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Can using a manual toothbrush connected to a smartphone app that provides guidance on improving brushing technique reduce plaque and improve gum health?

Submission date
09/03/2020

Recruitment status
Suspended

Registration date
14/04/2020

Overall study status
Completed

Last Edited
02/06/2020

Condition category
Oral Health

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Twice daily toothbrushing is recommended to prevent gum disease and tooth decay. However, it has been reported by dentists that many people fail to brush for two minutes, twice a day. Researchers are interested in other ways to improve toothbrushing outside of the dental practice setting. From other research, it is clear that connected toothbrushes are a way to engage users in improving their oral health and have the ability to produce data that has never been captured before. For example, connected toothbrushes can report how often someone brushes their teeth whereas previously this would have been reported by the individual themselves which is often not accurate. Furthermore, connected brushes and their apps can offer different brushing modes – such as coaching – which are available with instructions and challenges designed to improved brushing habits even more.
The aim of this study is to evaluate the data that is produced by the brush (how often a user brushes, how long and how well) by comparing groups that brush with and without a connected brushing app. This data will also be compared to levels of plaque and gingivitis as assessed by a dentist.

Who can participate?
Healthy adults aged 18 to 65 years old (inclusive) will be eligible for this study. Participants need to be in good dental health, with no signs of advanced gum disease or dental decay. Participants must also own a smartphone with access to Wi-Fi.

What does the study involve?
The study will last for 6 weeks, with a total of three visits. Participants will be randomly divided into two groups – offline brushing and connected brushing. Both groups will receive a study toothbrush which is to be used throughout the course of the study. One group will be expected to brush with the connected brushing app for the duration of the study (in Coach+ mode). All participants will undergo a dental assessment at two out of the three visits (plaque, gingivitis and 3D scanning) and complete a questionnaire at all three visits.

What are the possible benefits and risks of participating?
There are minimal risks to taking part. There may be some inconvenience with the three visits but the examiners are experienced clinicians and visits will be booked using the practice appointment system to ensure timing is on track and amount of time needed is minimised. Participants will be reimbursed for their time. Participants may enjoy using the connected toothbrush and will be able to keep the brush at the end of study.

Where is the study run from?
The University of Manchester (UK)

When is the study starting and how long is it expected to run for?
December 2019 to June 2020

Who is funding the study?
The University of Manchester (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
268892

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NHS001656, IRAS 268892

Study information

Scientific Title
A randomised controlled trial to assess changes in oral hygiene resulting from the use of a connected manual toothbrush and smartphone application

Study objectives
Use of a connected toothbrush and associated smartphone application (providing both coaching and feedback) improves oral health over a 6-week period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/03/2020, Wales REC 7 (Public Health Wales, Building 1, Jobswell Road, St David's Park, Carmarthen, SA31 3HB; +44 (0)1267 611164, +44 (0)1874 615949; Wales.REC7@wales.nhs.uk), ref: 20/WA/0074

Study design
Single-centre single-blind two-cell parallel-group randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Plaque and gingivitis

Interventions
The study utilises a randomised, parallel, two-group design.

Advertisements, in the form of posters, will be placed at the dental practice one month before the start of the study. If participants would like to participate in the study they can speak to a member of the research team at the research site (local dental nurse or local dentist). The member of the research team (local dental nurse) will provide potential participants with an information sheet with further detail on the study. Potential participants interested in taking part will be provided with an appointment to return for screening and recruitment.

All potential subjects will undergo a screening visit prior to the study date. Upon successful recruitment, subjects will participate in this clinical trial for 6 weeks, compromising of a baseline

visit, an interim visit (at week 3) and a final examination visit (at week 6). We would expect each visit to last no more than 40 min per participant with the exception of the interim study visit which may take less time (15-20 min) due to no clinical indices being measured.

At the screening visit (Day 0 Visit), the participant will have the opportunity to discuss the study in detail with a member of the research team (local dentist). Should the participant indicate a willingness to take part, they will be asked to sign an informed consent form. The examiner (local dentist) will carry out a brief dental exam to assess if the participant meets the inclusion criteria, this examination involves the use of an overhead operating light, a dental mirror and a dental probe.

Screening and Enrollment (V0), Day -21 to -7 - Selection criteria applied, informed consent procedure, Medical History, Oral Soft Tissue Assessment. Participants who are successfully recruited will be provided with toothpaste for use throughout the study (Colgate Cavity Protection, 1450 ppm Fluoride Toothpaste, provided by local dental nurse). This toothpaste is available commercially without a prescription.

Baseline visit (V1), Day 0 - Medical History, Oral Soft Tissue Assessment, Gingivitis Scoring, Plaque Scoring, Intra-oral scan (for a sub-set), Randomised into control or test group, provision of M1 toothbrush, carry out first brushing session in clinic, ensure brushing sessions have synced to smartphone application and patient-reported experience questionnaire completed.

Second visit (V2), Week 3 - Medical History, Oral Soft Tissue Assessment, ensure brushing sessions have synced to smartphone application and patient-reported experience questionnaire completed.

Final visit (V3), Week 6 - Medical History, Oral Soft Tissue Assessment, Gingivitis Scoring, Plaque Scoring, Intra-oral scan (for a sub-set), ensure brushing sessions have synced to smartphone application, patient-reported experience questionnaire completed and undergo dental polish (optional).

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
1. Plaque levels assessed using Rustogi Modified Plaque Index at baseline and 6 weeks
2. Gingivitis level assessed visually using Modified Gingival Index (MGI) at baseline and 6 weeks

Key secondary outcome(s))
1. Brushing duration assessed using the app at baseline visit, 3 weeks and 6 weeks
2. Surface coverage assessed using the app at baseline visit, 3 weeks and 6 weeks
3. Brushing frequency assessed using the app at 3 weeks and 6 weeks
4. Perceived value at the individual level through collection of patient-reported experience measures (PREMS) using a previously validated 15-point oral health and brushing questionnaire at baseline, 3 weeks and 6 weeks
5. Diagnostic utility of the 3D intraoral scans for the measurement of plaque and gingivitis levels intraorally assessed using a TRIOS intraoral scanner at baseline and 6 weeks

Completion date
26/06/2020

Eligibility

Key inclusion criteria
1. Male and female subjects aged 18 to 65 years inclusive
2. Available for the 6-week study duration
3. Have a smartphone and are familiar with using smartphone applications
4. Access to Wi-Fi where they are performing oral hygiene
5. Minimum of 20 natural teeth, including 1 molar in each quadrant, with no extensive restorations present i.e. no crowns, no fillings covering multiple surfaces (excluding 3rd molars)
6. Initial gingival assessment with at least 4 bleeding sites
7. Able to read, understand and agree to the informed consent procedure
8. Able to tolerate an oral examination by a dental professional
9. Good general health

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Fixed orthodontic appliances, including orthodontic bands that interfere with any clinical assessment (plaque scoring)
2. Presence of partial removable dentures
3. Five or more decayed, untreated dental sites (cavities)
4. Advanced periodontal disease, with oral lesions or periodontal pockets >5.5 mm (gum disease)
5. Medical condition which requires pre-medication prior to dental visits/procedures
6. Use of drugs that can affect salivary flow
7. Use of antibiotics 1 month prior to or during this study
8. Allergy to common dentifrice ingredients
9. Pregnant or breastfeeding
10. Unable to attend all 3 visits
11. Have a cognitive impairment that prevents participation in the informed consent procedure
12. Have participated in any other oral care study or consumer/panel test within the last 3 months

Date of first enrolment
21/04/2020

Date of final enrolment
07/05/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Windsor Dental
Denhill House
Denhill Road
Hulme
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M15 5NR

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
University/education

Funder Name
University of Manchester

Alternative Name(s)
University of Manchester in United Kingdom, University of Manchester UK, The University of Manchester, UoM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No