

# 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,

##### City

Tehran

##### Province

Tehran

##### Postal code

1964959563

##### Phone

+98 21 2200 9630

##### Email

Nikan@yahoo.com

## 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1439955991

#### Phone

+98 21 8241 5000

#### Email

aasohrabpour@tums.ac.ir

#### 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**

Dentistry

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## Person responsible for updating data

### 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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**Fax****Email**

farzad.emamverdi@yahoo.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 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