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

PROTOCOL

Draft version 0.6, 15th October 2025

ISRCTN: ISRCTN73613884
Ethics: 2025-21596-42949

PROTOCOL APPROVAL

The Chief Investigators confirm that the study will be conducted in compliance with the protocol, the principles of Good Clinical Practice (GCP), the Data Protection Act 1998 and the Declaration of Helsinki. All personnel directly involved in the study and who will be handling study data will be GCP trained. All members of the research team will be listed on the delegation log.

The Chief Investigators also confirm that they will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

Chief Investigators

Name	Michaela Goodwin
Date	26 August 2025
Signature	Michaela Goodwin

Version history

Amendment no.	Protocol version no.	Description of changes (including author of changes)	Date effective
	Version 0.5	Final	26th August 2025
	Version 0.6	Updated to change the follow up clinical examination from 4 months to 3 months so the examination doesn't fall over Ramadan. Added ISRCTN73613884	15th October 2025

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Funder	The study is funded through an unrestricted research grant provided by Colgate Palmolive

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TRIAL SUMMARY

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	
Clinical phase	The sponsor has confirmed that this trial is not evaluating an Investigational Medicinal product, Medical device, or an Advanced Therapy Medicinal	
Primary research question	What are the effects of a targeted multi-component prevention intervention compared to oral health education alone in schoolchildren?	
Population	Schoolchildren aged 7 or 8 years at time of recruitment (year 3 of primary school) attending state-funded primary schools within Greater Manchester	
Interventions	Arm 1. Multi-component intervention comprising a co-developed behaviour change intervention, provision of toothbrush, toothpaste (plaque disclosing tablet) for the child and family unit and co-developed school oral health educational materials	Arm 2. Existing school oral health educational materials
Follow-up duration	Six months	
Outcome assessment	Clinical: Plaque (Plaque Control Record) Child-reported: toothbrushing behaviour, habit formation, sugar intake, Parental (proxy) reported: toothbrushing behaviour, dental attendance, habit formation, sugar intake Parental reported: toothbrushing behaviour Process: implementation of school changes and behavioural intervention, acceptability of intervention components	

FUNDING AND SUPPORT IN KIND

This study was funded through an unrestricted research grant from Colgate Palmolive to The University of Manchester as part of the work carried out by the Dental Health Unit, a unique collaboration between Colgate Palmolive and the University of Manchester.

ROLE OF TRIAL SPONSOR AND FUNDER

The University of Manchester is the sponsor of the study and assumes overall responsibility for the initiation and management of the trial.

The funder will not have influence regarding the trial design, conduct, data analysis and interpretation, manuscript writing, or dissemination of results.

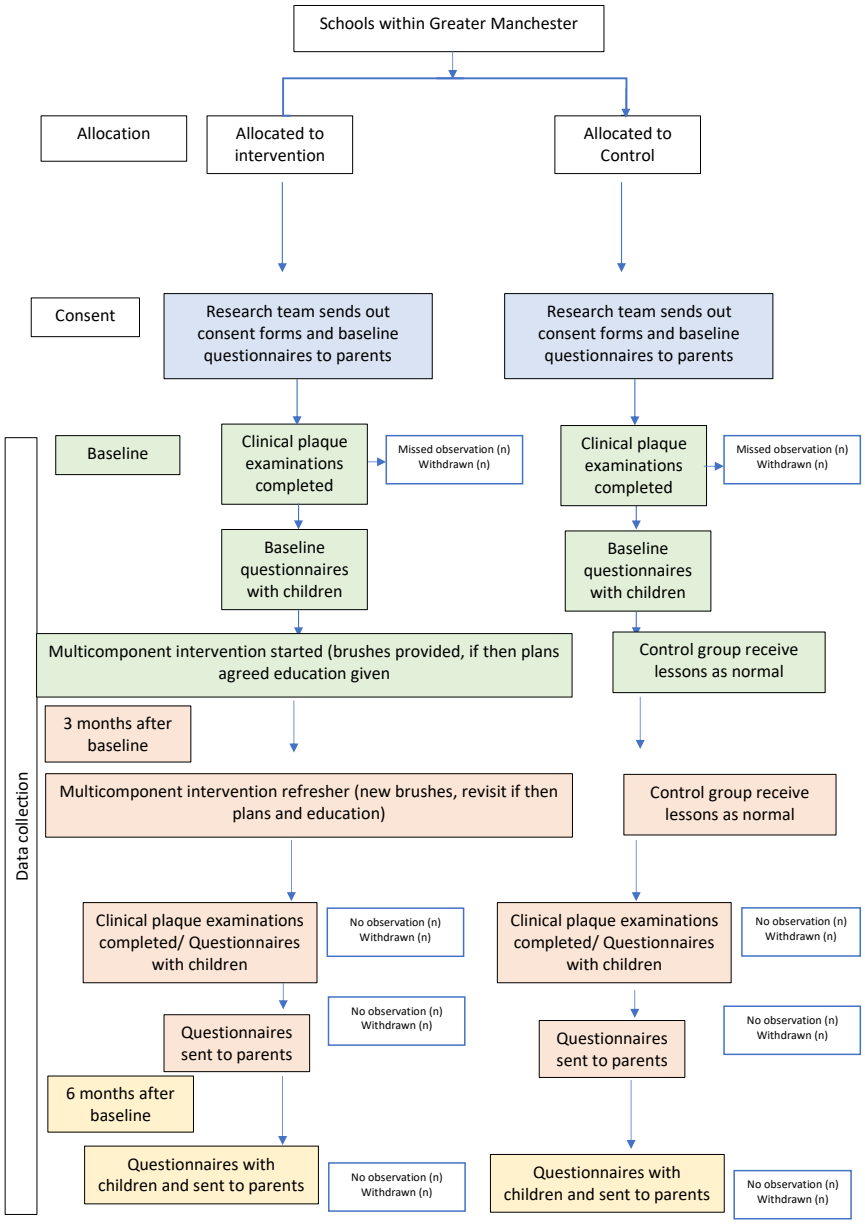
ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Trial Management Group

A Trial Management Group (TMG) will be convened to oversee the day to day running of the study. The TMG will meet regularly to ensure that the objectives of the trial are met. Membership of the TMG will include the CIs and Co-Investigators (Co-Is) as well as the Trial Co-Ordinators. The following collaborators will be invited to attend the management meetings:

Ms C Dixon, Clinical Lecturer (Paediatric Dentistry)/ Specialist in Paediatric Dentistry, The University of Manchester

TRIAL FLOW CHART



A cluster-randomised trial to evaluate the effects of a co-designed, multi-component, school-based behavioural intervention to improve oral health behaviours

1. INTRODUCTION

1.1 Background

In many areas of the country children's oral health is in crisis. Whilst the overall prevalence of dental caries is gradually reducing nationally, there is substantial variation in levels of oral diseases across the country, with regional pockets of high disease in areas of England underserved by medical and dental services (1). Many local authorities across the Northwest of England have a higher prevalence of dental disease for 5-year-olds than the national average, with some areas reporting over 40% of 5-year-olds having dental decay. In children, dental caries can have a negative impact on health and well-being with short- and long-term sequelae that include pain, difficulties with eating and sleeping (2), changes in behaviour (e.g., irritability), adverse psychological development (such as low self-esteem), and loss of school days with an associated impact on school performance (3-6). If left untreated, dental caries can progress and require extractions under general anaesthetic in hospital (2) with the NHS spending £50.9 million for caries-related tooth extractions in the financial year 2021 to 2022. This is a significant increase compared with the costs in the previous financial year 2020 to 2021 (7).

Since the COVID-19 pandemic many people have struggled to access dental services. Access to NHS dentistry, free for children at the point of contact, has been a long-standing issue, but one that has been exacerbated by the pandemic and from which dental practices have struggled to recover. Due to the reduction in NHS dentists, many parents and caregivers find themselves unable to register their children with a dentist and do not have the means to afford private dental treatment (8). Whilst arguably the best place for a child to be seen for prevention and treatment is at a general dental practice, this option isn't always available to families. Consequently, oral diseases go undiagnosed and untreated. Community settings are an alternative solution to offer some forms of preventive care.

NHS Core20plus 5 plan for children (9) specifically cites children's oral health as an area of concern. The recent "NHS dentistry recovery and reform plan" (10) and the inclusion of children's oral health in the political manifestos of major parties highlight the sustained interest in this area with a continued focus on prevention.

The Childsmile programme was rolled out nationally in Scotland in 2011, and through both a universal and targeted approach in community and education settings delivers distributed toothbrushing, supervised toothbrushing and targeted fluoride varnish applications for children in nurseries and early years education. In Wales, the Designed

to Smile programme has delivered a similar programme of oral health improvement to young children since 2009. Whilst there are many impactful local and regional efforts by Oral Health Improvement Teams in England such as oral health promotion delivered through the Department for Education and Department for Health Family Hub initiative, there is no single, national programme for prevention for young children. Further, in Scotland, Wales and England efforts are concentrated on prevention in young children in a nursery or early years education setting; there are few co-ordinated efforts for prevention in children of primary school age (7+ years of age). Research has shown that keeping children's primary dentition caries free is important for reducing the prevalence and severity of caries in their permanent dentition. The focus on early years is, therefore, critically important. However, there is currently a lack of co-ordinated community level support for older children at a time when their permanent teeth are emerging and who are at an important transitional stage to semi-independence of oral self-care. These children, particularly those from communities that experience socio-economic disadvantage, are at the highest risk of missing out on professional prevention and the provision of resources for self-care.

Our study aims to evaluate the effects of a targeted, multi-component prevention intervention compared to oral health education alone in early Key Stage 2 (children aged 7 to 9 years). The research question of interest is whether the provision of bespoke educational materials and self-care resources sufficient for the family unit, when coupled with behaviour change techniques to establish good oral hygiene can result in beneficial changes in oral health. Implementation intentions provide a promising approach to oral health promotion. They are designed to help people to make plans about how they will enact behaviours as part of everyday life, in this case forming good oral health behaviours.

The primary objective is to compare the effects of a multi-component intervention delivered in a school setting combining behavioural science approaches, co-developed education materials and provision of toothbrush and toothpaste packs for the child and family unit compared to oral health education alone on plaque scores at three months. An embedded process evaluation will focus on understanding the dynamic and complex relationship between the intervention and context, including how the behavioural intervention translates to the home environment, to explain how and why the interventions work or fail, and the acceptability and value the teachers placed on the different components.

The study builds upon the successful delivery of the Leapfrog school-based study by members of the research team. The Leapfrog study showed that the team are able to recruit and retain schools and pupils from communities experiencing socio-economic disadvantage and challenges with access to dental care in Greater Manchester, working collaboratively with members of the local Oral Health Improvement Team. The study is supported by Consultants in Dental Public Health from the Northwest Dental Public Health Directorate, the Manchester Oral Health Improvement Team, and Headteachers of local primary schools. Public and community engagement has shaped the design of this research.

The primary outcome of this study is plaque score at three months. This outcome will indicate whether improved oral hygiene behaviours have occurred over a relatively short period of time. Should the intervention show promise we would like to explore whether the intervention results sustained benefits over a longer term, and particularly the effects on tooth decay.

2. OBJECTIVES & OUTCOMES

The aim of this study is to evaluate the effects of a targeted multi-component prevention-based intervention compared to oral health education alone in primary school children.

2.1 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 three months.

2.2 Secondary objectives

Secondary objectives will evaluate the longer-term effects of the intervention at both three and six 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.

2.3 Primary outcome:

- 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.

2.4 Secondary outcomes

- 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).
- Parental self-reported toothbrushing behaviour and habit formation will be collected online or by post at the parent/caregiver's preference.

- 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.

3. TRIAL DESIGN

A two-arm, parallel group, cluster-randomised trial of superiority comparing the effects of a multi-component intervention with oral health education alone in primary school children.

Follow-up will be for six months and will be undertaken in all consented and recruited schools in Greater Manchester.

In parallel to this study, we will undertake a process evaluation to explore the attitudes and beliefs of schoolteachers, parents and children to the provision of prevention activities in a non-clinical setting, the acceptability and value of incorporating caries preventive education and practises into the school day, if they utilised the components of the intervention (fidelity), what factors supported or were barriers to this process and how this can be transferred to the family setting.

4. TRIAL SETTING

State-funded primary schools located in geographical areas of Greater Manchester that have been identified by the local authority as having a higher than average burden of disease as indicated by national epidemiological surveys, will be invited to participate.

5. TRIAL POPULATION

Children in Year 3 (aged 7 to 8) attending state-funded primary schools located in areas of high deprivation in Greater Manchester, where the caries prevalence is above average. Our decision to include children in primary school has been made on the basis that there are several UK public health initiatives targeting very young children in early years settings but few evaluating the effects of oral health programs on older children; the move from infant to primary school is an important period of transition where children are developing independence in terms of oral hygiene behaviours and of making healthy choices. Where oral health programs in early years settings have been rolled out, and where children have established good habits at an early stage, it is important that this is maintained as the permanent dentition erupts.

School and participant inclusion criteria have been defined to ensure that participants in the trial are similar to those that would receive the intervention if it were commissioned and delivered as part of a targeted dental public health program.

5.1 Planned school inclusion criteria

To be eligible for inclusion in the trial schools must be willing to: provide written consent to participate in the study; implement the allocated trial arm; and agree to provide space for the trial clinical assessment at baseline, 3 months, on school premises.

5.2 Planned parent and child inclusion and exclusion criteria

Parents/caregivers of children in year 3 (aged 7 to 8 years at the time of recruitment) in participating schools will be invited by letter to consent to their child's participation in the trial and to complete an eligibility assessment form.

Inclusion criteria

- children aged 7 to 8 years at the time of recruitment and their parent/caregiver

Exclusion criteria

Children:

- with hypersensitivity to Sodium Fluoride and\or other ingredients used in toothpaste or in the disclosing solution/ tablet used for the clinical assessment
- who have participated in any other clinical study during the three months preceding the initial examination
- with the presence of ulcerative gingivitis/stomatitis

6. RECRUITMENT AND TRIAL PROCEDURES

6.1 Recruitment

6.1.1 Selection and recruitment of schools and participants

Schools will be assessed for eligibility by the study team in accordance with information provided by the local (Greater Manchester) oral health improvement teams.

Recruitment will proceed in two phases: recruitment of schools, followed by recruitment of participants.

Recruitment of schools: State-funded primary schools located in areas of Greater Manchester identified by the local authority as having higher than average burden of disease as indicated by national epidemiological surveys will be invited to participate. An open invitation to eligible schools will be sent to the school's headteacher, requesting expressions of interest for participation in the trial. All recruited schools will be reimbursed for their participation.

Recruitment of participants: Schoolchildren in year 3 (aged 7 or 8) attending schools which have consented to take part will be invited to participate in the trial. Parents/caregivers of potentially eligible participants will be sent a Participant Information Sheet (PIS) (Appendix F) providing them with details of the study along with the consent form (Appendix H) and baseline questionnaire (Appendix M). Consent and questionnaire response can either be provided online (Qualtrics) to a consent form, face to face using e-tablets on school grounds (by the CRN or research team) or paper based by a consent, PIS and questionnaire available to take home in the school bag. A

£20 voucher, intended for the child, will be provided to the parents or caregivers of each participating child at the end of the study, following the completion of the final clinical examination.

6.1.2 Screening

Once written parental/caregiver consent has been obtained, child eligibility will be double-checked by the research team prior to enrolment into the trial and any clinical examination. Pupils will be eligible for participation, providing that they meet the inclusion criteria (see child inclusion criteria) as assessed by the study team following information provided by parents/guardians. We will record the number of children who were ineligible to consent.

6.1.3 Payment

Participating schools will receive £1500 compensation for hosting the Community dental service for the clinical examinations, support for consent, data collection, and utilising the behaviour change and education intervention components. Study participants will be offered a £20 shopping voucher as a token of thanks at the end of data collection.

6.2 Informed consent

Parents/caregivers of potential participants will receive a letter of invitation and a Participant Information Sheet. Included in the communication will also be a brief eligibility determination questionnaire. If eligibility is met, then participants will need to complete a consent form to take part. The study team will check eligibility based on parental/caregiver responses.

All participants will be made aware that they are free to withdraw at any time from the study without giving reasons and without prejudicing future care.

Children who refuse to participate in the trial at the point of clinical examination will be deemed not to have provided assent for the trial.

All Participant Information Sheets will be translated into the most common languages as advised by the Schools.

6.3 Randomisation and allocation concealment

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 co-ordinator following randomisation.

6.4 Blinding

Due to the nature of the intervention, it is not possible to mask the trial participants or the teaching staff delivering the intervention to the treatment allocated. The trial statistician and the study team will be blinded to the allocation during all analyses by use of a code to identify the two groups. The key to the code will be held by a named independent researcher within the Division of Dentistry. A randomisation list will be available in the unlikely event that emergency unblinding be required.

Assessors of the clinical outcome will be blinded to treatment allocation. Due to the nature of the intervention, it is not possible to blind the participants or their parents/caregivers to trial arm allocation. Self-reported outcome assessment will therefore not be blinded.

6.5 Data collection

Outcomes will be measured using a variety of methods including clinical assessment (plaque scores) conducted by the CDS, questionnaires (habit formation, toothbrushing behaviour, sugar consumption)

6.5.1 Schedule of data collection

Data collected	Method	Baseline	3 months	6 months
Demographic, socio demographics, dental attendance	Questionnaire * (Appendix M)	x		
Plaque score (PCR)	Clinical assessment (Appendix L)	X	X	
Brushing Behaviour	Questionnaire	X	X	X
Toothbrushing habit formation (parent) Habit formation for brushing their child's teeth	Questionnaire * (Appendix M)	X	X	X
Toothbrushing habit formation (child)	Child self-completed	X	X	X

One question on habit formation and one question on brushing the previous day	(Appendix M)			
Brief Oral Health Survey (parent reported on behalf of child)	Questionnaire * (Appendix M)	X	X	X
Brief Oral Health Survey (child reported)	Child self-completed (Appendix M)	X	X	X
School: feasibility of implementation and acceptability	Qualitative interview (teachers, parents and children) (Appendix O and Q)		X	X
Feedback survey	Teacher survey (Appendix P)			x
Implementation-Intention Questionnaire	Parents (Appendix S)	x	x	x

* Electronic or postal depending on preference

6.6 Quantitative data

Demographic data will be collected from the parent/caregiver on gender, education and employment, and on family membership. Demographic data will be collected on the child's gender, age, ethnic group, and school attended will be collected at baseline. The postcode of the child's main residence will be collected for the purpose of establishing area-level deprivation score, using the Indices of Multiple Deprivation (http://dclgapps.communities..gov.uk/imd/idmap.html). Additionally, information on dental attendance of the child and parent/caregiver will be collected. Demographic information will be collected at baseline either online via online questionnaire (Qualtrics) or on paper once consent has been provided, according to parental/caregiver preference.

Assessments will include the following:

6.6.1 Plaque control record (PCR).

Plaque on tooth surfaces will be collected using the Plaque Control Record (O'Leary, 1972). This is a simple means of recording presence of plaque on individual tooth surfaces calculated as follows: number of surfaces with plaque/number of total tooth surfaces x 100. The clinical examination is non-invasive, utilises a mirror and drying tip. It will also require a plaque disclosing solution which stains the gums and teeth briefly blue or red, which can be removed by brushing. Plaque disclosing is regularly used in dental examinations and can also be used at home and bought in shops. The examination is expected to take no more than 10 minutes per examination. A visual assessment of the presence or absence of plaque on each

surface will then be performed by a member of the Community Dental Service in accordance with the PCR.

6.6.2 Toothbrushing habit formation (Parent completed)
Questionnaire to elicit parental habits around brushing their child's teeth

6.6.3 Toothbrushing habit formation (Child completed)
Questionnaire to elicit child's habit on brushing their own teeth

6.6.4 Brief Oral Health Survey (Parent/caregiver completed)
This questionnaire focuses on parental reported child toothbrushing and sugar consumption, and the value placed by the family on oral health.

6.6.4 Brief Oral Health Survey (Parent completed)
As above, but for the parent.

6.6.5 Brief Oral Health Survey (Child completed)
Three questions on brushing behaviour.

6.6.6 Brief dental attendance survey (Parent/caregiver completed)
This questionnaire focuses on child dental attendance.

6.6.7 Brief dental attendance survey (Parent/caregiver completed)
This questionnaire focuses on parent/caregiver dental attendance.

6.6.8 Feedback surveys will be provided to teachers and parents to gain an understanding of what worked, why and what could be improved across the key components of the intervention such as educational resources.

6.6.9 Implementation-Intention Questionnaire (If-Then Planning Scale) (Parent/caregiver completed)
It captures children's inclination to follow their new behaviour (oral health routine).

All questionnaires are included in the Appendix (M).

6.7 Qualitative data
Qualitative work will focus on two groups: (a) teachers and (b) parents/children

(a) Teachers attitudes and the value the place on the intervention will be to better understand what worked well, what created barriers and look at how best to support implementation for such initiatives in the future if appropriate.

In a qualitative approach, we will explore the teachers' attitudes, and opinions regarding the multi component intervention. A combination of focus groups and one-to-one interviews (depending on availability) will take place with teachers and staff within

schools. We will aim for interviews to include at least 15 teachers. Data saturation will be monitored throughout, and data collection will cease when saturation is reached.

Parents attitudes and opinions regarding the interventions be explored through a qualitative, semi-structured approach. A similar approach as with dental teams will be followed where parents of children will be invited to an interview to understand what, in their experience, worked well with the multi component intervention, if there were any barriers and shortcomings in their experience and if anything could be improved. We aim for 15 interviews to be completed with parents. Data saturation will be monitored throughout, and data collection will cease when saturation is reach

For children, given their age, a different approach to understand their experiences and provide them with a chance to hear their voices and opinions will be utilised. Children will be asked for their opinions on the different components of the intervention, but they will also be offered the opportunity to produce a picture of their experience and the parts they remember for the intervention. Asking children of a certain age to populate and communicate their experiences using art is not new but it is rarely used within healthcare research (20). The benefits of this approach can be multiple from offering children a platform to share their experiences to helping with the dissemination of findings through visual and artistic approaches. In total, we aim for at least 5 children to engage in this process and share their experiences.

While written consent will be obtained to take part in the clinical part of the study, qualitative interviews consent will be obtained from participants through a verbal consent script prior to the commencement of any interview questions. Participants will be asked to clearly state their names in the audio recording following a comprehensive explanation of the study's objectives and the purpose of the interview, which would be read aloud individually by the research staff and provided to participants in a clear and concise language. Participants will be asked to confirm “Yes” or “No” to taking part in the interview with additional points will be clearly stated. Prior to soliciting consent, participants will undergo a confirmation of understanding to ensure comprehension of the study's aims and importance of their response. Only after this confirmation will verbal consent be sought for participation in the qualitative interview. Additionally, participants will be informed of their right to refuse participation or withdraw consent at any point during the interview process. The verbal consent process will be thoroughly documented, including the date of consent, and confirmation of the participant's agreement to participate. Alternatively, written consent can also be sought if requested by participants. Participants who consent to partake in the interview will be sent a hard copy of the consent form via email or post. Qualitative interviews will be recorded on a recording device. Information shared by consented participants will only be used for research purposes, Audio recordings will be pseudo anonymised with participant ID, and at a later stage in the study, the audio files will be renamed to “Parent 1” to destroy the link between the name and the participant ID. After data analysis is completed, data will be deleted and destroyed after two years. Only approved transcriptions services will be used, audio recordings will be transferred from devices onto secure UoM storage as soon as possible following the interview and deleted from the audio recording device.

6.7 Data processing

Clinical collected by the CDS will use paper CRFs, which will be collected by a member of the research team at the time following the clinical assessment. Data from child self-reported questionnaires will be collected directly through a Qualtrics database using an e-tablet. Parental questionnaire data will be collected directly through a Qualtrics database or through postal paper-based questionnaire depending on respondent preference. Questionnaire and CRF data will be entered into the trial database at the Dental Health Unit. Two reminders will be sent to those participants who do not respond within four weeks. All data will be monitored for range, accuracy and consistency.

Data will be securely transferred to the Dental Health Unit for entry into the trial database.

6.8 Change of status / withdrawal procedures

Participants will remain in the trial unless they choose to withdraw consent. All data collected up to the point of complete withdrawal will be retained and used in the analysis.

7 INTERVENTIONS

There will be two trial arms.

The intervention arm will comprise a multi-component intervention consisting of:

- Behaviour change intervention: implementation intention co-produced by the child; educational materials based around COM-B for the family unit (See Appendix A for details of the behaviour change intervention)
- Provision of self-care resources: toothbrush and toothpaste pack every three months with plaque disclosing tablet. In line with DBOH recommendations for children seven 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 three months)
- 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 (See appendix B for BDBF materials)

The comparator arm will be existing school-based oral health education only.

8 SAFETY

The sponsor and Chief Investigators have determined this is a low-risk trial and therefore adverse events are unlikely. We will record any adverse events related to the

study e.g. allergic reactions to disclosing tablet/solution. Any Serious Adverse Events will be reported to the Chief Investigator and sponsor. We will also record if the child has had any dental problems/treatments and whether any medication was given.

We do not expect there to be any direct risks for those taking part in the study. The dental assessments are similar to routine dental assessments carried out in clinics. Disclosing tablets/solution contain a food dye called erythrosine and parents/caregivers will be asked if their child is allergic to food dyes.

9 STATISTICS & DATA ANALYSIS

A Detailed Statistical Analyses Plan (SAP) will be produced which will include, but not limited to the investigational plan and study design, listing of outcomes and final analysis of effectiveness. The SAP will set out the summary measures to be reported; methods of analysis, plans for handling missing data, withdrawals, and use of intention to treat analysis.

9.1 Sample size

The typical class size for year 3 children is around 33 children. A sample size of 10 schools in each trial arm with 13 children *per* school (130 children in each group, 260 children in total) would have 90% power to detect a difference of 20% percentage points in plaque scores at 3 months, assuming an intra-school correlation coefficient of 0.03 and an alpha level of 0.05. Assuming an attrition of approximately 15% the total sample size would need to be increased to 306 children, 15 children per school.

9.2 Statistical analysis

Analyses will be conducted using Stata Statistical Software: Release 18 (StataCorp, College Station, TX, USA) and performed by the study statistician blind to the allocation. An intention-to-treat analysis will be undertaken. Children who changed schools during the course of the trial will be analysed according to their allocation at baseline. Statistical methods to account for the clustering of observations within schools will be used throughout.

Demographic and baseline characteristics will be summarised and displayed in tables for all randomised participants. Frequency counts and percentages will be used to present categorical data. Number of participants, mean, mode, median, SD, minimum, maximum and IQR will be used to present continuous data.
The primary outcome measure will be analysed using a generalised linear model with adjustment for the minimisation variable and baseline value. Secondary outcomes will be analysed using generalised linear models with adjustment for minimisation and baseline variables as appropriate. Statistical significance will be at the 2-sided 5% level and reported along with corresponding 95% confidence intervals derived.

All analyses will be performed on an intention to treat basis. The main statistical

analyses will be based on all participants as randomised, irrespective of subsequent compliance with the trial arm allocation; this will be detailed in the SAP.

10 TRIAL MANAGEMENT

Trial management will be carried out within the core research group at the Dental Health Unit at The University of Manchester and led by the Senior Trial Co-Ordinator with support from the Trial Co-Ordinator. The research team will meet formally approximately monthly during the course of the trial with additional interim meetings as required.

11 RESEARCH GOVERNANCE, DATA PROTECTION AND SPONSORSHIP

Ethical Approval for the trial will be secured from The University of Manchester ethics committee. The University of Manchester will act as sponsor. (Trial Registration: ISRCTN73613884).

12 ETHICS AND REGULATORY APPROVALS

The protocol will be reviewed and approved by The University of Manchester. The trial will be conducted according to the principles of Good Clinical Practice provided by Research Governance Guidelines. The ethical considerations around this trial have been carefully thought through. As this is a behavioural and education intervention with toothbrush and toothpaste and plaque disclosing tablets which can be purchased by participants, this has been determined as a low-risk study.

13 QUALITY ASSURANCE

Data monitoring and Quality assurance
The study will be monitored by the research team at the University of Manchester Dental Health Unit, Williams House, Manchester Science Park, Lloyd Street North, Manchester, M15 6SE, England at periodic intervals during the study to ensure the study is being conducted according to Good Clinical Practice Guidelines. A trial master file for the study will be created and maintained during the study. The study will be subject to the audit and monitoring regime of the University of Manchester.

14 FINANCE AND INSURANCE

This study is funded by The University of Manchester via an existing internal research account. Vouchers as a thank you for participation will be purchased using funds from the existing internal research account.

15 END OF TRIAL

- The trial will end by August 15th 2026.

16 DATA HANDLING, RECORD KEEPING AND ARCHIVING

Details are provided in the Data Management Plan

17 AUTHORSHIP AND PUBLICATION

Following completion of the study, the results may be published in peer reviewed scientific journals, as an internal report or publications on websites. Participants can request a copy of the study results using the contact details provided on the participant information sheet.