

The CLOTHES Trial

An information sheet for children aged 11 to 15

Eczema can be a horrible condition sometimes making your skin red, itchy and sore. This can be both painful and embarrassing. As you know it can be treated with creams and you may have been advised to wear loose cotton clothing and avoid having wool and other rough fabrics next to your skin.

Some companies have developed special silk clothing which might help children with eczema, like you. However, there is no proof that these clothes work, but we would like to find out.



We would like to investigate whether wearing silk clothing under your normal clothes can help your eczema. To do this we need 300 children like you to take part in a 'clinical trial'. 150 children will be asked to continue with their normal eczema treatment and start wearing the silk clothing right away, and 150 children will be asked to continue with their normal eczema treatment for 6 months and then to wear the silk clothing after that.

We need to have these two groups so that we can compare, over time, the skin of children who wear the clothes right away to the skin of the children who wear the clothes a little bit later. Having these two groups is the only way we can answer the question:



'do these special clothes help kids with eczema?'

Answering this question could maybe help us treat a lot more children like you in the future, but we would not be able to answer our question if we did not have both groups: **all children who help us in the study, whether they wear clothes right away or later are very important to helping us in our investigation!**



In order to make the study as scientific as possible, a computer will decide who will wear the clothes right away and who will wear them after 6 months. You would have an equal chance of being asked to start right away or start after 6 months.



150 children to start wearing clothing now



150 children to start wearing clothing in 6 months

If you agree to take part, you would be asked to come to the clinic 4 times – once at the start of the trial and then 2, 4 and 6 months later. At the clinic you would have your eczema examined by a research nurse. The nurse would not be told whether you had been wearing the silk clothing so that they would not be swayed by knowing that you had or had not been wearing the clothes.

It is important that you do not to tell the nurse and not to wear the clothes to your appointment!!! This will make the results far better.



At these appointments your parent or guardian would also be asked some questions and asked to complete some short questionnaires which you could help with.



During the study, you (or your parent/guardian) would be asked to record information about your eczema and its treatment in a diary card each day and also in a short questionnaire each week which can be completed either on-line or by post. You (or your parent or guardian) would also be asked to note when you had worn the silk clothing.



When everyone has completed the study, the data will be analysed. We will compare eczema in children who wore the clothes for the first six months and those who didn't. We will also look at the children who started to wear the clothes later to see if there were any changes in their eczema after they started to wear the clothes.



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The results will be used to help doctors to understand if silk clothing is useful for children like you who have eczema. If you don't want to take part in this clinical trial, it will not affect any of the treatments you receive now or in the future.

Please ask your parent/guardian and research nurse if you have any questions.



Thank you for reading this!