Changing Habits tO Prevent ChIld CariEs (CHOICE): A Randomised Controlled Trial of a Family- Focused Therapeutic Conversation Delivered by Dental Nurses in Primary Care

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<Trust/Site address 3>
<postcode>
Tel: <telephone number>

Parent/Primary Caregiver Information Sheet for CHOICE

- You have been given this information sheet as your child might be suitable to take part in this research study. Before you decide, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully.
- If you wish you can discuss it with friends, relatives and/or get independent advice via your local Child Advice and Liaison Service (PALS) or equivalent.
- Taking part is voluntary. If you don't want to take part then you don't need to give a reason why.
- CHOICE is a study that supports families to prevent tooth decay in their child.
- Suitable participants will be receiving NHS dental care, have tooth decay in at least one tooth, and be aged 3-7 years old.
- We aim to recruit 908 children from 40 general dental practices in four regions of the UK (Northern. Ireland, East of England, Yorkshire and Cheshire and Merseyside)

If you have any questions about this study, please talk to your research team

Name: <PI/DN Name>

Contact Number: <PI/DN Number>

Why are we doing the CHOICE study?

Child tooth decay is a major problem in the UK and many children end up in hospital to have teeth removed due to severe decay. We know the advice and support for parents and carers of these children on how to improve dental health is lacking.

Once a child has had tooth decay, children may develop further tooth decay in the future because family routines and lifestyles may not change as a result of the child having had treatment for tooth decay.

The CHOICE study aims to find out whether a structured conversation (known going forward as the 'intervention') between the dental nurse and parents/primary caregivers can improve the health of your child's teeth. In order to make a fair and balanced comparison, half the families will have the intervention with the dental nurse and half will not have the intervention. Both groups will receive normal care from their dentist. With these equally divided groups we'll be able to assess if the intervention with the dental nurse works in preventing/reducing future tooth decay.

For those allocated to the intervention group, the study aims to provide parents/primary caregivers with advice and plans suitable for their child and family to help prevent future tooth decay.

This may include the knowledge and skills to develop healthy tooth brushing habits and an understanding of how reducing sugar in the diet can prevent child tooth decay.

We also want to see if dental practices are the best places to deliver this to families. A previous study that involved children in a hospitals, who had been admitted for tooth extraction, showed the intervention worked in preventing/reducing future tooth decay. We are hoping that providing this support at an earlier time point, such as in dental practices, will reduce the number of children needing to be admitted into hospital to have a tooth extraction.

We plan to ask 908 sets of parents/primary caregivers and children to take part in the study when they attend for a dental check-up with their dentist. Eligible children will be aged between 3-7 years old and will have at least one decayed tooth. Study duration will last for 2 years. You will receive a free dental pack (containing a toothbrush and toothpaste) for your child when you sign up to the study.

The results from this study will be used to help us improve treatments for children with tooth decay.

Why has my child been invited to take part?

Your child has been chosen because your child's dentist has seen decay in at least one tooth and would like to invite them to take part in the study.

Does my child have to take part?

No, taking part is voluntary. It is up to you to decide whether or not you and your child should take part.

If you decide that you and your child should not take part then your child will still receive the usual treatment their dentist offers. Their dentist can provide you with more information on this.

If you decide that you and your child will take part you can also change your mind at any time without giving a reason.

The decision you make on whether you and your child should take part or not will not affect the standard of care they receive now or in the future.

What does taking part involve for my child and me?

If you agree your child can take part, you will be asked to sign an electronic informed consent form. You will be given a copy of the consent form and the information sheet to keep. Your dental practice and the clinical trials unit running the study (Liverpool Clinical Trials Centre) will also receive a copy of the consent form that will be securely filed.

Once you have signed the consent form, the dentist will then complete some checks during their routine dental assessment on your child to ensure that your child is suitable for the study. If after the routine dental assessment, the dentist feels your child is not suitable for the study your child will not be invited to take part. If your child is suitable we will ask you for your contact details so that we can keep in touch with you about the study.

Either at the first visit or the second visit, you will be asked to complete some questionnaires about your child's details; your family's typical oral health behaviours; your child's quality of life and how you believe oral health impacts on your child's quality of life.

After the first visit and once the questionnaires are completed, your child will be put in to one of two groups, the 'intervention' group or the 'control' group. This is called randomising and more information on this process is detailed further down in this information sheet.

If your child has been put into the intervention group, then you will be asked to meet with the dental nurse for approximately 30 minutes. We hope this can be done during your first visit but if not, another visit that is convenient for you can be arranged, however it must be within 6 weeks of being allocated to a group. During this 30 minute meeting, you will learn about how to prevent further tooth decay in your child. The dental nurse will support you and help to identify areas of your home life that can be changed, and you will set goals that will help achieve this. We will help you to set one or two goals of your choice. These goals will usually focus on controlling sugar in your child's diet and tooth brushing. We know that both can help prevent tooth decay. Once this meeting is over you will be asked to complete 2 surveys with some questions on how you feel the meeting with the dental nurse has gone. Your child will then receive the usual dental care.

If your child has been put into the 'control' group, then they will only receive their usual dental care.

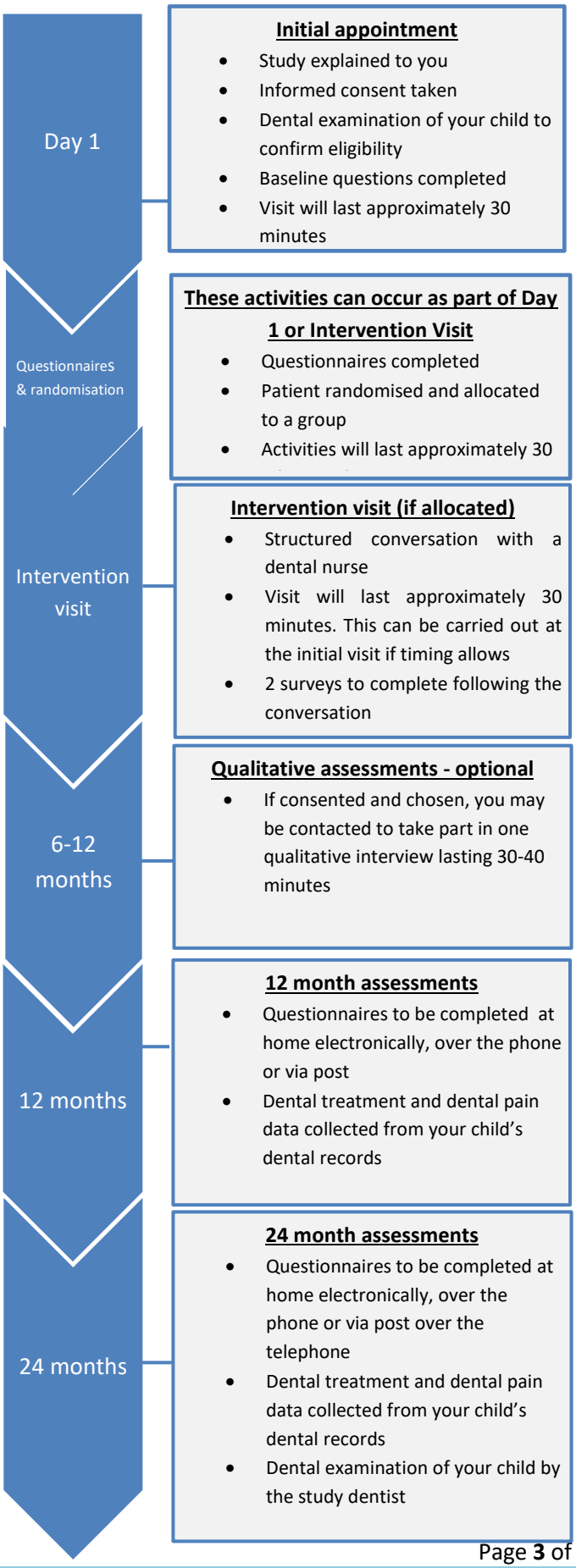
At 12 months and 24 months following group allocation, you will be asked to complete the same questionnaires that you completed at your initial visit, regardless of

which group your child has been placed into. You will also be asked if your child has had any health concerns/issues that you think could be related to the study. A link will be sent to you in order for you to complete the questionnaires electronically in your own time. This may be followed up with a phone call to complete these over the phone or a copy may be posted out for you to complete and return to the LCTC.

At these time points, we will also get in touch with your dentist to see if your child has had any dental pain or treatment since the last visit and if they have experienced any issues related to the study. At the end of 24 months, your child will have another dental check-up. This will be in addition to your child's routine care and will take place at either the dental practice or your child's school. Your child's school may be contacted for the check-up to take place at school. The check-up will be performed by the study dentist and not their usual dentist. If it is not possible for this check-up to be done at the dental practice or in school then it may be possible to be carried out at home.

If your child has been placed in the intervention group, then we will ask you on the consent form if you are happy to be contacted between 6-12 months after the intervention to be asked a few extra questions such as what you thought about speaking to the dental nurse and did this change how you look after your child's teeth. These are known as qualitative interviews and will be carried out remotely via video call or telephone call and will ask about your experiences on the study. These conversations will be recorded (by recording a video-call or via a phone attached to a Dictaphone) and the recordings will be held securely in Queen's University Belfast for them to analyse.
On the consent form we will also ask if you are happy for us to collect information from administrative dental records for any siblings of your child taking part in the study who are up to 11 years old. The siblings must live in the same household and attend the same dental practice as your child taking part in the study. You must also have parental responsibility for the siblings to be able to agree to their data being collected.

Study Timeline



What is the intervention being tested?

The 'intervention' that has been discussed in the above section is called the Dental RECUR – Brief Negotiated Interview (DR-BNI) and is a structured conversation between yourself and one of the study dental nurses.

The intervention will be undertaken by a dental nurse who has had special training for the study. They will work with you and your family to support and motivate you to change the old habits that led to tooth decay. They will work with you to help you decide on goals that work for you and your family and will discuss three key dental behaviours (regular tooth brushing with a fluoridated toothpaste, controlling how much sugar is in your child's diet and going to the see the dentist regularly). These will be discussed in a non-judgemental way, and you will be asked to choose one or two behaviours that you feel that you could change for your child.

We plan to perform all of the intervention conversations face to face in the dental practice, either at your initial dental appointment straight after being told which group your child has been allocated, or at a time that is convenient for you within 6 weeks of being allocated to a group. If it doesn't work to have the conversation face to face due to covid-19 (or other exceptional circumstances), it may be possible for you to have the conversation via video call or phone call.

How will I know which treatment my child is going to have?

In research studies we often split patients up into groups to look at how different treatments work. In the CHOICE study patients will be split into two groups at random:

· One group will receive the 'intervention' (a 30 minute structured conversation with a dental nurse plus usual dental care from their dentist).

· The other group will receive usual dental care from their dentist.

It is really important that each group in the CHOICE study has a similar mix of patients in it, so we know that if one group of patients does better than the other it is very likely to be because of the intervention and not because there are differences in the types of patients in each group.

We use a computer programme that will place your child into one of the groups 'at random' – you might hear this described as 'randomisation' or 'random allocation', but they all mean the same thing. Neither you nor your child's dentist can choose which group they are in.

In the CHOICE study your child is equally as likely to be in the group receiving the intervention as they are in the group receiving usual dental care.

What are the alternatives for treatment?

If you choose not to take part in the study, then your child will receive the usual standard of care.

What are the benefits and risks of taking part?

Potential benefits

The CHOICE study intervention may lead to the adoption of healthy behaviours that may improve your child's oral health. The changes can become part of new daily routines within your family setting which can result in healthier habits that are long lasting, and the whole family can potentially benefit. The intervention may prevent some children needing more invasive treatments including extractions under general anaesthetic.

Potential risks

The intervention involves a supportive conversation using goals that are tailored to your child and family. It hopes to teach you, as parents/primary caregivers, how to change habits that lead to tooth decay in favour of healthier family routines. The intervention is delivered by a trained dental nurse. It is possible that you may become concerned when discussing your child's dental health. Should this happen, we will take time to talk over any concerns that you may have.

If any safeguarding issues are identified during the conversation than local guidance will be followed by the dental practice.

We hope that the results from the study will help dentists and patients in the future when making decisions about treatment.

What happens if I change my mind?

If at any point you decide that your child should stop taking part in the study, they will still receive treatment and the follow up usually offered by their dentist.

If you do decide they should stop taking part we will ask you if you would like them to:

· continue to complete follow up visits for the study **or**

· stop taking part with no more study visits.

If you lose capacity to consent during the study your child will be withdrawn from the trial and no further data will be collected. However, any identifiable data (data collected with your agreement that can identify you) that has already been collected will be kept securely and used in the study.

What happens when the study stops?

The study will end around two years after your child has been allocated to a group however, we will ask permission to collect data in the future from your child's dental treatment records both at the dental practice and hospital records (if they attend hospital for dental extractions). You will be asked if dental records from administrative organisations (including dental extractions) can be followed up for any siblings (aged up to 11 years at study entry) of your child, that you have parental responsibility for, living in the same household and who attend the same dental practice as your child. This will be for up to 10 years from the end of the study. This will be part of a different study and should your children be over the age of 16 at this point, they will be invited to participate via yourself and will be required to consent for this data to be collected.

If your child was randomised to the intervention, you will be able to take home the leaflets used and completed to look back on. You will be able to keep these after the end of the study.

It is intended that the results of the study will be presented at conferences and published in medical journals so that we can explain to the dental community what our research results have shown. They may also be used to apply to the regulatory authorities to make the intervention widely available and/or for research related to the development. Confidentiality will be ensured at all times and neither you nor your child will be identified in any publication.

If you would like to access the results of the study they will be included on the CHOICE website. The research team at your dental practice will also be informed of the results and can communicate these results to you.

Will taking part in the study be kept confidential?

Yes. The only people that have access to your/your child's data are those that need it for the conduct of the study. This includes the study dentists and nurses, LCTC, the central research team, inspectors or auditors on behalf of the Sponsor organisations and the regulatory authorities.

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

In order to access your child's routine healthcare data, the LCTC will share your child's personal details, which will include their name, sex, NHS number / Health and Care (H&C) number, date of birth and postcode, with 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). We plan to ask for your child's data for up to 10 years from the end of study, but this may be extended in future to follow-up your child's long term health status. Data from these external organisations (or their successors) will be shared with members of the CHOICE research team at Queen's University Belfast, who are doing some of the study analysis.

Further information about how we use your data and keep it safe can be found on the CHOICE website, www.choice-trial.org.

Who is running the study?

Queen's University Belfast is the Sponsor for this study and are responsible for managing it. They are based in the 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). The central research team are researchers from Queen's University Belfast.

The study has been reviewed by West Midlands – Edgbaston Research Ethics Committee to make sure that the study is scientifically and ethically acceptable. This study is funded by the National Institute for Health Research (NIHR).

Your dentist will not receive any payment for including your child in this study.

Information sharing for other research

If you agree to take part in this study, you will have the option to allow future research at other organisations using your data collected as part of this study. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your 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.

Where can I find out more about how my and my child's 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
- 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).

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 NHS 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.

This study is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (NIHR; study identifier 131817). The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

Thank you for taking the time to read and consider this information sheet. Should you decide that your child can take part in the study, you will be given a copy of the information sheet and a signed consent form to keep.

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.

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FOR SITE USE ONLY:

Site Name:			
Participant Study Number			
Participant Initials:		Participant DOB:	/ /

Parent/Primary Caregiver Consent Form

Once you have read and understood each statement please initial each box:	**Initial**
Example: I confirm that I have read and understand the Patient Information Sheet.	*JBS*
1. I have read and understood the information sheet for this study. I have had the opportunity to ask questions and have had these answered satisfactorily.	
2. I understand that participation is voluntary and that I am free to withdraw my child and myself from the study at any time, without giving a reason, and without their care or legal rights being affected.	
3. I agree for my child and I to participate in the above study.	
4. I give permission for a copy of this fully completed consent form that includes my name and my child's data to be sent to the LCTC (where it will be kept in a secure location), to allow confirmation that my consent was given.	
5. I understand that relevant sections of my child's dental notes and any data collected during this study may be looked at by authorised individuals from the LCTC, the central research team at Queen's University Belfast, representatives of the Sponsor and regulatory authorities. I give permission for these individuals to have access to my records and data.	
6. I agree for the relevant data on my child's dental treatment to be collected from my child's dental practice for the purposes of this study.	
7. I agree for my child's personal data (including name, sex, NHS/H&C number, date of birth and postcode) to be shared by LCTC with external administrative organisations as stated in the section titled 'Will taking part in the study be kept confidential' so they can provide Health Economic researchers working on the study at Queen's University Belfast with information regarding my child's dental data and hospital attendances. NHS/H&C number:	
8. I understand that my child's data will be kept by the LCTC, Queens University Belfast and at my child's dental practice, in a confidential manner, for 10 years from the end of the study.	
9. I understand and agree that the intervention (if allocated to the intervention) will be recorded and the recordings will be sent securely to Queen's University Belfast.	

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10. I understand that the contact details that I have provided will be used by the central research team to contact me to ask for information at 12 months and 24 months following my child being allocated to a group. If I move home, I am happy for my dental practice to provide my new address to LCTC/central research team.	
Telephone number:	
Email address:	
Address, including postcode:	
11. I agree to the Head Teacher of my child's school being contacted to inform them that my child is participating in a research study and I am happy for the 24 month dental examination to be carried out at the school if necessary. If my child moves school during the study, I confirm that I am happy for my child's original school to provide details of the school my child has moved to.	
School name and address:	

The statements below are optional (your child can still take part in the study even if you do not wish to agree to these). Only initial these boxes if you agree to these statements.

	Yes	No
12. I agree to allow information and data or results arising from this study to be used in future healthcare and/or dental research providing mine and my child's confidentiality is maintained.		
13. I am happy for my contact details to be shared with Queen's University Belfast and to be contacted during the trial (between 6-12 months following intervention) to take part in qualitative interviews if my child is allocated to the intervention group.		
14. I consent to my child's dental data being collected, for up to 10 years from the end of study. Should they turn 16 during this time, I am happy to be contacted in order to pass on an invite to my child for them to consider having their data collected for the future study.		
15. I agree for my child's siblings personal data (including name, sex, NHS/H&C number, date of birth) to be shared by LCTC with external administrative organisations as stated in the section titled 'Will taking part in the study be kept confidential' so they can provide Health Economic researchers working on the study at Queen's University Belfast with information regarding my		

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child's siblings dental data and dental extractions that take place in hospital. This will be for up to 10 years from the end of study. Should they turn 16 during this time, I am happy to be contacted in order to pass on an invite to my child for them to consider having their data collected for the future study. Name _____ DOB _____Sex: Male/Female Name _____ DOB _____ Sex: Male/Female Name _____ DOB _____ Sex: Male/Female Name _____ DOB _____ Sex: Male/Female		
16. I agree for my dental practice to provide NHS/H&C number of my child's siblings (aged up to 11 years of age on study entry) to Queens University Belfast and LCTC.		
17. I agree that I or my child may be contacted in the future in relation to this and other related studies.		

To be completed by the Parent/Primary Caregiver								
Your child's **full** name (please print):		Your child's DOB:						
Your **full** name (please print):								
Your signature:		Date:	d	d	m	m	y	y

To be completed by the Researcher (after the participant has completed the form):								
Researcher **full** name (please print):								
Researcher signature:		Date:	d	d	m	m	y	y