



CLOTHES Trial Summary

The purpose of this study is to establish whether therapeutic silk clothing is effective in the long-term management of eczema in children.

Background

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 rough fibres next to the skin. In response to this need, new clothing products have become available in recent years, and these are now marketed as having beneficial effects in the treatment of eczema. The therapeutic silk garments included in this study are available on prescription through the NHS, but the trial evidence supporting their use is currently limited.

Objectives

- To assess whether silk therapeutic clothing used in addition to standard eczema care, reduces eczema severity in children with moderate to severe eczema over a period of six months
- To estimate the cost-effectiveness of silk therapeutic clothing from an NHS and a family perspective

Study Design

The CLOTHES trial is an observer-blind, parallel group randomised controlled trial (RCT) to evaluate the addition of silk therapeutic clothing, compared to standard eczema care over a period of six months.

At the end of the 6-month trial period, participants allocated to standard care will be provided with the clothing and both groups will be followed-up for a further two months.

Additional qualitative research will be conducted alongside the trial in order to identify possible barriers and facilitators to adoption of the therapeutic clothing in the NHS.

Research Team

This trial is being led by researchers from the Centre of Evidence Based Dermatology at the University of Nottingham, but the research team includes researchers from many parts of the UK including the Nottingham Clinical Trials Unit, University of Portsmouth, University of East Anglia, Barnet & Chase Farm NHS Trust, Addenbrookes NHS Trust and a patient representative.

Chief Investigator: Dr Kim Thomas

Trial Coordinator: Ellie Harrison

www.nottingham.ac.uk/CLOTHES

Research plan

We plan to invite 300 children with moderate to severe eczema to take part in an 8-month study. Half of the children will be given therapeutic clothing in addition to their usual treatments, and half will continue with their usual eczema treatments alone. The main outcome of eczema severity will be assessed at the start of the study, and then every two months for the first six months. After this time, all children will receive the garments and continue to be followed up for a further two months.

By giving clothing to the participants allocated to the usual care group after six months, we hope it will improve recruitment into the trial, and reduce the number of participants who drop out of the study.

Trial Design

Length of study		0 to 6 months		7 to 8 months
Intervention Group	Randomisation	Standard care + silk clothing	End of RCT	Standard care + silk clothing
Control Group		Standard care only		Standard care + silk clothing

Families taking part in the trial will know what treatments their child is receiving, and so improvements in the eczema will be measured by a research nurse who does not know which group the child has been allocated to. We will also measure children's and parents' views of the treatment before and during the study.

The study will take place in five UK hospitals with a proven track record of recruiting into eczema trials like this one. Suitable families will be identified from general practices and through direct advertising, as well as at the participating hospitals. Children will come to clinic four times during the trial and information will be collected about their eczema (assessed by nurses and the participants), use of eczema medications, eczema symptoms, acceptability of the garments and quality of life. A cost-effectiveness analysis will be conducted to see if the garments represent value for money to the NHS and to families.

Project timetable

The trial is funded for three years, starting in June 2013. It is anticipated that recruitment will take up to 18 months starting in November 2013.

Funding:

The CLOTHES Study is funded by the Health Technology Assessment Programme of the National Institute for Health Research (Ref: 11/65/01).