



Participant Information Sheet

HABIT: A study to explore and improve oral health and tooth brushing advice given by Health Visitors

Study Number: 230315

We would like to invite you to take part in a research project. Before you decide to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. This sheet tells you about the purpose of this project and what will happen if you take part.

What is the purpose of this research?

We would like to explore how Health Visitors can support you as parents to adopt and maintain good oral health behaviours for your baby.

We have worked with some Bradford parents and Health Visitors to develop a set of oral health materials, called HABIT. These HABIT materials are designed to be used by Health Visitors when they visit parents who have babies aged 9-12 months.

We would like to study if these materials are accessible to you and whether they help you to adopt and maintain good oral health behaviours. The resources include an information package accompanied by several video clips. We have also provided your Health Visitor with training on how to use these HABIT materials.

Who is doing the research?

The study is being undertaken by staff working at the University of Leeds, School of Dentistry.

Why have I been asked to participate?

You have been asked to help with this study because you are a parent of a baby aged 9-12 months old and are about to receive a home or clinic visit from your Health Visiting team. At these visits you will discuss lots of things about your baby and receive advice on how to keep your baby healthy. In total thirty Bradford parents are involved in this study.

Do I have to take part?

No, the study is entirely voluntary and you do not have to take part if you don't want to and this will not affect the services you receive from Health Visitors or any other authorities in any way.

What will happen to me if I agree to take part?

If you agree to take part, you will meet our research team four times. At these visits we will enquire about your baby's tooth brushing practices and oral health behaviours.

The first meeting will be arranged two weeks before you receive a universal home or clinic visit by a Health Visitor for your 9-12 months old baby. We would like to talk about your current tooth brushing practices for your child, count how many teeth they have and check their mouth is healthy. A trained dental therapist will look in your baby's mouth. As part of this dental examination, we will use a food dye which is vegetable based to look for plaque. The dental therapist will paint the food colouring onto your child's teeth with a small brush and then use a soft tissue to wipe it away. This will not hurt your child but they may find it tastes funny. If your child is allergic to food colouring agents or you wish us to not perform the activity we will look at your child's teeth without using the colouring agent. We then would like to film how you brush your baby's teeth. The filmed material will be used for scientific purposes and accessed only by the research team and no one else will be able to see the videos. If you wish, we will not film the activity and just have a chat about your child's tooth brushing practices.

We will also provide you with the Magic Timer app for your phone/tablet and will ask you to use it after you have brushed your child's teeth. If you prefer, instead of using the app, we will provide you with the Magic Timer diary and will ask you to fill it in after each time you have brushed your child's teeth. The app is freely available to members of public and there are no commercial agreements or contracts with the app company. We will ask you to use the app after each time you brush your baby's teeth. Identically, if you prefer using the Magic Timer diary, we will ask you to write down how often and how long you brush your baby's teeth. It will take no longer than 30 seconds to fill in the app or the diary. We will ask to look at the app or diary at our second and third meetings. This will allow us to learn about how often and how long you brush your baby's teeth.

Universal home visit by your Health Visitor will be arranged two weeks after our first meeting. The Health Visitor will discuss with you your baby's development and as a part of the visit they will chat with you about your baby's oral health. The Health Visitor will use our newly developed HABIL oral health resources which include information sheets and videos. You are welcome to keep the resources if you wish.

Two weeks and three months after your Health Visitor visits you, we will organise a second and third meeting with you. These meetings will be the same as the first meeting and include the same activities.

The fourth meeting will be arranged as soon as possible after the third meeting. We would like to hear about your experience of brushing your baby's teeth and the oral health advice provided to you by the Health Visitor using the HABIL oral health materials.

We will contact you to arrange a convenient time and location for these meetings. For the first three meetings these could be either at your home or in a health care setting where you normally see your health visitor, and the fourth meeting can be arranged in a location that is convenient for you such as your home, or a public place like a coffee house or a café where you would feel comfortable talking about your baby's oral health and tooth brushing. You will be asked to sign a consent form before the first meeting and at the beginning of the fourth meeting to confirm you are happy to take part. You will be given a copy of the information sheet and signed consent form to keep.

The first three meetings will last approximately 15-45 minutes and the fourth meeting will last around 45-60 minutes. We will cover any transport costs and in each meeting we will give you a £10 'Love2Shop' gift voucher to thank you for your time. The trained dental therapist and a researcher will attend the meetings.

If during the meetings and discussions you feel uneasy in any way or worried, you can refuse to answer the questions and stop the discussion and activities at any time without giving an explanation.

If you agree, we would like to audio-record all discussions as this will help us to better understand the conversations and accurately remember what was said. The records will be transcribed by a professional

transcriber who has signed a confidentiality agreement with the University of Leeds. Audio-recordings will be kept in a secured access University of Leeds network and permanently deleted after they are transcribed.

Audio and video recordings will be kept strictly confidential and only members of the HABIT research team will have access to them. They will be stored in the highest security restricted access University of Leeds network.

If we would like to use your audio or video recordings for Health Visitor training or other professional activities, we will arrange a further meeting with you. At this meeting we will show you which audio or video we want to use and why we want to use it. You are free to disagree and this will not have any impact on you, your baby or your participation in the study. If you agree, we will obtain further written consent from you to use it for this specific purpose. The materials will not be available to the members of public nor used on social media or public website.

Your personal contact details will be kept for twelve months and any other identifiable data will be kept for twenty years after the end of the study as this is a requirement of the Medical Research Council who funds this project.

What are the benefits/disadvantages of taking part?

The HABIT oral health materials and advice provided by Health Visitors will hopefully help you as a parent to look after your baby's teeth and adopt good oral health behaviours. In addition, to compensate your time after each meeting we would like to give you a 'Love2Shop' gift voucher for £10.

Can I withdraw from the study at any time?

If you do take part and then change your mind afterwards you can withdraw from the study at any time up until the conversation from the fourth meeting has been written up from the audio recording.

Will the information obtained in the study be kept confidential?

Everything you say will be kept strictly confidential and you will not be identified in any way. Any information that might personally identify you from the interview will be removed from the written record and the audio recording will be destroyed. Filmed material will be accessible only to the members of the research team and no one else will be able to see them. Only members of the research team will have access to the data which will be stored securely at the University of Leeds and handled in strict accordance with the 1998 Data Protection Act. With your consent, anonymised data from this study may be used in future research studies.

What will happen to the findings of the study?

At the end of the study we will publish our findings in professional and academic journals and you will not be identified in any report or publication. If you would like a copy of these materials to read for yourself, please contact us.

What if there is a problem?

If you have any concerns about this study please contact a member of the research team in the first instance. Similarly, if you find any aspects of the conversation upsetting or concerning please contact one of the research team who may also be able to suggest an appropriate professional to talk to. If you remain unhappy about any part of this project or any activity of a member of the research team and wish to complain formally, you can do this by contacting Dr Peter Day (Tel. +44 (0)113 343 6139 or email: p.f.day@leeds.ac.uk)

Who has reviewed this study?

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This study has been reviewed by the NHS England Research Ethics Committee and has been approved by them (Number).

What happens now?

A Clinical Research Officer (name and surname) from Bradford District Care Foundation NHS Trust will contact you in next few days to see if you are interested joining the study. If you agree, the Clinical Research Officer (name and surname) will arrange a meeting with you at a time and place most convenient to you. The Clinical Research Officer together with you will go through this information sheet and will answer all your questions, if you have any. If you agree, the Clinical Research Officer will securely pass your contact details on to the HABIT Research Fellow, Dr Ieva Eskyte, who will contact you to arrange the first meeting.

The Clinical Research Officer will provide you with the password 'Toothbrushing Habit'. When Dr. Ieva Eskyte calls you to arrange the first meeting, she will have to confirm the password after introducing herself and before continuing the conversation. This will reassure that the call is not scam.

You can keep this information sheet. You will be provided with a photocopy of the signed consent form (if you decide to take part).

Thank you for taking the time to read this information sheet.

If you would like more information or have any questions or concerns about the study please contact Dr Ieva Eskyte on i.eskyte@leeds.ac.uk .