

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

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| Submission date 18/11/2019 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 20/11/2019 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 05/09/2022 | Condition category Oral Health | <input type="checkbox"/> 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?
Dr Christian Wehner
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Study design

Split-mouth randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Plaque index measured using site-specific plaque index at baseline and 8-weeks

Secondary outcome measures

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

Overall study start date

01/05/2016

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

Age group

Adult

Sex

Both

Target number of participants

10

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

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Sponsor information**Organisation**

Medical University of Vienna

Sponsor details

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Sponsor type

University/education

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/02/2020

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 |