

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Comparison of the effectiveness of different brushing methods with the usual method in removing microbial plaque in 11th and 12th grade students.

Protocol summary

Study aim

Comparison of the effectiveness of different brushing methods with the usual method in removing microbial plaque in 11th and 12th grade students

Design

A simple randomized clinical trial with parallel, single-blind, phase 2 block design on 72 participants

Settings and conduct

Schools in Tehran in two stages, at first, all participants brush in their usual way. Then they are divided into 2 equal groups and brush in 2 ways that will be taught. Plaque and gingival indexes are measured at each stage. It is double-blinded that participants do not know the goals and names of the methods But they know the whole study process and the existence of parallel groups. Examiners are also unaware of the purpose of the research.

Participants/Inclusion and exclusion criteria

Inclusion criteria including: 1. Healthy students of the eleventh and twelfth grade 2. No previous receipt of special oral health training 3. At least 6 teeth in each quadrant of the mouth Exclusion criteria: 1. Existence of oral lesion 2. Having an orthodontic appliance or removable prosthesis 3. Existence of periodontal problems and the presence of envelopes with a depth of 4 mm or more 4. Being a smoker 5. Existence of special disabilities that interfere with the skill of using a toothbrush. 6. History of systemic diseases (diabetes 1 and 2, rheumatic fever, leukemia, etc.) 7. Taking any non-steroidal antibacterial or anti-inflammatory drugs, corticosteroids and, immunosuppressants within 1 month Before and during the study.

Intervention groups

Firstly all participants brush in their usual way. Then they will divide into 2 equal groups and brush in 2 ways that will be taught. Plaque and gingival index will be measured at each stage

Main outcome variables

Plaque index; Gingival index; patient-reported outcome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201218049748N1**

Registration date: **2021-08-05, 1400/05/14**

Registration timing: **prospective**

Last update: **2021-08-05, 1400/05/14**

Update count: **0**

Registration date

2021-08-05, 1400/05/14

Registrant information

Name

Farzad Emamverdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 5611

Email address

farzad.emamverdi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-22, 1400/06/31

Expected recruitment end date

2021-11-20, 1400/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of different brushing methods with the usual method in removing microbial plaque in 11th and 12th grade students.

Public title
Efficiency of different brushing methods

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy students of the eleventh and twelfth grade No previous receipt of special oral health training At least 6 teeth in each quadrant of the mouth

Exclusion criteria:
1. Existence of oral lesion Students with orthodontic appliance or removable prosthesis Existence of periodontal problems and the presence of pockets with a depth of 4 mm or more Being a smoker Existence of special disabilities that interfere with the skill of using a toothbrush History of systemic diseases (diabetes 1 and 2, rheumatic fever, leukemia, etc.) Taking any non-steroidal antibacterial or anti-inflammatory drugs, corticosteroids and immunosuppressants within 1 month Before and during the study

Age
From **12 years** old

Gender
Both

Phase
2

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with block design. Individual randomization unit . randomization tool also sealed envelopes.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants will be blind from the goals of the study and the name of the brushing methods. Data collectors will be blind from the goals of the study. The whole study process and the existence of parallel groups will be explained to the participants.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the School of Dentistry - Tehran University of Medical Sciences

Street address

Tehran dental school, North Kargar Ave, enghelab Eslami Sqr,

City

Tehran

Province

Tehran

Postal code

1439955991

Approval date

2020-04-19, 1399/01/31

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1399.008

Health conditions studied

1

Description of health condition studied

Efficiency of different brushing methods compared to the usual method of each person .

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plaque index

Timepoint

At the beginning of the study (after 48 hours without brushing) . after brushing in the usual way, after 48 hours of not brushing, after brushing in the trained methods.

Method of measurement

With disclosing agent and examination intraoral mirror

2

Description

Gingival index

Timepoint

At the beginning of the study (after 48 hours without brushing) . after brushing in the usual way, after 48 hours of not brushing, after brushing in the trained methods.

Method of measurement

Clinical examination with intraoral mirror and periodontal probe.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Initially, all volunteers will not brush their teeth for next 48 hours. Then they will brush with their usual brushing method twice a day and the plaque index and gingival index will record.

Category

Other

2

Description

Category

Other

3

Description

Intervention group : Do not brushing for next 48 hours. Plaque index and gingival index will be recorded. then they will brush twice in 24 hours using Modified Bass method. and after that, plaque index and gingival index will record.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikan Boys high school

Full name of responsible person

Mohsen Kashani Vahid

Street address

No. 21, Corner of Yasman Alley, At the beginning of Chenaran St, Shahid Fayyazi (Fereshteh) St, Above Parkway intersection, Hazrat Vali-e-Asr St,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Amirali Sohrabpour

Street address

Shafa building, Italy St, Keshavarz Blvd, Tehran

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Grant name

Grant code / Reference number

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

No

Title of funding source

Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

Full name of responsible person

Farzad Emamverdi

Position

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Reza Yazdani

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Farzad Emamverdi

Position

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Latest degree

A Level or less

Other areas of specialty/work

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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 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