

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)

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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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

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

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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

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Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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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