

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison of effect of using dental floss before and after brushing on plaque index and gingival index of posterior teeth in dental students of Gorgan dental faculty

#### Protocol summary

##### Study aim

The main purpose of this study is to investigate the effect of flossing before and after brushing on plaque index and gingival index.

##### Design

The Crossover clinical trial study, Single randomized, Phase 3.

##### Settings and conduct

This study will be conducted in the Faculty of Dentistry, Golestan University of Medical Sciences. Before starting the study, the plaque index (Silness & Loe) and the gingival index (Loe & Silness) will be measured. All people participating in the study will be given standard oral and dental hygiene training (Modified bass) including flossing by a periodontics. If the patients need scaling, it will be done. Measurements will be done at intervals of two weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria • Healthy physically and mentally • Having all posterior permanent teeth except wisdom teeth • Age between 20 and 40 years • No active caries or extensive restorations or veneers on the posterior teeth  
Exclusion criteria • People with orthodontic braces • People without interdental contact • Severe dental irregularity • Periodontal problems • Having a systemic disease affecting the periodontium tissue • Use of systemic drugs affecting periodontal tissue • Alcohol and smoking • Pregnancy and breastfeeding • Taking antibiotics for one week in the last three months

##### Intervention groups

This study is Cross-over Use dental floss before brushing  
Use dental floss after brushing

##### Main outcome variables

Plaque Index , Gingival Index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231123060153N2**

Registration date: **2024-07-21, 1403/04/31**

Registration timing: **retrospective**

Last update: **2024-07-21, 1403/04/31**

Update count: **0**

##### Registration date

2024-07-21, 1403/04/31

##### Registrant information

##### Name

Amir reza Ahmadiania

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3253 6270

##### Email address

ar.ahmadiania@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-03, 1403/01/15

##### Expected recruitment end date

2024-04-03, 1403/01/15

##### Actual recruitment start date

2023-04-05, 1402/01/16

##### Actual recruitment end date

2024-04-06, 1403/01/18

##### Trial completion date

2024-05-18, 1403/02/29

**Scientific title**

Comparison of effect of using dental floss before and after brushing on plaque index and gingival index of posterior teeth in dental students of Gorgan dental faculty

**Public title**

The effect of flossing and brushing on plaque and gingival index

**Purpose**

Health service research

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

Physically and mentally healthy people Having all posterior permanent teeth except wisdom teeth People aged between 20 and 40 years

**Exclusion criteria:**

People with orthodontic appliances People without interdental contact Crowding and malposition of posterior teeth People with periodontal disease Active caries or extensive restorations or crown of posterior teeth Having a systemic disease affecting the periodontal tissue Taking medications that affect periodontal tissue Consumption of alcohol and cigarettes Pregnancy and lactating Taking antibiotics in the last three months for one week.

**Age**

From **20 years** old to **40 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **32**

Actual sample size reached: **32**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization of study groups: In the first stage, people are randomly divided into toothbrush-dental floss (A) and dental floss-toothbrush (B) groups. Random block method will be used to assign people to groups. For this purpose, all six positions of letters A and B are considered in blocks of four. Table 1: Table 1: Generated random block (1) AABB (2)BBAA (3)ABAB (4)BABA (5)ABBA (6)BAAB To allocate 16 students in each group (32 people in total), 8 blocks of 4 are needed. To select 8 blocks first, 8 random numbers between 1 and 6 will be generated by repetition (with placement). Thus, a sequence of letters A and B will be created containing 32 letters (16 letters A and 16 letters B). The random numbers generated in the R software and the random block attributed to the numbers generated using the above table are as follows Block number Randomly generated number Attributed block 1 4 BABA 2 5 ABBA 3 6 BAAB 4 6 BAAB 5 1 AABB 6 2 BBAA 7 4 BABA 8 3 ABAB For example, the first person who meets the study entry criteria is in group B, the second person is in group A, the third person is in group B, and the fourth person is in

group A. And it continues until 32 people respectively. People are matched in terms of age and sex.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The examiners are not aware of the type of intervention (single blind).

**Placebo**

Not used

**Assignment**

Crossover

**Other design features**

In this study, referring to Turkezban et al.'s study (11) with a confidence level of 0.95 and a test power of 0.80, and taking into account the purpose of comparing the average plaque index before and after using the following formula, a total of 32 people were randomly sampled. students will be selected from the community under study. The students will be assigned to two groups by block allocation, the first group will use toothbrush-dental floss for two weeks and the second group will use dental floss-brush and after two weeks, its plaque index and gingival index will be measured. and two weeks of wash out will be taken into account and after that their plaque index and gingival index will be measured and again the students of the first group will first use dental floss-brush and the second group will use toothbrush-floss and after two weeks the plaque index And the gingival index will be measured.

**Secondary Ids**

empty

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

Ethics committee of Golestan University of Medical Sciences

**Street address**

Gorgan, Shahrek Shahryar, Shahryar 5, Gorgan Faculty of Dentistry

**City**

Gorgan

**Province**

Golestan

**Postal code**

4916648679

**Approval date**

2022-07-03, 1401/04/12

**Ethics committee reference number**

IR.GOUMS.REC.1401.129

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

Gingival Index, Plaque Index

**ICD-10 code**  
**ICD-10 code description**

Behavior

## Primary outcomes

### 1

#### **Description**

Gingival Index, Plaque Index

#### **Timepoint**

Before starting the intervention in both groups, Two weeks after intervention in each group, two weeks after cleansing, two weeks after intervention

#### **Method of measurement**

For the gingival index variable, we first measured the four surfaces of the teeth with the help of a probe and if 0: normal gums, 1: mild inflammation, slight color change, no swelling, no BOP2: moderate inflammation, redness, swelling and glossiness of the gums with BOP3: severe inflammation with Redness and swelling, wounds and continuous bleeding, and for the index plaque variable from Fuchsin tablets, which is based on the amount of tooth surface color using the following formula (number of teeth)/(teeth 100 (percentage) x 4)

## Secondary outcomes

### 1

#### **Description**

Gingival Index , Plaque Index

#### **Timepoint**

Before starting the intervention in both groups, Two weeks after intervention in each group, two weeks after cleansing, two weeks after intervention

#### **Method of measurement**

For the gingival index variable, we first measured the four surfaces of the teeth with the help of a probe and if 0: normal gums, 1: mild inflammation, slight color change, no swelling, no BOP2: moderate inflammation, redness, swelling and glossiness of the gums with BOP3: severe inflammation with Redness and swelling, wounds and continuous bleeding, and for the index plaque variable from Fuchsin tablets, which is based on the amount of tooth surface color using the following formula (number of teeth) divided (teeth 100 (percentage) x 4)

## Intervention groups

### 1

#### **Description**

Intervention group: using a toothbrush after using dental floss

#### **Category**

Behavior

### 2

#### **Description**

Control group: using dental floss after using a toothbrush

#### **Category**

## Recruitment centers

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Gorgan dental faculty

##### **Full name of responsible person**

Amirreza Ahmadiania

##### **Street address**

2nd Floor, Research and Technology Vice-Chancellor, Golestan University of Medical Sciences Higher Education Complex, 1st Shasat Kolah Road

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##### **Phone**

+98 17 3234 4830

##### **Email**

ar.ahmadiania@gmail.com

## Sponsors / Funding sources

### 1

#### **Sponsor**

##### **Name of organization / entity**

Gorgan University of Medical Sciences

##### **Full name of responsible person**

Amirreza Ahmadiania

##### **Street address**

Golestan university of medical sciences

##### **City**

gorgan

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+98 17 3234 4830

##### **Email**

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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**

Gorgan 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**

Gorgan University of Medical Sciences

**Full name of responsible person**

Amir reza Ahmadinia

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

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**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**

Gorgan University of Medical Sciences

**Full name of responsible person**

Amir reza Ahmadinia

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

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

**Data Dictionary**

No - There is not a plan to make this available

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

The documents will be attached to the file.

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

The access period starts from 1402

**To whom data/document is available**

Everyone can access the documents.

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

If the requesters need, the data will be sent to them.

**From where data/document is obtainable**

By sending an email to the responsible author, the data will be sent to the requester.

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

By sending an email to the responsible author, the data will be sent to the requester.

**Comments**