd.  
**City**  
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**Postal code**  
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**Phone**  
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## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Zeinab Mosayebi

**Position**  
Student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Zeinab Mosayebi  
**Position**  
Student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
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**Street address**  
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Hamadan  
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**Email**  
zm.mosayebi@yahoo.com

## 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**

All data is potentially shareable after de-identifying individuals

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

The access period starts 6 months after the results are published

**To whom data/document is available**

The data will be available only to researchers working in

academic and scientific institutions

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

People who intend to use the study data for review articles and meta-analysis

**From where data/document is obtainable**

Zeinab Mosayebi emails

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

After checking the requester's email by Zeinab Mosayebi, if the conditions are met, the data will be sent to them 3 days later.

**Comments**