

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Effect of health educational program on promoting oral health among elementary school students: Developing an educational model

#### Protocol summary

##### Study aim

this study aimed to evaluate the effect of oral health promotion program on oral health elementary school students and presenting an educational model.

##### Design

Clinical trial with control group, with parallel groups, randomized, on 190 students.

##### Settings and conduct

This study was conducted in girls' schools in Hamadan city. 190 female students were selected and included in the study by multi-stage cluster sampling method. Educational interventions were implemented in the form of 10 educational sessions for students and one session for mothers for two months. The interventions were done through the game method and with the help of 7 educational videos, 3 pamphlets, 5 posters, role playing, holding a oral health celebration, and forming a telegram group. The follow-up period was three months.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Being 11-12 years old, being a girl, parents' consent to their child's participation in the study, student's consent to participate in the study.  
Exclusion criteria: Having systemic diseases, having Oral Mucosal Lesions, having orthodontics, needing any emergency dental treatment.

##### Intervention groups

The intervention consisted of an educational program based on the social cognitive theory. The control group did not receive any intervention.

##### Main outcome variables

knowledge, social cognitive theory constructs, brushing twice a day using fluoride toothpaste and flossing at least once a day and Plaque Index, Community Periodontal Index, Simplified Oral Hygiene Index.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20141128020129N2**

Registration date: **2022-10-18, 1401/07/26**

Registration timing: **retrospective**

Last update: **2022-10-18, 1401/07/26**

Update count: **0**

#### Registration date

2022-10-18, 1401/07/26

#### Registrant information

##### Name

**Name of organization / entity**

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 0511

##### Email address

s.shirahmadi@umsha.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2016-03-08, 1394/12/18

#### Expected recruitment end date

2016-06-19, 1395/03/30

#### Actual recruitment start date

2016-09-22, 1395/07/01

#### Actual recruitment end date

2017-03-19, 1395/12/29

#### Trial completion date

2017-06-20, 1396/03/30

#### Scientific title

Effect of health educational program on promoting oral health among elementary school students: Developing an educational model

#### Public title

Effect of health educational program on promoting oral health among elementary school students

#### **Purpose**

Education/Guidance

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Being 11-12 years old being a girl student's consent to participate in the study parents' consent to their child's participation in the study

##### **Exclusion criteria:**

Having systemic diseases, Having Oral Mucosal Lesions, Having orthodontics, Needing any emergency dental treatment

#### **Age**

From **11 years** old to **12 years** old

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **190**

Actual sample size reached: **190**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

. In this study, subjects were selected by multistage cluster sampling. The ministry of education classifies Hamadan into two educational regions (region one and region two). First, three girls' schools were randomly selected (each school in one of the privileged, semi-privileged, and unprivileged areas) from each educational region based on the health care availability rate. Afterward, one fifth-grade class was selected from the list of classes of each school using simple random sampling. In the end, the schools were randomly allocated to intervention and control groups after the primary evaluation of the level of plaque, gum health, oral and dental health status, and completing the questionnaire. In total, while each group of intervention and control was allocated 102 students, seven participants were removed from each group due to incomplete pretest and post-test questionnaires and the parent's lack of cooperation

#### **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**

The 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**

2016-02-13, 1394/11/24

##### **Ethics committee reference number**

IR.UMSHA.REC.1394.473

#### **Health conditions studied**

#### 1

##### **Description of health condition studied**

Dental Calculus and Debris

##### **ICD-10 code**

K03.6

##### **ICD-10 code description**

Deposits [accretions] on teeth

#### 2

##### **Description of health condition studied**

Periodontal diseases

##### **ICD-10 code**

K05

##### **ICD-10 code description**

Gingivitis and periodontal diseases

#### **Primary outcomes**

#### 1

##### **Description**

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

##### **Timepoint**

Before the start of the study, immediately after the end of the intervention, three months after the end of the intervention

##### **Method of measurement**

Standard questionnaire

#### 2

##### **Description**

Use dental floss at least once a day

##### **Timepoint**

Before the start of the study, immediately after the end of the intervention, three months after the end of the intervention

##### **Method of measurement**

Standard questionnaire

## Secondary outcomes

### 1

#### Description

The percentage of dental plaque in each person

#### Timepoint

Before the start of the study, immediately after the end of the intervention, three months after the end of the intervention

#### Method of measurement

Clinical examination by a dentist

### 2

#### Description

Determining the rate of periodontal tissue health of each person

#### Timepoint

Before the start of the study, immediately after the end of the intervention, three months after the end of the intervention

#### Method of measurement

Clinical examination by a dentist

### 3

#### Description

Determining the rate of dental debris and calculus in each person

#### Timepoint

Before the start of the study, immediately after the end of the intervention, three months after the end of the intervention

#### Method of measurement

Clinical examination by a dentist

## Intervention groups

### 1

#### Description

Intervention group: The education program in this study included one education session for mothers and 10 education sessions for students. In the education session for mothers, tips were presented about the importance of oral health and its role in the general health, and the goals and implementation of the intervention program. Interventions in students were done through the game method and with the help of 7 educational videos, 3 pamphlets, 5 posters, role playing, holding a health and oral health celebration and forming a telegram group. Students were trained in the following areas: familiarizing students with tooth structure and periodontal structure, knowledge of oral and dental diseases (decay and periodontal diseases) and their causes, ways to prevent oral and dental diseases. In order to remind students to practice oral and dental hygiene behaviors, daily brushing and flossing records were provided to the students. In order to investigate the

oral hygiene behaviors of the students at home, the researcher checked the forms of the students once a week in each class. A group called "Oral Health" was created on Telegram and family members of students, teachers and administrators of each school, professor of social dentistry and health education joined this group. The educational videos that were played in the classes in every session, educational materials related to oral health were uploaded in the group and the questions of the members were answered about issues related to oral health. Students were asked to take pictures of themselves while brushing and flossing and post them in the group. The educational intervention ended with the celebration of oral health in each school. The parents of the students participated in the celebration held in the school. In this ceremony, students performed their shows for parents, principal and school teacher.

#### Category

Prevention

### 2

#### Description

Control group: They received routine programs and training at school.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Malek Mohammadi Primary School

##### Full name of responsible person

kobra Sharifian

##### Street address

Shahidan Samari Alley, Ayatollah Kashani Blvd

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6010738448

##### Phone

+98 81 3252 2548

##### Email

prm@medu.ir

### 2

#### 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

### 3

#### **Recruitment center**

**Name of recruitment center**  
Haj Mohammad Javad Alavi1 Primary School  
**Full name of responsible person**  
Mehrangiz Eskandari  
**Street address**  
Madani town  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6513817433  
**Phone**  
+98 81 3429 6837  
**Email**  
prm@medu.ir

### 4

#### **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

### 5

#### **Recruitment center**

**Name of recruitment center**  
Simai Baharan 2 Primary School  
**Full name of responsible person**  
Zahra Zabarjadi  
**Street address**  
Number 608, West Azad Street, Jihad Street  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6513817433

**Phone**  
+98 81 3821 0322  
**Email**  
prm@medu.ir

### 6

#### **Recruitment center**

**Name of recruitment center**  
Sadegh Dahihi 2 Primary School  
**Full name of responsible person**  
Aqdas Herati  
**Street address**  
Koi Kosar, Hesar Road Ali Abad  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6513817433  
**Phone**  
+98 81 3422 4216  
**Email**  
prm@medu.ir

### 7

#### **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

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Saeid Bashirian  
**Street address**  
Public Health School, University of Medical Science,  
Shahid Fahmide Ave., Pajuhesh Squer  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**

۶۵۱۷۸۳۸۷۳۶

**Phone**

+98 81 3131 4058

**Email**

s.shirahmadi@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**

Samane Shirahmadi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Department of Community Oral Health, School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh St., Pajuhesh square

**City**

Hamadan

**Province**

Hamadan

**Postal code**

۶۵۱۷۸۳۸۷۳۶

**Phone**

+98 81 3838 1059

**Fax**

**Email**

s.shirahmadi@umsha.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Samane Shirahmadi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Department of Community Oral Health, School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh St., Pajuhesh square

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**Postal code**

۶۵۱۷۸۳۸۷۳۶

**Phone**

+98 81 3838 1059

**Fax**

**Email**

s.shirahmadi@umsha.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Samane shirahmadi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

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**Postal code**

۶۵۱۷۸۳۸۷۳۶

**Phone**

+98 81 3838 1059

**Fax**

**Email**

s.shirahmadi@umsha.ac.ir

**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**

Samane Shirahmadi emails

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

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

**Comments**