

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of using toothbrush stick with toothbrush comparing with toothbrush on controlling plaque index of dental students, A randomized clinical trial (RCT)

Protocol summary

Study aim

determining the effect of using toothbrush stick on plaque control

Design

with control group, with parallel groups, Single blinding, 60 participants, Randomized web

Settings and conduct

Sixty dental students of Babol University of Medical Sciences (30 males and 30 females) will be selected using simple random sampling method. Participants will sign a consent form before participating to this study. The duration of the study will be three weeks. Participants will be examined the day before intervention, and on the 7th, 14th and 21st days after the intervention. Plaque index and gingival index will be recorded using olary and loe and silness methods respectively. The study will be single blind. A person other than the examiner will do a web-based randomization at <https://Randomization.com>. He will distribute toothbrush and toothbrush stick in to the intervention group (toothbrush stick with toothbrush) and the control group (toothbrush only).

Participants/Inclusion and exclusion criteria

inclusion criteria: Student of Babol Dental School; Age range 18-25 years plaque index range 20-30% No inclusion criteria: orthodontic appliance; Dental prosthesis; Extensive restoration

Intervention groups

The intervention group will use a toothbrush stick every morning after breakfast and toothbrush and toothpaste every night before going to bed; The control group will use only toothbrush and toothpaste every morning after breakfast and every night before going to bed.

Main outcome variables

Plaque index; Gingival index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200819048464N1**

Registration date: **2020-10-01, 1399/07/10**

Registration timing: **retrospective**

Last update: **2020-10-01, 1399/07/10**

Update count: **0**

Registration date

2020-10-01, 1399/07/10

Registrant information

Name

Mohammad Mehdi Naghibi Sistani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3222 5985

Email address

m.naghibi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-04-24, 1399/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using toothbrush stick with toothbrush comparing with toothbrush on controlling plaque index of dental students, A randomized clinical trial (RCT)

Public title

the effect of using toothbrush stick on controlling gingival indices in comparison with toothbrush

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Student of babol dental school Age range 18-25 years
Plaque index range 20-30%

Exclusion criteria:

Orthodontic appliance Dental prosthesis Extensive restoration

Age

From **18 years** old to **25 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

Web Randomization on site <https://Randomization.com>, six block method A colleague other than the researcher does the randomization and keep the randomization list and give participants a toothbrush and toothpaste or toothbrush stick

Blinding (investigator's opinion)

Single blinded

Blinding description

Research Fellow, Impact Assessor, Data Analyzer A colleague other than the researcher give participants a toothbrush and toothpaste or toothbrush stick

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences. Ganj Afrooz St.

City

Babol

Province

Mazandaran

Postal code

۴۷۷۴۵-۴۷۱۷۶

Approval date

2020-06-06, 1399/03/17

Ethics committee reference number

IR.MUBABOL.REC.1399.219

Health conditions studied

1

Description of health condition studied

Plaque index

ICD-10 code

-

ICD-10 code description

-

2

Description of health condition studied

Gingival index

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Percent of tooth surface with plaque (plaque index)

Timepoint

Measuring plaque index at the beginning of the study, on days 7, 14 and 21 after using toothbrush stick

Method of measurement

calculating colored tooth surface by Olary method

Secondary outcomes

1

Description

Gingival index

Timepoint

At the beginning of the study, on days 7, 14 and 21 after the start of the study

Method of measurement

With Williams probe under unit light and dental mirror by loe and silness method

Intervention groups

1

Description

Intervention group: They will use toothbrush stick every morning after breakfast and toothbrush and toothpaste using Modify Bass method every night before going to bed.

Category

Prevention

2

Description

Control group: Every day after breakfast and before bed, they will use only toothbrushes and toothpaste using the Modify Bass method.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Babol University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Naghibi Sistani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

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Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Ganj Afrooz St.

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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

Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Babol University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Naghibi Sistani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Dentistry

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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

I do not want to explain

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