



## The CALM project: making going to the dentist easier for children

### Information sheet for parents/carers

We would like to invite you and your child to take part in our research project called the CALM project. Before you decide whether to take part, we would like to explain to you why the project is being done and what it would involve for you both.

You will have the opportunity to ask questions at your child's first dental appointment, and you can also talk to other people about this project if you wish.

#### What is the purpose of the project?

Many children and young people feel worried or afraid about visits to the dentist. This project will look at different ways of helping young people overcome their fears so it is easier for them to have their dental treatment carried out both now and in the future.

#### Why have I been invited?

We have invited you and your child to take part in this project because your child has said they feel worried or afraid about visits to the dentist. We want to talk to about 600 young people in total who feel the same way, and their parents or carers.

This project is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA 131805). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

### Do I have to take part in the project?

No, it's up to you and your child to decide, and it's your choice together. You can choose for just your child to take part or for you both to take part.

If you choose not to take part, it will not affect any treatment or care your child will have in the future.

### What will I have to do if I agree to take part?

If you do choose to take part, you will be asked to sign a consent form to say you agree. We will also ask your child to sign an assent form - which shows us that they agree.

### What will happen during the project?

If you agree that your child can take part, your child will be asked to complete three questionnaires over the next year.

You can decide if you also want to take part yourself and complete three questionnaires. If you decide you don't want to take part yourself you only need to complete the consent form for your child. Just your child will complete the questionnaires. There is a table at the end of this sheet which provide more details about the ways you can take part.

Your child will then have dental treatment carried out in one of two ways. They will either have 1) treatment carried out how your dental practice usually does it or 2) you will be offered some extra resources for you and your child to use with your dentist. The extra resources include a self-help guide for young people with a form for them to fill out and an information sheet for parent/carers.

The dentist involved will talk the young person and their parent/carer through the resources and the dental treatment they need.

Whether your child has treatment as usual or is offered the resources will be picked at random using a computer programme.

You and your child may also be asked if you would like to talk to a researcher during a short interview about what you thought of the dental treatment. You can take part in the interview without your child and your child can take part in the interview without you having to. If you choose not to take part it will not affect any treatment or care your child will have in the future.

### What are the possible benefits of taking part?

The project will not change the dental treatment or care your child receives at the dental practice. Taking part may help your child manage their fears about going to the dentists better. We also hope that it will help other young people in the future.

### What are the possible disadvantages or risks of taking part?

There are **no** risks to you or your child from taking part in the project. We know that talking about something you are anxious about or afraid of can be difficult, but you and your child don't have to talk about anything you don't want to.

### Will I be compensated for taking part?

No you will not be paid for taking part, it is completely voluntary, your child will receive a £10 thank you voucher on finishing the project. If you choose to take part yourself you will also receive a £10 thank you voucher when you finish the project.

### Can I change my mind?

Yes. If you change your mind please contact the project team using the details at the end of this information sheet . This will not affect your child's dental care in any way. If you decide to withdraw from the project we will use the information obtained from you up to that point. Your rights to access, change, or move you or your child's information are limited, as we need to manage the information in specific ways in order for the research to be reliable and accurate.

If your child loses capacity during the study they will be withdrawn from the study. We will use the information obtained from you or your child up to that point.

### What happens when the project stops?

Your child will have their visits to the dental practice as normal.

### Will anyone else know we have taken part in the project?

No-one apart from your dental practice and our project team will know. All the information from the project will be kept securely at your dental practice, the York Trials Unit (University of York) and/or the University of Sheffield.

The next part of this letter is all about what information we will collect from you and what happens to it if you choose to take part.

### Will my personal information be collected?

A copy of the consent form and any other documents for the project will be kept securely at the dental practice in a locked cabinet, with access only for research staff. These documents will be taken by the project team and held securely at the University of York. Alongside the consent form, members of the project team will collect some information regarding you and your child from your dental practice. This will include your child's age, gender, ethnicity, postcode and information about their dental record and treatment.

### Who is responsible for the information collected?

Sheffield Teaching Hospitals NHS Foundation Trust will be the project Sponsor for this project. Sheffield Teaching Hospital and York Trials Unit (University of York) will hold joint data controller responsibilities which means that each organisation is responsible for looking after information collected during the project and using it properly. The team will also include researchers from:

- School of Clinical Dentistry, University of Sheffield
- School of Dentistry, University of Cardiff
- School of Dental Sciences, Newcastle University
- Leeds Dental Institute, University of Leeds

### What will happen to the information collected if we take part?

Information collected during the project will be processed and stored in accordance with the General Data Protection Regulation (GDPR; introduced on 25<sup>th</sup> May 2018). The legal basis for processing information we collect about you and your child is that it is carried out in the public interest and for scientific and research purposes.

Personal information collected during the project that identifies you or your child will be stored securely and confidentially at York Trials Unit (University of York), in paper form and on password-protected databases. Only some members of the project team and data management team will have access to this information. The people who analyse the information will not be able to identify you or your child.

Personal information that identifies you or your child will be kept securely for 10 years after the end of project, after which it will be destroyed.

Researchers may use your name and contact details to contact you about the project. People from Sheffield Teaching Hospital and regulatory organisations

may look at the information we collect about you or your child to check the research is being done well.

To safeguard the rights of you and your child, we will use the minimum personally-identifiable information possible.

Information collected by the project team may be shared with other researchers for research purposes only, but they will not be given your name or your child's name.

For more information you can also go to: <https://www.hra.nhs.uk/information-about-patients/>

If you have any questions or concerns about the project, or about how your personal data, and your child's personal data will be used, please contact the researcher leading the project: Professor Zoe Marshman (contact details below).

You can also go to:

<https://www.sheffieldclinicalresearch.org/>

<https://www.york.ac.uk/healthsciences/research/trials/trials-gdpr/>

<https://www.york.ac.uk/records-management/dp/>

If you wish to raise a complaint about how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). Our Data Protection Officer is Michael Maginnis and you can contact him by phone (0114 2265153) or email ([STH.Infogov@nhs.net](mailto:STH.Infogov@nhs.net))

### **What will happen to the results of the project?**

The results will be published in a scientific journal, but your answers will be private, and we will not use your name on anything. We will let all the young people and parents and carers who took part in the project know about what we found out.

### **Who is organising and funding the project?**

The project is being organised by Zoe Marshman, who is a Professor in Dental

Public Health in the School of Clinical Dentistry. Funding to support this project was awarded by the National Institute for Health Research: Health Technology Assessment [HTA 131805].

### Who has checked the project?

All the research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. Their role is to look after your interests. This project was checked by Cambridge South Research Ethics Committee [22/EE/0013].

### What if I wish to complain about the way in which this project has been conducted?

If you have any cause to complain about any aspect of this project, e.g. the way you have been approached or treated, please contact the project lead: Professor Zoe Marshman (contact details below).

For complaints to the University of Sheffield please contact: the University Secretary, University of Sheffield, Western Bank, Sheffield, S10 2TN, email [university.secretary@sheffield.ac.uk](mailto:university.secretary@sheffield.ac.uk) or phone (0114) 2221211

For complaints to the Sheffield Teaching Hospitals NHS Foundation Trust please contact: the Patient Advice and Liaison Service (PALS), email [STH.PALS@nhs.net](mailto:STH.PALS@nhs.net) or phone (0114) 2712450

### What do I do next?

There is a consent form for you to fill in. If you are happy for your child or you both to take part, please complete the consent form at the time of your appointment or afterwards when you are ready.

### Contact details

If you want to know more, please look at the project website: [www.sheffield.ac.uk/dentalschool/research/CALM](http://www.sheffield.ac.uk/dentalschool/research/CALM)

If you have a question about the project, please feel free to contact:

Professor Zoe Marshman  
Email: [z.marshman@sheffield.ac.uk](mailto:z.marshman@sheffield.ac.uk)  
Telephone number: 07703179151

Or by writing to: School of Clinical Dentistry, Claremont Crescent, University of Sheffield, Sheffield, S10 2TA

The different ways you and your child can take part and the time it will take are shown in the table below:

<b>Child who agrees to take part</b>				
<b>Activity</b>	<b>Number of times</b>	<b>Time taken</b>	<b>Who with</b>	<b>Where</b>
Assent form (agreeing to take part)	1	10 mins	One of the members of the dental team	The dental practice
Questionnaires	3	10 mins	One of the members of the dental team	Filled in at the dental practice or at home by the child
Interview	1 (if agree to do it and they are selected)	Maximum of 45 mins	Person from research team	Child's home or by telephone or video call

<b>Parent/carer who agrees to take part themselves</b>				
<b>Activity</b>	<b>Number of times</b>	<b>Time taken</b>	<b>Who with</b>	<b>Where</b>
Consent for child to take part	1	10 mins	One of the members of the dental team	The dental practice
Consent to take part themselves	1	2 mins	One of the members of the dental team	The dental practice
Questionnaires	3	10 mins	One of the members of the dental team	The dental practice or at home by child
Interview	1 (if agree to do it and	Maximum of 45 mins	Person from research team	Parent/carer's home or by telephone or video call

	you are selected)			
<b>Parent/carer who does not want to take part themselves</b>				
Consent for child to take part	1	10 mins	One of the members of the dental team	The dental practice

**Thank you for reading this information.**

**Please feel free to ask any questions if you need to.**

**This information sheet is for you to keep.**