Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effectiveness of Interdental Aids in Reducing Plaque in Patient with Gingivitis

Protocol summary

Study aim
To determine the effect of interdental aids on plaque reduction in patients with gingivitis

Design
Clinical trial, randomized, parallel, phase 2-3 on 54 patients

Settings and conduct
For 54 eligible patients referred to the Periodontics department of Yazd School of Dentistry who have gingivitis, a periodontal chart will be completed, including the following: probing depth, full mouth plaque index, and bleeding index will be recorded at the time of the examination. Then, all patients will receive Phase I Therapy, which includes scaling and oral hygiene instruction (OHI). Scaling will be performed using hand and ultrasonic instruments, based on the patient's treatment needs. OHI will be provided by the project's trained implementer, tailored to each group, and will include brushing twice a day and using an interdental cleaning device once a day for a duration of 4 weeks. The patients will be divided into 3 groups of 18 subjects each. Patients will be recalled after 4 weeks, and the variables of probing depth, full mouth plaque index, bleeding index, and patient-reported ease of use will be recorded. The data obtained from the 4-week examination will be compared with the initial examination data, and the data will be subjected to statistical analysis

Participants/Inclusion and exclusion criteria
inclusion: patient's age is between 18-50 years patient has generalized gingivitis no history of periodontal treatment in last 6 months No history of antibiotic consumption in the last 3 months exclusion: Failure of the patient to attend the follow-up session Identification of a systemic disease that affects periodontal conditions during the study

Intervention groups
Group 1: Use a soft toothbrush and soft pick Group 2: Use a soft toothbrush and dental floss Group 3: Use a soft toothbrush and wooden toothpick

Main outcome variables
probing depth, full mouth plaque index, bleeding index, ease of use

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241014063362N2**
Registration date: **2025-11-14, 1404/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-14, 1404/08/23**
Update count: **0**

Registration date
2025-11-14, 1404/08/23

Registrant information

Name
Mahsa Fakhari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01

Expected recruitment end date
2026-08-23, 1405/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Interdental Aids in Reducing Plaque in Patient with Gingivitis

Public title
Comparison of the Effectiveness of Interdental Aids in Reducing Plaque in Patient with Gingivitis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patient's age is between 18-50 years Patient has generalized gingivitis No history of periodontal treatment in last 6 months No history of antibiotic consumption in the last 3 months Patient is physically healthy in terms of systemic health (patient is free of any physical-motor restrictions that limit hygienic practices) Absence of inflammatory conditions in the oral mucosa such as Aphthous Ulcers and Lichen Planus No use of drugs affecting the periodontium, such as anticonvulsants, calcium channel blockers, and immunosuppressants. No history of smoking Patient's crowding is less than 4 mm
Exclusion criteria:
Failure of the patient to attend the follow-up session Identification of a systemic disease that affects periodontal conditions during the study
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization is performed using Simple Random Allocation. First, a sequence of random numbers from 1 to 54 is generated using the PASS 2021 software. The software output is a follow-up Excel file containing the numbers from 1 to 54 and a unique code for the study units. The patients who meet the criteria from numbers 1 to 54 are considered and allocated to one of the intervention groups (A, B, or C).
Blinding (investigator's opinion)
Single blinded
Blinding description
To ensure Blinding of the referrals (patients), we use the help of a third person who is unaware of the interventions, and the table is provided to them. When a study unit (patient) is referred and meets the criteria, the intervention group (A, B, or C) is asked from the third person by phone based on the patient's number, and the patient is assigned to one of the specified groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd
Street address
Central Organization of Shahid Sadougi University of Medical Sciences and Healthcare Services, Shahid Dr. Bahner Square
City
yazd
Province
Yazd
Postal code
8916978477
Approval date
2025-08-03, 1404/05/12
Ethics committee reference number
IR.SSU.DENTISTRY.REC.1404.029

Health conditions studied

1

Description of health condition studied
gingivitis
ICD-10 code
K05
ICD-10 code description
Gingivitis and periodontal diseases

Primary outcomes

1

Description
Full mouth plaque index
Timepoint
At the beginning of the study (before the intervention) and 4 weeks after use
Method of measurement
Percentage of plaque-bearing surfaces on existing teeth

2

Description
Bleeding index
Timepoint

At the beginning of the study (before the intervention) and 4 weeks after use

Method of measurement

Percentage of surfaces with bleeding in existing teeth during probing

3

Description

Probing depth

Timepoint

At the beginning of the study (before the intervention) and 4 weeks after use

Method of measurement

Distance from gingival margin to sulcus depth

4

Description

Ease of use (Patient satisfaction)

Timepoint

4 weeks after use

Method of measurement

Visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Using a soft toothbrush (Rejoy, Iran) and toothpaste (Pooneh, Iran) along with dental floss (Oxygen, Iran) - brushing twice a day and flossing once a day

Category

Prevention

2

Description

Intervention group: Use a soft toothbrush (Rejoy, Iran) and toothpaste (Pooneh, Iran) with a wooden toothpick (Bamboo, Iran) - brushing teeth twice a day and using a wooden toothpick once a day

Category

Prevention

3

Description

Intervention group: Using a soft toothbrush (Rejoy, Iran) and toothpaste (Pooneh, Iran) with a soft pick (Oral B, America) - brushing twice a day and using a soft pick once a day

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Faculty of Dentistry, Yazd

Full name of responsible person

Roghaye Eslami Nosrat Abadi

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The beginning of Imam Reza Blvd., Imam Reza Square, the end of Imam Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amir Hooshang Mehrparvar

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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

Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Roghaye Eslami Nosrat Abadi
Position
student
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available