

# CLOTHES Trial: Clothing for the relief of eczema symptoms

<b>Submission date</b> 11/10/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/10/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/01/2019	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

## Plain English Summary

### Background and study aims

Eczema is a condition that causes the skin to become itchy, red, dry and cracked. Specialist silk clothing has been promoted recently as a new treatment option for people with eczema, but it is unclear if these garments really do provide additional benefits for patients. Research is needed to find out whether or not these new products live up to the impressive claims that are currently being made. As a result, we are about to conduct a study of silk clothing for the management of eczema in children.

### Who can participate?

Children between 1 and 15 years of age who have quite bad eczema.

### What does the study involve?

Each child will be enrolled in the study for 8 months in total, and will be asked to attend their local recruiting hospital on four different occasions. Children participating in the study will be put into one of two groups. The first group will receive three sets of silk underwear – this will be either a bodysuit and leggings, or vest and leggings depending on the child's age. The children will be asked to wear the clothing underneath their normal clothes day and night for six months - if possible! The second group will not receive the clothing straight away but will be given the clothing to try for themselves after the first 6 months of the study has finished. Throughout the study all of the children will be free to continue with their usual eczema treatments, such as emollients and topical steroids, and will be asked to complete a weekly questionnaire at home so that they can tell us how the eczema has been, and how often the clothing has been worn.

### What are the possible benefits and risks of participating?

If we can show that these clothes provide additional benefits for patients, then this would be an important finding, and many eczema sufferers could benefit. Equally, if the research shows that the clothes provide no useful benefit, then patients and the NHS can save money by not using treatments that have been shown to be ineffective.

### Where is the study run from?

Recruitment is taking place in hospitals in five main areas – Nottingham, Cambridge, north London, Portsmouth and the Isle of Wight. This study is being led from the Centre of Evidence

Based Dermatology at the University of Nottingham, and will be co-ordinated from the Nottingham Clinical Trials Unit.

When is the study starting and how long is it expected to run for?  
Recruitment is due to start in November 2013 and will continue for about 18 months.

Who is funding the study?  
National Institute for Health Research (UK)

Who is the main contact?  
Professor Kim Thomas  
Kim.Thomas@nottingham.ac.uk

**Study website**  
<http://www.nottingham.ac.uk/clothes>

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Kim Thomas

**Contact details**  
Centre of Evidence Based Dermatology  
University of Nottingham  
King's Meadow Campus  
Lenton Lane  
Nottingham  
United Kingdom  
NG7 2NR  
-  
Kim.Thomas@nottingham.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
15132; HTA 11/65/01

## Study information

**Scientific Title**

Randomised controlled trial of silk therapeutic CLOTHing for the long-term management of Eczema Symptoms in children

## **Acronym**

CLOTHES

## **Study hypothesis**

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

### **Primary Objective**

To assess whether silk therapeutic clothing, when used in addition to standard eczema care, reduces eczema severity in children over a period of six months.

### **Secondary Objective**

To estimate the within trial cost-effectiveness of silk therapeutic clothing with standard care, compared to standard care alone, from an NHS and a family perspective.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Nottingham 1, First MREC approval date 16/07/2013, ref: 13/EM/0255

## **Study design**

Randomised interventional treatment trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

Patient information sheets can be found at [www.nottingham.ac.uk/clothes](http://www.nottingham.ac.uk/clothes)

## **Condition**

Topic: Primary Care Research Network for England, Skin, Generic Health Relevance and Cross Cutting Themes; Subtopic: Not Assigned, Skin (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Dermatology, All Diseases, Paediatrics

## **Interventions**

Children will be randomised into one of two groups - standard care plus silk clothing, or standard care only (for the 6-month RCT period). Participants allocated to standard care will receive the

clothing after the 6-month clinic visit, and both groups will be followed up for a further 2 months by questionnaire.

Silk therapeutic clothing, The medical device under investigation is a knitted, sericin-free silk therapeutic garment with a CE mark for use in eczema.

For both arms: duration of treatment is 6 months, duration of follow-up is 8 months

Study Entry : Single Randomisation only

### **Intervention Type**

Other

### **Phase**

Phase IV

### **Primary outcome measure**

Eczema severity measured by the objective Eczema Area and Severity Index (EASI); Timepoint(s): Baseline, 2 months, 4 months, 6 months

### **Secondary outcome measures**

1. Global assessment of the eczema by research nurses (IGA) and by participants (PGA); Timepoint(s): Baseline, 2 months, 4 months, 6 months
2. Three Item Severity scale (TIS) used to assess eczema severity; Timepoint(s): Baseline, 2 months, 4 months and 6 months
3. Use of topical treatments; Timepoint(s): Throughout the trial
4. Self reported eczema symptoms using the Patient Oriented Eczema measure (POEM); Timepoint(s): Weekly throughout the trial
5. Health Related Quality of Life (DFI, EQ-5D-3L, ADQoL, CHU-9D); Timepoint(s): Baseline and 6 months
6. Durability of garments and acceptability of use.; Timepoint(s): 6 months and 8 months, and adherence; Timepoints: Throughout the trial
7. Cost-effectiveness and cost utility; Timepoint(s): 6 months

### **Overall study start date**

01/11/2013

### **Overall study end date**

02/05/2016

## **Eligibility**

### **Participant inclusion criteria**

1. Children aged 1 to 15 years at baseline
2. Diagnosis of moderate or severe eczema (atopic dermatitis). Presence of eczema will be confirmed using the UK. Diagnostic Criteria for Atopic Eczema and eczema severity judged using the Nottingham Eczema Severity Scale (NESS)
3. Resident within travelling distance of a recruiting centre
4. Children with at least one patch of eczema on the trunk or limbs
5. Parent/legal guardian able to give informed consent
6. Target Gender: Male & Female

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

1 Years

**Upper age limit**

15 Years

**Sex**

Both

**Target number of participants**

UK Sample Size: 300; Description: 150 allocated to standard eczema care + silk clothing (active), 150 allocated to standard care (control)

**Participant exclusion criteria**

1. Children who have taken systemic medication (including light therapy) or oral steroids for eczema within the previous three months
2. Children who have started a new treatment regimen within the last month
3. Children who have used wet/dry wraps  $\geq 5$  times in the last month
4. Children who are currently using silk clothing for their eczema and are unwilling to stop using the clothing during the trial
5. Children who are currently taking part in another clinical trial
6. Children who have expressed a wish not to take part in the trial

**Recruitment start date**

01/11/2013

**Recruitment end date**

01/05/2015

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**University of Nottingham**

Nottingham

United Kingdom

NG7 2NR

# Sponsor information

## Organisation

University of Nottingham (UK)

## Sponsor details

Research Innovation Services

Kings Meadow Campus

Lenton Lane

Nottingham

England

United Kingdom

NG7 2NR

-

abc@email.com

## Sponsor type

University/education

## Website

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

## ROR

<https://ror.org/01ee9ar58>

# Funder(s)

## Funder type

Government

## Funder Name

Health Technology Assessment Programme

## Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

The study used identifiable individual patient data which is subject to ethics, consent and privacy restrictions. However within these constraints, the trialists will make fully anonymised data available on request wherever possible, e.g. for individual patient data meta-analysis.

Applications for data access should be made via the CLOTHES Data Access Committee (contact [sponsor@nottingham.ac.uk](mailto:sponsor@nottingham.ac.uk) ref: RC3215, and copy in the Chief Investigator kim.thomas@nottingham.ac.uk).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	02/09/2015		Yes	No
<a href="#">Results article</a>	results	01/04/2017		Yes	No
<a href="#">Results article</a>	results	11/04/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No