

Submission of trial suggestion vignette to the UK Dermatology Clinical Trials Network

This is your Network, so feel free to submit ideas that you feel are important to your own clinical practice. It would be helpful if you could use the following headings:

What is the research question?

Does wearing silk clothing (Dermasilk™) reduce the severity of disease in children with atopic eczema?

Condition of interest

(Include patient group, type of lesion, location etc)

Children with atopic eczema according to UK Diagnostic criteria for atopic eczema. (May need to include only those with moderate/severe eczema in order to show an effect).

What treatments do you propose to include?

(Include main intervention and comparators)

Main intervention: Dermasilk™ clothing

Comparator: normal clothing / normal care, or compare with cotton clothing. (If comparing with cotton, this will require a large sample size as it is likely that the two will be similar).

Possibly consider a 3-arm trial (silk, cotton, normal care) – but this has methodological difficulties that would need to be thought through very carefully.

What outcome measures will you use?

Blinding of participants is likely to be difficult, so objective outcomes would be best as primary outcome.

Disease severity: possible outcomes include: SCORAD, SASADD

Scratch meters: if successful in softened water eczema trial.

Patient reported outcome: POEM is good

Try to capture chronicity of disease / disease flares.

Use of topical corticosteroids / calcineurin inhibitors

What group of patients do you propose to study?

(Include main inclusion/exclusion criteria)

Children up to 16 years old (or limit to younger children – 7 yrs (?) if cost of providing larger sizes is an issue).

Keep exclusions down to an absolute minimum.

No change to existing treatment regimen in last 4 weeks (?)

Not used systemic treatment (including PUVA) in last 3 months.

What existing evidence is there?

We recently searched Medline, Embase and the Cochrane Controlled Trials Register from 1966 to June 2008 using the terms *atopic dermatitis* and *eczema*, *DermaSilk*, *silk*, *fabric*, *material*, *cotton* and *cloth*, and search terms for *randomized controlled trials*.

No systematic reviews of silk clothing in AE were found. (A section on specialised clothing was included in the HTA systematic review of treatments for AE, but this did not include silk clothing www.nchta.org/execsumm/summ437.htm). We identified two randomised controlled trials^{1, 2} and two further small studies^{3, 4} that were not considered as they were not truly randomised (they compared the left and right sides of the same patient without randomisation).

Both of the clinical trials evaluated were poorly reported, complicated and involved very small numbers of patients, making them both almost impossible to interpret. Despite the lack of good studies, it is still possible that these special silk fabrics have something to offer AE patients. Neither of the studies identified any adverse effects and the garments appeared to be well tolerated by the children. A good quality, independent clinical trial is needed in order to answer the clinical questions of whether simple silk underclothing offers any advantage over cotton clothing.

1. Ricci G, Patrizi A, Bendandi B, Menna G, Varotti E, Masi M. Clinical effectiveness of a silk fabric in the treatment of atopic dermatitis. *Br J Dermatol* 2004;150(1): 127-131.

2. Koller DY, Halmerbauer G, Böck A, Engstler G. Action of a silk fabric treated with AEGIS™ in children with atopic dermatitis: A 3 month trial. *Pediatr Allergy and Immunol*. 2007;18(4): 335-338.

3. Senti G, Steinmann LS, Fischer B, et al. Antimicrobial Silk Clothing in the Treatment of Atopic Dermatitis Proves Comparable To Topical Corticosteroid Treatment. *Dermatology* 2006;213(3): 228-233.

4. Ricci G, Patrizi A, Mandrioli P, et al. Evaluation of the antibacterial activity of a special silk textile in the treatment of atopic dermatitis. *Dermatology* 2006;213(3): 224-7.

If this proposal has been submitted elsewhere, please give details.

No

Why is this suggestion particularly suitable for study through the Network?

We could use information from the SWET trial which has a database of potential participants who may be willing to participate in such a trial.

Which funding bodies do you suggest should be approached?

NIHR Health Technology Assessment

Please add here any other information or comments that would help with the discussion of this vignette:

If you would like us to submit this idea to the HTA through their affiliate members' scheme, please also include the following:

Why is this research important to the NHS?

(For advice on this question please refer to the HTA website (<http://www.nchta.org/>))

Dermasilk™ has recently been licensed for use and is now available on prescription. However, there is little evidence that it is effective. A definitive RCT should be carried out before this product becomes firmly embedded in practice.

This research question has been logged as an uncertainty in the DUETs database.

Trial suggestions submitted to the Network will be considered at the next available Steering Group meeting at which you or your representative will be required to attend. If the group would like to take your suggestion further, you will be asked to submit an Outline Proposal.

Please email or post your completed form to:

UK Dermatology Clinical Trials Network
Room A103
King's Meadow Campus
Lenton Lane
Nottingham
NG7 2NR
Email: ukdctn@nottingham.ac.uk