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Comparing the effect of small brushes specially designed to clean between teeth on the health of supporting structures of the teeth

Submission date
18/11/2019

Recruitment status
No longer recruiting

Registration date
20/11/2019

Overall study status
Completed

Last Edited
05/09/2022

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Interdental brushes help to prevent gum disease by getting rid of pieces of food and plaque from between the teeth. They have small bristled heads designed to clean between teeth and come in different widths to suit the sizes of the gaps in the teeth.
The aim of this study is to evaluate the cleaning efficacy of waist-shaped compared to straight soft interdental brushes in patients undergoing non-surgical gum (periodontal) treatment.

Who can participate?
Dental patients aged 35 years or over who require non-surgical periodontal therapy

What does the study involve?
Participants will be asked to use two different styles of interdental brushes to clean in between the teeth in either side of their mouth. They will be instructed to use the same style on the same side of their mouth for the duration of the study (8-weeks). At the start and the end of the study participants will have a full inspection of teeth and gums.

What are the possible benefits and risks of participating?
Benefits: possible improvement in gum health
Risks: None expected

Where is the study run from?
Medical University of Vienna, Austria

When is the study starting and how long is it expected to run for?
February 2017 to February 2018

Who is funding the study?
Medical University of Vienna (Medizinische Universität Wien), Austria

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
1670/2016

Study information

Scientific Title
The influence of different interdental brush designs on the efficacy of plaque removal during non-surgical periodontal treatment: A splitmouth randomized controlled trial

Study objectives
Waist-shaped interdental brushes yield better cleaning efficacy than straight designed brushes in patients undergoing periodontal therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/10/2016, Ethics Committee of the Medical University of Vienna (Borschkegasse 8b /6; A-1090 Vienna, Austria; ethikkommission.meduniwien.ac.at; +43 1 40 400 – 21470), ref: Nr. 1670/2016

Primary study design
Interventional

Study design
Split-mouth randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Periodontal problems

Interventions
Following inclusion into the study, a periodontal status comprising whole-mouth probing pocket depths (PPD) and bleeding on probing (BOP) assessment, PCR, approximal plaque index (API), papillary bleeding index (PBI), and smoking status were evaluated (time point 1, T1). Patients received supragingival debridement and were instructed not to use further oral hygiene cleaning devices except for electric tooth brush with the same brush head, which has been given to the patients as well as to apply the same toothpaste. Initial periodontal therapy was started at the second visit (T2), and PCR, API, and PBI were assessed again. A blinded examiner determined the Plaque Index (PI) according to Silness & Loe at eight areas of the teeth adjacent to the interdental spaces including the following: buccomesial, buccal, buccodistal, distal, distolingual, lingual, mesiolingual and mesial.

Two interdental brushes of either soft straight or waist-shaped design were randomly allocated to the four sites. With regard to the size of the interdental spaces, the following brushes were applied: straight soft interdental brushes of either 3 mm diameter (red) or 4 mm diameter (blue), or waist-shaped brushes of either 5-3-5 mm diameter (No. 3, white) or 7-4-7 mm diameter (No. 5, red), respectively. Randomization was performed via a online available tool.For each patient, the two brushes were randomly assigned to either the right or the left side with the concordant dental interspaces. For oral hygiene, additionally to an electric toothbrush and tooth paste, patients were instructed only to use the interdental brushes at the previously determined sites. Following this procedure, non-surgical periodontal therapy using curettes and sonic scaler was performed by skilled periodontists with a specialization in periodontology (SH, HH, CW, Division of Conservative Dentistry and Periodontology, University Clinic of Dentistry, Medical University of Vienna, Vienna, Austria). Patients were provided with a sufficient number of interdental brushes for home use until the next appointment. To complete periodontal therapy, time point three (T3) was scheduled within two weeks after T2. Reevaluation was performed eight weeks later at the final appointment (T4).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Interdental brushes

Primary outcome(s)
Plaque index measured using site-specific plaque index at baseline and 8-weeks

Key secondary outcome(s)
1. Probing pocket depth measured using periodontal probe at baseline and 8-weeks
2. Bleeding on probing measured by visual inspection at baseline and 8-weeks

3. Plaque control record (PCR) measured using visual inspection at baseline and 8-weeks
4. Approximal plaque index (API) measured using visual inspection at baseline and 8-weeks
5. Papillary bleeding index (PBI) measured using visual inspection at baseline and 8-weeks

Completion date
01/09/2018

Eligibility

Key inclusion criteria
1. ≥ 35 years of age at time of periodontal therapy start
2. No history of periodontal therapy
3. No physical or mental impairment
4. No medication influencing saliva flow
5. No special dietary restrictions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
10

Key exclusion criteria
1. Presented with oral diseases other than periodontal disease
2. Suffered systemic diseases that could influence the outcome of therapy (e.g. uncontrolled diabetes mellitus)
3. Not using an electric toothbrush from the same brand
4. Did not have four interdental spaces eligible for the used interdental brushes

Date of first enrolment
01/02/2017

Date of final enrolment
01/02/2018

Locations

Countries of recruitment
Austria

Study participating centre
Medical University of Vienna
University Clinic of Dentistry
Sensengasse 2a
Vienna
Austria
1090

Sponsor information

Organisation
Medical University of Vienna

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
University/education

Funder Name
Medizinische Universität Wien

Alternative Name(s)
Medical University of Vienna, MediUni Wien

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Austria

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2021	28/05/2020	Yes	No
Protocol file	version 1.2	26/09/2016	05/09/2022	No	No