CHOICE Data Processing Website Statement

CHOICE is a research study that supports families to prevent tooth decay in their child. If you have agreed to take part in CHOICE, or are considering taking part, you will have received the study information sheet. The information sheet contains all the key details about study involvement and if you have any questions about this you should ask the dentists and dental nurses looking after you, or who have invited you to take part.

On this page you can find more detailed information about how the CHOICE team are using your/your child's data, who will have access to information about you/your child, and who to contact if you have any questions about how your/your child's data is handled.

Who is running the study?

Queen's University Belfast is acting as the Sponsor of this study and is responsible for managing it. They are based in United Kingdom. They have asked that the day to day running of the study is carried out by a team based at the Liverpool Clinical Trials Centre (LCTC, part of the University of Liverpool), with help from the health economists and qualitative researchers at Queen's University Belfast (the central study team). Each site (dental practice) has contracted with the Sponsor to deliver the trial on their behalf. The clinical care is provided at the site under a contract with the National Health Service.

The study has been reviewed by the Health Research Authority and the National Research Ethics Service Committee to make sure that the study is scientifically and ethically acceptable. This study is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (NIHR; study identifier 131817).

How will my and my child's information be collected and handled?

This trial will collect personal data (e.g. participant names), including special category personal data (i.e. participant dental information) and this will be handled in accordance with all applicable data protection legislation. Data (including special category) will only be collected, used and stored if necessary for the trial (e.g. evidencing provision of consent, for data management and central monitoring, statistical analysis, regulatory reporting, etc.). At all times, this data will be handled confidentially and securely.

Breaches of data protection principles or regulations identified by LCTC will be notified promptly to the trial Sponsor and The University of Liverpool's Data Protection Officer and appropriate processes followed. Queens University Belfast is the Data Controller for this study and will need to use information from your child and from their dental records for this research project.

This information will include your name and your child's

- Name
- NHS/Health & Care number*
- Date of birth
- Sex
- Ethnicity
- Postal address
- Telephone number
- Name and address of primary school your child attends/will attend once of school age

*NHS number is only used in England and Wales. Health & Care number is used in Northern Ireland.

People will use this information to do the research or to check your child's records to make sure that the research is being done properly.

Individuals from Queens University Belfast, the LCTC and regulatory organisations may look at your child's dental and research records, and the consent form you sign to check the accuracy of the research study.

People who do not need to know who you and your child are will not be able to see yours or their name or contact details. Your child's data will have a code number instead.

The contact information that we collect on the consent form regarding you and your child will be securely stored by the Liverpool Clinical Trials Centre (LCTC), which is part of the University of Liverpool and coordinates the study. The LCTC will then securely pass yours and your child's contact details to the CHOICE study team at Queen's University Belfast electronically.

They will use your contact details to:

- Organise your child's final dental check-up
- Contact you if you have consented and are chosen to take part in the qualitative interviews
- Contact you to arrange completion of the questionnaires 12 months and 24 months following group allocation.
- Keep you updated on the study progress via newsletters.
- Inform the Headteacher of your child's school that your child is taking part in a research study and to request permission for the 24 month dental check-up to be carried out at the school if necessary.

The data will flow as follows in the study:

- Data will be collected from the dental practice records using an electronic data system and will be transferred securely to the LCTC.

- At 12 months and 24 months following group allocation, a link will be sent to you to complete the required questionnaires electronically in your own time. If the questionnaires are not completed electronically, then you may be contacted via a telephone call to complete them over the phone or a copy may be posted out to you for you to complete and return to the LCTC. The data will be entered onto the trial database at LCTC and held securely until secure transfer to Queen's University Belfast occurs for analysis.

- Recordings taken whilst the 'intervention' (structured conversation) occurs will be recorded using an encrypted Dictaphone and transferred electronically and securely to Queen's University Belfast.

- Recordings collected from the optional qualitative interviews (using video call recording or a Dictaphone if over the phone) will be held securely in Queen's University Belfast.

- Data from the final dental assessment will be entered directly onto the trial database which is held securely by LCTC.

At the end of the study, the Health Economics team working at Queen's University Belfast will request information on your child's dental appointments (including hospital and A&E attendances) either directly from your dentist and/or via external administrative organisations. These may include NHS Digital or NHS Business Services Authority (BSA) in England, or Business Services Organisation (BSO), or Patient Administration System (PAS) in Northern Ireland (or their successors). To access your child's healthcare data, your child's personal details, which will include their name, sex, NHS number / Health and Social Care number, date of birth and postcode, will be shared with these administrative organisations by the LCTC. This will enable them to provide information already in their possession on your child's hospital attendances from when they enter the study up until 10 years from the end of study.

The chosen administrative organisations will then share this health information, which is regarded as a special category of information, with relevant members of the CHOICE research team at Queen's University Belfast. This data will have your child name, date of birth and other identifiers removed. At the end of the period specified in the

Data Sharing Agreements between Queens University Belfast and the administrative organisations, the data provided by these organisations will be securely destroyed. We will keep all information about you and your child safe and secure. If you consent to your child's sibling's data being collected, then the same process will be followed.

Once we have finished the study, we will keep the data for 10 years, so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

What will happen to the audio-recordings/interviews I give?

The intervention will be recorded using an encrypted dictaphone. This is to ensure that the dental nurse is following the correct procedures in line with the protocol for the intervention and to gather information about the behavioural goals you choose. This data will be sent electronically and securely to Queen's University Belfast and reviewed by the CHOICE central research team. Once the audio recordings have been transcribed, the recording will be deleted. It will not be possible to identify you from the transcription.

If consented and chosen to take part in the qualitative interviews, these conversations will also be recorded (using videocall recording or via a phone attached to a Dictaphone) and the recordings held securely in Queen's University Belfast for them to analyse. Once the audio recordings have been transcribed, the recording will be deleted. It will not be possible to identify you from the transcription.

What are my choices about how my/my child's information is used?

You can choose for your child to stop being part of the study at any time, without giving a reason, but we will keep information about you and your child that we already have.

In some cases , we may need to continue to collect limited information about any side-effects of the study intervention your child may experience. We will only do this where we are required to do so by law.

We need to manage your child's records, and the consent form you sign in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you or your child.

Information sharing for other research

When you agree for your child to take part in a research study, the information about their health and care may be beneficial to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. You and your child's information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research, or equivalent standards**.**

If you agree for your child to take part in this study, you will have the option for them to take part in future research using their data saved from this study.

Where can I find out more about how my information is used?

You can find out more about how we use yours and your child's information:

- at the study website: www.choice-trial.org.uk
- at www.hra.nhs.uk/information-about-patients
- by asking one of the research team
- by sending an email to choice.study@liverpool.ac.uk or
- by ringing us on 0151 795 5294
- in the Health Research Authority leaflet available from www.hra.nhs.uk/childdataandresearch
- by contacting the Queen's University Belfast Data Protection Officer:
  Email: info.compliance@qub.ac.uk

Telephone number: 028 90972505.

- Queen's University Belfast's Research Privacy Notice sets out the legal bases for processing: https://www.qub.ac.uk/privacynotice/Research/ListofResearchPrivacyNotices/PrivacyNoticeforResearchParticipants.html

If you are not happy with the way your information is being handled, or with the response received from us, you have the right to lodge a complaint with the Information Commissioner's Office at Wycliffe House, Water Lane, Wilmslow, SK9 5AF (www.ico.org.uk).

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with one of the local research team who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this by contacting local NHS Child Advice and Liaison Service (PALS) or equivalent. Members of the local dental team should be able to provide this information to you.

Every care will be taken in the course of this clinical study. However, in the unlikely event that your child is harmed by taking part in this research project of the study Sponsor (Queen's University, Belfast), compensation may be available and they may have to pay their related legal costs. The dentist where your child receives treatment has a duty of care to them whether or not you agree for them to participate in the study and the study Sponsor accepts no liability for negligence on the part of the dentist's employees. However, if your child is harmed and this is due to someone's negligence at the dentist, then they may have grounds for a legal action for compensation against the Dental Surgery where they are being treated but they may have to pay for their legal costs. The normal National Health Service complaints procedures should be available to them.