

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 913 450 6859

##### Email address

m.fakhari@ssu.ac.ir

##### 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 Sadoughi 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

**Street address**

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

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**Email**

info@ssu.ac.ir

**Web page address**

https://dentistry.ssu.ac.ir/

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Amir Hooshang Mehrparvar

**Street address**

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

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**Email**

info@ssu.ac.ir

**Web page address**

https://dentistry.ssu.ac.ir/

**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**

Dentistry

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10th Alley, Imam Jafar Sadegh st., vakil st.,Jomhour  
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reslami2002@gmail.com

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

Yazd University of Medical Sciences

**Full name of responsible person**

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**Position**

student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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

Yazd University of Medical Sciences

**Full name of responsible person**

Roghaye Eslami Nosrat Abadi

**Position**

student

**Latest degree**

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**Other areas of specialty/work**

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**Email**

reslami2002@gmail.com

**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