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# A clinical study to compare the dental plaque removal of an electric versus a manual toothbrush with children age 3-6 years and 7-9 years.

**Submission date**
27/04/2020

**Recruitment status**
No longer recruiting

**Registration date**
28/04/2020

**Overall study status**
Completed

**Last Edited**
08/06/2021

**Condition category**
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Despite being largely preventable, dental caries remains a significant health problem among children in both developing and industrialized nations. 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 kids electrical to a kids regular manual toothbrush (both will be used with a regular toothpaste) in the reduction of dental plaque in a pediatric population aged 3-9 years.

Who could participate?
General healthy children between 3-9 years old with evidence of afternoon dental plaque.

What did the study involve?
Participants will be randomly assigned to one of four treatment sequences. Every participant will use each of the two toothbrushes (either kids manual or kids electrical toothbrush) twice. At each visit (period 1 to period 4), dental plaque was measured pre- and post-brushing.
Participants will be instructed to refrain from brushing their teeth after their morning brushing prior to all afternoon visits.
All participants will be instructed to use their regular home oral hygiene products for the duration of the study in between visits.

What will be the possible benefits and risks of participating?
The study is designed to compare the efficacy of an electrical toothbrush to a regular manual toothbrush in a replicate-use, single-brushing, randomized, four period crossover design. Participants will use each test product under supervision twice at the study site. Products will be returned at the end of the study.

The electrical and manual toothbrushes and the dentifrice provided in this study will be currently marketed. The risk from chemical or mechanical hazards was negligible, or no greater than what would have been encountered during daily life.
This study involves the use of toothbrushes with toothpaste as part of a normal oral hygiene routine. No behavior with incremental risk is 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 was the study run from?
Hadassah - Hebrew University Medical Center (Israel).

When was the study starting and how long was it expected to run for?
May to June 2019.

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

Who is the main contact?
Prof. Avi Zini,
AviZ@hadassah.org.il

# Contact information

### Type(s)
Scientific

### Contact name
Prof Avi Zini

### Contact details
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# Additional identifiers

### Protocol serial number
Clinical Protocol 2019058

# Study information

### Scientific Title
A pilot study to evaluate plaque removal efficacy by toothbrushing in two pediatric age group

### Study objectives

The objective of this research is to investigate whether the use of an electric toothbrush will result in better oral health when compared to a regular manual toothbrush with children in different age groups (measured for plaque using the Turesky Modified Quigley-Hein Plaque Index [TQHPI]).

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 27/05/2019, Hadassah Medical Organization Helsinki Committee (P.O.B 12272, Jerusalem 91120, Israel; no tel. provided; Helsinki@hadassah.org.il), ref: 0240-19-HMO

## Primary study design
Interventional

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

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
General healthy children between 3-9 years old with evidence of afternoon dental plaque

## Interventions
Every participant will use each of the two toothbrushes (either kids manual or kids electrical 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.
Age group 3-6 years: Parents will brush the teeth of their kids. Parents will be provided with red safety glasses which prevent them from seeing the disclosed plaque.
Age group 7-9 years: Kids will brush their teeth under supervision by themselves, unaided by a mirror.
Electrical toothbrush: Parents/participants will be instructed to brush their (kids') teeth with the assigned electrical toothbrush and the marketed dentifrice for two minutes following the manufacturer's usage instructions.
Control (manual toothbrush): Parents/participants will be instructed to brush their (kids') teeth with the manual toothbrush 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 were taken at each afternoon visit (pre- and post-brushing).

## Intervention Type
Other

## Primary outcome(s)
At each visit (period 1 to period 4), dental plaque (pre- and post-brushing) will be measured using the Turesky Modified Quigley-Hein Plaque Index (TQHPI)

## Key secondary outcome(s)

A new exploratory plaque index will be measured at each visit (period 1 to period 4, pre- and post-brushing) in the age group of kids 7-9 years old

### Completion date
30/06/2019

## Eligibility

### Key inclusion criteria
1. Come to the site with a parent or legal guardian which has given written informed consent and received a copy of their consent following the guidelines of the Institutional Review Board of Hadassah University
2. Be 3 to 9 years old
3. Be in good general health condition as determined by the Investigator/designee based on a review/update of their medical history for participation in the study
4. Possess a minimum of 16 natural teeth with facial and lingual scorable surfaces
5. Agree to delay any elective dentistry, including dental prophylaxis and to report any non-study dentistry received for the duration of this study
6. Have evidence of afternoon dental plaque (per investigator's discretion)
7. Agree to maintain their same regular at-home oral hygiene routine and oral care products for this study duration
8. Agree not to participate in any other oral care study for the duration of this study
9. Agree to return for their scheduled visits and to follow all study procedures
10. Refrain from eating, drinking* and chewing gum for at least 3 hours prior to this visit and agree to follow the same restriction prior to all visits; *(Exception being allowed small sips of water up until 45 minutes prior to their appointment time.)
11. Refrain from performing any other oral hygiene after their regular morning oral hygiene prior to this visit and agree to the same restriction prior to all visits

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
3 Years

### Upper age limit
9 Years

### Sex
All

### Total final enrolment
41

### Key exclusion criteria
1. Any disease or condition that could be expected to interfere with examination procedures or with the subject safely completing this study (including allergies to dyes or the need for pre-medication prior to dental procedures)
2. Any condition requiring immediate dental treatment
3. Fixed facial or lingual orthodontic appliances
4. Use of antibiotics within two weeks prior to study initiation
5. Receive dental prophylaxis within one month prior to study initiation

### Date of first enrolment
30/05/2019

### Date of final enrolment
04/06/2019

## Locations

### Countries of recruitment
Israel

### Study participating centre
**Dental clinic Dr. Esti Davidovich**
Aharon Becker 8
Mikado Center
Tel Aviv
Israel
6964316

## 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? |
|---|---|---|---|---|---|
| Results article | | 01/11/2020 | 08/06/2021 | Yes | No |