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A school-based study, co-designed with teachers and families to help improve children's oral health behaviours

Submission date 12/09/2025	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 08/10/2025	**Overall study status** Ongoing	
Last Edited 09/02/2026	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Tooth decay (dental caries) is one of the most common health problems in children. In some parts of England, especially in Greater Manchester, many children suffer from tooth decay and do not see a dentist regularly. This can cause pain, problems with eating and sleeping, missed school days, and sometimes the need to have teeth removed in hospital.
This study will look at whether giving children and families extra support — including free toothbrushes and toothpaste, school activities, and new teaching materials about looking after teeth — helping children to develop good toothbrushing habits and improves their oral health. The study aims to find out whether this approach works better than the standard oral health education that schools currently use.

Who can participate?
Children in Year 3 of primary school (aged 7 to 8 years) in Greater Manchester can take part if their school agrees to join the study. Parents or carers will need to give consent for their child to take part. Boys and girls can both join. Children with certain health issues (such as allergies to the plaque disclosing tablet) will not be included.

What does the study involve?
Schools that agree to join will be randomly placed into one of two groups.
One group will receive the multi-component programme, which includes:
1. Toothbrush and fluoride toothpaste packs for the child and family
2. Plaque disclosing tablets (which briefly stain plaque so it can be seen when brushing)
3. Special school lessons and materials about healthy teeth, developed with teachers and families
4. A simple planning exercise to help children and families fit toothbrushing into daily routines
The other group will continue with the standard oral health education materials already used in schools.
All participating children will have a simple dental check-up at school at the start and again after 3 months. This will involve using a harmless coloured tablet to show plaque on the teeth, which

is then brushed away. Children and parents will also answer short questionnaires about toothbrushing and diet. Some teachers, parents and children will be interviewed about their experience of the programme.

What are the possible benefits and risks of participating?
Children in both groups will receive useful information about looking after their teeth. Families in the intervention group will also receive free toothbrushes, toothpaste, and extra materials to support healthy habits. The study will help us understand the best ways to support families with children's oral health in future.
There are very few risks. The dental check-ups of the teeth are similar to those done in clinics. The plaque disclosing tablets may briefly stain teeth but this disappears after brushing. Rarely, children allergic to certain food dyes may react, but these children will not be included in the study.

Where is the study run from?
The study is being run by the Dental Health Unit at The University of Manchester, in partnership with local dental public health teams and schools in Greater Manchester (UK)

When is the study starting and how long is it expected to run for?
September 2025 to August 2026

Who is funding the study?
The study is funded by through a research grant provided by the Colgate-Palmolive company to the University of Manchester Dental Health Unit (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2025-21596- 42949

Study information

Scientific Title
BEE Smiley: a cluster-randomised trial to evaluate the effects of a co-designed, multi-component, school-based behavioural intervention to improve oral health behaviours

Acronym
BEE Smiley

Study objectives
Primary objective:
To determine the effects of a multi-component intervention delivered in a school setting combining behavioural science approaches, co-developed educational materials, and provision of self-care resources compared to oral health education alone on plaque scores at 3 months.

Secondary objectives:
Secondary objectives will evaluate the longer-term effects of the intervention at both 4 and 6 months on toothbrushing behaviour, habit formation and sugar consumption. Parental self-reported toothbrushing frequency will also be assessed. Process outcome assessment will evaluate implementation of the educational materials and the behavioural intervention and the acceptability and value the teachers, parents and children place on the different components.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 16/07/2025, The University of Manchester Research Ethics Committee (Oxford Road, Manchester, M13 9PL, United Kingdom; +44 (0)161 306 6000; research.ethics@manchester.ac.uk), ref: 2025-21596-42949

Study design
Two-arm parallel-group cluster-randomized school-based interventional trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Oral health behaviours (plaque control, toothbrushing habits, and sugar intake)

Interventions
Randomisation will be at the cluster (school) level. A computer-generated randomisation schedule will be used to randomise eligible and consenting schools to the intervention or comparator groups (STATA). Data from national epidemiological surveys previously demonstrated that children attending larger schools have significantly higher caries experience than those attending smaller schools. The randomisation algorithm will use size of school (single- or double-form entry) as a minimisation covariate to allocate treatment to intervention and comparator groups in a 1:1 ratio. A random element will be incorporated into the randomisation algorithm. Allocation will be concealed until the point of randomisation. An independent researcher within the Division of Dentistry will communicate the allocated treatment group to the study team. Allocation will be concealed until assignment. Schools (and participants) will be informed of their allocated treatment group in writing by the trial coordinator following randomisation.

The intervention arm will comprise a multi-component intervention consisting of:
1. Behaviour change intervention: implementation intention co-produced by the child; educational materials based around COM-B for the family unit
2. Provision of self-care resources: toothbrush and toothpaste pack every 3 months with plaque disclosing tablet. In line with DBOH recommendations for children aged 7 years and upwards, fluoride toothpaste containing fluoride at a concentration of 1,350 to 1,500 will be provided. Additional manual toothbrushes and 1450 ppm F toothpaste will be supplied for family use every 3 months)
3. Educational materials: co-developed curriculum materials, school-based oral health promotion incorporating elements of the Colgate-Palmolive Bright Smiles Bright Futures materials (BSBF), https://www.colgate.com/en-us/mission/oral-health-commitment/bsbf/educational-resources?bsbf-age-group=age-7-12

The other group will continue with the standard oral health education materials already used in schools.

All participating children will have a simple dental check-up at school at the start and again after 3 months. This will involve using a harmless coloured tablet to show plaque on the teeth, which

is then brushed away. Children and parents will also answer short questionnaires about toothbrushing and diet. Some teachers, parents and children will be interviewed about their experience of the programme.

Intervention Type
Behavioural

Primary outcome(s)
Plaque score at 3 months as indicated by PCR value from index teeth from the clinical assessment conducted by members of the CDS/dental hygiene/therapists. The primary outcome will be extracted from the Case Report Form completed by a member of the CDS/dental hygiene /therapists. This outcome will indicate whether improved oral hygiene behaviours have occurred over a relatively short period of time.

Key secondary outcome(s))
1. Self-reported secondary outcomes of habit formation in relation to behaviour change using items based on the 'Self-reported behavioural automaticity index' and Oral Health Activities Questionnaire will be taken at baseline, 3 months, and 6 months through questionnaires administered on an e-tablet (children will be supported to complete the questionnaire by the research team, CRN, or teachers).
2. Parental self-reported toothbrushing behaviour and habit formation will be collected online or by post at the parent/caregiver's preference through the Brushing Behaviour Questionnaire, Toothbrushing Habit Formation Questionnaire and Brief Oral Health Survey at baseline, 3 months and 6 months.
3. School-level outcomes will include a process evaluation (fidelity to the intervention, context, and support of the intervention), and the acceptability and value of different components will be explored through qualitative analysis (qualitative interviews) at 6 months.

Completion date
15/08/2026

Eligibility

Key inclusion criteria
School inclusion criteria:
1. Provide written consent to participate in the study
2. Implement the allocated trial arm
3. Agree to provide space for the trial clinical assessment at baseline, 3 months, on school premises

Child inclusion criteria:
Children aged 7 to 8 years at the time of recruitment

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group

Child

Lower age limit
7 years

Upper age limit
8 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Child exclusion criteria:
1. With hypersensitivity to Sodium Fluoride and/or other ingredients used in toothpaste or in the disclosing solution/ tablet used for the clinical assessment
2. Who have participated in any other clinical study during the 3 months preceding the initial examination
3. With the presence of ulcerative gingivitis/stomatitis

Date of first enrolment
17/09/2025

Date of final enrolment
01/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Church of England school of resurrection
Pilgrim Drive
Manchester
England
M11 3TQ

Study participating centre
Longsight Community Primary School
1A Farrer Road Longsight

Manchester
England
M13 0QX

Study participating centre
St James C Of E Primary School
Cromwell range
Manchester
England
M14 6HW

Study participating centre
Birchfields Primary School
Lytham Road
Manchester
England
M14 6PL

Study participating centre
Holy Name Roman Catholic Primary School Manchester
Denmark Road
Moss Side
Manchester
England
M15 6JS

Study participating centre
St Anthonys primary school
Dunkery Road, Wythenshawe
Manchester
England
M22 0NT

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

Study participating centre
St Anne's RC Primary School
Carruthers Street Ancoats
Manchester
England
M4 7EQ

Study participating centre
Briscoe Lane Academy
Briscoe Lane
Manchester
England
M40 2TB

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

Study participating centre
Bridge Hall Primary School
Cuddington Crescent
Bridge Hall
Stockport
England
SK3 8LX

Study participating centre
All Saints' Church of England Primary School
Brickbridge Road, Marple, Stockport, Cheshire
Greater Manchester
England
SK6 7BQ

Study participating centre
Outwood Primary School
Outwood Road
Heald Green

Cheadle
England
SK8 3ND

Study participating centre
Thorn Grove Primary School
Woodstock Avenue
Cheadle Hulme
Cheadle
England
SK8 7LD

Study participating centre
Mellor Primary School
Knowle Road
Mellor
Stockport
England
SK6 5PL

Study participating centre
St Mary's Catholic Voluntary Academy
Lowry Drive, Marple Bridge
Greater Manchester
England
SK6 5BR

Study participating centre
High Lane Primary School
Andrew Lane, High Lane, Stockport
Greater Manchester
England
SK6 8JQ

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
What will be shared: A fully anonymised participant-level dataset, together with supporting documentation (e.g. protocol, and statistical analysis plan). No identifiable information will be shared.

When: The anonymised dataset will be deposited after the trial is completed and main results are published, anticipated by the end of 2026.

For how long: The dataset will be permanently stored in Figshare at the University of Manchester Library, ensuring long-term access.

Access criteria: Data will be openly available to all interested researchers and the wider public without restrictions, in line with University of Manchester data sharing policies.

With whom: Researchers at other institutions, policymakers, and others will be able to access and reuse the anonymised dataset.

For what types of analyses: The data may be used for further research on child oral health, replication or verification of results, and secondary analyses consistent with the study’s aims.

By what mechanism: Data will be shared through the University of Manchester's Figshare repository, accessible online.

Consent: Participant information sheets and consent forms informed parents/guardians that anonymised data may be shared for research purposes.

Data anonymisation: All data will be fully anonymised prior to sharing, with direct and indirect identifiers removed to minimise any risk of re-identification.

Ethical and legal restrictions: No restrictions are anticipated beyond the removal of identifiers. Data sharing will comply with the UK Data Protection Act and GDPR.

Other comments: The trial results, summary findings in plain English, and key documents (protocol) will also be made publicly available.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			17/09/2025	No	Yes
Participant information sheet	version 3	13/05/2025	04/11/2025	No	Yes
Protocol file			17/09/2025	No	No
Protocol file	version 0.6	06/10/2025	04/11/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes