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Evaluation of a school-based brushing programme using a smart toothbrush

Submission date
10/08/2023

Recruitment status
No longer recruiting

Registration date
28/12/2023

Overall study status
Completed

Last Edited
18/08/2025

Condition category
Oral Health

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

Plain English summary of protocol
Background and study aims
Dental caries (tooth cavities) in children remain an important public health issue, especially in areas of North West England and Greater Manchester. Dental caries are a preventable disease through adequate and frequent oral hygiene practices. School brushing programmes supporting optimal oral hygiene practices face barriers to implementation. Connected technologies and toothbrushes can overcome some of those barriers and support children to achieve optimal oral hygiene.
The main aim of this study is to explore the acceptability of a smart, connected brush with primary school age children living in underserved areas of Greater Manchester.

Who can participate?
Children aged 8-11 and their caregivers in primary schools across Greater Manchester

What does the study involve?
Teachers will provide students with the brushes and show them how to use them (after teachers receive training from the research team). Parents in the text message intervention group will be signed up to receive text messages too. Parents will complete a series of baseline measurements as outlined in our data collection document. Children will start using the product after they complete the baseline measurements for a 3-month period. Children will use the brush with parental support each morning and night. Teachers will receive a weekly dashboard showing how each class/school is doing to encourage children to brush more if necessary. At the end of the study, teachers and parents will receive a brief feedback form.

What are the possible benefits and risks of participating?
There are very few risks of taking part in the study. The brush is approved and used across the US with very little risk posed to children taking part. The app complies with all relevant data protection and safety laws. All data will be anonymised and safely stored to avoid any issues during and after the study.
Participants will be helping the researchers to better understand how to support children to create better oral hygiene routines and the role schools can play in this process. Children will be allowed to keep the brush at the end of the study and each participating family will receive a voucher for their participation in the study.

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

When is the study starting and how long is it expected to run for?
September 2022 to August 2023

Who is funding the study?
Colgate-Palmolive (USA)

Who is the main contact?
1. Dr Michaela Goodwin, michaela.goodwin@manchester.ac.uk
2. Dr George Kitsaras, georgios.kitsaras@manchester.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
326880

Central Portfolio Management System (CPMS)
55635

Protocol serial number
2023-15413-27815

Study information

Scientific Title
Exploring the feasibility of a school-based connected-brushing programme and its acceptability to teachers, children and caregivers

Acronym
Leapfrog

Study objectives
Feasibility study to explore the acceptability of a smart, electric brush in primary school age children in underserved areas of Greater Manchester

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/12/2022, University of Manchester Proportionate UREC (Oxford Road, Manchester, M13 9PL, United Kingdom; +44 (0)1613066000; propUREC@manchester.ac.uk), ref: 2023-15413-27815

Primary study design
Interventional

Study design
Feasibility cluster randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Improving oral hygiene practices in primary school children in underserved areas of Manchester

Interventions
All participating children will receive a smart, electric toothbrush to use each day at home (morning and bedtime). The smart, electric brush captures information on coverage, duration

and frequency of brushing commuting these data to children while they brush via an accompanying app.

Apart from the brush, teachers will have access to a brief, class-level dashboard where they can see how their class is doing (in comparison with other classes) and set challenges for the children to help them achieve better goals (or maintain good practices if they do well).

Finally, a subset of children will be assigned text message support (delivered to their parents' mobile phones). Text messages will contain messages directed at parents and children to emphasize key messages and to motivate them to continue using the brush.

All intervention elements will be delivered for 3 months (follow-up period). Brushes will be used at home directly by children with parental supervision. Teachers will receive access to the weekly dashboard on Monday each week. On school closures (Easter, Summer break, half-term etc) no dashboard will be provided. In the text message subgroup, parents will receive messages in a tapered approach with more text messages at the start and less towards the end of the study. In total, each parent will receive nine text messages over the course of the study.

Allocation on treatment arms will be at the school level (simple randomisation [flipping a coin]) with participating schools receiving either the connected brush and text messages or receiving only the connected brush.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hum by Colgate Smart toothbrush

Primary outcome(s)
Feasibility of using a smart, electric brush by children, assessed using:
1. Consent rate recorded as the number of participants consented at 2 weeks following the initial approach by the study team
2. Recruitment rate recorded as the number of participants who completed at least one of the study surveys post-consent (post-baseline)
3. Recruitment pathways for future studies recorded as the number of new sites (first time involved in research studies) taking part in the study
4. Acceptability of the interventions on schools and parents recorded at follow-up through surveys and brief feedback interviews

Key secondary outcome(s)
1. Knowledge, attitudes and practices regarding oral health measures by a KAPs questionnaire at baseline and end of follow-up
2. Oral hygiene practices measured by a brief oral hygiene survey at baseline, 1-week, 1-month, 2-month and 3-month follow-up

Completion date
05/08/2023

Eligibility

Key inclusion criteria
1. Children enrolled and attending primary schools in Greater Manchester aged 8 to 11 years
2. Participants must have WIFI in their home and a smart device that is compatible with the toothbrush and app. Access to Apple iPhone (newer than 8) or iPad (newer than 5th generation) or Android users (running Android 6.0 and up) with access to an Internet connection
3. Not having previously used the smart, electric brush that is distributed during the study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 Years

Upper age limit
11 Years

Sex
All

Total final enrolment
400

Key exclusion criteria
1. Concurrent participation in another oral health clinical study
2. Any oral or general health condition which may preclude the participation of the child in the study, as determined by the parent/caregiver
3. Current or previous use of the Hum by Colgate Toothbrush by the child

Date of first enrolment
01/03/2023

Date of final enrolment
01/05/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oasis Academy Harpur Mount
Alfred Street
Harpurhey
Manchester
United Kingdom
M9 5XR

Study participating centre
Longsight Community Primary
Farrer Road
Longsight
Manchester
United Kingdom
M13 0QX

Study participating centre
Ringway Primary School
Rossett Avenue
Manchester
United Kingdom
M22 0WW

Study participating centre
Pike Fold Primary School
Old Market Street
Manchester
United Kingdom
M9 8QP

Study participating centre
St James' CofE Primary School
Cromwell Range
Manchester
United Kingdom
M14 6HW

Study participating centre
St Anthony's Catholic Primary School
Dunkery Road

Wythenshawe
United Kingdom
M22 0NT

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Industry

Funder Name
Colgate-Palmolive Company

Alternative Name(s)
Colgate-Palmolive Company, Colgate, Colgate Palmolive

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
Datasets generated during and/or analysed during the current study will be available upon request from Dr George Kitsaras (georgios.kitsaras@manchester.ac.uk). Data will be shared depending on the nature of the request, only anonymised data will be shared. Data relating to the smart toothbrush will not be shared as they might involve IP not publicly available. Data can be requested at any point once analyses are completed (start of 2024). All participants have provided written consent. Data to be shared will be fully anonymised. Legal restrictions apply to IP-related data which will not be shared publicly.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/02/2025	13/02/2025	Yes	No
Results article		15/08/2025	18/08/2025	Yes	No