

Mind and Skin - the neurocutaneous axis in severe atopy

Focus groups, interviews and surveys evaluating the emotional, cognitive and sociological impact of atopic eczema and its associated sleep disturbance

Participant information sheet - for participants 16 years and over

Why have I been invited to take part? What is a focus group, interview and survey?

You have been invited to take part because you have atopic eczema (often referred to as eczema). As you already know, eczema is a very itchy skin condition and many people with eczema scratch throughout the night, disturbing their sleep. Having poor sleep can impact greatly on concentration, mood and behaviour, as well as affect home, school and working lives in children, adults and their families. Eczema often affects visible parts of the body and having any visible difference or a chronic skin condition can influence how we feel about ourselves, or how others see us. Eczema treatments are often quite time consuming and avoiding eczema triggers can affect people's hobbies, jobs and relationships, which can make some people feel isolated or left-out.

A focus group is when a small group of people come together to discuss a specific topic, in this case eczema. Often a focus group brings together people with shared experiences or interests to see what similarities they have and to discuss what is important to them. An interview is where you speak to a person from the research team one-on-one and they talk to you about your experiences. A survey is a set of questions asking you about your experiences and you would complete it online.

At the moment, there is a lack of information about how having eczema affects people's lives and how interactions with the external world and society are affected by having eczema. We would like to use focus groups, interviews and surveys to gain further information. They will explore many themes, including but not limited to skin symptoms (such as itch and skin), sleep patterns and sleep disturbance, and other negative consequences of eczema (for example social isolation, shame and stigma). We would also like to discuss how having eczema might influence your family, such as by affecting their sleep, their work and/or their thoughts and behaviours.

Do I have to take part?

No, you do not have to take part; participation is entirely voluntary and your clinical care will not be affected, regardless of your decision. If you do decide to take part, you can keep this sheet and will be asked to sign a consent form. By signing the consent form, you will be confirming your willingness to take part. The research does not alter the treatment you receive. Your specialist will start and stop treatments as determined by your clinical condition.

What will happen if I take part?

People attending the focus group will have eczema and be a similar age to you. The focus groups may be held in person, or may be online, for example using Microsoft Teams or Zoom. The exact duration and number of focus groups will depend on the format, as well as participants' and facilitators' discussions.

The focus group will be around 60 (up to 90) minutes long.

You would only be required to attend one interview, either in person or online, which will last for around 30 minutes.

We will try to arrange focus groups and interviews at a time which is convenient to you, for example school holidays or during the evening.

The topics for discussion at the focus groups and interviews will be semi-structured, meaning that the research team has an idea of what we would like the participants to discuss, but the focus groups and interviews will be guided by participants' thoughts and ideas. An experienced facilitator who has worked with both young people and adults before will run the focus groups and interviews. The facilitator may use different techniques to discuss and explore thoughts, feelings and emotions, for example art, illustration and modelling. In addition to the facilitator, someone from the research team may be present to observe and make notes about the discussions. You may choose how much or how little you want to speak during the focus group or interview. You may also choose to leave the focus group or interview at any time.

What are the benefits of taking part?

Participating in this study may not benefit you directly, but the information obtained from this study will help the research team and other healthcare workers to better understand eczema and its effects on sleep, mood, emotions. We also hope that the study will increase people's awareness of how difficult eczema can be, which may benefit other people with eczema in the future.

You will get to share your experiences of having eczema with other similar patients. It can help some people to know that there are other people having similar problems, as having a chronic condition can sometimes be isolating.

What are the possible disadvantages and risks of taking part?

We expect that discussions in the focus group or interview will not be different from the kinds of things you discuss with family or friends, but you may find answering some of the questions upsetting, or hearing other people's experiences may bring up some emotions you were not expecting. You will not be required to discuss anything that you do not wish to.

The team of facilitators, including a clinical psychologist, will provide further support to any participant should this be required. There will be a private room for confidential discussions should you wish to use this.

We ask that if you decide to participate in the focus groups, that you attend them all. We understand that other commitments may come up which might stop you attending. You will be able to withdraw from the focus group if you choose to at any time, without any impact on your care.

What will happen to my data?

The focus groups and interviews will be recorded, so that we can accurately report and study what is discussed. If the focus groups or interviews are held online we will make video recordings. If held in person we will make audio recordings. The information collected by the researchers (the recordings and notes) will be kept in a secure location.

We will use a specialist service (transcription company outside the hospital/University) or a member of the research team to transcribe (write down word-for-word) what was discussed. The transcription will then be analysed to explore themes and any shared or differing experiences of having eczema. We will use a reputable company who work with researchers regularly and have signed an agreement to protect your data.

Studying what is discussed at the focus groups, interviews and surveys will help us to write a report, which we would like to publish in medical journals and on medical websites. The report may also be discussed on eczema patient organisation websites, newsletters or publications, and on social media. Reports of this kind usually involve combining many people's views or thoughts into themes or concepts, but sometimes these concepts are best illustrated by a direct quotation. If we use any direct quotations from you, we will not use your name so you will not be identifiable.

We will need to use information gathered from you and your medical records for these focus groups or interview. We will keep all information about you safe and secure. This information will include your:

- Name and initials
- Date of birth
- Hospital and NHS number
- Contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep your information safe and secure.

This information will not be shared outside the research team (the Chief Investigator, approved collaborators and members of the study team) and officials from the university/hospital or regulatory agencies who need to check that the research is being carried out according to the law.

Some of your information will be sent abroad. Research collaborators, who may be located outside of the country or region in which you live. Your study data will always be kept confidential, secure and de-personalised (this means they will not be able to identify you) and used only for the purposes of approved medical research. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. 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 may choose how much or how little you want to speak during the focus group and interviews, and if you prefer not to discuss certain topics then you can choose not to. You can also stop being part of the focus groups and interviews at any time, without giving a reason, but we will keep information about you that we already have collected.

We need to manage your records in a specific ways for the research to be reliable. This means we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

How will your data be kept secure and confidential?

King's College London and Guy's and St Thomas' NHS Foundation Trust are the sponsor for this study, and we will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly, and we are bound by a code of confidence. Individuals from KCL and Guy's and St Thomas' and regulatory bodies may look at your medical and research records to check the accuracy of the research study. KCL and Guy's and St Thomas' will keep identifiable information until you are 25 years old as per current recommendations for participants under 18 years old at the time of enrolment. This data will be archived at a secure facility, and later destroyed.

We have a number of rigorous procedures in place to protect your personal data and keep it secure as follows:

- Computer security is in place to block unauthorised access to the computers/systems that hold personal information.
- If your data is provided as part of a larger dataset to researchers outside of the Mind-Skin team, information that could identify you will not be provided.

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

- At www.hra.nhs.uk/information-about-patients/
- By asking one of the research team
- By sending an email to Albert Chan, Contact: info-compliance@kcl.ac.uk
- Our leaflets available from the following websites:
KCL: www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research
GSTT: www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx

What if there is any problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [Principal Investigator's name: Professor Carsten Flohr, telephone number: 02071887188, ext. 51162, email address: carsten.flohr@kcl.ac.uk]. If you remain unhappy and you wish to complain formally, you can do this through the hospital's Patient Advisory Liaison Service (PALS) at Guy's and St Thomas' NHS Foundation Trust (phone: 02071888801, email address: pals@gstt.nhs.uk). Should you want to complain to an external agency about the way we are

handling your data, you can contact the Information Commissioner's Office (ICO) in the UK, via their website.

In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against Guy's and St Thomas' NHS Foundation Trust London and/or King's College London, but you may have to pay your legal costs. The normal National Health Service or Health Service Executive complaints mechanisms will still be available to you (if appropriate).

How do I withdraw from the study if I want to?

Participants are asked to discuss any concerns they might have with the research team.

You can withdraw from the study at any time after giving your signed consent by contacting the research team. You will be given a withdrawal form where you can state your will. Unless you tell us otherwise in the form, we will keep all information that we have obtained up until the point of withdrawal, and we will not collect any further information. If you decide to withdraw from the study, your standard clinical care will not be compromised in any way.

Who has reviewed the study?

Before any research study can go ahead, it has to be checked by an independent Research Ethics Committee and the Health Research Authority (HRA) to make sure that the research is fair and transparent. The Research Ethics Committee reviewed and approved this study in the UK on 18-MAY-2022.

Who is organising the study?

The study is being co-ordinated and sponsored by the St John's Institute of Dermatology at Guy's & St Thomas' NHS Foundation Trust and King's College London. The lead researcher at Guy's and St Thomas' NHS Foundation Trust is Professor Carsten Flohr Consultant Dermatologist, together with his team and collaborators in the Department of Global Health and Social Medicine at King's College London and the Department of Communication & Psychology, Aalborg University, Denmark.

The wider research team includes staff from Paediatric Sleep Medicine, Paediatric Neuroimaging at Guy's and St Thomas' NHS Foundation Trust and the Institute of Psychiatry, Psychology and Neuroscience at King's College London. The study is jointly funded by the King's Together Grant, from Kings College London and the Medical Research Foundation.

Where can you see further study information and results?

Once the study is complete we will email participants the results in a newsletter.