



Participant Information Sheet

Final Version 1.1_06-Dec-2023
IRAS Project ID: 329123

Eczema Bathing Study – how often should we bathe?

Have you ever wondered how often to have a bath or shower when you have eczema?

If so, this study is for you!

Everyone is welcome. We are looking for people with eczema, of all ages and all backgrounds, to take part.

When we say “you” in the information below, this means the person taking part in the study – that could be yourself or your child, or someone that you look after.

If you agree to take part in the study, we will put you into one of two groups:

Weekly Bathing Group: will be asked to have a bath or shower 1 or 2 times per week

Daily Bathing Group: will be asked to have a bath or shower 6 or more times per week

- You will be in the study for **4 weeks**
- You will answer some questions online about your eczema each week
- You **can still wash your face and body** at the sink using a flannel or sponge on days when you do not have a bath or shower
- You **can also wash your hair** between showers or baths
- You can **continue to use your eczema treatment** as often as you need to

Why is this study important?

We don't know if taking baths or showers more often or less often is best for your eczema.

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In this Eczema Bathing Study, we are trying to find out if having a bath or shower weekly is better than having a bath or shower every day. To answer this question, we need about 400 people to take part in our study.

There are good things about having a bath or shower every day. However, for people with eczema, it might be better to bathe less often. Here is why.....

Good things about bathing often:

- Keeps the skin clean
- Helps to add water to the skin
- Washes away things that may cause an eczema flare-up

Bad things about bathing often:

- Can dry the skin out
- Washes away natural oils in the skin
- Alters the skin acidity (sometimes known as pH) – this can make eczema worse
- Products used in the bath or shower can damage the skin

I am interested in taking part in the study! What do I do now?

Please read the information below and/or watch our videos to help you decide if taking part is right for you or your child.

Please **get in touch** if you have any questions: RapidEczemaTrials@nottingham.ac.uk

If you would like to take part click the 'Join Now' button on our website:

www.RapidEczemaTrials.org/eczema-bathing-study

Things to know before joining the study

1. Who can take part?

You **can** take part if you:

- Have eczema
- Live in the UK
- Are at least 1 year old in age
- Are willing to change how often you have a bath / shower for 4 weeks

You **cannot** take part if:

- If you don't have eczema symptoms at the moment
- You only have eczema on your hands

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- Your eczema is only in places where your skin is in contact with nickel e.g. jewellery
- Your eczema is only around varicose veins
- You have started a new eczema treatment, other than moisturisers (sometimes called emollients), in the last 4 weeks.
- You are taking part in another eczema study where you are trying something new for your eczema like a treatment or medicine.
- You are planning to swim more than twice a week in the next 4 weeks (including surfing, scuba diving etc)
- Someone else from your household is already taking part in the Eczema Bathing Study

If you are under 16 years old your parent/carer will need to agree that you can take part.

2. Who has set up the study?

People living with eczema and parents of children with eczema have teamed up with researchers from the University of Nottingham.

Together, they are trying to find out how often to bath or shower with eczema.

The Eczema Bathing Study is part of the Rapid Eczema Trials project (www.RapidEczemaTrials.org). This project is a new approach to running clinical trials. It allows people with eczema to answer questions that they have about how best to care for their eczema. The project is funded by the National Institute for Health and Care Research (NIHR) and sponsored by Nottingham University Hospitals NHS Trust.

3. Do I have to take part?

No, it's up to you whether to take part in this study. If you have any questions, you can contact us and we will try and answer them: RapidEczemaTrials@nottingham.ac.uk

If you do agree to take part, we'd love you to complete the 4-week study. But if you decide to take part now and change your mind later, that is fine too. **You can stop taking part at any time, without having to give us a reason, unless you want to.**

4. What will I have to do if I take part?

We will ask you to answer some questions online about you and your eczema. This will help us find out if you are able to take part in the Eczema Bathing Study.

You will then complete an online consent form to say that you are happy to take part in the study. If you are aged under 16 years your parent/carer will need to complete the consent

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form. There will be an optional section on the consent form for children and young people under 16 to confirm they would like to take part.

A special computer programme will put you into one of two groups:

Weekly Bathing Group: will bath or shower 1 or 2 times per week

Daily Bathing Group: will bath or shower 6 or more times per week

This will be done randomly, meaning it works like the toss of a coin. It helps make sure our study is a fair test.

You will be in the study for 4 weeks. You will be asked to follow the bathing pattern for the group that you have been put into. You can continue to use your usual eczema treatments as often as you need to. We ask that you do not start any new treatments during the study if possible.

Each week we will ask you to fill out some online questionnaires about your eczema. You will receive a link to the questionnaires by email or with your permission, by text. We will also send you reminders by email or text to tell you when they need completing. Towards the end of the study, we may give you a friendly call as a reminder to fill in the final questionnaire.

Children may fill in the questionnaires themselves if they are able to, or with the help of an adult. A parent/carer can complete the questionnaire on behalf of a child, but we encourage you to discuss the answers with your child (if appropriate). If an adult is completing the questions on behalf of a child, ideally this should be the same adult throughout the study.

Everything we will ask you to do will be online. This means you can access it with your computer or smartphone/tablet from home. If you don't have access to the internet at home, you can still take part. You can complete the questionnaires at a public place with free Wi-Fi, such as a library or cafe.

If you complete the final study questionnaire at 4 weeks, you can enter a prize draw if you would like to. You could win £25 or a child-friendly book about living with eczema as a thank you for taking part.

[For adult participants only:]

You may also be asked if you would be willing to talk to a researcher about your experience of being in the study. You do not have to agree to do this if you would prefer not to.

5. What are the benefits to taking part?

It may help us to understand more about managing eczema in the future. Some people like to feel they are helping others by taking part, and some people like to try new things out for themselves.

6. What are the risks of taking part?

It is possible that some people may find their eczema gets better but some might find that it gets worse. You can still use your regular creams and treatments to help relieve the symptoms.

Your safety is always our priority. We do not think you are likely to come to any harm in this study, but if you experience any problems, you can contact the study team at RapidEczemaTrials@nottingham.ac.uk

7. What if I'm worried about extra costs from taking part in the study?

We can support you if you are worried about increased costs from taking part in the study. Just let us know and we can arrange some financial help.

8. What will happen if I don't want to carry on with the study?

If you change your mind at any time and don't want to carry on in the study, that is okay. It is up to you if you want take part. If you decide you don't want to carry on, we will still keep and use the information collected before you stopped taking part.

If you are unsure at any stage, then please contact us at RapidEczemaTrials@nottingham.ac.uk

9. What happens at the end of the study?

When your time in the study ends after 4 weeks, you can have a bath or shower as often as you like.

You might like to sign-up to the Rapid Eczema Trials newsletter at <https://rapideczematrials.org/> to receive regular updates about the whole Rapid Eczema Trials project.

Once the Eczema Bathing Study has finished for all participants, we will share the results with everyone who took part and will put the results on the website for others to see.

The results will also be published in scientific medical journals, presented at conferences, and shared with the wider eczema community.

10. How to contact us

You can contact the Eczema Bathing Study research team at RapidEczemaTrials@nottingham.ac.uk

11. Who is organising and funding this study? How has it been approved?

The study is being organised by Nottingham University Hospitals NHS Trust (the Sponsor) and is coordinated by the University of Nottingham. The study is funded by the National Institute for Health and Care Research (NIHR). All research involving people is checked by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given favourable opinion by London-Surrey Research Ethics Committee (23/PR/0899).

People with eczema have worked as citizen scientists and identified **how best to take a bath or shower** as a question important to them. They have worked in teams with researchers and doctors to help design important parts of this study. People with experience of eczema are also involved in the teams that oversee the running of the study.

How will information about me be used?

Researchers at the Nottingham Clinical Trials Unit will need to use information from you for this research project. The Nottingham Clinical Trials Unit is part of the University of Nottingham.

This information will include your name and contact details. The researchers will use this information to do the research. It is also used to check 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.

All information about you will be kept safe and secure.

If you give us permission to, we will share your name and telephone number with Esendex, our text messaging provider and their sub processors. They will use this information to send you text message reminders about the study questionnaires whilst you are taking part in the study. Esendex will keep the information shared with them for two years or until the end of the RAPID Eczema Trials Project (whichever occurs first) before it is destroyed.

After the study ends, some of the data will be kept so the results can be checked. You will also be informed about the study results. Reports will not provide information about individual participants. It will not be possible to work out that you took part.

We will share some of the data publicly including with the eczema community, but it will not be possible to tell who has taken part. This sharing is important to open science to the public and let others use our data to help stop research waste.

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.

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.

After 5 years your data collected during the study will be disposed of securely.

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

You can find out more about how we use your information at:

- www.hra.nhs.uk/information-about-patients/
and www.hra.nhs.uk/patientdataandresearch
- <https://www.nuh.nhs.uk/privacy-notice>
- <http://www.nctu.ac.uk/data-protection/data-protection.aspx>
- or by sending an email to RapidEczemaTrials@nottingham.ac.uk

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