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A clinical study to assess the efficacy of two electric toothbrushes with two different modes of action to reduce dental plaque and gingival inflammation

Submission date
07/10/2024

Recruitment status
No longer recruiting

Registration date
07/10/2024

Overall study status
Completed

Last Edited
24/02/2025

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

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 effectiveness of a new electrical brush to a marketed sweeping sonic brush in the reduction of gingivitis and dental plaque over a 4-week period.

Who can participate?
Generally healthy adults aged 18 years and over 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 electric toothbrush) or the control group (marketed sweeping 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 group. Plaque measurements will be taken at baseline (pre- and post-brushing) and the week 4 visit (prebrushing 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 hazards is negligible, or no greater than what would have been encountered during daily life. Both electrical toothbrushes are 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?
August 2024 to December 2024

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

Who is the main contact?
Jasmin Erb, erb.j@pg.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
2024061

Study information

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

Study objectives
The objective of the study is to evaluate and compare the efficacy of an oscillating/rotating power brush to a marketed sweeping 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
Ethics approval required

Ethics approval(s)
approved 24/09/2024, Advarra IRB (6100 Merriweather Dr., Ste 600, Columbia, 21044, United States of America; +1 (0)4108842900; cirbi@advarra.com), ref: Pro00081932

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

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
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 (oscillating/rotating electric toothbrush) or the Control group (marketed sweeping sonic electric toothbrush). The randomization will be done using a computer-based program which is provided by the sponsor.

Test Group: Oral-B iO2 electric toothbrush with Oral-B iO Gentle Care brush head (OP030 /OR017).
Control Group: Laifen Wave White ABS (LFTB01-P) electric toothbrush handle with Laifen Super-Clean brush head.
Both groups will use a regular fluoridated toothpaste (Crest Cavity Protection, 0.243% Sodium Fluoride).

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)

Oral-B iO2 electric toothbrush with Oral-B iO Gentle Care brush head (OP030/OR017), Laifen Wave White ABS (LFTB01-P) electric toothbrush handle with Laifen Super-Clean brush head, regular fluoridated toothpaste (Crest Cavity Protection, 0.243% Sodium Fluoride)

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

Key secondary outcome(s))
1. Whole mouth plaque measured using the Rustogi Modification of the Navy Plaque Index (RMNPI) from baseline (pre-brushing) at Week 4
2. Whole mouth plaque removal measured using the Rustogi Modification of the Navy Plaque Index (RMNPI) at Baseline (single brushing)
3. Gingivitis measured using the Modified Gingival Index (MGI) from baseline at Week 4

Completion date
06/12/2024

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 mainly 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 localized or generalized gingivitis with a range of 10% to 70% bleeding sites (sites with a score of 1 in the Gingival Health Assessment at Screening)
6. Agree not to participate in any other oral care study for the duration of this study
7. 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
8. Agree to refrain from using any non-study oral hygiene products for the study duration
9. Agree to return for all their scheduled visits and to follow all study procedures
10. Refrain from brushing their teeth or from performing any other oral hygiene procedure anytime within the 12 hours prior to the Baseline Visit and agree to follow these same restrictions prior to all visits
11. 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

Upper age limit
99 years

Sex
All

Total final enrolment
143

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. Three or more carious lesions requiring restorative treatment
5. Active treatment for the following conditions: periodontitis, cancer, or a seizure disorder
6. Taking an antibiotic or using a chlorhexidine mouth rinse any time within the previous 2 weeks
7. Have diabetes
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 device (overnight removable retainers, bite splints & night guards are allowed)
10. Oral/gum surgery within the previous 2 months
11. 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)
12. Having a dental prophylaxis at any time within the previous 4 weeks

Date of first enrolment
15/10/2024

Date of final enrolment
31/10/2024

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