The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Insert Trust Logo

THE BEEP STUDY

A randomised controlled trial to determine whether application of emollient from birth can prevent eczema in high risk children

You are invited to take part in our research study

- It is important you understand why the study is being done, and what it would involve for you if you decide to take part.
- Please take time to read this information. Talk to others if you wish, and ask if you would like more information.
- It is for you to decide if you want to join the study or not. If you agree to take part, you are free to withdraw at any time without giving a reason. If you choose not to take part, your care will continue in the normal way.
- Thank you for reading this information.

Important things that you might like to know

- One in five children of school age suffers with eczema.
- Children born into families with a history of eczema, asthma or hayfever are more likely to develop eczema.
- We want to find out if applying moisturisers every day for the first year of life will make a difference to whether children will develop eczema or not.
- If you decide to take part, you will be given advice to follow **either**:-
  - i. best practice skin care routine for your baby **or**
  - ii. best practice skin care routine including applying moisturiser to your baby at least once a day for a year. The moisturiser will be provided free of charge.
- Which group you are in will be decided by chance, like tossing a coin, and to be a fair test, you will not be able to choose which group you are in.
- You will be asked to complete some short questionnaires which will be sent and returned either on-line or by post.
- You will see a researcher just after your baby's 2nd birthday to assess whether they have developed eczema.

Contents

How to contact us

If you have any questions about this study, at any time, please contact the study team at:-

☎ [TO BE ADDED]

✉ [TO BE ADDED]

1. Why we are doing this study

Eczema is a skin condition that can make the skin red and itchy. Approximately one in five school age children have eczema and we know that children born into families with a history of eczema, asthma or hayfever are more likely to develop eczema. There are many different ways of *treating* childhood eczema, but nothing that we can say with any certainty that *prevent* eczema.

Emollients (moisturisers) are one of the commonly used treatments for childhood eczema, but they have not been properly studied for the ***prevention*** of eczema. There are some good reasons to think that skin care advice including the regular application of moisturiser from birth might prevent eczema, but there may be no effect so we need to do this study (a fair test) to find out the answer.

2. Why have I been invited to take part?

You are being invited to take part in this study because you are pregnant or have very recently had a baby and you, your partner or your children have a history of eczema, asthma or hayfever.

3. What will happen if my child and I take part?

If you take part you will be seen by a researcher, either at home or at the hospital, whichever you prefer. During this visit, the researcher will fully explain the study to you and then you will be asked to sign a consent form. We will collect some information about you and your baby, your contact details and the name of your GP and/or midwife. This visit will take approx. 20-30 minutes. We will let your GP know you and your baby are taking part in the study.

We will ask you to contact the study team to let us know when your baby has been born. If we don't hear from you, we will contact you when your due date has passed as it is important you start the study within 3 weeks of your baby being born.

You and your baby will then be allocated to receive **either**:

i. Best practice skin care advice for your new-born baby **or**

ii. Best practice skin care advice which will also include instructions about applying a moisturiser (provided by the team) to your baby's skin, at least once a day for a year.

Which of the two skin care advice packages you get is decided by chance by a process called randomisation, meaning there is equal chance of being in either group. Neither you nor the research team will be able to choose which group you are allocated to. This is done so that at the end of the study we can be sure that any differences between the babies in the two groups are due to which skin care advice they received, rather than anything else.

We will contact you to check you have received the advice package. You and your child will be involved until just after your child's 5th birthday. During this time, we will ask you to complete nine questionnaires at the start the study and then at 3, 6, 12, 18, 24, 36, 48 and 60 months. The questionnaires will include questions about any skin problems, eczema, wheezing, hayfever-like or food allergy symptoms or diagnosis, visits to the doctors and prescriptions, use of skin and wash products, feeding and your quality of life. Some of the questionnaires are slightly longer than others but we estimate it will take you between 10 and 30 minutes to complete each.

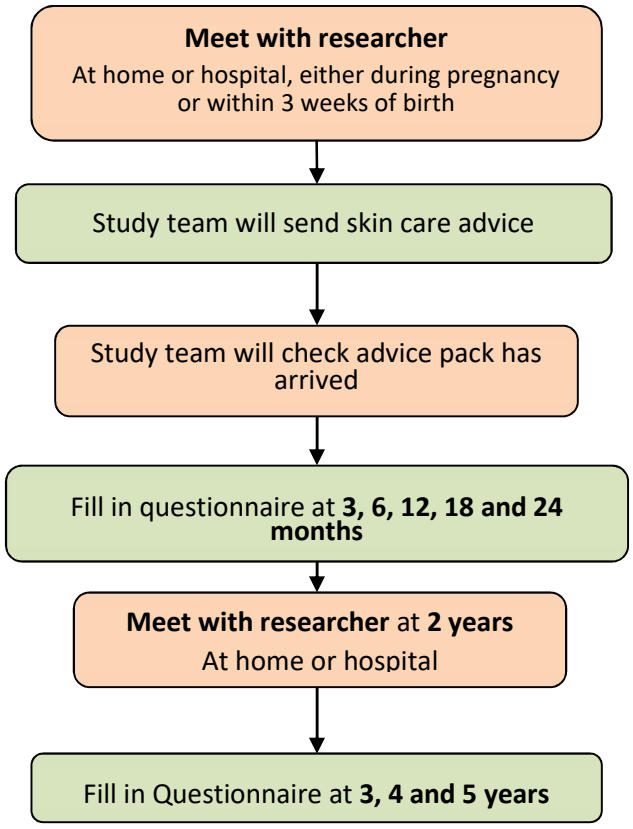
The questionnaires can be completed online via a secure website (or we can send you a paper copy if you prefer). If you are completing the questionnaire online, we will email you to let you know when to complete it. Half of the participants will receive a text message reminder about the questionnaire. We will then compare how many questionnaires were completed by the group who received the reminders to how many were completed by the group who didn't receive the reminders. This information will tell us if participants find text reminders helpful, which will help the research team understand how to better run studies.

Around the time of your child's 2nd birthday, a researcher will contact you to arrange to see you and your child, either at home or at the hospital, which ever you prefer. Your child's skin will be examined for any signs of eczema. You will be offered a £10 voucher around this time as a thank you for helping with the study. Half of the trial participants will receive the voucher before they see the nurse, the other half will receive the voucher after they see the nurse. We do not know if receiving vouchers encourages participants to attend appointments or not. By comparing visit attendance of these two groups, we will have

information about how to improve our studies in the future.

We will ask you to let us know if you change your contact details. If we cannot get hold of you, then we may contact your GP (unless you ask us not to) to check if you have moved house and/or to ask about any skin problems your child has had.

If you decide to take part in the study, you are free to withdraw at any time and although we may ask, you don't have to give a reason. Taking part in this will not affect the normal care you or your child would receive in the future.



4. Will any genetic tests be done?

There is an optional genetic test in this study – you can decide whether you wish to part in this part of the study or not. If you do the researcher will collect some saliva at the visit just after your child's 2nd birthday. This will be done by your child spitting in a pot or a swab taken from their mouth (a painless procedure of rubbing a cotton bud on the lining of the cheek). If the researcher is unable to collect the sample at the visit for any reason, we may send you a kit thought the post for you to collect the sample from your child.

The samples will be sent to the University of Dundee for analysis and the results sent securely back to the study co-ordinating centre at the University of Nottingham. We will look at one eczema gene that may be relevant to childhood eczema to help us find out more about changes in DNA that may affect how well the skin acts as a barrier. We will not do any other genetic testing.

We will not send you the genetic test results because they aren't useful in helping or guiding treatment for the individual child. The researcher can explain why this is if you would like to know more.

If you agree, any remaining samples will be stored for 15 years at the University of Dundee and tested for other genes found to be associated with eczema in the future. The samples will only be made available to the existing research team. If you choose not to allow this, then any remaining samples will be disposed of in accordance with the Human Tissue Authority's codes of practice.

You can still take part in the optional genetics study even if you don't want your child's samples stored afterwards; just indicate this on the consent form.

5. Possible disadvantages or risks?

There is very little risk involved in taking part and we don't expect to discover any new side-effects of the skin care advice.

Taking part in this study will take up some of your time as you will need to follow the skin care advice until your baby is 1 year old and complete the questionnaires every 3, 6 or 12 months until your child is 5 years old.

For those receiving the advice to also apply the moisturiser for a year, there is a low risk that this could cause skin infections because it may block the pores in the skin.

You will need to take extra care when handling your baby (especially for the first hour after application) when you have applied the moisturiser as their skin will be more slippery than normal. We recommend using enough moisturiser to make the skin surface develop a slight sheen.

If your child is starting to stand/toddle we recommend you do not apply the moisturiser to the soles of their feet or if you do apply to the soles, wipe off any excess. You will also need to be sure to wipe up any spillages to avoid any slips and falls.

6. Possible benefits?

We cannot say whether taking part in this study will help your child but this study should provide parents, doctors and other health professionals with guidance about whether applying moisturisers helps prevent eczema and so possibly benefit other children in the future.

7. Will my taking part be kept confidential?

Yes. All information which is collected about you and your child during the study will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Any information about your child which leaves the co-ordinating centre will have your name and address removed and a unique code will be used so neither you or your child can be recognised from it. You or your child will not be named or otherwise identified in any study publication.

Some of the data collected for the study will be looked at by authorised persons from the University of Nottingham and participating hospital trusts to check that the study is being carried out correctly.

In order to be able to contact you, we will need to keep your name and contact details which will be held securely, with restricted access. Only appropriate members of the research team will have access to this data. Your contact information will be kept by the University of Nottingham for 3 years after the end of the study so that we are able to contact you about the findings of the study *and possible follow-up studies* (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it.

All the study data will be kept for seven years. After this time your child's data will be disposed of securely. During this time, all precautions will be taken by all those involved to maintain your child's confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

8. Results of the study

When all the children have reached 2 years of age, we will analyse the data collected so far and publish the results in scientific journals and present them at medical conferences. We will publish the longer term findings of the study when all the children involved in the study have reached 5 years of age. We will send you a copy of the study findings unless you ask us not to.

9. What if there is a problem?

If you have any concerns or questions about any aspect of this study you should speak to the study team who will do their best to answer them for you.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure, Patient Advisory and Liaison Service (PALS). Details can be obtained from your local hospital.

In the event that something does go wrong and you are harmed during the study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

10. Who is funding the study?

This study is being run completely independently of industry. It is funded by the research arm of the NHS, the National Institute for Health Research (NIHR) via their Health Technology Assessment Programme (project number 12/67/12). The project receives no funding from other sources and has and aims to inform NHS care.

11. Who has reviewed the study?

This study has been reviewed and given favourable opinion by the West Midlands - Solihull Research Ethics Committee (REC). The REC looks after the rights, wellbeing and dignity of people invited to take part in research studies. THE NIHR has also reviewed the study as part of the funding process.

Thank you for your time