

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparison of the effects of audio-visual and in-person oral health education on the plaque index, awareness and performance of 9–11-year-old children

#### Protocol summary

##### Study aim

compare the plaque index and changes in the awareness and performance after oral hygiene instruction using the video and in-person educational techniques in children 9–11 years old

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 105 students. Simple randomization was done by students choosing even, odd and zero random numbers from inside the bag.

##### Settings and conduct

Four schools were randomly selected from the elementary schools in Birjand. Two schools from the areas that were in the upper socio-economic level of the society and two schools from the areas that were in the lower socio-economic level of the society were randomly selected. Similar Soft toothbrushes were provided and they were asked to brush their teeth at school before measuring the plaque index. In addition, a questionnaire whose validity and reliability had been confirmed was used to record the awareness and performance of each child in terms of orodental health. A disclosing agent was then given to each student to chew for one minute and then spit it out. Then, each student's plaque index immediately after the oral hygiene instruction, one week, and three months after it, was determined.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria consisted of 9–11 years of age, no visual, hearing, and physical problems, and no dental (both educational and therapeutic) interventions in the past six months. The exclusion criteria consisted of wearing fixed or removable orthodontic appliances, no interest in participating in the study, and systemic conditions.

##### Intervention groups

In intervention group 1, in-person oral hygiene education  
In intervention group 2, audio-visual oral hygiene

education In control group, No educational intervention was made.

##### Main outcome variables

Plaque Index score (PI); oral health evaluation score; Oral health performance score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230311057679N1**

Registration date: **2023-05-07, 1402/02/17**

Registration timing: **retrospective**

Last update: **2023-05-07, 1402/02/17**

Update count: **0**

##### Registration date

2023-05-07, 1402/02/17

##### Registrant information

##### Name

Fatemeh Esmaeilzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3882 9664

##### Email address

fa.es.8860@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-04, 1398/01/15

##### Expected recruitment end date

2019-04-21, 1398/02/01

**Actual recruitment start date**

2019-04-04, 1398/01/15

**Actual recruitment end date**

2019-04-21, 1398/02/01

**Trial completion date**

2019-07-21, 1398/04/30

**Scientific title**

Comparison of the effects of audio-visual and in-person oral health education on the plaque index, awareness and performance of 9–11-year-old children

**Public title**

Investigating the impact of health education

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

9–11 years of age no visual, hearing, and physical problems no dental (both educational and therapeutic) interventions in the past six months

**Exclusion criteria:**

using fixed or removable orthodontic appliances no interest in participating in the study systemic conditions

**Age**

From **9 years** old to **11 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **105**

Actual sample size reached: **105**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization, individual randomization, random numbers were put into a thick cloth bag and each student was asked to choose a number at random, if the selected number is other than odd numbers, the student is in the first intervention group, which is in-person oral health education and if it is even, the student will be included in the second intervention group, which is audio-visual health education, and if the number is zero, the student will be included in the control group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

By naming three different health education groups as A, B, and C, the principle investigator, who was a university professor and responsible for data collection and outcome assessors, was unaware of the health education method used in each group.

**Placebo**

Used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Birjand University of Medical Sciences

**Street address**

Central Organization of Birjand University of Medical Sciences, Ghaffari Street, Birjand, South Khorasan.

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853076

**Approval date**

2019-02-25, 1397/12/06

**Ethics committee reference number**

IR.BUMS.REC.1397.362

**Health conditions studied****1****Description of health condition studied**

Oral health, Plaque index

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Average dental plaque index

**Timepoint**

Immediately after intervention, 7 days after intervention, 3 months after the intervention

**Method of measurement**

O'Leary index

**Secondary outcomes****1****Description**

Change the level of awareness after oral health education

**Timepoint**

Before the intervention, immediately after the intervention, 7 days after the intervention, 3 months after the intervention

**Method of measurement**

## 2

### Description

Change the level of performance after oral health education

### Timepoint

Before the intervention, immediately after the intervention, 7 days after the intervention, 3 months after the intervention

### Method of measurement

WHO Oral Health Questionnaire for Children

## Intervention groups

### 1

#### Description

Intervention group 1: in-person oral health education

#### Category

Other

### 2

#### Description

Intervention group 2: audio-visual oral health education

#### Category

Other

### 3

#### Description

Control group: Health education was not given

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Birjand University of Medical Sciences

##### Full name of responsible person

Mehrnaz Khademi

##### Street address

Central Organization of Birjand University of Medical Sciences, Ghaffari Street, Birjand, South Khorasan.

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Birjand University of Medical Sciences

##### Full name of responsible person

Vice-Chancellor of Research of Birjand University of Medical Sciences

##### Street address

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#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Birjand 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Fatemeh Esmaeilzadeh

##### Position

Resident of pediatric dentistry

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dentistry

##### Street address

Vakil Abad Avenue, Mashhad University of Medical Sciences, Dental School, Mashhad, Iran

##### City

Mashhad

##### Province

Razavi Khorasan

**Postal code**  
9138813944  
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+98 51 3882 9664  
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EsmaeilzadehF991@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Esmaeilzadeh  
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Resident of pediatric dentistry  
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## Person responsible for updating data

### Contact

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Mashhad University of Medical Sciences  
**Full name of responsible person**  
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**Latest degree**  
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EsmaeilzadehF991@mums.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

Comparison of the effects of audio-visual and in-person oral health education on the plaque index, awareness and performance of 9–11-year-old children

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

starting in 2023

### To whom data/document is available

for everyone

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

There is no specific item

### From where data/document is obtainable

EsmaeilzadehF991@mums.ac.iraf

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

As soon as they send and ask for

### Comments