



### **Title of study:**

**A randomised controlled feasibility trial to determine whether families are willing to change baby bathing practice during the first months of life (BabyBathe WP-3)**

#### **Participant Information Sheet**

**Version 1.2 (10/08/22) IRAS Project ID: 311086**

### **You and your baby 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 young children suffers with eczema.
- Bathing babies can cause changes in their skin which might make eczema more or less likely to occur.
- We want to find out if families are willing to follow advice about how they bathe their baby, as this might be a way to prevent eczema in the future.
- If you decide to take part, you will be given advice to follow either:-
  - i. No special advice about bathing your baby or
  - ii. Advice about how to bathe your baby.
- Which group you and your baby 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.

### **Why are we doing this study?**

Eczema is a skin condition that can make the skin red and itchy. About one in five young children have eczema. There are many different ways of treating childhood eczema, but we don't yet know how to prevent eczema.

Bathing babies causes changes to the skin which might make eczema more or less likely to occur. We think that it may be possible to prevent eczema by advising families how to bathe their baby. However, it is uncertain whether families would follow such advice. In order to understand whether it would be worthwhile doing a large trial to test bathing advice for preventing eczema, we need to do this feasibility study.

### **Why have I been invited to take part?**

You are being invited to take part in this study because you are pregnant.

### **Do I have to take part?**

No. It is up to you to decide whether or not to take part. We will describe the study and go through this information sheet. If you do, you will be given this information sheet to keep and asked to sign

a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time or not take part will not affect the standard of care you receive

### **What will happen to me and my child if I take part? What will I have to do?**

If you take part you will be seen by a researcher at your 36/40 pregnancy scan. 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 (including whether you or close family members have a history of any eczema), your contact details and the name of your GP and/or midwife. This visit will take about 20-30 minutes. We will let your GP know you and your baby are taking part in the study.

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

- i. No special advice about bathing your baby ('standard care') **or**
- ii. Specific advice about how to bathe your baby ('bathing advice').

Whether you receive bathing advice or standard care 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 in how babies are bathed are due to the advice that families 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 is 6 months old. During this time, we will ask you to complete questionnaires at the start the study, after your baby is born and at the end of the study when your baby is 6 months of age. During your baby's participation on the study we will send a very short questionnaire each week by text, online or paper according to your preference. This will ask about your baby's health and bathing habits and skincare regimen. We estimate it will take you around 5 minutes to complete the questionnaire each time.

Around the time your child is 6 months old, a researcher will contact you to arrange to see you and your child, either at home or in hospital. Your child's skin will be examined for any signs of eczema and you will be asked some questions. This visit will take about 20-30 minutes.

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 changed contact details 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.

### **What are the possible benefits of taking part?**

We cannot say whether taking part in this study will help you or your child. However, this study should provide parents, doctors and other health professionals with guidance about the feasibility of trying to change the way families bathe their babies, so will possibly benefit other children in the future.

### **What are the possible disadvantages of taking part?**

There is very little risk involved in taking part and we don't expect to discover any new problems linked with bathing babies in different ways in this study.

Taking part in this study will take up some of your time as you will need to follow the bathing advice until your baby is 6 months old and complete the questionnaires up until this time.

There is a low risk that advice to bathe your baby more often or less often might lead to minor skin issues such as slippages, skin irritation or skin infections. We are interested to know whether this is

the case and whether this makes it difficult for you to follow the bathing advice that you receive during the study

### **What if there is a problem or I need further information?**

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): 020 8725 2453.

### **What if my baby or myself is harmed through participation in the study**

St Georges, University of London has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. We would not be bound to pay compensation where:

- The injury resulted from a drug or procedure outside the trial protocol and/or
- The protocol was not followed.

These arrangements do not affect your right to pursue a claim through legal action.

### **Will my taking part in this study 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. 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 nor 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 St George's University of London 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 teams at St George's Hospital and St George's University of London will have access to this data. All precautions will be taken by all those involved to maintain your child's confidentiality.

### **How will we use information about you?**

We will need to use information from you for this research project. This information will include your:

- Name
- Contact details (postal address, email address, mobile/telephone number)
- NHS number

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep identifiable information (your contact details) about you from this study for five years after the study has finished in case we need to contact you regarding your or your child's participation on the study. We will write our reports in a way that no-one can work out that you took part in the study.

### **What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the study, we would like to continue collecting information about your baby's health from your GP. If you do not want this to happen, tell us and we will stop. We need to manage your records in specific ways for the

research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

### **Where can you find out more about how your information is used?**

You can find out more about how we use your information from the following websites:

St George's, University of London (SGUL) Privacy link:

<https://www.sgul.ac.uk/privacy>

St George's Hospitals Foundation Trust (SGHFT) Privacy link:

<https://www.stgeorges.nhs.uk/about/privacy-notice/> <https://www.stgeorges.nhs.uk/education-and-research/research/research-privacy-notice/>

For general information on how the NHS uses research data please visit:

<https://www.hra.nhs.uk/information-about-patients/>

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

When all the children have reached 6 months of age, we will analyse the data collected so far and publish the results in scientific journals and present them at medical conferences. You and your child will not be identifiable from any of the results or reports. We will send you a copy of the study findings unless you ask us not to.

### **Who is organising and funding the research?**

The trial is being run by St George's University of London who are also the sponsors of the trial. This study is being funded by the research arm of the NHS, the National Institute for Health Research (NIHR) via their Research for Patient Benefit Programme (NIHR203170). The project receives no funding from other sources and aims to inform NHS care.

### **Who has reviewed the study?**

This study has been reviewed and given favourable opinion by the North of Scotland (1) 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.

### **Further Information and Contact Details**

If you would like further information, please contact: Lucy Goldsmith (researcher) on [lgoldsmi@sgul.ac.uk](mailto:lgoldsmi@sgul.ac.uk) or telephone XXXXX or Study lead: Dr Michael Perkin, Reader in Clinical Epidemiology, St George's, University of London Email: [mperkin@sgul.ac.uk](mailto:mperkin@sgul.ac.uk) Tel: 0208 725 2786

If you are worried about the University's handling of your information, you have the right to make a complaint to the Information Commissioner's Office: <https://ico.org.uk/concerns/>

However, if you have any questions relating to data protection, in the first instance, please send these to our data protection team at the following address: [researchdata@sgul.ac.uk](mailto:researchdata@sgul.ac.uk)

**Thank you for taking the time to read this information sheet**