

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The efficacy of brushing and flossing sequence on interdental plaque reduction in young subjects with intact papilla; cross over clinical trial

#### Protocol summary

##### Study aim

Determining the effect of brushing and flossing sequence on the reduction of interdental plaque in young subjects with intact papilla

##### Design

The sampling method is available from dental students of Qazvin Dental School. This study will have two phases. There will be a two-week interval between the two phases to eliminate the effect of the first phase of the study. The sample size was estimated at 37 people.

##### Settings and conduct

Participants will be given a soft toothbrush, toothpaste and floss. This study will be done in two phases and each phase will last 48 hours. There will be a two-week interval between the two phases. Before the start of each phase for individuals Professional prophylaxis will be performed with rubber cup and prophylaxis paste. They will then be asked to refrain from any activity for 48 hours to control plaque and maintain oral hygiene. After 48 hours, participants will randomly enter the first group (brush). -floss) or the second group (floss-brush). Group 1 (brush-floss): First, participants will be given a disclosing detector tablet. Then the index plate will be taken by Rustogi Modified navy plaque index method. Then the toothbrush with modified bass method for 2 minutes and then floss for 2 minutes will be used. Then the index plate will be registered again. The second group (Floss-brush): All the steps are similar to the first group, except that first floss and then toothbrush will be used.

##### Participants/Inclusion and exclusion criteria

Participants will be dental students of Qazvin Dental School, whose average age is 20 to 25 years. Individuals must meet the inclusion criteria

##### Intervention groups

Before each study phase, prophylaxis will be performed for participants with a brush and prophylaxis paste.

##### Main outcome variables

Reduction of interdental plaque

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210803052063N1**

Registration date: **2021-11-06, 1400/08/15**

Registration timing: **prospective**

Last update: **2021-11-06, 1400/08/15**

Update count: **0**

##### Registration date

2021-11-06, 1400/08/15

##### Registrant information

##### Name

Fahimeh AliAkbari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3355 5625

##### Email address

aliakbaryfahimeh977@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-05, 1400/09/14

##### Expected recruitment end date

2022-01-04, 1400/10/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The efficacy of brushing and flossing sequence on interdental plaque reduction in young subjects with intact papilla; cross over clinical trial

**Public title**

The efficacy of brushing and flossing sequence on plaque

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Does not exist crown on teeth Having all their permanent teeth(except third molars) Individuals with a normal unstimulated salivary flow rate Individuals free from cavitated carious lesions Intact papilla at interdental area

**Exclusion criteria:**

Systemic illness or periodontitis Severe crowding Gingival recession Diastema

**Age**

From **20 years** old to **25 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **37**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization. The method of randomization is that a person other than the facilitator of the envelope will give statistics to the participants according to the list of consultants and they will be asked to implement the envelope about the content of the envelope.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the performer and statistical analyzer will be blind until after data analysis. First, the list is prepared by a statistical consultant, in which sequence do the numbers 1 to 37 enter first, and in each phase, first brush or floss? Then, a person other than the presenter randomly selects a number from 1 to 37 for each person and categorizes the statistics of the people according to the list. The paper is given to the participants for each person who enters the sequence first. While studying, brushing and flossing leaves the presenter alone to be completely blind

**Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

**Street address**

Bahonar blvd. Qazvin university of medical science

**City**

Qazvin

**Province**

Qazvin

**Postal code**

15315-34199

**Approval date**

2021-06-07, 1400/03/17

**Ethics committee reference number**

IR.QUMS.REC.1400.106

**Health conditions studied****1****Description of health condition studied**

Dental plaque

**ICD-10 code**

K02

**ICD-10 code description**

Dental caries

**Primary outcomes****1****Description**

Calculation of dental plaque using modified navy plaque index

**Timepoint**

The study will be conducted in two phases. On the first day of the first phase of prophylaxis and on the third day of the first phase, the index plate will be recorded. After two weeks, on the first day of the second phase of prophylaxis and on the third day of the second phase, the index plate will be registered.

**Method of measurement**

Modified navy plaque index

**Secondary outcomes**

empty

**Intervention groups****1****Description**

This is a crossover study that will performed in two phases. At the beginning of each phase, prophylaxis will be performed for the participants for all dental surfaces using golchadent prophylaxis Paste, Golchai co, Alborz,

Iran prophylaxis brush and prophylaxis paste. they will asked to discontinue all forms of oral hygiene for 48 hours. In one phase, they will first brush, then floss. In the other phase they initially will use dental floss then brush.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Qazvin University of Medical Sciences

**Full name of responsible person**

Fahimeh Ali Akbari

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**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Seyed Mahdi Mirhashemi

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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**

Qazvin 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**

Qazvin University of Medical Sciences

**Full name of responsible person**

Fahimeh Ali Akbari

**Position**

dentistry 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**

Qazvin University of Medical Sciences

**Full name of responsible person**

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dentistry student

**Latest degree**

A Level or less

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All shareable information except people's names

**When the data will become available and for how long**

Access starts 3 months after the results are published

**To whom data/document is available**

The fable community is accessible to everyone

**Under which criteria data/document could be used**

The use of data is free to the public

**From where data/document is obtainable**

Qazvin Dental School Library

**What processes are involved for a request to access data/document**

Visit the library of the School of Dentistry

**Comments**