Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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+98 81 3838 1059
Email address
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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
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Hakim St., Ostadan
City
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Hamadan
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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
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Province
Hamadan

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6513817433

Phone
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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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Province
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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

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6516795835

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6

Recruitment center

Name of recruitment center
Hor Riyahi primary school

Full name of responsible person
Iraj Torabian

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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

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Province
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Email
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Phone
+98 81 3131 4058
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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
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School of Dentistry, Hamedan University of Medical Science, Shahid Fahmide Blvd.
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Person responsible for scientific inquiries

Contact
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Position
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Latest degree
A Level or less
Other areas of specialty/work
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Latest degree
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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
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