School of Medicine

The CLOTHES Trial

Clothing for the relief of Eczema Symptoms

The University of Nottingham

UNITED KINGDOM · CHINA · MALAYSIA

Randomised controlled trial of silk therapeutic clothing for the long-term management of atopic eczema in children

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BACKGROUND

Silk garments are available on prescription in the UK for the treatment of eczema (syn. atopic dermatitis, atopic eczema) despite a lack of evidence of their effectiveness.

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.

METHODS

Parallel group randomised (1:1 ratio) controlled, observer-blind trial of 6 months duration. Included 300 children aged 1 to 15 years with moderate-to-severe eczema.

Intervention: Standard care plus 100% sericin-free knitted silk garments

Control: Standard care

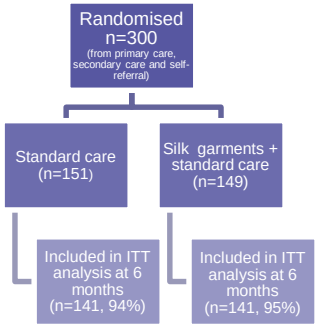
Primary outcome:

Eczema severity: Eczema Area and Severity Index (EASI) at baseline 2, 4 and 6 months (assessed by nurses blinded to treatment allocation).

Secondary outcomes:

Investigator and Patient Global Assessment, Three Item Severity scale (TIS), use of topical treatments, POEM – patient-reported symptoms, Quality of Life, safety (skin infections and hospitalisation for eczema) and cost-effectiveness.

RESULTS



Baseline Characteristics

Mean age: 5.1 years, 58% boys, 79% white

100% moderate to severe in last year (Nottingham Eczema Severity Scale)

72% moderate or severe Investigator Global Assessment (IGA) at baseline

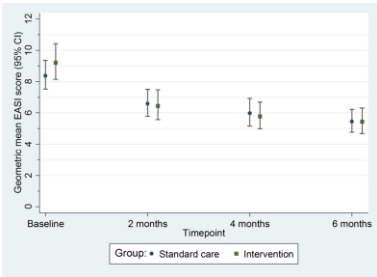
73% seen previously in secondary care for eczema

Adherence

- 82% participants wore garments >50% of the time
- No reduction over time

RESULTS

Primary Outcome – Eczema severity (EASI)

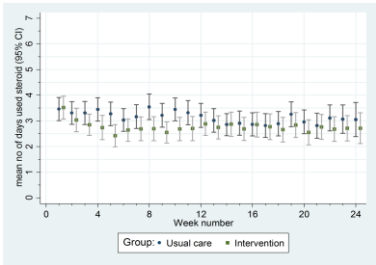


Ratio of geometric means: 0.95, 95% CI 0.85 to 1.07)

Equivalent to -1.5 to 0.5 in the original EASI scale units

EASI score was log transformed and analysed using a multilevel model to account for the repeated measures adjusting for baseline EASI score and the stratification variables age and site as covariates.

Secondary Outcome – Topical steroid use



Mean difference -3.7 days of topical steroid (95% CI -9.6, 2.3) p = 0.23

Safety

No difference in skin infections or hospitalisations

Cost-effectiveness

- No reduction in other health resource use
- Incremental cost effectiveness ratio: £74,720/QALY
- Cost of garments £547 per participant

CONCLUSIONS

This adequately powered trial, with good follow-up and adherence rates demonstrates that silk clothing is unlikely to provide additional benefit over standard care in children with moderate to severe eczema.

ACKNOWLEDGEMENTS

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NHS National Institute for Health Research