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A clinical study to assess the efficacy of an electric toothbrush to reduce dental plaque and gum inflammation in persons who have braces to align teeth

Submission date
08/02/2022

Recruitment status
No longer recruiting

Registration date
15/02/2022

Overall study status
Completed

Last Edited
16/06/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
For patients undergoing orthodontic treatment (braces) with the use of fixed appliances, the maintenance of proper hygiene critical for oral health can be a challenge. The presence of brackets, archwires, and other appliance components limits their hygiene accessibility and therefore may lead to increased plaque (a sticky film of bacteria that constantly forms on teeth) accumulation that may enhance the risk of tooth decay and gum disease. New electric toothbrushes are under continuous review for efficacy improvement.
The objective of this study is to evaluate and compare the effect of an electric toothbrush versus a manual toothbrush in the reduction of dental plaque among a general population with fixed orthodontic appliances over a 12-week period using the Turesky Modified Quigley-Hein Plaque Index. The secondary objective is to assess the reduction of gingivitis using the Löe Silness Gingival Index.

Who can participate?
Generally healthy adults and adolescents (at least 13 years old) with evidence of dental plaque and gingivitis

What does the study involve?
Participants will be randomly assigned to either the test group (an electrical toothbrush) or the control group (a regular manual toothbrush). Participants will use their assigned toothbrush with a regular toothpaste twice daily at home for the duration of the study in place of their regular toothbrush and toothpaste. Toothbrushes will be returned at the end of the study. The study is designed to assess if the participants in the test group experience an improvement in oral health. Plaque measurements will be taken at: Baseline visit (pre- and post-brushing), Week 6, and Week 12 visits (both pre-brushing only). Gingivitis measurements will be taken at: Baseline, Week 6, and Week 12 visits. The individual appointments at Baseline, Week 6 and Week 12 will be scheduled for approximately the same daytime for all three visits. Subjects will be instructed to abstain from any oral hygiene for 12 hours prior to all visits.

What are the possible benefits and risks of participating?
Participation will help with the development of products that aim to improve oral health. There will be no notable risks involved with participating. This study involves the use of toothbrushes as part of a normal oral hygiene routine. No behaviour with increased risk will be requested from participants. The toothpaste provided in this study is currently marketed. The risk from chemical hazard is negligible, or no greater than what would have been encountered during daily life. Also, both kinds of toothbrushes are currently marketed. Toothbrushes are not anticipated to cause any serious or long-term effects on oral tissue including gum recession.

Where is the study run from?
Universitätsmedizin der Johannes-Gutenberg-Universität Mainz (Germany)

When is the study starting and how long is it expected to run for?
December 2021 to August 2022

Who is funding the study?
Procter and Gamble Company (USA)

Who is the main contact?
Prof. Dr. Christina Erbe, PhD
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Clinical Protocol 2021097

Study information

Scientific Title
A clinical evaluation to compare a power toothbrush to a manual toothbrush in the reduction of plaque and gingivitis among a population with fixed orthodontic appliances

Study objectives
The objective of this study is to evaluate and compare the efficacy of an electric toothbrush versus a manual toothbrush in the reduction of dental plaque among a general population with fixed orthodontic appliances over a 12-week period using the Turesky Modified Quigley-Hein Plaque Index. Secondary objective is to assess the reduction of gingivitis using the Löe Silness Gingival Index.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval 10/05/2022, Ethik Kommission der Landesärztekammer Rheinland-Pfalz (Deutschhausplatz 3, 55116 Mainz, Germany; +49 6131 2882263; ethik-kommission@laek-rlp.de), ref: 2022-16383

Study design
Single-center examiner-blind 12-week 2 treatment parallel-group randomized study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Evidence of dental plaque and gingivitis in an orthodontic population

Interventions
Participants are stratified at baseline on mean gingivitis score, number of bleeding sites, mean pre-brushing plaque index and age. Within these strata, participants are randomly assigned to either the Test group (electric toothbrush) or the Control group (regular manual toothbrush). The randomization will be done using a computer-based program which is provided by the sponsor.

Participants are instructed to use the study products according to the manufacturer's instructions (electrical toothbrush) or in their customary manner (manual toothbrush) at home twice daily (morning and evening) in place of their normal oral hygiene for the duration of the study (12 weeks). Both products will be used with a regular marketed dentifrice.

Plaque measurements will be taken at: Baseline visit (pre- and post-brushing), Week 6, and Week 12 visits (both pre-brushing only). Gingivitis measurements will be taken at: Baseline, Week 6, and Week 12 visits.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
1. Dental plaque (pre-brushing) measured by Turesky Modified Quigley Hein Plaque Index at baseline, week 6 and week 12.
2. Gingival inflammation measured by Modified Gingival Index at baseline, week 6 and week 12.

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
15/12/2021

Completion date
30/08/2022

Eligibility

Key inclusion criteria
1. Give written informed consent (including her/his guardians in case of being adolescent) and be given a signed copy of the Informed Consent form
2. Have fixed orthodontic appliances in both dental arches
3. Be at least 13 years old and typically use a manual toothbrush
4. Possess a minimum of 16 natural teeth (excluding third molars) with facial and lingual scorable surfaces
5. Have a whole mouth average Baseline TQHPI score of 1.75
6. Have a Baseline whole mouth mean LSGI score of at least 1.75 but not more than 2.5
7. Be in general good health as determined by the Investigator/designee based on a review /update of their medical history
8. Agree not to participate in any other oral care study for the duration of this study
9. Agree to return for scheduled visits and follow the study procedures
10. Agree to refrain from use of any non-study oral hygiene products (Exception: floss if they are currently using) for the duration of the study
11. Agree to delay any elective dentistry, including dental prophylaxis, until the completion of

the study and to report any non-study dentistry received during the course of this study
12. Refrain from brushing their teeth or from performing any other oral hygiene procedure anytime within the 12 hours prior to -- Refrain from medicated lozenges, breath mints, eating, drinking*, chewing gum and using tobacco for at least 4 hours prior to this visit and agree to follow these same restrictions prior to all visits. *(Allowed small sips of water up until 45 minutes prior to their appointments.)

Participant type(s)
Healthy volunteer

Age group
Other

Sex
Both

Target number of participants
60

Key exclusion criteria
1. A condition requiring the need for antibiotic premedication prior to dental procedures
2. Severe periodontal disease, including but not limited to, purulent exudates, generalized mobility, and/or severe recession
3. Teeth that are grossly carious, fully crowned, or extensively restored
4. Active treatment for the following conditions: periodontitis, cancer, or a seizure disorder
5. Report to be nursing or pregnant, or intend to become pregnant any time during the course of this study
6. Taking an antibiotic or using a chlorhexidine mouth rinse any time within the previous 2 weeks
7. Having a dental prophylaxis any time within the previous 4 weeks
8. Have any of the following: removable partial dentures, peri/oral piercings, a pacemaker or other implanted device
9. Oral/gum surgery within the previous two months
10. A disease or condition that could possibly interfere with examination/procedures or with the subject’s safe completion of this study

Date of first enrolment
24/03/2022

Date of final enrolment
07/04/2022

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsmedizin der Johannes-Gutenberg-Universität Mainz
Augustusplatz 2

Mainz
Germany
55131

Sponsor information

Organisation
Procter & Gamble (United States)

Sponsor details
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Sponsor type
Industry

Website
http://www.pg.com/en_US/

ROR
https://ror.org/04dkns738

Funder(s)

Funder type
Industry

Funder Name
Procter and Gamble

Alternative Name(s)
Procter & Gamble, PandG, The Procter & Gamble Company, P&G

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The study protocol, statistical analysis plan, and other additional documents are not intended to become available online.

Intention to publish date
31/03/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because if the raw data is available but not analyzed appropriately by qualified experts in the area, it may lead to misinterpretation of the results.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			16/06/2025	No	No