



Bath Additives for the Treatment
of cHildhood Eczema

Bath Additives for the Treatment of cHildhood Eczema (BATHE)

We would like to invite you to take part in our research study. This leaflet explains why the research is being done and what it would involve for you and your child.

What is the purpose of this research?

Children with eczema are advised to regularly use emollients (non-cosmetic moisturisers that you leave on the skin) and we know that applying emollients directly to the skin in this way helps to relieve eczema symptoms. Some doctors and nurses also recommend using bath emollients (moisturisers that you add to the bath) but there is no evidence to show whether or not this helps. We would like to find out whether adding emollients to the bath helps children with eczema or not.

Why have I been invited?

Your GP is helping us with our research by sending this information about the study to carers of children who have had dry skin or a rash or eczema.

Do I have to take part?

It is up to you and your child whether to take part in the study. Please read this information sheet to help you decide. You can phone us if anything is unclear or if you have any questions about the study at all. If you decide not to take part your child's care will not be affected in any way. If you do decide to take part your GP will be informed of your child's participation and which group s/he is allocated to. If you or your child change your mind about taking part then you are free to withdraw at any time, without giving a reason.

What will happen to me and my child if I take part?

If you would like to take part in this study then please complete the questionnaire included in this pack and return it directly to the study team in the enclosed FREEPOST envelope. A nurse will contact you to arrange a convenient appointment with you (and your child if you wish, although this is not essential) at your GP surgery. At this appointment the nurse will explain the study in greater detail and answer any questions that you may have. The nurse will also ask you to complete a questionnaire about your child's eczema. The appointment will take about 30 minutes.

Your child will be allocated to one of two treatment groups either (1) usual care for eczema **with** bath emollient, or (2) usual care for eczema **without** bath emollient. In order to make the study a fair test, your child will be placed into one of these two groups by chance, using a randomisation program:

- If your child is assigned to the bath emollient group then you will be given a repeat prescription for a bath emollient. You will need to bath your child using this bath emollient (or another brand if you prefer) at least once a week for a year.
- If your child is assigned to the usual care without bath emollient group we will ask you to commit to NOT adding any emollient to your child's bath for a year.

Whichever group your child is randomised to, you will still be free to use any other medications and treatments and to see your GP if necessary. All other aspects of your child's care will remain the same.

We would like you to fill in questionnaires about your child's eczema at regular intervals for the duration of the study so that we can find out whether using bath emollient makes any difference. We would ask you to answer a few short questions once a week for the first 4 months of the study and then once a month for the rest of the year. Ideally the questionnaires will be completed on-line, using a computer. However, you can answer the questions on paper or by e-mail if this is more convenient for you. If you decide to complete the questionnaire on paper we will include a pre-paid envelope for you to return it to the study team. When you have completed the study, your child's GP notes will be looked at by a member of the practice team or a researcher to see if

there have been any eczema-related consultations or prescriptions during that 12-month period. Your practice will not tell us any other information about you or your child.

We might ask if we can interview you to find out if there are any ways of making the study run more smoothly, but you don't need to do this to take part in the study.

What will happen if my child's eczema gets worse with the bath emollient?

An uncommon side effect of bath emollients is that they may cause skin to become red or irritated. If this happens to your child then please contact your GP and ask for a prescription for a different bath emollient. If the problem persists then please discuss with your GP or with the study team.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be kept strictly confidential. Personal details will be stored separately from any other information in a password-protected file and paper documents will be stored in a locked filing cabinet. These details will not be shared outside the study team and when the study is complete they will be archived in line with University procedures. No personally identifiable information such as names or address will ever be shared with any other organisations.

What will happen to the results of the research study?

We will use information from the study to write reports and journal articles but they will not include any information that makes it possible for you to be identified. At the end of the study we will send you a summary of the results of the study for your information.

Who is organising and funding the research?

This study is organised by researchers at the Universities of Southampton, Cardiff and Bristol. The study is funded by the National Institute for Health Research, which is part of the Department of Health.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given a favourable opinion by the NRES Committee North East - Newcastle & North Tyneside 1 (Ref: 14/NE/0098).

What if there is a problem?

If you are concerned about the conduct of this study or any people involved in it then please contact either of the trial coordinating centres below. You may also contact Barbara Halliday, Director of Legal Services at the University of Southampton: email rgoinfo@soton.ac.uk or phone 02380 595058. If you remain unhappy and wish to complain formally you can do so through the NHS complaints procedure. Details are available from your own practice.

Should you feel that you suffer any negative consequences because of your involvement in this study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence you may have grounds for legal action against the University of Southampton.

What next?

If you would like to take part then please complete the questionnaire. Please fill in your contact details so that we are able to send you more information about how to join the study.

If you cannot or do not wish to take part in the study it would be helpful for us if you could fill in the reply slip and return it in the FREEPOST envelope.

If you would like to know more about the study or discuss anything in this information sheet please contact:

Kate Martinson
BATHE Study Manager
Department of Primary Medical Care
University of Southampton
Aldermoor Close
Southampton SO16 5ST

tel: 023 8024 1087
fax: 023 8070 1125
e-mail: bathe@soton.ac.uk

www.southampton.ac.uk/bathe