

A study to assess the use of an electric tooth brushing kit to reduce dental plaque and gum disease in teenagers undergoing an orthodontic treatment

Submission date 24/06/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/07/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/08/2023	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

For patients undergoing orthodontic treatment 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 accumulation that may enhance the risk of caries and gingivitis. New electric toothbrushes are under continuous review for efficacy improvement.

The objective of this study is to evaluate and compare the efficacy of an electric toothbrush kit versus a manual toothbrush in the reduction of dental plaque among a population aged 13-19 years 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 teenagers (13-19 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 kit with 2 different brush heads) or the control group (a regular manual toothbrush). Participants will use their assigned toothbrush with regular toothpaste twice daily at home for the duration of the study in place of their regular toothbrush and toothpaste. 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. Participants 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 a chemical hazard is negligible, or no greater than what would have been encountered during daily life. 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?

August 2022 to December 2022

Who is funding the study?

Procter and Gamble (USA)

Who is the main contact?

Prof. Dr. Christina Erbe, PhD (Germany)

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Contact information

Type(s)

Scientific

Contact name

Prof Christina Erbe

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

2022044

Study information

Scientific Title

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

Study objectives

The objective of this study is to evaluate and compare the efficacy of an electric toothbrush kit versus a manual toothbrush in the reduction of dental plaque among a population aged 13-19 years with fixed orthodontic appliances over a 12-week period using the Turesky Modified Quigley-Hein Plaque Index. The secondary objective is to assess the level of gingivitis using the Löe Silness Gingival Index.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Submission pending as of 01/07/2022, Commission of the State Medical Association of Rhineland-Palatinate (Kommission der Landesärztekammer Rheinland-Pfalz, Körperschaft des öffentlichen Rechts, Deutschhausplatz 3, 55116 Mainz, Germany; +49 6131 28822-63/-64/-65/-67; ethik-kommission@laek-rlp.de), ref: not available

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 the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Evidence of dental plaque and gingivitis

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 regularly 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

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Electrical toothbrush, manual toothbrush

Primary outcome measure

Dental plaque (pre-brushing) measured by Turesky Modified Quigley-Hein Plaque Index at baseline, week 6 and week 12

Secondary outcome measures

Gingival inflammation measured by Löe Silness Gingival Index at baseline, week 6 and week 12

Overall study start date

01/06/2022

Completion date

16/12/2022

Eligibility

Key inclusion criteria

1. Give written informed consent (including her/his guardians) and be given a signed copy of the Informed Consent form
2. Have fixed orthodontic appliances in both dental arches
3. Aged between 13 and 19 years old and typically use a manual toothbrush
4. Minimum of 16 natural teeth (excluding third molars) with facial and lingual scorable surfaces
5. Whole mouth average Baseline TQHPI score of 1.75
6. Mild to moderate gingivitis with a range of 10% to 70% bleeding sites
7. General good health as determined by the Investigator/designee based on a review/update of their medical history

8. No participation 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 the 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 all visits and agree to follow these same restrictions prior to all visits
13. 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

Total final enrolment

64

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:
 - 4.1. Periodontitis
 - 4.2. Cancer
 - 4.3. Seizure disorder
5. Taking an antibiotic or using a chlorhexidine mouth rinse any time within the previous 2 weeks
6. Having dental prophylaxis any time within the previous 4 weeks
7. Have any of the following:
 - 7.1. Removable partial dentures
 - 7.2. Peri/oral piercings
 - 7.3. A pacemaker or other implanted device
8. Oral/gum surgery within the previous two months
9. 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

29/08/2022

Date of final enrolment

09/09/2022

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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Mason

United States of America

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timh@pg.com

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

1. Planned publication in a high-impact peer-reviewed journal
2. The study protocol, statistical analysis plan, and other additional documents are not intended to become available online.
3. 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.

Intention to publish date

01/02/2023

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			17/08/2023	No	No