

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

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

Design

clinical trial ,Single blind ,simple randomization,sample number:60 persons

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Inc. criteria: Age between 9-12 years old. 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 1: Includes 20 children .Training done by using modeling (EEI Educational Industries brand, 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)
Intervention group2: Includes 20 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: plaque index will be determine at the beginning, they do not receive any health education, but their plaque will be measured at the end of the study.

Main outcome variables

Dental plaque change; Changing the level of oral health knowledge.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161119030971N4**

Registration date: **2022-01-14, 1400/10/24**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-14, 1400/10/24**

Update count: **0**

Registration date

2022-01-14, 1400/10/24

Registrant information

Name

Nahid Askarizadeh

Name of organization / entity

Dental branch, Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 21225645713

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-09, 1400/10/19

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 microbial plaque in children 9 to 12 years old

Public title
Evaluation of the effect of two different methods of oral health education and its repetition .

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
children must be between 9-12 years old
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: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the rand function of Excel software, the samples will be assigned into 3 research group by block randomization with block of size of 4. 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.1400.132

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reduce dental plaque

Timepoint

At the beginning , 2weeks later , 10 weeks later

Method of measurement

O'Leary plaque index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Includes 20 children . In this group teaching how to brush and floss done by using modeling (EEI Educational Industries brand, 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 group 2: including 20 goodies. In this group, the training of brushing and flossing through the film will be done once, at the beginning, then, once every two weeks from the beginning, the training will be repeated. (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 Plaque index 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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Nahid Askarizadeh

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

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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

30

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

Shamim Eshaghi Nasab

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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Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Shamim Eshaghi nasab

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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