

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the effect of flossing by teaching the correct technique on clinical periodontal indices

Protocol summary

Study aim

Evaluation of the effect of correct flossing technique on periodontal clinical indicators

Design

Clinical trial with control group, 2 arm parallel group, single-blinded, randomized, on 100 patients, randomization was done with random numbers table.

Settings and conduct

Location: General Department, Faculty of Dentistry, University of Isfahan. How to do: Select 100 patients from dental school referrals. Method: Random allocation of patients to two groups of control and intervention using random numbers table. Blindness: The therapist is blinded because the therapist who performs the examination and scaling and root planning knows the patients only through random codes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: At least 20 existing teeth People having calculus on their teeth People completely healthy physically and mentally People who are not used to using dental floss (use less than 2 times a week) Having the necessary cooperation to observe health Presence of Ramford's teeth or replacement teeth! Non-inclusion criteria: Moderate to severe periodontitis Deep caries, overhang and crown Gingival recession Pregnancy Mouth breathing People who are taking antibiotics or aspirin People who have gingival hyperplasia

Intervention groups

Intervention group: After the initial sampling, index recording and scaling and root planning, people were taught the technique of brushing once a day by the Rolling method using a soft toothbrush along with the use of thin fluoridated dental floss once a day. Control group: After the initial sampling, index recording and scaling and root planning, people were taught the technique of brushing once a day by the Rolling method using a soft toothbrush.

Main outcome variables

Clinical attachment level; Bleeding on marginal probing;

Approximal Plaque Index; Calculus Surface Index; Probing depth index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150210021029N6**

Registration date: **2022-12-10, 1401/09/19**

Registration timing: **prospective**

Last update: **2022-12-10, 1401/09/19**

Update count: **0**

Registration date

2022-12-10, 1401/09/19

Registrant information

Name

Sima Kiani

Name of organization / entity

Department of Periodontology, dental school, Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of flossing by teaching the correct technique on clinical periodontal indices

Public title

Effect of flossing on gingiva indices

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

At least 20 existing teeth People having calculus on their teeth People completely healthy physically and mentally People who are not used to using dental floss (use less than 2 times a week) Having the necessary cooperation to observe health Presence of Ramford's teeth or replacement teeth

Exclusion criteria:

Moderate to severe periodontitis Deep caries, overhang and crown Gingival recession Pregnancy Mouth breathing People who are taking antibiotics or aspirin People who have gingival hyperplasia

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants selection in the study will be performed by simple randomization method, individually and with random number table tools. In this way, a number will be written in front of the name of each person from the list of clients, then a table will be designed based on the sample size of the study, and we'll blindly touch a number of table numbers. The selected numbers will be included in the study if they are eligible after the examination. The intervention will be performed in a parallel design, and the choice of individuals' quadrant for Intervention or Control will be randomly performed with coin instruments. In such a way that for both quadrants which their numbers are accidentally put in the list, we drop a coin and if it's head for the first quadrant brushing instruction and for the second, brushing and flossing will be taught and vice versa if it is tails.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participant: He knows about using a toothbrush with dental floss (intervention group) or using a toothbrush alone (control group). Care provider and investigator: The person who records the indices and then does the scaling and root planning, is unaware of the names and groups of the participants and communicates with them only through the code assigned to each patient. Data analyst: The data is evaluated numerically without specifying the name and the intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjerib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2022-11-23, 1401/09/02

Ethics committee reference number

IR.MUI.RESEARCH.REC.1401.252

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

Clinical periodontal indices

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Clinical attachment level

Timepoint

At baseline (before the intervention) and at 6 weeks and 3 months later

Method of measurement

Williams periodontal probe (Juya®, Pakistan)

2

Description

Bleeding on marginal probing

Timepoint

At baseline (before the intervention) and at 6 weeks and 3 months later

Method of measurement

Williams periodontal probe (Juya®, Pakistan)

3

Description

Approximal Plaque Index

Timepoint

At baseline (before the intervention) and at 6 weeks and 3 months later

Method of measurement

Williams periodontal probe (Juya®, Pakistan)

4

Description

Calculus Surface Index

Timepoint

At baseline (before the intervention) and at 6 weeks and 3 months later

Method of measurement

Williams periodontal probe (Juya®, Pakistan)

5

Description

Probing depth index

Timepoint

At baseline (before the intervention) and at 6 weeks and 3 months later

Method of measurement

Williams periodontal probe (Juya®, Pakistan)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the initial sampling, index recording and scaling and root planning, people were taught the technique of brushing once a day by the Rolling method using a soft toothbrush along with the use of thin fluoridated dental floss once a day.

Category

Prevention

2

Description

Control group: After the initial sampling, index recording and scaling and root planning, people were taught the technique of brushing once a day by the Rolling method

using a soft toothbrush.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry; Isfahan University of Medical Sciences

Full name of responsible person

Sima Kiani

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Faculty of Dentistry, Isfahan University of Medical Sciences, Hezarjerib Ave, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nakisa Torabinia

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Vice chancellor for Research; Isfahan Dental School; Isfahan University of Medical Sciences, Hezarjerib street

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Sima Kiani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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

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Full name of responsible person

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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

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

Data related to Personal information and Indicators examined in the study. All Data can be shared after making people unidentifiable.

When the data will become available and for how long

Up to One year after publication of the Article

To whom data/document is available

Researchers working in Academic and Scientific Institutions

Under which criteria data/document could be used

In addition to mentioning the name and academic affiliation, the applicant must have signed a letter stating that he or she does not intend to publish or use any of our study data in person

From where data/document is obtainable

Applicants can contact this E-mail: skiani.dnt@gmail.com

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

The Project Manager will provide the requested Documents via E-mail no later than One week after

receiving the E-mail from the Applicant
Comments