

## BATHE

### Baseline Appointment Checklist

1.	<p><b>Introduction</b></p> <p>Ask the parent/carer (and child if present) if they have any questions before you start. Check they understand what is meant by 'bath emollient'; if not explain simply that:</p> <p><i>"Bath emollients are liquids that can be added to bath water. Some people think they help with eczema but others think they don't and there is no research evidence either way."</i></p>
2.	<p><b>Explain the purpose of the study</b></p> <p><i>"At the moment some GPs prescribe bath emollients to almost all children with eczema and some don't prescribe them at all. Also, dermatologists /skin specialists are not sure whether they help improve eczema or not. BATHE is a Fair Test or Randomised Trial of bath emollient, as this is the best way of finding out for definite whether they help children with eczema. What this means is that we ask the computer to randomly put half of the children who agree to take part in the 'bath emollient' group and half in the 'no bath emollient' group. And then we ask both groups to do their very best to stick to their groups for 12 months so that we can really answer that question confidently."</i></p>
3.	<p><b>Check the child's eligibility</b></p> <p>i. Is the parent/carer aware that they could be randomised to either the 'bath emollient' or 'no bath emollient' group and that they will be asked to do their best to stick to this for 12 months? <i>"Would you be happy for your child to be allocated either of the groups: usual eczema care with bathe emollient or usual eczema care without bath emollient?"</i></p> <p>ii. Is the child happy to take part in the study?</p> <p>iii. Is the child aged between 1 and 12 years – e.g. had their 1<sup>st</sup> birthday but not had their 12<sup>th</sup> birthday?</p> <p>iv. Does the child have a bath at least once a week?</p>
4.	<p><b>Informed Consent</b></p> <p>Ask the parent/carer if they have read the Information Sheet and if they have any questions.</p> <p>Ask the parent/carer to complete the Consent Form (and consider offering child assent form if appropriate and present).</p>
5.	<p><b>Questionnaires</b></p> <p>Ask the parent/carer if they are able to complete the questionnaires online <i>"We</i></p>

	<p><i>are asking people to complete their questionnaires online in this study. Is that OK for you?"</i></p> <p>(if not offer paper questionnaire and make a note on the <b>RECRUITMENT LOG</b>)</p> <p>Emphasise the necessity to answer questions weekly due to the relapsing/remitting nature of the illness –e.g. <i>"We really value your time. It is very important for the study that you complete these weekly as that is really the best way to find out how your child's eczema is over the next 4 months, rather than at 1 or 2 time points".</i></p> <p>Emphasise to the parent/carer that here are only 8 questions and tell them we will send them either text, telephone* or e-mail reminders (each week for the first 4 months and then once a month after that until completion) – email for online users, text/telephone for paper users.</p> <p><b>*NB Please ask when is the most convenient time of the day to phone them</b></p>
<p><b>6.</b></p>	<p><b>Log-In BATHE online questionnaires/LifeGuide</b></p> <ol style="list-style-type: none"> <li>i. Log in to BATHE online site and ask the parent/carer to CREATE A PASSWORD in LifeGuide.</li> <li>ii. NB Stress to the parent/carer to either click on the link in their email or on the link on the BATHE website to access online questionnaires. (<a href="http://www.soton.ac.uk/bathe">www.soton.ac.uk/bathe</a>). If they use the web address stated on the card then type this into the navigation bar at the top of the screen and NOT using a search engine. Suggest they might wish to bookmark it as a 'favourite'.</li> <li>iii. Add their PID (provided on their screening questionnaire)*</li> <li>iv. Ask the parent/carer to fill in the baseline questionnaire in LIFEGUIDE.</li> </ol> <p><b>*NB take a list of participant ID numbers to appointments</b></p>
<p><b>7.</b></p>	<p><b>Randomisation</b></p> <ol style="list-style-type: none"> <li>i. Ensure they have completed randomisation and made a note of username (their email address) and the password on the card supplied.</li> <li>ii. The CSO should add their name and phone number to the card.</li> <li>iii. If allocated to the control group then stress to parent (and child if present) how important this group is in order to answer the study question.</li> <li>iv. If randomised to Emollient, ask if they have any preferences about which one they would like to use and inform them how they can obtain repeat prescriptions (previously agreed with surgery).</li> <li>v. NB If they already use one of the 3 'approved' Bath Emollients for the Study they can continue to use this and obtain their repeat prescriptions as usual.</li> <li>vi. Give them 'HOW TO WASH' leaflet and discuss principles:</li> <li>vii. <i>"What do you use to wash your child at the moment?" "One of the best things you can do for eczema is to avoid using soap."</i></li> </ol> <p>Advise that they use the child's usual leave-on emollient as a soap substitute. If</p>

	they don't have one then arrange for prescription at the end of the baseline appointment. Ask if they have any questions and see below for answers to frequently asked questions
<b>8. Prescription</b>	Seek prescription for bath emollient, if required – explain to carer how to obtain repeats. Explain that if they feel the BE is irritating their child's skin then they can request to change to a different one.
<b>9. Flag/System Alert</b>	Ask practice staff to place alert on system indicating that child is participating in BATHE and their group allocation. <b>NB the precise system to be used at each Practice should have been established at the 'sign up visit'.</b>
<b>10. Thank You</b>	Thank them for their participation and give them an appropriate gift for the child and their first voucher – add the Voucher Serial Number and PID information on the Voucher Log  <b>ENSURE THE PARTICIPANT'S DETAILS ARE ON THE SCREENING LOG</b>
<b>11. <u>Frequently Asked Questions</u></b>	<p><b>WHEN SHOULD THEY CONTACT THEIR GP?</b></p> <p>If they have any issues about their eczema or its' treatment</p> <p><b>WHEN SHOULD THEY CONTACT THE RECRUITING CENTRE?</b></p> <p>If they have any issues with the study – problems with LifeGuide or the paper questionnaires, or they no longer wish to help with the study. Draw their attention to the following section in the Information Sheet:</p> <p><i>'What do I do if I want to withdraw my child from the study?'</i></p> <p><b>What will happen if my child's eczema gets worse?</b></p> <p>If your child is in either group and their eczema is getting worse then please discuss this with your GP as it might mean that they need to change one of their treatments.</p> <p><b>Are there any Side Effects to Bath Emollients?</b></p> <p>One possible side effect of bath emollients is that they may cause skin to become red or irritated. If this happens to your child after they bath 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.</p> <p><b>If your child is really struggling (especially if in No Emollient Group) try to remain in study until first end point of 16 weeks. What if I don't have access to internet/an email address?</b></p> <p>Ideally the questionnaires will be completed on-line, using a computer. However, if this is not convenient for you and you would rather complete it using the paper</p>

version then this can be sent to you by email or by post depending on which you prefer. If you decide to complete the questionnaire by post we will include a pre-paid envelope for you to return it to the study team.

**What if I don't want my child's notes reviewed?**

A year after the study, your child's GP notes will be looked at by a member of the practice team or a researcher if you agree to this. Re-enforce – *"this is only to see if your child has had any appointments or prescriptions for eczema and not to look at any other information about your child"*