

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Evaluation of the effect of two different methods of oral health education and its repetition on the reduction of Streptococcus mutans in plaque in children 9 to 12 years old

#### Protocol summary

##### Study aim

Evaluation of the effect of two different methods of oral health education and its repetition on the reduction of Streptococcus mutans in plaque in children 9 to 12 years old

##### Design

Clinical trial, single blind simple randomization, sample number: 36 persons

##### Settings and conduct

The study is performed in the pediatric dep. of dental school by 11th sem. students on the effect of two different methods of oral health education and their repetition. Method: Children are randomly grouped. Teach intervention groups. Evaluation of dental plaque in intervention and comparison groups. Blinding: People who evaluate the outcome and evaluate the data.

##### Participants/Inclusion and exclusion criteria

Incl. criteria: Age between 9-12 years old, Children with erupted 1st molar, central and lateral incisor in both jaw that have intact surfaces. Excl. criteria: children with mental and physical disabilities children with fixed or movable orthodontic appliance children with Abscess children with teeth crowding children who use mouthwash children with systemic disease children who take drugs that affect the condition of the gums

##### Intervention groups

Intervention group: Includes 12 children. Training done by using modeling (Educational Equipment Industries brand (EEI), made in Iran in dimensions 19x14x14 cm), once, at the beginning. Then the training will be repeated every two weeks from the beginning. (Generally 4 times in two months) Intervention group: Includes 12 children. In this group video training will be done once, at the start time, then, the training will be repeated every two weeks from the start time. (Generally 4 times in two months) Comparison group: they do not receive any health education, but like other

groups, their SM in plaque will be measured at the end of the study.

##### Main outcome variables

Change in SM in dental plaque; change the level of oral and dental health education

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161119030971N5**

Registration date: **2022-01-30, 1400/11/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-30, 1400/11/10**

Update count: **0**

##### Registration date

2022-01-30, 1400/11/10

##### Registrant information

##### Name

Nahid Askarizadeh

##### Name of organization / entity

Dental branch, Islamic Azad University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21225645713

##### Email address

n\_asgarizadeh@dentaliau.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-08, 1400/10/18

##### Expected recruitment end date

2022-03-09, 1400/12/18

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the effect of two different methods of oral health education and its repetition on the reduction of Streptococcus mutans in plaque in children 9 to 12 years old

**Public title**  
Evaluation of the effect of two different methods of oral and dental health education and their repetition

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Children must be between 9-12 years old Children with erupted 1st molar , central and lateral incisor in both jaw that have intact surfaces .  
**Exclusion criteria:**  
Children with mental and physical disabilities Children with fixed or movable orthodontic appliance Children with Abscess Children with teeth crowding Children who use mouthwash Children with systemic disease Children who take drugs that affect the condition of the gums

**Age**  
From **9 years** old to **12 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **36**

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

**Randomization description**  
Using the Excel option rand software, the samples will be divided into 4 blocks based on the amount of sugar consumption by complete block randomization method, which includes: once sugar consumption per day, twice sugar consumption per day, 3 times Consumption of sugary substances per day and more than 3 times daily consumption of sugary substances. This process is performed by a person who is not present in the clinical work and follow-up of patients (statistics and methodology consultant) and the type of intervention will be provided to the researcher in envelopes in numbered packages and the researcher will open the lock immediately The type of specialized intervention will be informed.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Single blind in that the outcome assessor and data analyst were both unaware of the groups when examining the indicators.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Dental College Medical Sciences of Islamic Azad University  
**Street address**  
Dental College ,Medical Sciences , Islamic Azad University No.9, 9th Neyestan Alley ,Pasdaran Ave.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
19585/175

**Approval date**  
2021-11-29, 1400/09/08

**Ethics committee reference number**  
IR.IAU.DENTAL.REC.1400.131

**Health conditions studied**

**1**

**Description of health condition studied**  
Evaluation of the effect of two different methods of oral health education and its repetition .

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

**Primary outcomes**

**1**

**Description**  
Change in SM in dental plaque

**Timepoint**  
At the beginning , 2weeks later , 10 weeks later

**Method of measurement**  
Specific culture medium for Streptococcus Mutans

**Secondary outcomes**  
empty

## Intervention groups

### 1

#### Description

Intervention group1 : Includes 12 children . In this group oral and dental training done by using modeling (Educational Equipment Industries brand(EEI), made in Iran in dimensions three times bigger than normal size, 19x14x14 cm) , once, at the beginning. Then the training will be repeated every two weeks from the beginning. (Generally 4 times in two months)

#### Category

Other

### 2

#### Description

Intervention group2: Includes 12 children . In this group oral and dental training video will be done once, at the start time, then, the training will be repeated every two weeks from the start time. (Generally 4 times in two months)

#### Category

Other

### 3

#### Description

Comparison group: unlike the Intervention groups, they do not receive any health education. But like the other groups, their SM count will be measured again at the end of the study

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental College Medical Sciences of Islamic Azad University

##### Full name of responsible person

Nahid Askarizadeh

##### Street address

Dental College ,Medical Sciences , Islamic Azad University No.9, 9th Neyestan Alley ,Pasdaran Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

19585/175

##### Phone

+98 21 2276 3459

##### Email

nahidaskarizadeh@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Nahid Askarizadeh

##### Street address

No.4 , 8th Baharestan Alley , Pasdaran Ave.

##### City

Tehran

##### Province

Tehran

##### Postal code

37334009000

##### Phone

+98 21 2277 9836

##### Fax

##### Email

nahidaskarizadeh@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Islamic Azad University

#### Proportion provided by this source

100

#### Public or private sector

Private

#### 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

Islamic Azad University

##### Full name of responsible person

Seyyed Mehdi Moshtaghioon

##### Position

Dental student

##### Latest degree

A Level or less

##### Other areas of specialty/work

Dentistry

##### Street address

No.9, 9th Neyestan Alley ,Pasdaran Ave.,Dental College of MedicalSciences , Islamic Azad University

##### City

Tehran

##### Province

Tehran

##### Postal code

19585/175

**Phone**

+98 21 2251 2134

**Email**

Seyyedmehdimoshtaghiun@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Nahid Askarizadeh

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

No.9, 9th Neyestan Alley ,Pasdaran Ave.,Dental  
College of Medical Sciences , Islamic Azad University

**City**

Tehran

**Province**

Tehran

**Postal code**

19585/175

**Phone**

+98 21 2256 4571

**Email**

nahidaskarizadeh@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Seyyed Mehdi Moshtaghiun

**Position**

Dental student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

No.9, 9th Neyestan Alley ,Pasdaran Ave.,Dental  
College of Medical Sciences , Islamic Azad University

**City**

Tehran

**Province**

Tehran

**Postal code**

19585/175

**Phone**

+98 21 2251 2134

**Email**

Seyyedmehdimoshtaghiun@gmail.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

there is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available