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Comparing the efficacy of oral irrigator and dental floss in removal of dental plaque after single-use

Submission date 01/11/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 20/11/2024	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 15/11/2024	**Condition category** Oral Health	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Gingivitis and dental caries are common diseases caused by dental plaque, which can build up between teeth even with regular brushing. Interdental cleaning tools like dental floss and oral irrigators can help remove this plaque. However, many people find flossing difficult due to the manual dexterity required. Oral irrigators are easier to use and may be more effective. This study aims to compare the effectiveness of dental floss and oral irrigators in removing plaque and to evaluate how well participants can use these tools.

Who can participate?
Patients attending Um Al-Qura University Teaching Hospital who are 18 years or older and willing to sign a consent form.

What does the study involve?
Participants will clean their teeth using both dental floss and an oral irrigator. They will be randomly assigned to use one tool on one side of their mouth and the other tool on the other side. Before the study visit, participants will be asked not to brush their teeth or use any floss for 6-8 hours. An examiner will measure plaque levels before and after cleaning.

What are the possible benefits and risks of participating?
Participants will get to try both dental floss and an oral irrigator, helping them find the best method for their oral hygiene. They will also receive instructions on proper use and learn more about the importance of flossing. There are no significant risks involved.

Where is the study run from?
The study is conducted at the Faculty of Dentistry at the University of Umm Al-Qura in Saudi Arabia.

When is the study starting and how long is it expected to run for?
July 2023 to March 2024

Who is funding the study?
The study is initiated and funded by the investigators.

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
HAPO-02-K-012-2023-10-1783

Study information

Scientific Title
Comparing the efficacy of oral irrigator and dental floss in removal of dental plaque after single-use: a split-mouth study design

Study objectives
There is no significant difference between the efficacy of dental floss and oral irrigator in plaque removal.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/10/2023, Institutional Research Ethics Board (IRB): Biomedical research ethics committee (Umm Al-Qura University, Makkah, 24352, Saudi Arabia; +966 (0)125270000; irb.uqudent@uqu.edu.sa), ref: HAPO-02-K-012-2023-10-1783

Study design
Randomized controlled clinical trial with a single-blinded and a split-mouth design

Primary study design
Interventional

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Prevention of gingivitis and dental caries

Interventions
Eighty-five participants were recruited and asked not to brush their teeth and not to use any type of floss 6-8 hours before the visit. DMFS score, gingival index, staining, and calculus were assessed to evaluate the participant’s oral health.

The participants were thoroughly instructed on using both aids through detailed video tutorials. Additionally, an examiner closely observed the participants during the performances and provided hands-on guidance to ensure they were using the aids correctly. Participants randomly

decided on which side they would use dental floss (Oral B) and on which side they would use the oral irrigator (Waterpik Cordless Plus Water Flosser), both aids were used by the participants themselves. Sillness and Loe plaque scores were recorded before and after the performances by an examiner who was blinded to which method was used for which side. For inter-comparison and intra-comparison, a t-test was used, and a p-value of ≤0.05 was assessed to be statistically significant.

Each intervention was conducted during a single visit, with each visit lasting approximately 25 minutes. There was no follow-up required for participants after the intervention; however, there was a 15-minute interval between the pre- and post-intervention plaque assessments. The duration taken by each participant for the intervention itself was 5 minutes.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dental Floss, Oral Irrigator

Primary outcome(s)
1. Dental plaque is measured using the Sillness and Loe plaque index at baseline
2. Dental plaque is measured using the Sillness and Loe plaque index after cleaning with an oral irrigator
3. Dental plaque is measured using the Sillness and Loe plaque index after cleaning with dental floss

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
14/03/2024

Eligibility

Key inclusion criteria
1. Adult (18 - 65 years old)
2. Visiting Um Al-qura Teaching Hospital
3. Able to watch video tutorials and comprehend live instructions
4. Agree to participate in the intervention and answer all the questionnaires.
5. Didn’t use any type of floss or brush their teeth 6-8 hours prior to the trial

Participant type(s)
Patient, Population

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
85

Key exclusion criteria
Does not meet the previous inclusion criteria, also:
1. Who didn’t complete the given questionnaire
2. Did not approve to participate in the trial and did not sign the consent form.

Date of first enrolment
27/11/2023

Date of final enrolment
14/03/2024

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Um Alqura Dental Teaching Hospital
Makkah
Saudi Arabia
24352

Sponsor information

Organisation
Um Alqura University

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
Dr. Afnan Nassar, Umm Al-Qura University, Faculty of Dentistry, Saudi Arabia.
SPSS file (unidentified)
The data will be available upon request for two years.
Data can be accessed by the journal to which we will submit our article, any Saudi Governmental authority, researchers after careful consideration of their scientific intention to use.
All data are anonymous with no identification

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			15/11/2024	No	No
Participant information sheet	version 1.0		15/11/2024	No	Yes