

Evaluation of the impact on disease severity of treatment-related educational advice delivered by general practice-based clinical pharmacists to the parents/carers of children with atopic eczema: a randomised study

IRAS Number: 270218

Participant Information Sheet (parent / carer)

You are invited to take part in a study to provide further information and advice on managing children with atopic eczema

You are invited to take part in the above-named research study but before you decide, please read the following information.

What is the purpose of this study?

Atopic eczema affects up to 20% of children yet many parents/carers do not receive sufficient advice or information to help them manage their child's eczema effectively.

The study is looking at whether GP-based clinical pharmacists' advice to parents and carers of children with eczema on how to use topical treatments can improve the condition. Our aim is to find out whether the advice you receive from the pharmacist can lead to an improvement in the severity of your child's eczema by providing you with more information to help you manage the eczema as effectively as possible. We will find this out by comparing the responses from the study questionnaires and discussions with you at the consultation.

Why have I been invited?

You have been identified as someone who is the parent/carer of a child who has been diagnosed with atopic eczema.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you are considering taking part, please take this information sheet away with you and, if and when you feel ready, you will be asked to sign and return a consent form. Participation is entirely voluntarily. If you do agree to take part you are still free to withdraw at any time and without giving a reason and this will not affect the care that your child receives from the practice.

What will happen to me if I take part?

As this is a controlled trial, you will be allocated to one of two groups. One group will complete an online survey and have a consultation with the pharmacist whereas the other group will have a consultation and a follow up appointment. Both groups will receive the same information and advice but at different times.

The consultation is for research and is in addition to the normal care for your child's atopic eczema that you would expect from your GP surgery.

Group 1

During the consultation, the pharmacist will ask you a series of questions to help them understand what you already know about your child's eczema and provide any additional information to help you better manage the eczema. You will also be asked to complete a patient-orientated eczema measure (POEM) which provides an assessment of disease severity so that the pharmacist has a better idea of how your child's eczema is affecting them. We will also ask you to complete a further short questionnaire asking about which treatments you are currently using to help manage your child's eczema. These questionnaires should not take more than 2 – 3 minutes to complete. The consultation should take no more than 15 to 20 minutes. Four weeks later, you will be invited for a follow up appointment where the POEM will be completed again along with a follow up questionnaire; again the consultation will take no more than 15 to 20 minutes.

Group 2

You will be asked to complete the same POEM measure and baseline questionnaire as Group 1 but instead of doing them at the practice we will send you a link to complete them online. Four weeks later you will be invited for your consultation which will provide you with the same information and advice as Group 1. You will not need to come in for a follow up appointment.

Will my taking part in this study be kept confidential?

Yes, we will respect your confidentiality throughout the study but ask that you let us inform your GP of your participation in the study as the study is being carried out at your GP Practice.

Grounded Research Rotherham Doncaster & South Humber NHS Trust is the sponsor for this study. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Grounded Research Rotherham Doncaster & South Humber NHS Trust will keep identifiable information about you 12 months after the study has finished.

How will we use information about your child?

We will need to use information from your child's medical records for this research project. This information will include their initials/ NHS number/ name/ contact details/Date of Birth/ Medication history (current and past medical history).

Examination of questionnaire results (POEM)

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 about your child will not be able to see their name or contact details. Your child's data will have a code number instead so that the data will be anonymised.

We will keep all information about you safe and secure.

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 can stop being part of the study at any time, without giving a reason, but we may need to keep information about you that we already have (the answers you have given to the questionnaires and study measures). This is because the information sent outside of the Practice for analysis will be anonymised. This means that once the data has been finalised we won't know which responses belong to each individual.

Where can you find out 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/
- by asking one of the research team
- by sending an email to [rdash.groundedresearch@nhs.net], or
- by ringing us on [01302 798456].

You can find out more about how we use your information on our webpage; <https://www.rdash.nhs.uk/about-us/grounded-research/>

Are there any expenses or payments with regards to my participation in the study?

No. It is not expected that you will incur any additional costs, apart from perhaps transport to the surgery when you have your appointment with the pharmacist.

What are the possible benefits of taking part?

We hope that after receiving the information and advice from the pharmacist that you will be more confident at managing your child's eczema. You will also be helping to evaluate whether this type of screening service should become routine for pharmacists working within GP practices.

What are the possible disadvantages and risks of taking part?

It is not anticipated that there will be any disadvantages or risks associated with the study. However, if you experience any problems or unclear about the study, please contact the pharmacist at the surgery who can hopefully answer any of your questions.

Who is organising and funding the research?

This study is being funded by a grant from Fontus Health, a drug company which makes emollients although they have no input to the design of the study and you won't be asked to use their products for the study. The study has been sponsored by Rotherham Doncaster & South Humber NHS Trust who have helped the Chief Investigator to organise the research.

Who has reviewed the study?

This study has been reviewed by an NHS ethics committee and the Health Research Authority.

What if I have a complaint?

If you have a complaint about the way you have been approached or treated during this study, please feel free to contact the Chief Investigator Dr Rod Tucker (Rodtucker.tucker@gmail.com). Alternatively, if you want to talk with someone independent about the research, you can contact PALs telephone on 0800 015 or email: rdash.pals@nhs.net.