

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

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2

Recruitment center

Name of recruitment center

Shahid Oshtad Primary School

Full name of responsible person

Fahima Mohammadi Ezzati

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3

Recruitment center

Name of recruitment center
Haj Mohammad Javad Alavi1 Primary School
Full name of responsible person
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Recruitment center

Name of recruitment center
Shahid Sabrian Ranjbar Primary School
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Recruitment center

Name of recruitment center
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Recruitment center

Name of recruitment center
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7

Recruitment center

Name of recruitment center
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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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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

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Person responsible for scientific inquiries

Contact

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Hamedan University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Ph.D.

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

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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

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