

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 <i>No information</i> 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 <u>1</u> 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 <u>1</u> Description of health condition studied Oral Health ICD-10 code ICD-10 code description Primary outcomes <u>1</u> 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 <u>2</u> 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
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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

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3

Recruitment center

Name of recruitment center

Shahid Oshtad Primary School

Full name of responsible person

Fahima Mohammadi Ezzati

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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

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Mohamadieh St., Saeidieh

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Province

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6516948331

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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

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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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Hamedan

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Postal code
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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
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Latest degree
 A Level or less
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Phone
 +98 81 3838 1059
Fax
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	academic and scientific institutions
Data Dictionary	Under which criteria data/document could be used
Yes - There is a plan to make this available	People who intend to use the study data for review
Title and more details about the data/document	articles and meta-analysis
All data is potentially shareable after de-identifying individuals	From where data/document is obtainable
When the data will become available and for how long	Zeinab Mosayebi emails
The access period starts 6 months after the results are published	What processes are involved for a request to access data/document
To whom data/document is available	After checking the requester's email by Zeinab Mosayebi, if the conditions are met, the data will be sent to them 3 days later.
The data will be available only to researchers working in	Comments