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A study to evaluate the plaque removal efficacy of a new manual toothbrush

Submission date
03/09/2020

Recruitment status
No longer recruiting

Registration date
03/09/2020

Overall study status
Completed

Last Edited
19/11/2021

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
Control of supragingival (above the gumline) plaque is essential for effective oral hygiene. Oral hygiene devices such as toothbrushes are under continuous review for effectiveness and safety as new devices or improvements of features on existing devices are developed. The aim of this study is to assess the plaque removal effectiveness of a new manual toothbrush with a replaceable brush head against a marketed manual brush.

Who can participate?
Generally healthy adults with evidence of plaque

What does the study involve?
Participants will be randomly assigned to one of four treatment sequences. Every participant will use each of the two toothbrushes (either a new manual toothbrush with a replaceable brush head or a regular manual toothbrush) twice. At each visit (period 1 to period 4), dental plaque will be measured before and after brushing. Participants will be instructed to refrain from brushing their teeth for 24 hours before their appointment times for all visits. All participants will be instructed to use their regular home oral hygiene products for the duration of the study in between visits.

What are the possible benefits and risks of participating?
Products will be returned at the end of the study. Both manual toothbrushes and the dentifrice provided in this study are currently marketed. The risk from chemical or mechanical hazards is negligible, or no greater than what would have been encountered during daily life. This study will involve the use of toothbrushes with toothpaste 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. Taking part in this study poses minimal risk to participants.

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?
October 2020, planned duration: 2 weeks

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
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Clinical Protocol 2020100

Study information

Scientific Title
A study to compare the plaque removal efficacy of a new manual toothbrush with replaceable brush heads to a positive control manual toothbrush

Study objectives
The purpose of this study is to assess the plaque removal efficacy of a new manual toothbrush with a replaceable brush head against a marketed manual brush using the extended Turesky Modified Quigley-Hein Index (TQHPI).

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 31/08/2020, Veritas IRB Inc. (8555 Transcanada Hwy, Suite 201, Montreal, Quebec, H4S 1Z6, Canada; +1 (0)514 337 0442; Nathalie Hamzeh nhamzeh@veritasirb.com), ref: 16602-09: 37:0928-08-2020

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

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
General healthy adults with evidence of overnight dental plaque

Interventions
Every participant will use each of the two toothbrushes (either new manual toothbrush with a replaceable brush head or a regular manual toothbrush) twice. Participants will be randomly assigned to one of four treatment sequences (ABBA, BAAB, AABB, BBAA) according to a computer-generated randomization plan prepared in advance of study execution, where A and B are the two test toothbrushes. Both products will be used with a regular marketed dentifrice. Interventions will be scheduled at Day 1, Day 3, Day 5, and Day 7 (minimum of 48 h washout in between visits). At each visit participants will be instructed to brush their teeth with the assigned toothbrush for 1 minute in their customary manner. All participants will be instructed to use their regular home oral hygiene products for the duration of the study in between visits. Dental plaque measurements will be taken at each visit (pre- and post-brushing).

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Dental plaque (pre- and post-brushing) measured using the Turesky Modified Quigley-Hein Plaque Index (TQHPI) at each visit (Day 1, Day 3, Day 5, and Day 7)

Key secondary outcome(s))
Current secondary outcome measures as of 16/10/2020:
There are no secondary outcome measures

Previous secondary outcome measures:
Dental plaque measured using a new exploratory plaque index at each visit (Day 1, Day 3, Day 5, and Day 7, pre- and post-brushing) in the age group of 7-9-year-old children

Completion date
16/10/2020

Eligibility

Key inclusion criteria
1. Give written informed consent and receive a copy of the signed 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. Have been previously qualified to participate in a plaque panel
5. Possess a minimum of 16 scorable teeth (excluding third molars) with facial and lingual scorable surfaces
6. Abstained from all oral hygiene procedures for approximately 24 hours prior to this visit and agree to follow this same restriction prior to all visits
7. Abstained from 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 appointment
8. Agree not to participate in any other oral care study for the duration of this study
9. Agree to delay any elective dentistry, including dental prophylaxis, and to report any non-study dentistry received during the course of this study
10. Agree to refrain from using any non-study toothbrushes, dentifrices, mouth rinses, tooth whitening products or floss for the study duration other than their usual at-home toothbrush and toothpaste used between visits
11. Agree to maintain their same usual at-home toothbrush and toothpaste for the study duration
12. Agree to return for their scheduled visits and to follow all study procedures

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
52

Key exclusion criteria
1. Five or more carious lesions requiring restorative treatment
2. Active treatment for periodontitis
3. Active orthodontic therapy, or removable denture prosthesis
4. Any disease or condition that could be expected to interfere with examination procedures or

with the subject’s safe completion of this study (including allergies to dyes)
5. Using any antibiotics or a chlorhexidine mouth rinse any time within the 2 weeks prior to this visit

Date of first enrolment
28/09/2020

Date of final enrolment
02/10/2020

Locations

Countries of recruitment
Canada

Study participating centre
All Sum Research Center Ltd.
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Sponsor information

Organisation
Procter & Gamble (United States)

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. The 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?
Basic results		19/11/2021	19/11/2021	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes