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A clinical study among adolescents comparing an interactive electric toothbrush with smartphone app to a manual toothbrush

Submission date
15/06/2018

Recruitment status
No longer recruiting

Registration date
18/06/2018

Overall study status
Completed

Last Edited
27/06/2019

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Teenagers are at risk of developing tooth decay and gum inflammation because of challenges common to this age group: reduced parental oversight of oral hygiene, frequent consumption of high-sugar and acidic drinks and snacks, and increased social and academic demands and distractions that can impact motivation to perform regular, conscientious toothbrushing. Individually and collectively, these factors can contribute to greater levels of undisturbed dental plaque, which could promote cavity formation and gum disease. Combining oral hygiene aids with advanced technology-based features that resonate with the teen demographic is a novel way of encouraging brushing teeth.
The aim of this study was to assess the plaque removal efficacy of an interactive electric toothbrush in combination with the use of a smartphone application compared with a regular manual toothbrush in an adolescent population over a period of 2 weeks.

Who could participate?
Generally healthy volunteers aged 13-17 with evidence of dental plaque indicating the need for improvement in oral hygiene.

What did the study involve?
Participants were randomly allocated to either the test group (interactive electric toothbrush connected to a smartphone app) or the control group (regular manual toothbrush). Both groups used a standard anti-cavity toothpaste. Participants were requested to use their assigned products twice daily at home for the duration of the study. At the start of the study and at week 2 participants received oral exams, a dental plaque measurement and their brushing time was recorded.

What were the possible benefits and risks of participating?
The study was designed to assess if the participants in the test group experience an improvement in oral health. The participants received information and education from dental professionals about the weaknesses in their oral hygiene routine and which tooth surfaces they need to pay more attention to when brushing. In addition, their participation helped in the

development of products that aim to improve oral health. There were no notable risks involved with participating.

Where was the study run from?
Universitätsmedizin der Johannes Gutenberg Universität Mainz (Mainz University Medical School), Germany.

When was the study starting and how long was it expected to run for?
June 2014 to July 2015

Who was funding the study?
Procter & Gamble (USA)

Who is the main contact?
Dr. Christina Erbe, erbe@uni-mainz.de

Contact information

Type(s)
Scientific

Contact name
Dr Christina Erbe

Contact details
Universitätsmedizin der Johannes Gutenberg Universität Mainz
Klinik für Zahn-, Mund- und Kieferkrankheiten
Poliklinik für Kieferorthopädie
Augustusplatz 2
Mainz
Germany
55151

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Clinical Protocol 2014062

Study information

Scientific Title
A comparative assessment of plaque removal and toothbrush compliance between a manual and an interactive electric toothbrush among adolescents: a single-center, single blind randomized controlled trial

Study objectives
The central aim of this clinical investigation in adolescents was to assess whether brushing with an interactive electric toothbrush would provide additional plaque removal efficacy beyond that achieved with a standard manual toothbrush, for both the whole dentition, and in individual subject Focus Care Areas.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the State Medical Association Rhineland Palatinate, 14/12/2014, 837.451.14 (9690)

Study design
Single-center examiner-blind parallel-group randomized study.

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Dental caries prevention

Interventions
Participants were stratified based on gender, baseline whole mouth mean plaque, age, and number of 'Focus Care' areas. Within strata, participants were randomly assigned equally to either the interactive electric toothbrush connected to a smartphone application or the control group (regular manual toothbrush). Both groups used a standard anti-cavity toothpaste.
Participants of the Test group were instructed to brush their teeth with the assigned interactive electric toothbrush (including the use of the smartphone application) for 2 minutes twice daily (morning and evening). They were instructed to brush in each 'Focus Care' area identified for an additional 10 seconds after they completed their overall brushing (as indicated by the smartphone application).
Participants of the Control group were instructed to brush their teeth with the assigned regular manual brush for 2 minutes twice daily (morning and evening) as they normally do. They were instructed to brush in each 'Focus Care' area identified for an additional 10 seconds after they completed their overall brushing.
Participants were requested to use exclusively their assigned products at home for the duration of the study (2 weeks).

Intervention Type
Device

Primary outcome measure
Changes in afternoon dental plaque accumulation after morning brushing (not later than 8 am) via measures of Turesky Modified Quigley-Hein Index analysed for whole mouth means and in individual 'focus care areas' (areas with need for improvement of oral hygiene), conducted at baseline and at the end of the treatment phase.

Secondary outcome measures
Change in brushing time (compliance) from baseline to the end of the treatment phase. Brushing time was recorded by the clinical staff in a discreet way using a regular stopwatch.

Overall study start date
01/06/2014

Completion date
18/07/2015

Eligibility

Key inclusion criteria
1. Provided written informed consent (including her/his guardians) and given a signed copy of the Informed Consent form
2. Aged 13-17 years
3. Typically uses a manual toothbrush
4. In good general health as determined by the investigator/designee based on a review of their medical history
5. Minimum of 16 natural teeth (excluding third molars) with facial and lingual scorable surfaces
6. At least one, but not more than four, 'Focus Care' areas (per investigator discretion)
7. Whole mouth average screening Turesky et al Modification of the Quigley Hein (TQHPI) score of ≥1.75
8. Agrees not to participate in any other oral care study for the duration of this study
9. Agrees to delay any elective dentistry, including dental prophylaxis, until study completion and to report any non-study dentistry performed on them at any time during the course of this study
10. Agrees to maintain their same regular at-home toothbrush and toothpaste between Screening and the Baseline visit
11. Agrees to refrain from using any non-study oral hygiene products for the duration of the study, except using their regular at-home toothbrush and toothpaste between the Screening and the Baseline visit
12. Agrees to return for their scheduled visits and follow all study procedures
13. Agrees to refrain from brushing their teeth and from performing any other oral hygiene procedures after their morning brushing (which is to be no later than 8 am) prior to the Screening visit and agree to follow these same restrictions prior to all visits
14. Agrees to refrain from eating, chewing gum, and drinking (except small sips of water up until 45 minutes prior to their appointment) for at least 2 hours prior to the Screening visit and agree to follow these same restrictions prior to all visits
15. Familiar with Android smartphone

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
13 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Several caries, open or untreated caries, severe gingivitis or advanced periodontitis requiring prompt treatment
2. Active treatment for periodontitis
3. Smoking or any other type of tobacco use
4. Use of antibiotics or a chlorhexidine mouth rinse any time within the 2 weeks prior to the Screening visit
5. Fixed orthodontic appliances or removable partial dentures
6. Receiving a dental prophylaxis any time within the 4 weeks prior of the Screening visit
7. (Peri)oral piercings
8. Any disease or condition that could be expected to interfere with examination procedures or with the subject’s safe completion of this study

Date of first enrolment
26/01/2015

Date of final enrolment
30/01/2015

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsmedizin der Johannes Gutenberg Universität Mainz
Klinik für Zahn-, Mund- und Kieferkrankheiten
Poliklinik für Kieferorthopädie
Augustusplatz 2

Mainz
Germany
55131

Sponsor information

Organisation
Procter & Gamble

Sponsor details
8700 Mason-Montgomery Road
Mason
United States of America
45040

Sponsor type
Industry

Website
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
31/12/2018

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	results	03/08/2018		Yes	No
Participant information sheet			02/04/2019	No	Yes