ISRCTN80868903 https://doi.org/10.1186/ISRCTN80868903

A randomized clinical study to compare the efficacy of a new interactive toothbrush in the prevention of dental stain

Submission date 30/04/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/05/2021	**Overall study status** Completed	
Last Edited 11/06/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Tooth appearance can be dramatically impacted by extrinsic dental stains. Extrinsic dental stains are discolorations that accumulate on the external surface of the tooth and can be removed by toothbrushing, scaling, and/or polishing. Manual and electric toothbrushes have the potential to remove the surface dental stain by mechanical action. 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 prevention of dental stain over a 12-week period.

Who can participate?
Generally healthy adults with evidence of dental stain on the anterior teeth.

What does the study involve?
Participants will be randomly assigned to either the test group (a new interactive electric toothbrush with a whitening brush head) 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 the prevention of dental stain. Dental stain measurements will be taken at the first visit, week 4, and week 12 visits. At the first visit, participants will receive a partial prophylaxis on the anterior teeth to remove all surface stains.

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 be 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?
February 2021 to October 2021

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 2020137

Study information

Scientific Title
A clinical study to compare the stain prevention potential of a new power brush with a whitening brush head compared to a manual control toothbrush

Study objectives
The objective of this study is to assess the dental stain prevention potential of a new power toothbrush with a whitening brush head compared to a regular manual toothbrush.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/04/2021, Veritas IRB Inc. (8555 Transcanada Hwy., Suite 201, Montreal, Quebec, H4S 1Z6, Canada; +1 (0)514 337 0442; nhamzeh@veritasirb.com), ref: 2021-2679-5886-1

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
Dental stain on facial surfaces of the anterior teeth

Interventions
Participants are stratified at baseline on average modified Lobene composite score of the facial and lingual surfaces, smoking, the consumption of coffee/tea and age. 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).
Dental stain measurements are taken at baseline, week 4, and week 12 visits.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
1. Intensity and extent of extrinsic dental stain on the facial and lingual surfaces of the anterior teeth is measured using Composite Modified Lobene Stain Index at Week 4 and Week 12
2. Intensity and extent of extrinsic dental stain in four different regions (gingival, body, mesial and distal) on the facial surfaces of the anterior teeth is measured using Interproximal Modified Lobene Index at Weeks 4 and 12

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

Completion date

07/10/2021

Eligibility

Key inclusion criteria
1. Be at least 18 years of age and typically use a manual toothbrush
2. Provide written informed consent prior to participation and be given a signed copy of the informed consent form
3. Be in general good health as determined by the Investigator/designee based on a review /update of their medical history
4. Have a minimum of 10 anterior teeth suitable for grading (i.e., no crowns, bridge abutments, composites or porcelain veneers, large composite restorations or anterior calculus) with visible surface stain on the facial surfaces
5. Agree not to participate in any other oral care study for the duration of this study
6. Agree to return for scheduled visits and follow the study procedures
7. Agree to refrain from the use of any non-study oral hygiene products (including prescription rinses) for the duration of the study
8. Agree to delay any elective dentistry, including dental prophylaxis, until the completion of the study and to report any non-study dentistry received during the course of this study

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. Generalized gingival recession
2. Generalized malocclusion or overlapping of teeth
3. Inability to comply with brushing instructions (e.g. dexterity or comprehension issues)
4. Obvious periodontal disease, as evidenced by purulent exudate, tooth mobility, or any condition that could potentially compromise the integrity of the data
5. Fixed orthodontic appliances on the facial surfaces of their anterior teeth
6. Self-reported pregnancy or lactation
7. Severe or atypical intrinsic staining, such as that caused by tetracycline, fluorosis, or hypo-calcification on the facial surface of their anterior teeth
8. Carious lesions on the facial surface of their anterior teeth
9. Had a dental prophylaxis within the previous 2 months

10. Have any condition or disease, as determined by the Investigator/Designee, which could be expected to interfere with study procedures or with the subject’s safe completion of the study

Date of first enrolment
28/06/2021

Date of final enrolment
05/07/2021

Locations

Countries of recruitment
Canada

Study participating centre
All Sum Research Center Ltd
6635 Kitimat Rd. #36 & #37
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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.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes