ISRCTN82976541 https://doi.org/10.1186/ISRCTN82976541

A clinical study to assess the effectiveness of an electric toothbrush with two different mode settings to reduce dental plaque and gum inflammation

Submission date
28/03/2022

Recruitment status
No longer recruiting

Registration date
08/04/2022

Overall study status
Completed

Last Edited
14/07/2023

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 effectiveness of two different frequency settings for a new experimental electric toothbrush to a regular manual toothbrush in the reduction of gingivitis and dental plaque over an up to 2-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 test group 1 (electric toothbrush with a 100 Hz operating mode), test group 2 (electric toothbrush with an 85 Hz operating mode) or the control group (regular manual 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 two test groups experience an improvement in oral health in comparison to the control group. Gingivitis measurements will be taken at the start of the study, week 1 and week 2 visits of period 1; plaque exams will be conducted at the start of the study and week 1 visit of all three periods. After periods 1 and 2, participants will use their regular at-home oral hygiene products for 2 weeks (washout). The individual appointments 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 regular manual 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?
All Sum Research Ltd. (Canada)

When is the study starting and how long is it expected to run for?
January 2022 to June 2022

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

Who is the main contact?
Dr Chhaju Ram Goyal, DDS
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Contact information

Type(s)
Scientific

Contact name
Dr Hans-Christoph Timm

Contact details
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Clinical Protocol 2021118

Study information

Scientific Title
A pilot study to compare a new electrical toothbrush used with two different frequency settings to a manual control toothbrush in the reduction of gingivitis and plaque

Study objectives
The objective of the study is to evaluate and compare the efficacy of two different frequency settings for a new experimental power brush to a regular manual brush in the reduction of gingivitis and dental plaque over an up to 2-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 14/04/2022, VERITAS IRB (8555 Transcanada Hwy., Suite 201, Saint-Laurent (Montreal), Quebec H4S 1Z6, Canada; +1 (0)514 337 0442; no email provided), ref: 2022-3003-10392-4

Study design
Randomized controlled examiner-blind three-treatment crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over 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
Dental plaque and gingivitis

Interventions
Participants will be stratified at period-1 baseline on mean gingivitis score, number of bleeding sites, and tobacco use. Within these strata, participants will be randomly assigned to either test group 1 (electric toothbrush with 100Hz operating mode), test group 2 (electric toothbrush with 85Hz operating mode) or the control group (regular manual toothbrush).

At the baseline of Period 1, each group will also be randomly assigned to one of two treatment sequences for Periods 2 and 3 based on what the participants were assigned for Period 1. The randomization will be done using a computer-based program which is provided by the sponsor.

Participants will be instructed to use the study products according to the manufacturer 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 assignment (2 weeks in Period 1, 1 week in Periods 2 and 3). Both products will be used with a regular marketed dentifrice.

The oral examinations and gingivitis measurements will be taken at baseline, week 1, and week 2 visits of Period 1; plaque exams will be conducted at baseline and week 1 visit of all three periods. After Periods 1 and 2, participants will use their regular at-home oral hygiene products for 2 weeks (washout).

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
electric toothbrush with a 100 Hz operating mode, electric toothbrush with an 85 Hz operating mode, manual toothbrush

Primary outcome measure
1. Gingival inflammation and bleeding measured by Modified Gingival Index (MGI) and Gingival Bleeding Index (GBI) at baseline, week 1, and week 2 (Period 1 only)
2. Dental plaque measured by Rustogi Modification of the Navy Plaque Index (RMNPI) at baseline (pre- and post-brushing) and week 1 (pre-brushing only)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
28/01/2022

Completion date
30/06/2022

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 typically 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 Baseline whole mouth mean MGI score of at least 1.75 but not more than 2.5
6. Have a Baseline whole mouth pre-brushing RMNPI score of greater than 0.5
7. Have at least 20 but not more than 90 bleeding sites (sites with a score of 1 or 2 on the GBI index) for baseline exam
8. Agree not to participate in any other oral care study for the duration of this study
9. 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
10. Agree to refrain from using any non-study oral hygiene products for the study duration
11. Agree to return for all their scheduled visits and to follow all study procedures
12. 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
1.3 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
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
42

Total final enrolment
42

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
teeth that are grossly carious, fully crowned, or extensively restored
3. Active treatment for the following conditions: periodontitis, cancer, or a seizure disorder
4. Report to be nursing or pregnant, or intend to become pregnant any time during the course of this study
5. Taking an antibiotic or using a chlorhexidine mouth rinse any time within the previous 2 weeks
6. Have any of the following: orthodontic appliances, removable partial dentures, peri/oral piercings, a pacemaker or other implanted device
7. Oral/gum surgery within the previous 2 months
8. 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
11/04/2022

Date of final enrolment
25/04/2022

Locations

Countries of recruitment
Canada

Study participating centre
All Sum Research Center Ltd.
6635 Kitimat Rd. #36 & #37
Mississauga, Ontario
Canada
L5N 6J2

Sponsor information

Organisation
Procter & Gamble (United States)

Sponsor details
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Mason
United States of America
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+1 (0)513 622 1000
timm.h@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
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
30/06/2024

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		18/11/2021	14/07/2023	No	No