

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

<b>Submission date</b> 10/08/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/12/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/08/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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

### Contact name

Dr George Kitsaras

### ORCID ID

<https://orcid.org/0000-0002-1631-1730>

### Contact details

Dental Health Unit  
Williams House  
Manchester Science Park  
Manchester  
United Kingdom  
M15 6SE  
+44 (0)161 226 1211  
[georgios.kitsaras@manchester.ac.uk](mailto:georgios.kitsaras@manchester.ac.uk)

### Type(s)

Principal investigator

### Contact name

Dr Michaela Goodwin

### ORCID ID

<https://orcid.org/0000-0002-0375-3118>

### Contact details

Dental Health Unit  
Williams House  
Manchester Science Park  
Manchester  
United Kingdom  
M15 6SE

+44 (0)161 226 1211  
michaela.goodwin@manchester.ac.uk

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
326880

**Protocol serial number**  
2023-15413-27815, IRAS 326880, CPMS 55635

## 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

**Study design**  
Feasibility cluster randomized controlled trial

**Primary study design**  
Interventional

**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](mailto: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?
<a href="#">Results article</a>		11/02/2025	13/02/2025	Yes	No
<a href="#">Results article</a>		15/08/2025	18/08/2025	Yes	No