Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Ahmadinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3253 6270

Email address

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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

Primary outcomes

1

Description
Gingival Index، Plaqe 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 ، Plaqe 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) devided (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
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Gorgan dental faculty
Full name of responsible person
Amirreza Ahmadinia
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Phone
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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

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Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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Other areas of specialty/work

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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