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# A clinical study to assess the efficacy of a new interactive toothbrush in the reduction of gingivitis and dental plaque

**Submission date**
02/09/2020

**Recruitment status**
No longer recruiting

**Registration date**
03/09/2020

**Overall study status**
Completed

**Last Edited**
12/01/2022

**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 (inflammation of the gums) represents perhaps the most common disease of the periodontium (the tissues that surround and support the teeth), with a majority of adolescents and adults with teeth affected worldwide. Various factors have been implicated in the extent or severity of gingivitis. Of these, the microorganisms (e.g. bacteria) in dental plaque are recognized as playing a prominent role. Without adequate oral hygiene (e.g. toothbrushing), plaque accumulation may be rapid and visible gingival inflammation occurs within a few days. Even with extreme plaque accumulation, thorough oral hygiene and mechanical plaque removal are reported to reduce gingivitis and restore health. Control of plaque is an essential element in effective oral hygiene programs. Oral hygiene devices (toothbrushes) are under continuous review for efficacy 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 sensitive brush head to a marketed regular manual toothbrush in the reduction of gingivitis and dental 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 (new interactive electrical toothbrush) or the Control group (regular manual toothbrush). Participants will use their assigned products with a regular toothpaste twice daily at home for the duration of the study. Plaque measurements will be taken at the first visit (before and after brushing), week 1 and week 12 visits (both before brushing only). Gingivitis measurements will be taken at the first visit, week 1, and week 12 visits. The individual appointments at the first visit, week 1 and week 12 will be scheduled for about the same daytime 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?
The study is designed to assess if the participants in the Test group will experience an

improvement in oral health. Participants will use the study products at home in place of their regular toothbrush and toothpaste. Products will be returned at the end of the study. The dentifrice which will be 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 kind of toothbrushes are currently marketed. Toothbrushes are not anticipated to cause any serious or long-term effects on oral tissue including gingival recession. This study involves the use of toothbrushes as part of a normal oral hygiene routine. No behavior with incremental risk will be requested from participants. In addition, their participation will help in the development of products that aim to improve oral health. There will be no notable risks involved with participating.

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?
August 2020 to December 2020

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 Chhaju Ram Goyal

### Contact details
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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Protocol serial number
Clinical Protocol 2020101

# Study information

## Scientific Title
A 12-week clinical study to compare a new power brush with a sensitive 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 sensitive 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 12/12/2019, Veritas IRB Inc. (8555 Transcanada Hwy., Suite 201, Montreal, Quebec, H4S 1Z6, Canada; +1 (0)514 337 0442; nhamzeh@veritasirb.com), ref: 16474-09:44:1710-12-2019

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

## Primary study design
Interventional

## Study type(s)
Prevention

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

## Interventions
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 sensitive brush head) or the Control group (marketed regular manual toothbrush).

Participants are 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 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

### 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
17/12/2020

## 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 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
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
14/09/2020

### Date of final enrolment
18/09/2020

## Locations

### Countries of recruitment
Canada

### Study participating centre
**All Sum Research Center Ltd.**
6635 Kitimat Rd. #36 & #37
Mississauga, Ontario
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## 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. Study protocol, statistical analysis plan, and other additional documents are not intended to become available online.

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Poster results | | 23/07/2021 | 12/01/2022 | No | No |
| Poster results | | 23/07/2021 | 12/01/2022 | No | No |