



the CLOTHES trial

PARTICIPANT NEWSLETTER - RESULTS EDITION



The CLOTHES trial recruited and followed-up children with eczema aged 1 to 15 years old from five areas of England. We have now finished analysing the data and are pleased to share the results with you.

Thank you for taking part.

Why was a trial needed?

Eczema, also known as atopic dermatitis, is a common skin condition that can affect children. It causes the skin to become itchy, red and sore, which impairs sleep and affects the quality of life of children and their families.

Treatment for eczema usually includes moisturisers (emollients) and steroid creams, but patients and parents are often keen to find non-drug treatments for their eczema.

Some small studies had suggested that specialist silk clothing might help to improve the symptoms of eczema, but larger, well-designed studies were needed to be sure of these results.



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What did the results show?

The CLOTHES trial aimed to find out whether using silk clothes in addition to standard care would help children with moderate-to-severe eczema. In total 300 children, with the help of their families, participated in the trial.

The eczema of children wearing the silk clothes improved over the 6 months, but so did the eczema in of children who didn't wear the clothes.

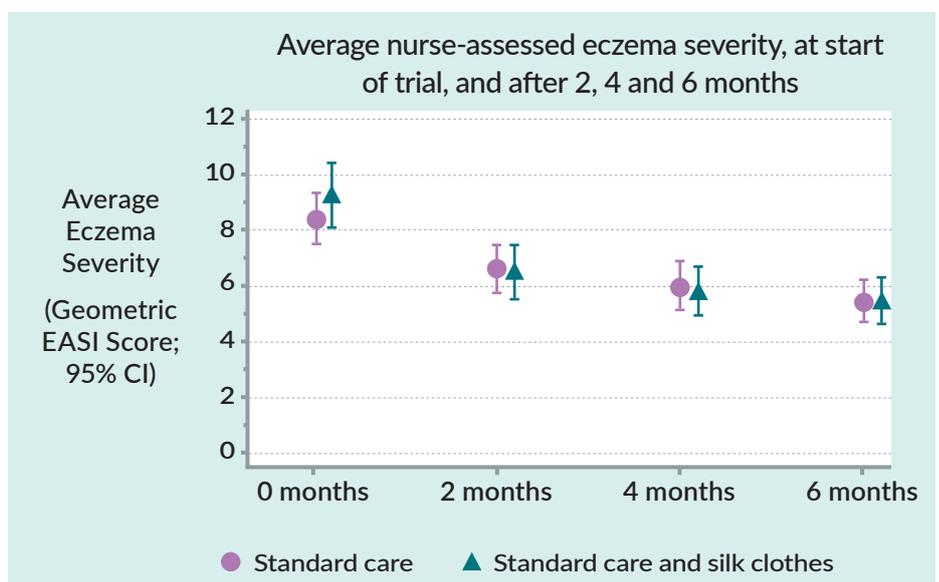
We found no difference between the two groups in eczema severity assessed by nurses.

We also looked at whether wearing the silk clothing more often affected the severity of the eczema, but did not find any difference.

There was no difference between the two groups in number of skin infections, or quality of life. Wearing the silk clothing did not reduce the number of doctor visits for eczema or use of eczema medications.

The weekly questionnaires completed by parents/carers or their children indicated that the eczema symptoms in the silk clothing group may have improved more than the eczema symptoms in the group who didn't wear the clothes. However, the difference between the groups was small, and was seen mainly in the first few months of the trial.

Although these weekly questionnaires suggest that the eczema improved more in the silk clothing group, this may be due to slight over-reporting of benefits by families who hoped the clothes would work. This is why the trial was designed to put special emphasis on the skin examinations made by the research nurses during clinic visits.



Being part of the CLOTHES trial

What did families think about participating in the CLOTHES trial? We invited children and their parents to talk to us about their experience of the trial and their thoughts about the silk clothes.

Most children and parents had had high hopes that the clothing would help their eczema. Many children were disappointed by the 'roughness' of the fabric and its tendency to make them feel hot and uncomfortable, as they were expecting the silk to be smooth and cooling.

A number of children and parents found the silk garments to be ill-fitting, and lacking durability (with holes and

ladders quickly developing). Children preferred to wear the garments when at home and at night, usually due to worries about the reaction of others. Some children found the clothes helped them sleep, which was linked to better wellbeing, but others were disappointed that the garments had not worked for them. However some children, who found the garments had made no difference to their eczema, still liked wearing them.

A minority of parents thought there was a positive impact on their child's condition, although they were unsure whether it was just the garment that helped, or other factors.

Children enjoyed being part of the trial and showed a significant level of altruism with the hope that taking part may help other children.

What will happen to the results now?

Although the trial has ended and we know the results, we haven't finished working on the CLOTHES trial yet. The next step is to make sure information about the findings reaches people it can help.

We've published the results of the CLOTHES trial in medical journals and have presented the research at conferences in the UK, Europe and South America. We are currently working with our networks and undertaking other activities to ensure the findings are widely distributed.

We've also made a short animation that gives an overview of the study and the results. It's ideal for sharing with family, friends, or with the wider world via social media sites. To access the animation, visit: www.nottingham.ac.uk/clothes



The results of this study will provide evidence to help policy makers, doctors, other healthcare professionals and patients make better informed decisions when choosing eczema treatments.



Professor Kim Thomas

Who conducted the trial?

The trial was led Professor Kim Thomas from the University of Nottingham and coordinated by The Nottingham Clinical Trials Unit.

The UK Dermatology Clinical Trials Network (UK DCTN) supported the development of the trial, and clinicians, nurses, researchers, statisticians and patients from across the UK were involved in designing and conducting the trial.

The trial was funded through a research grant by the National Institute for Health Research (NIHR), the research arm of the NHS.

We hoped you found the results of the trial interesting. If you'd like more information about the results, or details about any other aspect of the trial, please visit:

<http://www.nottingham.ac.uk/clothes>

The webpage contains links to all the articles we've published about this research, and to the comprehensive NIHR report which gives a fuller account about the background, methods and analysis used.

We would like to express our gratitude to the children and families that took part in the CLOTHES study. Your enthusiasm and dedication to attending visits and completing questionnaires made the trial possible.

Thank you!

The silk garments used in the study were kindly donated by Espère Healthcare Ltd. (UK and Ireland distributor for DermaSilk™, AlPreTec SrL. Italy) and DreamSkin™ Health Ltd.

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