Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Periodentology, dental school, Isfahan university of medical sciences

Country
Iran (Islamic Republic of)

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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
Isfehan
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
Street address
Faculty of Dentistry, Isfahan University of Medical Sciences, Hezarjerib Ave, Isfahan
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research@dnt.mui.ac.ir

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

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Person responsible for updating data

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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