

**BEE** Best Emollient  
for Eczema

## Best Emollient for Eczema (BEE) Study

### Interview Study Participant Information Sheet

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#### 1 Why we are doing this study

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Eczema is a common childhood condition where the skin is dry and itchy. Moisturisers (or emollients) are the main treatment for eczema, but there are many types and we do not know whether one type is better at treating eczema than another. We want to understand which moisturisers work best, which ones patients prefer and the reasons for this. In doing so, we will be able to make recommendations to GPs and patients on which ones to try first.

We are interviewing a small number of people who are already taking part (or were taking part) in the BEE study to find out more about their experiences with different types of moisturisers, including their study moisturiser. We are also interested in what they think about taking part in this kind of study.

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#### 2 Why have we been chosen for the BEE interview study?

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You have been chosen because you and your child agreed to join the main BEE study. We want to talk to a variety of people about their experiences of using moisturisers during the BEE study. If you have stopped using the study moisturiser we are still interested to hear about your experiences as it is important for us to know why people may stop using the moisturisers.

We plan to interview up to 60 parents/carers and, with permission, some older children who are taking part in the study. This information will help us to better understand which moisturisers for eczema parents and patients prefer and why. In future, this may help GPs to decide which moisturisers to recommend.

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#### 3 Do we have to take part?

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No, it is up to you whether or not you choose to take part in this part of the study. A researcher from the BEE study will contact you a few days after sending you the invitation to take part. They will give you more information about the interview study and discuss with you whether or not you are happy to be interviewed.

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#### 4 What will happen if we choose to take part?

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If you would like to be interviewed, the next step is to speak with one of the researchers. The researcher will arrange a meeting at a time and place that is convenient to you and your child (such as your home) or by telephone, if you prefer.

If you agree to take part in an interview in person, you will first be asked to sign a consent form. The researcher may also ask if you are willing for your child to participate in the interview. If the interview is conducted over the telephone, we will

take consent over the telephone. The interview will last between 20 and 60 minutes.

The interview will be informal – you will be asked a variety of questions about your views of moisturisers and your experiences of taking part in the BEE study. There are no correct answers. We want hear your experiences and views.

With your permission, the interview(s) will be recorded with a password-protected digital audio recorder (no video), but your real name will not be used in any subsequent written report or published material. The recordings and written notes based on the interviews will be securely stored at the University of Bristol.

We would like to speak with some people when they have just started using their moisturiser and others later on when they have been taking part in the study for a few months. If you take part in an early interview we may ask you if you would be happy to speak with us again, but it is up to you to decide if you would like to.

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## 5 Possible benefits of taking part

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We do not think there will be immediate benefits to participants who agree to be interviewed. However, the results will help us to understand what parents and patients think about moisturisers, which they prefer and which seem to work best. This information may help future patients to find a moisturiser that they like and works well for them. It may also help GPs to decide which moisturisers to recommend to other patients in future.

We are not able to offer any expenses or payments to people who participate in the study. We will, however, offer a £20 voucher to thank you and your child for your time.

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## 6 Possible disadvantages of taking part

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If you decide to be interviewed, you will be asked to give up 20-60 minutes of your time to meet with (or have a telephone call with) a researcher. However, the researcher will try to meet you at a time and place which is convenient for you and your child (your home, for example).

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## 7 More information about taking part

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What will happen if we don't want to carry on with the study?

You can withdraw from the interview study, or the main BEE study, at any time without giving a reason. This would not affect the standard of care you receive from your GP.

Please let the researcher know if you would prefer not to be interviewed. If you do not take part in an interview, you can still carry on with the main BEE study. If you wish to withdraw from all parts of the BEE study, please let the research team know.

What will happen to information about me/my child collected during the study?

All information you provide during an interview will be stored securely at the University of Bristol. We will keep the interview data separate from your personal details (e.g. name, address) and we can only link this information together with a secure code. Only authorised members of the research team will have access to the information. We will keep it for up to 5 years after the end of the study and then destroy it securely.

The research team will occasionally need to allow monitors from Regulatory Authorities to inspect the study paperwork, in order to meet legal,

ethical and safety requirements. All individuals who have access to data will be bound by strict data protection and confidentiality rules. Only if the researcher had concerns about the well-being of you or your child would they be obliged to report this to the relevant authorities.

At the end of the interview study, your data will be stored in an online database held by the University of Bristol. Making data more available to other researchers is now considered best scientific practice as it helps the development of new areas of research.

Access to the data will be restricted to legitimate researchers wishing to conduct further analysis of the data, following completion of a Data Access Agreement. All data will be anonymised. This means that an identification number is used for you and your child. It will not be possible to identify you or your child by name from any aspect of documentation or reporting for this research study.

## What will happen to the results of the study?

When the interview study is completed, the results will be published in a journal so healthcare professionals can learn about the main findings. If published, the identity of you and your child and all personal details will be kept confidential. No named information about you or your child will be published in any report about this study. We will also provide you with a summary of our findings from the study, if you wish.

## Who is organising and funding the study?

This trial is organised by the University of Bristol. The funder is the Health Technology Assessment (HTA) programme, which is part of the National Institute for Health Research. The trial has **not** received any funding, samples or promotional materials from the pharmaceutical industry.

## Who has reviewed the study?

This study has been reviewed by an independent group of people, called the Research Ethics Committee, to protect your safety, rights, well-being and dignity. The study has been given a favourable opinion by the NHS Research Ethics Committee (South West Central Bristol Research Ethics Committee: ref 17/SW/0089).

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## 8 Contact for further information

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If you have any questions regarding the interview study, please contact one of the research team below:

### Study Manager

Ms Sian Wells  
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### Interview Study Researcher

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Thank you for reading this leaflet.