The University of Nottingham

Clothing for the relief of Eczema Symptoms

CLOTHES Trial

Parent/guardian information sheet

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Title of study: **A clinical trial to see if using silk clothing helps in the relief of eczema symptoms**

Name of Chief Researcher(s): Professor Kim Thomas
Name of Local Researcher(s): Local details to be added

Where the word "parent" is used, please read parent/guardian i.e. those who have parental responsibility, which may include a legal representative such as a grandparent.

Your child is being invited to take part in a research study. Before you decide if you wish your child to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

What is the purpose of the study?

It has long been understood that clothing can cause irritation to the skin, and current guidelines recommend the use of loose cotton clothing and the avoidance of wool and other itchy or synthetic materials next to the skin. In recent years, new silk clothing products have been developed for the management of eczema symptoms, but there is no firm evidence to suggest that they work.

In order to decide whether silk clothing is a useful addition to the treatments currently available for children with eczema, 300 children with eczema will be asked to take part in this study: 150 children will be asked to wear the clothing straight away, and 150 children will be asked to wear the clothing in 6 months' time. This will allow us to compare if the clothing has any effect on the eczema

Why has my child been invited?

Your child has been invited to take part in this study as they are between 1 and 15 years old and has been diagnosed as having quite bad eczema.

Does my child have to take part in this study?

No. It is up to you and your child (where possible) to decide whether or not to take part. Your decision will not affect the standard of eczema care your child receives.

You are both free to withdraw from the study at any time without giving a reason. This will not affect the standard of eczema care your child receives or their legal rights.

What will happen to my child if s/he takes part?

The study will last for 8 months and your child will be asked to come into clinic at the hospital four times in total. A contribution towards reasonable travel expenses will be offered.

Screening

On your first visit to the nurse, the study will be explained to you and your child (if appropriate). If you are happy for your child to take part, you will be asked to sign a consent form. If your child is old enough, they can sign the form too, if they wish.

They will then be examined by a research nurse to make sure that they are suitable to take part in the study. If they are suitable, your child's eczema will be examined by the research nurse and you will be asked some questions about the eczema, the treatment they use and whether they experience many skin infections. You will also be asked to complete some short questionnaires.

This first visit will be between 60 and 90 minutes.

Group Allocation

In order to find out if silk clothing (bodysuits, leggings and vests) alongside normal eczema treatment is effective in the long term management of children with eczema, the children in this study will be split into two groups: one group will wear the clothing from the onset of their participation in the study, the other group will continue with their normal eczema treatment.

Clothing for babies / infants

Clothing for older children

The decision as to which group your child will be allocated to will be done randomly by a computer and they will have an equal chance of being in either group. You will be sent a letter from the unit who are running the study, soon after your first visit with the nurse, that outlines what group your child is in and what to do next.

It is important to realise that we currently do not know if the silk clothing will have any effect on the eczema so there is nothing to lose, or gain, by being in either of the two groups.

Clothing Now Group

For the first 6 months of the trial this group will be given the clothing to wear whilst continuing with their normal eczema care.

Three sets of garments will be sent after the first visit with the nurse, and you will be able request replacement clothes in the first 6 months if the clothing starts to wear out or becomes too small. You will be asked to return the clothing you would like replaced.

Over this first 6 months you will be asked to complete a short questionnaire each week to record information about your child's eczema, whether they saw any healthcare professionals about their eczema, whether they had any prescriptions for their eczema, and how many days and nights they actually wore the clothing that week.

This questionnaire can be completed either on-line or by post. If you choose to complete it on-line, we will ask for your e-mail address.

You will be given a diary card and a wall chart (with stickers if your child would like!) to help you remember this information from one week to the next.

Clothing Later Group

This group will continue with their normal eczema care over the first 6 months of the study.

Over this first 6 months you will be asked to complete a short questionnaire each week to record information about your child's eczema, whether they saw any healthcare professionals about their eczema, and whether they had any prescriptions for their eczema.

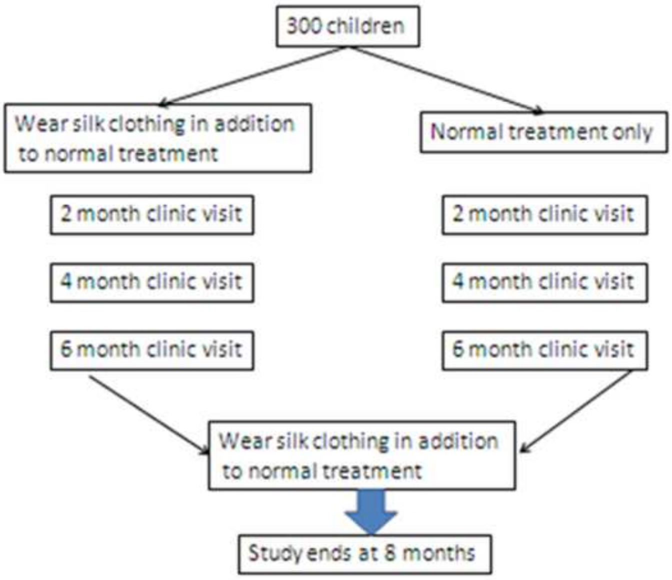
This questionnaire can be completed either on-line or by post. If you choose to complete it on-line, we will ask for your e-mail address.

You will be given a diary card and a wall chart (with stickers if your child would like!) to help you remember this information from one week to the next.

Nurse Visits

Your child will need to visit the nurse 3 times: at 2, 4 and 6 months. Your child will be examined by the research nurse and you will be asked about the eczema treatments they have used (not including the silk clothing) and if they have had any skin infections. You will also be asked how you think your child's eczema is by completing a short questionnaire. These three visits should take no longer than 30 minutes.

It is important that the research nurse looking after your child doesn't know whether your child is wearing the clothing or not. If the nurse knew this information it might mean that assessments of your child's skin might be influenced by this knowledge. This is called bias. We would ask that your child does not wear the clothing to any clinic visit or talk to the research nurse about the clothes.



Last two months of the study
For the last two months of the study, all children in the study will wear the clothing. The children who wore the clothing for the first 6 months will continue to wear the clothing they already received.

For the group who receives the clothing after the 4th visit with the nurse, 3 sets of garments will be sent to you at this point. If they do not fit when you receive them you will have an opportunity to send them back immediately and receive a replacement set in the correct size.

All children should continue wearing the clothing for the next two months of the study. At the end of the 8 month mark, a short questionnaire will be sent to you, and this will mark the end of the trial.

After the end of the trial, all children get to keep the clothes they were given during the trial, to wear as often or as little as they choose.

Saliva (spit) sample
During a clinic visit you will be asked if you are willing for your child give a saliva (spit) sample. If you don't want your child to give the sample, that's fine – they can still take part in the main study. Please just say that you would rather not take part in this.

If you choose for your child to give a sample, we will ask them to spit into a small pot, or if they are too young to spit, the nurse will collect some saliva on an absorbent cotton bud. .

What are the alternative treatments for my child?
This study does not restrict your child's current or future treatment and your child will still receive all their normal eczema treatments while in the study. The wearing of the clothes being tested is in addition to their normal treatment.

What are the possible disadvantages and risks of taking part?
Since your child will be receiving their normal eczema treatment throughout the study, no major risks or disadvantages to their eczema is expected. It may be that your child finds the clothing uncomfortable or that it makes them too hot. This can be addressed by checking that the size is correct for your child and perhaps using lighter clothing on top of the silk trial clothing (or wearing them as pyjamas at night).

Are there any possible side effects?
There are no known side effects to wearing the clothing but we will be collecting the information on the number of skin infections experienced by the children, just in case this is affected.

What are the possible benefits of taking part.
There are no direct benefits to you or your child from taking part in this study, although you may feel that visits to the research nurse is helpful. Some past study participants have said that they found regular monitoring of their eczema at home useful.

It is possible that your child's skin may improve through wearing the clothing, but we do not know if this is the case, and it is possible that the clothing may have no impact or make the eczema worse.

What happens when the research study stops?
When your child completes their 8 months in the study, the results of the study will not be known so we cannot make any recommendations for their future treatment at that time. You

will be able to keep the clothing at the end of the study. You can also speak to your child's doctor about their future eczema treatment.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the local researchers (their contact details are at the end of this sheet) who will do their best to answer your questions. If any questions remain you can contact the Chief Investigator of this study Professor Kim Thomas (kim.thomas@nottingham.ac.uk). If you remain unhappy and wish to complain formally, you can do this by contacting NHS Complaints via the Patient Advisory and Liaison Service (PALS). The details are at the end of this leaflet.

In the event that something does go wrong and your child is harmed during the research study there are no special compensation arrangements. If they are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my child taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice and all information about your child will be handled in confidence.

If your child joins the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to your child as a research participant and we will do our best to meet this duty.

All information which is collected about your child during the course of the research 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 research centre will have your name and address removed (anonymised) and a unique code will be used so that your child cannot be recognised from it.

All research data will be kept securely for seven years. After this time your child's data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your child's confidentiality. Only members of the research team will have access to their personal data.

In order to be able to contact you about how your child is getting on, your child's name and contact details will be made available to the researchers running this study. These details will be kept securely, with access restricted. Your child will not be named or otherwise identified in any study publication.

You will be asked to consent to your child's identifiable details being registered with the NHS Information Centre. These may be used to help us keep in touch with you and to follow up your child's health status. We will have confidentiality and security agreements in place to ensure your child's details are dealt with in the strictest confidence.

With your permission we will inform your child's GP that they are participating in this research study.

We have a mailing list to inform parents and guardians about skin research that is being carried out. If you would like to be added to that list you can indicate this on the consent form. The contact email address you provide will be held in a separate secure database.

What will happen if I don’t want to carry on with the study?

Your child’s participation is voluntary and they are free to withdraw at any time, without giving any reason, and without your or your child’s legal rights being affected. If your child withdraws then the information collected so far cannot be erased and this information may still be used in the project analysis.

Will any genetic tests be done?

If you agree, the research nurse will collect some saliva from your child’s mouth to test for a gene which may play a part in childhood eczema. The sample will be sent to a genetics laboratory at the University of Dundee for analysis.

We will only test for a gene that may be relevant to childhood eczema and we will not do any other genetic testing. Current guidelines suggest that you should not be informed of the results of this test as the findings will not be used to influence your child’s clinical care. The research nurse can explain why this is if you would like to know more.

The results from this testing will be sent securely back to the Nottingham Clinical Trials Unit (the co-ordinating centre).

What will happen to any samples my child gives?

Any remaining samples may be stored and used to test for other genes found to be associated with eczema in the future – this is optional (please indicate you agree to this on the consent form). The samples will be stored with a code unique to your child and securely at the Centre for Dermatology & Genetic Medicine of the University of Dundee (Ethics number 12/ES/0083). The samples will only be made available to the existing study team.

Any samples or data will be anonymised, and your child will not be identified in anyway. You do not have to agree to store your child’s sample to be able to take part in the genetics study. If you do not agree to this, any remaining samples will be disposed of in accordance with the Human Tissue Authority’s codes of practice.

What if relevant new information becomes available about the topic being studied?

Sometimes during the course of a research project new information becomes available about the topic being studied. If this happens, a member of the research team will tell you and your child (if applicable) about it and discuss whether you want your child to continue in the study. If you decide that you wish your child to continue in the study you will be asked to sign an updated consent form, which your child may also sign if they wish. Also, on receiving new information the research team might consider it to be in your child’s best interests to withdraw them from the study. If this happens, they will explain the reasons why. If the study is stopped for any other reason, you will be told why.

What will happen to the results of the research study?

When the study has been completed, the data will be analysed and the results published in a medical journal and presented at medical meetings. You will be sent a copy of the results unless you tell us that you would prefer not to receive them. The results will allow a recommendation to be made to doctors and nurses about whether silk clothing is useful in the treatment of eczema in children.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the National Institute of Health Research (NIHR) Health Technology Assessment Programme. The clothing being used in the study has been donated by the clothing suppliers for these garments.

Who has reviewed & approved the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by [NAME] Research Ethics Committee.

Further information and contact details

Contact Details of your local Research team

Name__________________________ and Telephone Number______________________

Contact details for any questions about the clothing

Name__________________________ and Telephone Number______________________

If you have any general queries about participating in research you can contact the Patient Advisory and Liaison Service (PALS) *Local PALS details to be added*.

THANK YOU FOR READING THIS INFORMATION SHEET