ISRCTN99297838 https://doi.org/10.1186/ISRCTN99297838

A clinical study to assess the efficacy of a new oral hygiene system in the reduction of gingivitis and dental plaque

Submission date
26/02/2020

Recruitment status
No longer recruiting

Registration date
27/02/2020

Overall study status
Completed

Last Edited
18/07/2022

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 represents perhaps the most common disease of the periodontium, with a majority of adolescents and dentate adults affected worldwide. Various factors have been implicated in disease extent or severity. Of these, the microorganisms in dental plaque are recognized as playing a prominent etiological role. In the absence of adequate oral hygiene, supragingival plaque accumulation may be rapid, and visible gingival inflammation manifested within a few days.
Even in extreme plaque accumulation conditions, thorough oral hygiene and mechanical plaque removal is reported to reduce gingivitis and restore health. Control of supragingival plaque is an essential element in effective oral hygiene programs. Oral hygiene devices are under continuous review for efficacy and safety, as new devices or improvements of features on existing devices are developed.
The objective of the study is to evaluate and compare the efficacy of a new oral hygiene system to a regular manual toothbrush in combination with a regular toothpaste 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.

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

What does the study involve?
Participants are randomly assigned to either the Test group (new interactive experimental electrical toothbrush, antimicrobial toothpaste, mouth rinse and dental floss) or the Control group (regular manual toothbrush and regular anti-cavity toothpaste). Participants assigned to the Test group are instructed to download and install the app for their toothbrush on their mobile device and to use the app when brushing for the duration of the study. Participants used their assigned products twice daily at home for the duration of the study.
Plaque measurements are taken at: Baseline visit (pre- and post-brushing), Week 1, and Week 12 visits (both pre-brushing only). Gingivitis measurements are taken at: Baseline, Week 1, and Week 12 visits. The individual appointments at Baseline, Week 1 and Week 12 are scheduled for

approximately the same daytime for all three visits. Participants are instructed to abstain from any oral hygiene for 12 hours prior to all visits.

What are the possible benefits and risks of participating?
The study is designed to assess if the participants in the oral hygiene system group will experience an improvement in oral health. Participants used the test products at home in place of their regular oral hygiene product for the duration of the study. Products are returned at the end of the study.
Both dentifrices, the mouth rinse and the dental floss provided in this study are 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 as part of the oral hygiene system 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.
Toothbrushes are not anticipated to cause any serious or long-term effects on oral tissue including gingival recession. This study involved the use of toothbrushes as part of a normal oral hygiene routine. No behavior with incremental risk is requested from participants. In addition, their participation helped in the development of products that aim to improve oral health. Taking part in this study posed minimal risk to participants.

Where is the study run from?
All Sum Research Ltd., Mississauga, L5N 6J2, Canada.

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

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
All Sum Research Center Ltd.
6635 Kitimat Rd. #36 & #37
Mississauga, Ontario
Canada
L5N 6J2
+ 1 (905) 812-1099
crgoyal@allsumrc.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019162

Study information

Scientific Title
A 12-week clinical study to evaluate the efficacy of an oral hygiene system on gingival health benefits

Study objectives
12 weeks use of an oral hygiene system will result in better gingival health when compared to a regular toothbrush and toothpaste (measured for gingivitis using the Modified Gingival Index [MGI] and Gingival Bleeding Index [GBI] and measured for plaque using the Rustogi Modification of the Navy Plaque Index [RMNPI]).

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; +1 514.337.0442; 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

Secondary study design
Randomised parallel trial

Study setting(s)
Other

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
Oral mild to moderate gingivitis

Interventions
Eligible participants will be stratified based on Baseline gingivitis score (MGI) (≤ 2.1 vs. > 2.1), whole mouth mean pre-brushing plaque (RMNPI) (≤ 0.60 vs. > 0.60), number of bleeding sites (≤ 25.0 vs. > 25.0) and tobacco use. Within these strata, participants will be randomly assigned to either the new oral hygiene system group (consisting of a new interactive electrical toothbrush, antimicrobial toothpaste, mouth rinse and dental floss) or the Control group (regular toothbrush and toothpaste) using a balance and assignment procedure on site. This assignment process and the distribution of test products will be conducted in a protected area that will ensure blinding of the examiner to the identity of the test products.

Oral Hygiene System: Participants will be instructed to download and install the App for their assigned brush on their mobile device and to use the App when brushing for the duration of the study. They will be instructed to brush their teeth with the assigned electrical toothbrush and the marketed dentifrice for 2 minutes twice a day (morning and evening) following the manufacturer's usage instructions and to floss the whole mouth once daily for the duration of the study. After brushing, participants will be instructed to rinse with 20ml of the mouth rinse for 30 seconds.

Control: Participants will be instructed to brush their teeth with the assigned products twice daily (morning and evening) in their customary manner. Participants will be instructed to rinse with water after brushing.

Participants used only the treatment products in place of normal oral hygiene products for the duration of the study.

Gingivitis measurements will be taken at: Baseline, Week 1, and Week 12 visits.
Plaque measurements will be taken at: Baseline visit (pre- and post-brushing), Week 1, and Week 12 visits (both pre-brushing only).

Intervention Type
Other

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 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)

Secondary outcome measures
No secondary outcome measures

Overall study start date
20/01/2020

Completion date
12/06/2020

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. Possess a smartphone which runs Android 7.0 to 10.0, or an iPhone that runs on iOS 11.0 to 13.0 and agree to download a toothbrushing app from the manufacturer of the assigned brush. The mobile device must support Bluetooth 4.2 (or higher)/Bluetooth Smart
6. Have a Baseline whole mouth mean MGI score of at least 1.75 but not more than 2.5
7. Have a Baseline whole mouth pre-brushing RMNPI score of greater than 0.5
8. 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
9. Agree not to participate in any other oral care study for the duration of this study
10. 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
11. Agree to refrain from using any non-study oral hygiene products for the study duration
12. Agree to return for all their scheduled visits and to follow all study procedures
13. 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
14. 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
Not Specified

Target number of participants
60

Total final enrolment
60

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 two months
9. Any disease or condition that could possibly interfere with examination/procedures or with the subject's safe completion of this study

Date of first enrolment
02/03/2020

Date of final enrolment
06/03/2020

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
8700 Mason-Montgomery Road
Mason
United States of America
45040
+1 513-622-1000
timm.h@pg.com

Sponsor type
Industry

Website
http://www.pg.com

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.

Intention to publish date
31/12/2020

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?

Results article	01/10/2021	18/07/2022	Yes	No