Best Emollient for Eczema (BEE) Study
Participant Information Sheet

We would like to invite you and your child to take part in a research study

- Before you decide whether to take part, it is important to understand why the research is being done and what taking part will involve for you and your child.
- Please read the following information carefully and discuss it with friends and relatives. Take time to decide whether or not you wish to participate.
- You are free to decide whether or not to join the study. If you choose not to take part, this will not affect the care you get from your GP (general practitioner).
- Please ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information sheet.

Important things you need to know

- Your child has been asked to take part because they have eczema and they are between six months and 12 years old.
- The main treatment for eczema is the regular use of moisturisers (known as emollients).
- There are many different moisturisers, but there are four main types: lotions, creams, gels or ointments. We don't really know if one is any better than another.
- If you agree to take part in the study, your child will be prescribed a moisturiser from one of the four main types that are commonly prescribed.
- In order for us to compare how effective the moisturisers are at treating eczema, we are asking people to use their study moisturiser for 16 weeks. We will also examine your child's skin before you start the study and at 16 weeks.
- We will ask you to regularly complete short questionnaires (weekly to begin with, then monthly) for 12 months to see how you get on.
- We may ask to interview you and your child about your experiences and opinions, but this is your choice.

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How to contact us

If you have any questions about this study, please email, ring or write to:

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Why we are doing this study

What are we studying?

Eczema is a common childhood condition where the skin is dry and itchy. It is usually diagnosed in the first two years of life. In the UK, most children are treated by their GP.

Moisturisers (or emollients) are the main treatment for eczema, but there are many types and we do not know whether one is better at treating eczema than another. This is a problem because patients may have to make several appointments before they are given a moisturiser that works for them. It may be that older, cheaper moisturisers are just as good as or better than newer, more expensive ones.

If we understand which moisturisers work best, which ones patients prefer and the reasons for this, GPs will be able to recommend to patients in the future which type of moisturiser to try first.

2 How the study works

How do we find out whether there is one moisturiser which helps most?

In order to compare how effective the four different types of moisturiser are, we are carrying out a large study (trial). We plan to include 520 children with eczema, aged between 6 months and 12 years, from 75 GP practices in England.

Parents and carers will be asked to use one locally recommended moisturiser (either a lotion, a cream, a gel or an ointment) as their only moisturiser for 16 weeks. During this time, parents/carers will be asked to avoid using other moisturisers as a "leave-on" treatment (this means applied and left on the skin, not used to wash with). Other treatments such as steroids, calcineurin inhibitors and bath emollients can still be used as usual. The moisturisers that we are comparing can also be used to wash with, if parents/carers wish to do so.

We will ask parents/carers to fill in short weekly surveys about their child's eczema symptoms, use of moisturisers and other treatments for eczema for 16 weeks. Thereafter, the surveys are monthly until the end of the study, at 12 months. This will help us to know how well these moisturisers work in the long-term and which ones patients prefer. It is important to collect this information regularly because eczema can change quite a lot over time.

A researcher will also assess the severity of the eczema at 16 weeks by looking at the skin. The researcher will not know which treatment a child has been receiving to ensure that this is a fair assessment.

After everyone's data has been collected, we will analyse this information to determine whether one type of moisturiser is better than another. These kinds of comparisons look at everyone in the study at the same time, rather than looking at individual children. It is not possible to identify anyone from these results and the information is kept confidential.

How is it decided who gets which moisturiser?

In this kind of study, neither the researchers nor the parent/carer gets to choose which treatment the child is prescribed. It is done using a special computer programme, by a process called 'randomisation'.

It's a bit like rolling a dice to decide which one of the four types of locally recommended moisturiser is prescribed, and it means that there

is an equal chance of being given any one of the moisturiser treatments.
This is the only fair way to compare them, and as far as existing research shows, they are all as good as each other.

The rest of this leaflet explains how you might be involved in our research study.

3 Why are we being asked to take part?

Your GP practice is supporting this study and your GP thinks your child may be suitable for the study. We have asked you and your child to take part because your child has been diagnosed with eczema and is aged between 6 months and 12 years.

4 What will happen if we choose to take part?

Enrolling you in the study

We have sent you this additional information because you have told us that you are interested in learning more about this study. If you would like to take part, the next step is to meet with one of the researchers at a time and place that is convenient to you and your child (such as your own home). You can then decide if you and your child would like to join the study.

First research visit

The researcher will contact you and arrange an initial assessment visit. The visit will take about 20-30 minutes to complete. At this appointment, the researcher will explain the study to you, check your child's eligibility and answer any questions you may have. With your permission, we may audio-record this appointment using a secure, password-protected (encrypted) digital recorder. This will help us to improve how researchers explain about study procedures. You can choose whether you agree to have the appointment audio-recorded or not, and will be given more information at the time. Your decision will not affect your future participation or care in any way.

You do not have to enter the study unless you feel completely happy with what you are being asked to do. If you are not eligible or do not want to take part, you will continue to receive your usual care from your GP.

The researcher will complete some study paperwork with you, including a consent form (there is an assent form for your child, if they are old enough). We will ask questions about your background, the health of your child and any eczema treatments they have used or are currently using. Based on the answers you give, the researcher will tell you whether you are eligible to take part in the next stage of the trial.

If your child is suitable for the study and you are willing to take part, the researcher will examine your child's skin. Your child will then be allocated by chance to one of the four locally recommended treatments: either a lotion, cream, gel or an ointment.

Next, the research team will ask your GP to issue a prescription for your child's study moisturiser. Please collect this as soon as it is ready and begin applying it two times a day or as frequently as needed. The trial manager will contact you within a week to check that you have picked up the moisturiser and started using it.

You will be asked to apply the study moisturiser on your child for 16 weeks (about four months), and avoid using other moisturiser treatments during this time. It is very important that you do not tell the researcher doing the follow-up visit

which of the study treatments you are applying at any time. This allows for a fair and unbiased comparison between the four types of treatment.

Taking part in the study will not stop you or your GP changing your child's medication or any other therapy, if this is what you want or decide is the best thing to do.

Follow-up surveys

The study will last for 12 months. We will ask you to complete a weekly diary to record your child's eczema symptoms and use of other eczema treatments for the first 16 weeks of the study. This will take about 5 minutes each week. You can choose whether to complete these using a secure online survey or a paper diary. Whatever method you choose, the research team will send you a reminder when the next survey is due.

The 6-week diary will also include questions about how eczema affects you and your family, and how well you and your child have been feeling. Including the usual weekly questions, this 6-week diary should take about 10 minutes to complete.

We will ask you to complete monthly questionnaires until the final, 12-month survey. These will take about 10 minutes to complete. They include the same questions as the weekly diaries, but also ask if you have had healthcare appointments or spent any money on treatments for your child's eczema.

The questionnaires at 16 weeks and at 12 months will be a bit longer. They might take up to 30 minutes to complete. They include the same questions as the monthly surveys, plus questions about how eczema affects you and your family, how well you and your child have been feeling, and your experiences with the study and your study moisturiser.

On the consent form, we will ask for your permission for us to review your child's medical records at the end of the study (for healthcare appointments and medications prescribed). If you agree, any information we record will have your child's name and address removed so that they cannot be recognised from it.

Second research visit

We also ask that you and your child meet the researcher at 16 weeks to re-assess their skin. This appointment will be at a time and place convenient for you and will normally take 15-20 minutes to complete.

Interviews about your experiences

We are interested in your views on taking part in research. The best way to collect this information is often face-to-face with a series of questions. A small number of people who are taking part in the study, as well as some people who decide not to continue with the study, will be invited to share their views on the study and the moisturiser they have been asked to use. We would like to interview parents/carers and some children early in the study, and then again around four months into the study. If you are invited and want to do this part of the study, we will go through what this would involve and ask for your additional consent first.

5 How is taking part in the study different from usual GP care?

The main difference will be that the moisturiser that is offered to your child will be determined by a computer, which will randomly select one of the four types of study treatment. As part of the study, we will ask that you try to use your study moisturiser as the only leave-on treatment for your child for 16 weeks. Each of the study treatments are commonly prescribed by GPs for

young children with eczema. Therefore, the treatment your child is prescribed could be the same even if you do not take part in the study.

You will be asked to complete weekly and monthly diaries to record your child's symptoms and use of any other eczema treatments. This is described in Section 4, "What will happen if we take part?"

If you participate in the study, your child's eczema will be assessed at the start and 16 weeks into the study by the researcher.

While taking part in the study, your child will continue to be looked after by their GP as normal. You can take your child to see their GP as often as you and he/she thinks necessary. No treatment will be withheld from your child during the course of this study.

6 What are the treatments that are being tested?

There are four types of treatment within this study. They are all moisturisers used to treat eczema in children that are currently locally recommended and available for your GP to prescribe:

- Lotion
- Cream
- Gel
- Ointment

We have chosen these treatments because they are commonly prescribed. Each is known to be effective on its own, but there is little research as to whether any one type is more or less effective than the others.

What are the side effects of the treatments?

Side effects from moisturisers are thought to be uncommon, but this is one thing we want to compare. The side effects that have been listed are usually increased redness or itching of the skin.

If your child is already known to be allergic or sensitive to any of the study moisturisers or their ingredients, they may not be able to take part.

7 Possible benefits and disadvantages of taking part

What are the possible benefits of taking part in the BEE study?

Most people find it rewarding to take part in medical research, and appreciate the additional monitoring and contact with the researchers.

Using the study moisturiser as recommended may improve your child's symptoms of eczema. However, this cannot be guaranteed.

This research will help doctors in the future to decide which treatments to recommend for children with eczema.

What are the possible disadvantages and risks of taking part in the trial?

This is a randomised controlled trial (study) and, therefore, you cannot choose which type of treatment your child receives. The treatment will be determined by chance using a computer.

It may be that you do not find the treatment helpful for your child. In addition, your child may experience side effects from the treatment. You should discuss any side effects with your child's usual GP, who will continue to be responsible for

your child's medical care. You can stop using the study moisturiser at any time. We would ask you to discuss this with your GP first, so that they can advise you on this and provide your ongoing care.

If you think your child develops any problems because of the study, you should record this in your diary and also discuss it with the researcher.

If you decide to take part in the study, you will be asked to give up some time to meet with a researcher two times over a period of four months for the assessments. 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). You will also be asked to complete weekly and monthly surveys regarding your child's eczema symptoms and use of other eczema treatments.

8 More information about taking part

Do we have to take part?

No, it is up to you to decide whether or not to take part. Invitation letters have been sent to all of the children who might be able to take part from your GP practice. If you choose to the join the study, you are free to withdraw from it at any time, without giving a reason. This would not affect the standard or type of care your child will receive.

Will I receive any payment for taking part?

No, we are not able to offer any expenses or payments to patients who participate in the study. We will, however, offer £10 vouchers at the beginning and part-way through the study to thank you for your time. We may also offer your child a small gift.

What happens if new information becomes available during the course of the study?

During a study, sometimes new information becomes available about the treatment being studied. If this happens, the research team will tell you and discuss whether you want to continue in the study.

If you decide to stop taking part in the study, your usual care with your GP will continue. If we think your child should withdraw from the study, we will explain the reasons and arrange for their eczema care to continue.

What happens when the study stops?

Very occasionally, a study is stopped early. If this happens, the reasons will be explained to you and arrangements made for your GP care to continue as usual.

If your child has been receiving a moisturiser which has been beneficial, you can discuss with your doctor whether this treatment should continue at the end of the study.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researcher or trial manager who will do their best to answer your questions. Alternatively, you could speak to the Chief Investigator, Dr Matthew Ridd (email: m.ridd@bristol.ac.uk, telephone: 0117 331 4557).

If you remain unhappy and wish to complain formally, the normal NHS complaints process is available to you. If your child is harmed by taking part, or if your child is harmed due to someone's negligence, then you may be able to take legal action.

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

All information will be held securely and in strict confidence. We keep the information we collect about your child separate from their personal details 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.

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.

We will use the information we collect to look at how best to help children with eczema. We will keep it for up to 5 years after the end of the study and then destroy it securely.

At the end of the study, your data may be made "open access". This means that it will be stored in an online database so that it is publicly available. However, all data is 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 is open access?

Open access means that data are made available, free of charge, to anyone interested in the research, or who wishes to conduct their own analysis of the data. We will, therefore, have no control over how these data are used. However, all data will be anonymised before it is made available, and so there will be no way to identify you from the research data.

Why open access?

Open access of research data and findings is considered best scientific practice. It is a requirement of many funding bodies and scientific journals. As a large proportion of research is publicly funded, the outcomes of the research should be made publicly available. Sharing data helps to maximise the impact of studies through wider use, and encourages new avenues of research.

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

You can stop using the study treatment at any time, but we would still like you to complete the follow-up surveys so that we can monitor your progress. If you don't want to carry on with the study assessments, however, you can completely withdraw from the study at any time. The information already collected will still be used.

Involvement of your GP

Your GP is supporting this research. If you join the study, we will tell your child's GP that he/she is taking part. Your child's GP will issue prescriptions for your child's study moisturiser. Otherwise, your child will receive the same care as they are currently getting from your GP practice.

What will happen to the results of the study?

When the 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 trial 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)

9 Contact for further information

If you have any questions regarding the study or how you might be involved further, please contact one of the research team below:

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Thank you for taking the time to read this leaflet and for considering whether to take part in this study.