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A study to compare the effectiveness of a new interactive toothbrush to a manual toothbrush in the reduction of gum disease and plaque over a 12-week period

Submission date
04/03/2021

Recruitment status
No longer recruiting

Registration date
04/03/2021

Overall study status
Completed

Last Edited
05/06/2023

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 a new interactive electric toothbrush with a whitening brush head to a marketed regular manual toothbrush in the reduction of gingivitis and plaque over a 12-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 (a new interactive 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 the baseline visit (before and after brushing), week 1, and week 12 visits (both pre-brushing only). Gingivitis measurements will be taken at the baseline, week 1, and week 12 visits. The individual appointments at baseline, week 1 and week 12 will be scheduled for about the same time for all three 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. 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?
All Sum Research Ltd. (Canada)

When is the study starting and how long is it expected to run for?
November 2020 to June 2021

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

Who is the main contact?
Dr Chhaju Ram Goyal, DDS
crgoyal@allsumrc.com

Contact information

Type(s)
Scientific

Contact name
Dr Chhaju Ram Goyal

Contact details
6635 Kitimat Rd. #36 & #37
Mississauga, Ontario
Canada
L5N 6J2
+1 (0)905 812 1099
crgoyal@allsumrc.com

Additional identifiers

Protocol serial number
Clinical Protocol 2020132

Study information

Scientific Title
A 12-week clinical study to compare a new power brush with a whitening brush head to a manual 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 interactive electrical brush with a whitening brush head to a regular manual brush in the reduction of gingivitis and dental plaque over a 12-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 22/01/2021, Veritas IRB Inc. (8555 Transcanada Hwy., Suite 201, Montreal, Quebec, H4S 1Z6, Canada; +1 (0)514 337 0442; nhamzeh@veritasirb.com), ref: 2021-2558-4024-4

Primary study design
Interventional

Study design
Single-center randomized controlled examiner-blind two-treatment parallel study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Mild to moderate gingivitis

Interventions
The randomization will be done using a computer-based program which is provided by the sponsor. Participants are stratified at baseline on tobacco use, mean gingivitis score, number of bleeding sites, and mean plaque index. Within these strata, participants are randomly assigned to either the test group (new interactive toothbrush with whitening brush head) or the control group (marketed regular manual toothbrush).

Participants are instructed to use the study products according to the manufacturer instructions (electric 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).

Gingivitis measurements are taken at baseline, week 1, and week 12 visits. Plaque measurements are taken at: baseline visit (pre- and post-brushing), week 1, and week 12 visits (both pre-brushing only).

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
1. Gingival inflammation and bleeding measured by Modified Gingival Index (MGI) and Gingival Bleeding Index (GBI) at baseline, week 1, and week 12
2. Dental plaque measured by Rustogi Modification of the Navy Plaque Index (RMNPI) at baseline (pre- and post-brushing), week 1, and week 12 (both pre-brushing only)

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
30/06/2021

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 whole mouth mean
8. Agree not to participate in any other oral care study for the duration of this study
9. Agree 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
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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
100

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. Have any of the following: orthodontic appliances, removable partial dentures, peri/oral piercings, a pacemaker or other implanted device
8. Oral/gum surgery within the previous 2 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
08/03/2021

Date of final enrolment
12/03/2021

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)

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		01/10/2022	05/06/2023	Yes	No