

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

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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

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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

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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

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