

Parent/Caregiver Information Sheet

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

Dear Parent or Caregiver,

We are writing to inform you of a research study we are conducting in primary schools within Greater Manchester in England. We would like for you and your child to take part in this. Below is some information about the study. Please take some time to consider your and your child's participation. If you have any questions, please use the contact details listed at the end of this letter.

What is the purpose of this study?

This study aims to evaluate the effects of a targeted multi-component prevention intervention compared to oral health education alone in primary school children. It will also build an understanding of whether providing education and toothbrushes in a non-dental setting combined with a behavioural change intervention designed to increase preventive self-care can result in beneficial changes in oral health.

Why is my child being asked to participate?

Your child has not been individually selected. Approximately 306 children, attending schools in Greater Manchester, will be asked if they would like to participate in this six-month research study.

Participation in this study is entirely voluntary. You may choose to withdraw from the study at any time and you do not have to give us a reason.

If you agree to take part in the study your child's school will be randomly allocated to either the intervention group or the control group.

If they are part of the intervention group, they will receive a new toothbrush at the start of the study and three months thereafter, along with plaque disclosing tablets. They will also be provided with some information to take home about keeping their teeth healthy (the family will also be provided with toothbrushes and toothpaste).

If they are part of the control group, they will receive the toothbrushes and paste at the end of the study (6 months from the start).

If you are part of the intervention group your child will be asked to use the new toothbrush when brushing their teeth.

What will happen to my child and I if we participate in the study?

Data collection

If your child is allocated to the intervention group, then:

A member of the research team will perform a screening check to determine whether your child is suitable to participate in the research study, this will involve collecting your child's information (age, date of birth, initials, gender, as well as information about any allergies and medicines).

As the parent/ caregiver you will be asked to complete a questionnaire when the study starts and then again at 4 months and 6 months later.

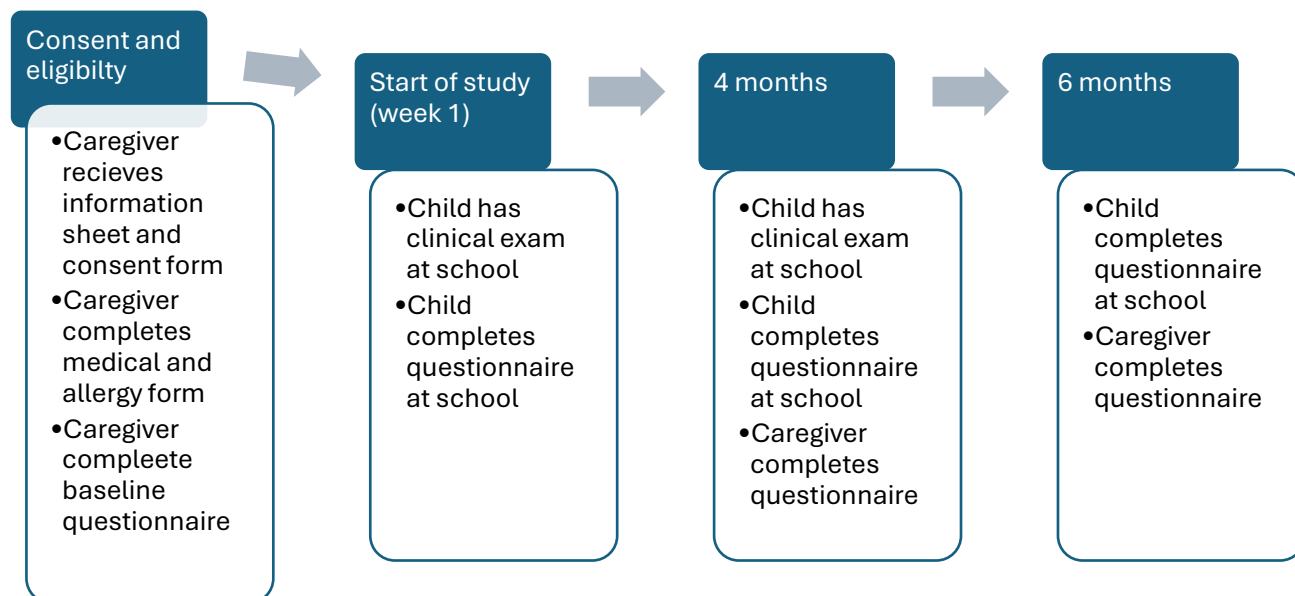
Your child will have a dental examination at school when the study starts and again 4 months. This will be carried out by qualified dental professionals and will be just like a regular dental examination at a dental practice.

During the clinical examinations, the research team will use plaque-disclosing solution to help visualize plaque on your child's teeth. Plaque is a sticky film that covers the teeth and contains bacteria. Regular brushing helps remove this film. The plaque-disclosing solution contains a harmless dye that, after being painted over the tooth surfaces, will temporarily stain the areas of the teeth where plaque is present. These stains will fade within the day and can be removed by brushing. We may ask your child to rub some lip salve or Vaseline onto their lips and around the corners of your mouth (to prevent staining). Please let us know in the medical history form if they cannot have lip salve or Vaseline. The dentists and dental hygiene/therapists will then carry out a short dental examination to count the number of teeth and record any plaque that can be seen on the teeth. Next, some pictures will be taken. These will be done with a camera only taking an image of the teeth. we do this so we can check the plaque scores provided by the dental team . None of the photographs will show your child's face – they will only be of their teeth. We would expect that all of the examinations will take no more than 10 minutes.

Your child will then be provided with a toothbrush and toothpaste pack every three months for home use during the study. You will be asked to support them and encourage their brushing (with the brush). You will be provided with full instructions on how to do this.

Your child will be instructed to brush their teeth twice daily (morning and evening) for two minutes each time with the toothbrush provided. A toothbrushing timer will be provided to help your child track the brushing time.

As part of the study, you will be invited to complete three questionnaires: one at the beginning, one after 4 months, and the final at 6 months. These can be completed online or by post.



We will also ask a small number of participants to take part in an interview, if you agree to be one of these participants, we will interview you regarding your and your child's opinions of the intervention, what you found useful, and the impact it may have had, the interview will last 30-60 minutes and will be audio recorded. Your child can also participate but depending on their age we may ask them to produce a picture of their experience or talk through their experience. Transcriptions will be retained for 5 years.

Where will all these photographs be kept and who has access to them?

We will store all the photographs and dental scores on computers that are secured with a password. None of the information that we collect will have your child's personal details on, i.e. the information will be pseudonymised. The only people to have access to the information are the scientists involved in the study. We hope to publish our results in a scientific journal to help other researchers in the future. No personal information concerning your child will be included.

Length of Participation

If you qualify to take part, we will ask your child to use the assigned toothbrush for 6 months.

Subject Responsibilities

Utilise the products provided and engage with the materials provided.

If your child is allocated to the control group:

Your child will have a dental examination at school when the study starts and again 4 months later. This will be carried out by qualified dental professionals and would be just like a regular dental examination at a dental practice.

During the clinical examinations, the research team will use plaque-disclosing solution to help visualize plaque on your child's teeth. Plaque is a sticky film that covers the teeth and contains bacteria. Regular brushing helps remove this film. The plaque-disclosing solution contains a harmless dye that, after being painted over the tooth surfaces, will temporarily stain the areas

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Your child will receive school oral health educational materials and can carry on with their normal oral hygiene routine.

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protects your rights. This states we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is it is “a public interest task” and “a process necessary for research purposes”.

What are my rights about the information you will collect about me?

Under data protection law, you have several rights regarding your personal information. For example, you can request a copy of the information we hold about you. If you would like to know more about your rights or how we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](https://documents.manchester.ac.uk/display.aspx?DocID=37095) (<https://documents.manchester.ac.uk/display.aspx?DocID=37095>).

Will my participation in the study be confidential and my personally identifiable information be protected?

In accordance with the data protection law, The University of Manchester is the Data Controller for this project. This means we are responsible for making sure your personal information is secure, confidential, and used only in the way you have been told it will be used. We will not share your information with other people or organisations or pass on your contact details without your permission.

All researchers and staff members are trained in data protection, and your data will be looked after in the following way:

- **Storage of Identifying Information:** Any identifying information (e.g., your name and contact details) will be securely stored separately from the study data. Your data will be assigned an ID number rather than your name, and the key linking your ID number to your identity will be accessible only to the research team.
- **Anonymisation:** Your data will be pseudo-anonymised, meaning that only your unique ID number will link to identifiable information you provided. After the data analysis is complete, we will destroy the key that links your ID number to your identity, making the data fully anonymous.
- **Data Security:** All data will be stored on University of Manchester-approved, securely backed-up servers or devices, with encrypted files and folders.
- **Contact Details for Future Studies:** We will ask for your consent to retain your contact information so we can inform you about future studies you may be interested in.
- **Retention of Consent Forms:** Your signed consent form (including your name and signature) will be securely stored separately for 5 years after the study ends, and only the research team will have access to it.

- **Anonymised Data Retention:** After the study ends, anonymised data will be securely stored for 5 years. It will be transferred to the DHU Research Data Storage (RDS) system, also known as Isilon, for long-term storage.
- **Sharing Anonymised Data:** With your informed consent, anonymised information may be shared with other researchers within The University of Manchester or with external organisations to support additional research. This information will not identify you and will not be used to contact you. We would like to deposit a fully anonymised dataset in an open data repository where it will be permanently stored. We will use Figshare at the University of Manchester Library. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

Potential disclosures

If during our conversation you or your child reveal any information which means you may be at risk of harming yourself or others, we will be required to break confidentiality to put you in touch with the correct support. This may involve signposting you to relevant support services, calling a family member or friend, the school or calling emergency services.

Individuals from the University, the site where the research is taking place and regulatory authorities may need to review the study information for auditing and monitoring purposes, in the event of an incident or to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you and your child as a research participant.

To provide you with your voucher for taking part and completing the questionnaires we will need to provide your details to the finance office at the University of Manchester for them to issue the voucher directly to you.

Will the outcomes of the research be published?

The information from this study will be published in a peer reviewed journal. We will also feedback the results through the school to parents/caregivers.

Disclosure and Barring Service (DBS) Check

All individuals who have contact with the children as part of this study will have the appropriate Disclosure and Barring Service check.

Who has reviewed the research project?

The project has been reviewed by The University of Manchester Research Ethics Committee (REF 2025-21596-3925).

Who is paying for this study?

This study will be funded by the University of Manchester via an unrestricted research grant funded by Colgate-Palmolive to the University of Manchester. The study products (toothbrushes and toothpaste) will be supplied directly from the Colgate-Palmolive company. Vouchers will be purchased using funds from the university research grant.

Participating schools will also receive compensation of £1,500 per school for hosting the plaque clinical examinations, supporting the consent and data collection process, checking the email IDs and names of participants who have consented to participate, and utilising the behaviour change and education intervention components.

What risks are there to my child taking part?

The risk of permanent harm, injury, or disability as a result of participation in this research study is extremely minimal. No known side effects or risks are associated with the use of the study toothbrush or disclosing solution, or disclosing tablet. In the event of any reactions, please stop using the product and follow the specific instructions on the back of the product's packaging on what to do in case of an allergic reaction. If any adverse events persist, seek immediate medical attention, and inform the Principal Investigator, Michaela Goodwin, at your earliest convenience.

Will I be compensated for taking part?

Children in the intervention group will be provided with a toothbrush and toothpaste at the start of the study, and later at 4 months and 6 months. Children in the control group will receive the toothbrush and toothpaste at 6 months after the study has started. 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.

Data Protection and Confidentiality

What information will you collect about me and my child?

To participate in this research study, we will need to collect information that could identify you and your child, called "personal identifiable information". Specifically, we will need to collect:

Name

Contact details

Address

DOB of child

Ethnicity

Email address

Names and other personal information will be kept confidential and will never be shared (including with the school or with the sponsor).

Who is running this study and what if I have a question?

Dr Michaela Goodwin at the Division of Dentistry, University of Manchester will be leading the study.

What happens if I do not want to take part or if I change my mind?

It is up to you if you want your child to take part in this study. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. You are free to withdraw your child from the study at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your child's data from the project once it has been anonymised as we will not be able to identify the specific data. This does not affect your data protection rights. If you decide not to take part, you do not need to do anything further. If you wish to withdraw from the study, please let us know by contacting Michaela Goodwin or the trial coordinator using the contact details below.

What if I want to make a complaint?

Minor complaints

If you have a complaint that you wish to direct to members of the local team, please contact:
Name: MICHAELA GOODWIN

Formal Complaints

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact:

The Research Ethics Manager, Research Office,
Christie Building, The University of Manchester,
Oxford Road,
Manchester, M13 9PL.

Or by emailing: research.complaints@manchester.ac.uk

Or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner's Office](#) about complaints relating to your personal identifiable information Tel 0303 123 1113 <https://ico.org.uk/make-a-complaint/>

Contact Details

If you have any queries or questions about the information provided, please contact –

Name: Michaela Goodwin

Email: Michaela.goodwin@manchester.ac.uk

Telephone number: +44 (0)161 2324711

If you wish to withdraw from the study, please contact:

Name: Michaela Goodwin

Or

Name: Beulah Gangaraju (Trial Coordinator)

Email: Beulah.gangaraju@manchester.ac.uk

Telephone number: +44 (0)161 2324711

What do I do now?

If you are happy for your child to take part in this study, please complete the attached consent form, eligibility form and demographic form, and return it to your school.

Your child will be asked on the day if they want to take part and they can withdraw from the study at any time.

I would like to thank you for reading this information sheet and considering your child's inclusion in the study.

Yours sincerely,

Dr Michaela Goodwin