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A 4-week study to assess the efficacy of a new electric toothbrush to reduce dental plaque and gingival inflammation

Submission date
13/02/2023

Recruitment status
No longer recruiting

Registration date
13/03/2023

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
Gingivitis is a common and mild form of gum inflammation that commonly occurs because plaque accumulates on the teeth. It can be prevented and treated with good oral hygiene. Toothbrushes are continuously tested for their effectiveness and safety as new devices or improvements of features on existing devices are developed. The aim of this study is to evaluate and compare the efficacy of a new experimental electrical brush to a marketed sonic brush in the reduction of gingivitis and dental plaque over a 4-week period.

Who can participate?
Generally healthy adults with evidence of plaque and mild to moderate gingivitis.

What does the study involve?
Participants will be randomly assigned to either the test group (oscillating/rotating experimental electric toothbrush) or the Control group (marketed sonic electric toothbrush). Participants will use their assigned toothbrush with a regular toothpaste twice daily at home for the duration of the assignment. 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 in comparison to the Control.
Plaque measurements will be taken at: Baseline (pre- and post-brushing) and Week 4 visit (pre-brushing only). Gingivitis measurements will be taken at: Baseline and Week 4. The individual appointments at Baseline and Week 4 will be scheduled for about the same time for all visits. Participants will be instructed to abstain from any oral hygiene for 12 hours before 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 behavior 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. The experimental electrical toothbrush is made from materials used in currently marketed brushes

and the Control sonic electric toothbrush is currently marketed. There are no anticipated risks from the materials used in the experimental toothbrush. Also, toothbrushes are not anticipated to cause any serious or long-term effects on oral tissue including gum recession.

Where is the study run from?
Procter & Gamble, Oral Health Science Center (USA)

When is the study starting and how long is it expected to run for?
February 2023 to June 2023

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

Who is the main contact?
Malgorzata Klukowska, PhD, DDS
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
Clinical Protocol 2022084

Study information

Scientific Title
A 4-week study to compare a new oscillating/rotating electric toothbrush to a sonic toothbrush in the reduction of gingivitis and plaque

Study objectives
The objective of the study is to evaluate and compare the efficacy of a new experimental power brush to a marketed sonic brush in the reduction of gingivitis and dental plaque over a 4-week period by using the Modified Gingival Index, the Gingival Bleeding Index and the Rustogi Modification of the Navy Plaque Index.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/03/2023, Advarra IRB (6100 Merriweather Dr., Suite 600, Columbia, MD 21044, United States; +1 410.884.2900; no email provided), ref: Pro00069023

Primary study design
Interventional

Study design
Single-center examiner-blind 4-week 2-treatment parallel-group randomized study

Study type(s)
Prevention

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 tobacco use. Within these strata, participants are randomly assigned to either the Test group (experimental oscillating/rotating electric toothbrush) or the Control group (marketed sonic electric 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 at home twice daily (morning and evening) in place of their normal oral hygiene for the duration of the study (4 weeks). Both products will be used with a regularly marketed dentifrice.

Plaque measurements will be taken at: Baseline (pre- and post-brushing) and Week 4 visits (pre-brushing only). Gingivitis measurements will be taken at: Baseline and Week 4 visits.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
New oscillating/rotating electric toothbrush, sonic toothbrush

Primary outcome(s)
Number of bleeding sites change from baseline at Week 4 measured by the Gingival Bleeding Index

Key secondary outcome(s)
1. Whole mouth plaque change from baseline (pre-brushing) at Week 4. Plaque will be measured using the Rustogi Modification of the Navy Plaque Index (RMNPI)
2. Whole mouth plaque removal at Baseline (single brushing) measured as above

3. Gingivitis change from baseline at Week 4. Gingivitis will be measured using the Modified Gingival Index (MGI)

Completion date
23/06/2023

Eligibility

Key inclusion criteria
1. Give written informed consent prior to study participation and be given a signed copy of their informed consent form
2. Be at least 18 years of age and exclusively use a manual toothbrush
3. Be in good general health as determined by the investigator/designee based on a review /update of their medical history
4. Possess a minimum of 16 natural teeth with facial and lingual scorable surfaces
5. Have a whole mouth pre-brushing RMNPI score of greater than 0.5 for Baseline exam
6. Have localized or generalized gingivitis with a range of 10% to 70% bleeding sites (sites with a score of 1 or 2 on the GBI index) for Baseline exam
7. Agree not to participate in any other oral care study for the duration of this study
8. Agree to not to have any elective dentistry, including dental prophylaxis, until study completion and to report any non-study dentistry received at any time during the course of this study
9. Agree to refrain from using any non-study oral hygiene products for the study duration
10. Agree to return for all their scheduled visits and to follow all study procedures
11. Refrain from brushing their teeth or from performing any other oral hygiene procedure anytime within the 12 hours prior to Baseline Visit and agree to follow these same restrictions prior to all visits;
12. Refrain from medicated lozenges, breath mints, eating, drinking*, chewing gum and using tobacco (of any kind) 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
164

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. Self-reported pregnancy or nursing
4. Any carious lesions requiring restorative treatment
5. Suffer from diabetes
6. Active treatment for the following conditions: periodontitis, cancer, or a seizure disorder
7. Taking an antibiotic or using a chlorhexidine mouth rinse any time within the previous 2 weeks
8. Taking anti-inflammatory or anti-coagulant medications any time within the previous 2 weeks
9. Have any of the following: orthodontic appliances, removable partial dentures, peri/oral piercings, a pacemaker or other implanted - oral/gum surgery within the previous 2 months
10. A disease or condition that could possibly interfere with examination/procedures or with the subject's safe completion of this study (including allergies to dye)

Date of first enrolment
08/05/2023

Date of final enrolment
12/05/2023

Locations

Countries of recruitment
United States of America

Study participating centre
Procter & Gamble, Oral Health Science Center
8700 Mason-Montgomery Rd
Mason, OH
United States of America
45040

Sponsor information

Organisation
Procter & Gamble (United States)

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 and G, 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

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?
Results article		01/02/2025	16/06/2025	Yes	No