Determining Effects of Superfine Sheep wool in INfantile Eczema (DESSINE): a randomized paediatric crossover study*

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Summary

Background Despite limited evidence, woollen clothing has traditionally been considered to be an irritant that should be avoided by individuals with atopic dermatitis (AD). Wool fibres come in a range of diameters, and have beneficial thermodynamic and moisture transport properties.

Objectives This study examines the effects of superfine merino wool on symptoms in participants with mild-to-moderate AD.

Methods The trial was a 12-week, randomized, assessor-blinded, crossover, prospective, cohort study of 39 patients with mild-to-moderate AD, aged between 4 weeks and 3 years, comparing superfine merino wool ensembles with standard cotton clothing chosen by parents. Participants were assigned to wool or cotton clothing and assessed every 3 weeks for 6 weeks, before crossing over to wear the other clothing material for a further 6-week period, with similar 3-weekly reviews. The primary end point was the SCORing Atopic Dermatitis (SCORAD) index after each 6-week period, with Atopic Dermatitis Severity Index (ADSI), Infants’ Dermatitis Quality Of Life Index (IDQOL) and topical steroid use as secondary end points to measure AD severity and quality of life.

Results Overall, compared with baseline, superfine wool ensembles were associated with a reduction in mean SCORAD of 2.5 [95% confidence interval (CI) −4.7 to −0.4] at 3 weeks and 7.6 (95% CI −10.4 to −4.8) at 6 weeks when compared with the cotton ensembles. A similar change was observed in ADSI and IDQOL scores for the same period. Body steroid use was also reduced. Conversely, changing ensembles from wool to cotton resulted in an increase in scores.

Conclusions Superfine merino wool may assist in the management of childhood AD.

What’s already known about this topic?

- There are few published reports of the effects of wool on atopic dermatitis, and these papers date back to the 1950s when reporting did not meet current standards.
- Since then, improvements in specification of wool-fibre diameter and in wool processing have enabled the production of less irritant clothing, which is also less contaminated by allergens.
- There is little available clinical evidence for adverse or beneficial effects of superfine wool.
Atopic dermatitis (AD) is a chronic relapsing, pruritic skin condition usually presenting early in childhood. AD affects around 30% of children. Its prevalence varies geographically and is increasing in many countries. Itch, sleeplessness, behavioural change and effects on activities of daily living contribute to disease burden. AD severity correlates inversely with quality of life. The familial impact of moderate and severe AD has been shown to exceed that of diabetes.

Genetic, inflammatory, microbial and environmental factors contribute to the skin barrier defect in AD, which predisposes to allergen sensitization. AD is potentially the first step of the ‘atopic march’, leading to asthma and allergic rhinitis. Given the prevalence, burden and complications of AD, minimizing adverse environmental triggers could greatly benefit individuals, families and healthcare systems. Management is complex and includes irritant and allergen identification and avoidance, moisturizers, anti-inflammatories, bleach baths, antibiotics, wet dressings and sometimes systemic immunosuppression. Poor compliance, owing to costs, time constraints and fear, complicates treatment. Better strategies for primary and secondary prevention are required.

Triggers for AD include heat, irritants and an adverse climate. Few studies have examined the effects of clothing in AD. Patients are advised to avoid woollen clothing, as early commentaries indiscriminately described wool as ‘spiky’, over-heating and irritant; these papers failed to distinguish between fibre types.

Hanifin and Rajka included ‘wool’ intolerance in their AD diagnostic criteria. Moreover, 39% of U.K. schoolchildren with AD believe that ‘wool’ exacerbates AD. However, wool fibres vary in thickness. Improved fibre diameter specification and advanced processing have refined garment properties. More itching is induced by contact with fibres of mean diameter 36 μm compared with those of 20 μm. Prickle and itch are generally not sensed if woollen garment mean fibre diameters are less than 19–21 μm.

Merino wool is generally less than 24 μm in diameter. Basic merino types include strong (broad) wool 23–24.5 μm, medium wool 19.6–22.9 μm, fine 18.6–19.5 μm, superfine 15.0–18.5 μm and ultrafine < 15 μm.

Wool fibres, composed of keratin, are the most hygroscopic of the common apparel fibres, allowing ready absorption and release of moisture vapour in the clothing microclimate to buffer humidity changes. They hold up to 35% of their own weight in water, compared with ~ 25% for cotton and 2–3% for polyester. Wool demonstrates superior properties of insulation, water absorbency, fire resistance and liquid repellency compared with other natural and manmade fibres. Its thermoregulatory and moisture transport properties may possibly benefit patients with AD, as skin barrier dysfunction leads to moisture and temperature dysregulation.

A recent study supported the tolerability and possible benefit of merino wool clothing in adult AD. The present study examines the effectiveness of superfine merino wool clothing compared with cotton clothing in reducing AD severity in children aged 0–3 years and assesses its tolerability and effect on quality of life in paediatric AD.

What does this study add?

- This study challenges generalizations that wool is to be avoided by children with eczema.
- This is the first original clinical study to examine the clinical effects of superfine merino wool on (childhood) atopic dermatitis.
- This clinical study highlights the need for further studies on the effects of clothing, and of the microenvironment between clothing and the skin, on atopic dermatitis.

Study approval

The study was approved by the Royal Children’s Hospital (RCH) institutional ethics committee (HREC34037A). Each parent or legal guardian provided written informed consent before any study-related procedures began. The trial is registered on the clinicaltrials.gov protocol registration and results system (NCT02534428).

Study population

Patients were recruited from the RCH Melbourne dermatology clinic, which is a tertiary care centre. Patients aged 0–3 years with mild-to-moderate AD, determined by a SCORing Atopic Dermatitis (SCORAD) index >1 and ≤ 50, with a legally acceptable representative capable of understanding the informed consent document and providing consent on their behalf, were eligible. Exclusion criteria included past adverse reactions to merino wool, anticipated inability to attend visits, and unstable eczema, defined by treatment escalation or increased topical anti-inflammatory use during the previous 2 months.

Study design

A single-centre, randomized, outcome assessor-blinded, crossover, prospective cohort study was conducted. Participants in the wool-first arm received 6 weeks of superfine merino wool...
clothing followed by 6 weeks of standard clothing, whereas the cotton-first arm participants began with standard clothing followed by superfine merino wool. The standard clothing of all participants was made of cotton.

Demographic and contact details were ascertained at the initial appointment. Children were reviewed at 3-weekly intervals. Participants in the wool-first group received five ensembles of 100% superfine merino wool clothing to be worn for at least 6 h a day, based on realistic wear patterns. Participants also received Eco Wool Wash detergent. A further ensemble was given at week 3. Participants in the cotton-first group received superfine merino wool clothing at week 6 (five ensembles) and at week 9 (one ensemble). At each review, clothing type, duration of daily wear and AD treatments used during the preceding 3 weeks, were recorded. At 6 weeks, children in the wool-first group changed from wool to cotton clothing, with re-collection of wool ensembles, while those in the cotton-first group changed from cotton to wool. At week 12, merino ensembles were returned to families. Travel expenses were reimbursed.

AD management was standardized to minimize confounding variables. Standard RCH AD management includes moisturization of the full skin surface at least twice daily, including after daily baths, hydrocortisone 1% ointment, pimecrolimus (in infants > 3 months) or tacrolimus (in children > 2 years) applied to facial eczema twice daily as required, and mometasone (0.1%) or methylprednisolone (0.1%) applied to body eczema, wet dressings and antibacterial measures as required.

Randomization and blinding

Patients were assigned to either the wool-first or cotton-first arm by a nonscoring investigator (R.D., E.L., L.T.), using a computer-generated random allocation list by block randomization with a variable block size of between four and eight patients on a 1 : 1 schedule (S.S.D., R.C.D.). Participants were assigned a study number (1–40) during screening. The allocation list, sequentially numbered and participant files and corresponding clothing ensembles were locked in a departmental cabinet, which could be accessed by only nonscoring investigators (R.D., E.L., L.T.). Participants were allocated to an unblinded dermatology nurse (E.L., L.T.) for consultations. A separate blinded, trained researcher assessed each patient’s SCORAD and the Atopic Dermatitis Severity Index (ADSI), at recruitment and on review (S.H., J.S.). Where possible, the same investigator who performed the baseline assessment scored the child on reviews. During assessments, the nurse stored clothing away from view in order to prevent the unblinding of assessors. Participants and guardians were unblinded but instructed to conceal their study arm from assessors.

Assessments

The primary outcome was change in AD severity, measured using the objective components of the SCORAD (oSCORAD) after 6 weeks of intervention. Secondary outcomes were eczema severity using the oSCORAD after 3 weeks, ADSI and quality-of-life assessment using the Infants’ Dermatitis Quality of Life Index (IDQOL) after 3 weeks and 6 weeks of intervention. At the initial appointment and at each review, parents completed the IDQOL survey. An independent, blinded assessor administered the SCORAD and ADSI. Topical steroid (TS) use was recorded at each review.

The SCORAD is the most tested measure of AD severity, with reliability and validity shown by 15 studies. It measures global severity using a scale ranging from 0 to 103, based on disease extent, six morphological parameters and two subjective markers.

The ADSI assesses localized eczema severity and complements SCORAD by scoring a particular target area; the assessor selected the most severely affected area that was reliably in contact with clothing. Erythema, pruritus, exudation, excoriation and lichenification were scored on a scale of 0 to 3 to give a maximum score of 15, with high scores indicating increased severity. It has demonstrated sensitivity and correlates well with instrumental AD measurements including transepidermal water loss.

The IDQOL was adapted from the Dermatology Quality of Life Index for children under 4 years of age. Caregivers rate a child’s AD severity using subjective domains such as eating, bathing, mood change and sleep disturbance. The total score for 10 questions ranges from 0 to 30; higher scores indicate greater disease burden.

Compliance was assessed by noting the frequency and daily duration of garment use at each review for the preceding 3-week period. Daily diaries were supplied to document garment use and collected at each review.

Sample size calculation

A sample size of 36 (18 participants per group) was selected to allow for the detection of a clinically important greater reduction in SCORAD from baseline to 6 weeks of 8.2 units for the wool ensemble clothes compared with the cotton clothes, assuming an SD for change of 8.7, based on previously published estimates, power of 0.8 and an alpha level of 0.05. To allow for a dropout rate of up to 10%, a total of 20 participants per group was required.

Statistical analysis

All analyses were performed using the intention-to-treat principle. The mean oSCORAD, ADSI and IDQOL were examined. As the change in SCORAD scores were normally distributed, independent group t-tests using mean differences were used. A secondary analysis using a nonparametric Mann–Whitney U-test was also performed for SCORAD, ADSI and IDQOL, and the results were similar. Additionally, a generalized linear model was used (using a Gaussian family and an identity link function) to estimate the effect of wool on change in SCORAD from baseline, while adjusting for the child’s sex and age. An
interaction term was fitted with the group (wool-first vs. cotton-first) to test whether the effect varied by order of treatment.

### Results

#### Recruitment

In total, 39 patients with mild-to-moderate AD were enrolled between 10 June 2014 and 10 February 2015. Twenty were assigned to the wool-first arm and 19 to the cotton-first arm. Participants ranged in age from 1 month to 3 years at the time of recruitment. Figure 1 shows the consort flow diagram.

#### Baseline data

At baseline, there were some differences between the cotton-first and wool-first groups (Table 1). Children in the wool-first group were younger and had a greater proportion of Assessed for eligibility ($n = 159$)

- Did not meet inclusion criteria ($n = 84$)
  - Misdiagnosis ($n = 1$)
  - Unsuitable age, severity or unstable ($n = 83$)
- Refused enrolment ($n = 36$)
  - No time ($n = 35$)
  - Transport problem ($n = 1$)
- Informed consent and randomization ($n = 39$)

**Wool first ($n = 20$)**

- Week 0 ($n = 20$)
  - SCORAD, ADSI, IDQOL, diary review.
  - Dispense 5 woollen ensembles.
  - Instruct on wool wear and care.

- Week 3 ($n = 19$)
  - SCORAD, ADSI, IDQOL, diary review.
  - Dispense 1 more wool ensemble.

- Week 6 ($n = 18$)
  - SCORAD, ADSI, IDQOL, diary review.
  - Retrieve woollen ensembles.
  - Change to cotton ensembles.

- Week 9 ($n = 17$)
  - SCORAD, ADSI, IDQOL, diary review.

- Week 12 ($n = 15$)
  - SCORAD, ADSI, IDQOL, diary review.
  - Woollen ensembles returned.

**Cotton first ($n = 19$)**

- Week 0 ($n = 19$)
  - SCORAD, ADSI, IDQOL, diary review.
  - Verify standard clothing fabric as cotton.

- Week 3 ($n = 19$)
  - SCORAD, ADSI, IDQOL, diary review.

- Week 6 ($n = 18$)
  - SCORAD, ADSI, IDQOL, diary review.
  - Dispense 5 woollen ensembles.
  - Instruct on wool wear and care.

- Week 9 ($n = 17$)
  - SCORAD, ADSI, IDQOL, diary review.
  - Dispense 1 woollen ensemble.

- Week 12 ($n = 16$)
  - SCORAD, ADSI, IDQOL, diary review.

**Fig 1.** Consort flow diagram. SCORAD, SCORing Atopic Dermatitis; ADSI, Atopic Dermatitis Severity Index; IDQOL, Infants’ Dermatitis Quality Of Life Index.

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children who had fathers with a history of hay fever. Sex and markers of AD severity appeared to be similar between the groups.

Compliance with clothing use

During the 6-week treatment period, woollen clothing use was reasonably high. Of children with available data in the wool-first group, 17 of 18 at 3 weeks and 15 of 15 at 6 weeks reported daily woollen garment use. Similarly, the figures for the cotton-first (wool-second) group were 15 of 17 and 13 of 16 children at 9 weeks and 12 weeks, respectively. Daily usage diaries were properly completed at 3 weeks and 6 weeks for 16 of 18 and 12 of 15 children, respectively, for the wool-first group and 11 of 17 and 10 of 16 children, respectively, for the cotton-first group. According to the diaries, 6-h minimum daily wear times were satisfied in over 85% of participant days in both groups.

Outcomes

Primary outcome: SCORing Atopic Dermatitis

SCORAD scores decreased from baseline to week 12 in both groups, but this was more pronounced in the cotton-first group (Fig. 2, Table 2). There was limited improvement in SCORAD from baseline to week 6 in both groups (Table 3) with no evidence that the SCORAD change was different between the two groups (Table 2). The cotton-first group showed substantial reduction in eczema severity after changing to wool, from 6 weeks to 9 weeks and again at 12 weeks (mean of 11–13-point reduction). No improvement occurred in the wool-first group after changing to cotton, with a trend towards worsening AD from 6 to 12 weeks (Table 3, Fig. 3).

Generalized linear modelling confirmed these findings. Combining the wool-period data of both groups, the magnitude of SCORAD reduction from baseline was greater at 6 weeks of treatment [7–6, 95% confidence interval (CI) −10·4 to −4·8] than at 3 weeks (−2·5, 95% CI −4·7 to −0·4). Neither age at enrolment (P = 0·69) nor sex of the child (P = 0·99) were associated with change in SCORAD, while higher baseline SCORAD values were associated with a greater reduction in SCORAD (P < 0·01) during the follow-up. These effects were not greatly altered when adjusted for age, sex and baseline severity (−2·6, 95% CI −4·6 to −0·62 at 3 weeks and −7·2, 95% CI −9·4 to −5·0). While the impact of the wool garments appeared to be greater in the cotton-first group than in the wool-first group, this was not significantly different at either week 3 (P = 0·198) or week 6 (P = 0·634).

Secondary outcomes

Atopic Dermatitis Severity Index (Table 3) In parallel with the SCORAD observations, wool garment use was associated with a significant ADSI score reduction, particularly for the cotton-first group. Comparing the combined wool-period data of both groups with baseline, a median ADSI score reduction of −1 [interquartile range (IQR) −2–0] at 3 weeks (P < 0·01) and −2 (IQR −3 to −1) at 6 weeks of use was observed (P < 0·01). There was a trend towards worsening ADSI scores in the wool-first group when changed over to cotton.

Infants’ Dermatitis Quality of Life Index Significant decreases in IDQOL scores were observed during wool intervention for the cotton-first group (Table 2). After combination of both

Table 1 Baseline characteristics of study participants

| Participant characteristics | Cotton first | Wool first |
|----------------------------|-------------|-----------|
| Male participants, % (n/N) | 68 (13/19) | 60 (12/20) |
| Median age at enrolment (IQR) | 22 (4–34) | 10 (7–21) |
| Eczema severity | | |
| Median baseline SCORAD (IQR) | 15·5 (10·5–20·5) | 11 (7–19) |
| Mean baseline SCORAD (SD) | 16·6 (0·6) | 13·4 (7·9) |
| Mean baseline ADSI (IQR) | 4 (2–5) | 3 (2–4) |
| Median baseline IDQOL (IQR) | 8·5 (5–10) | 7 (4–11) |
| Comorbid disease, % (n/N) | | |
| Asthma | 5 (1/19) | 15 (3/20) |
| Hay fever | 16 (3/19) | 25 (5/20) |
| Family history | | |
| Mother, % (n/N) | | |
| Eczema | 42 (8/19) | 35 (7/20) |
| Asthma | 16 (3/19) | 20 (4/20) |
| Hay fever | 47 (9/19) | 45 (9/20) |
| Father, % (n/N) | | |
| Eczema | 32 (6/19) | 45 (9/20) |
| Asthma | 32 (6/19) | 30 (6/20) |
| Hay fever | 32 (6/19) | 70 (14/20) |
| Sibling, % (n/N) | | |
| Eczema | 42 (8/19) | 30 (6/20) |
| Asthma | 16 (3/19) | 10 (2/20) |
| Hay fever | 21 (4/19) | 5 (1/20) |
| Mean (SD) daily environmental conditionsa | | |
| Temperature during treatment phase | 18·2 (2·8) | 19·2 (1·7) |
| Temperature during control phase | 18·5 (2·6) | 18·1 (2·7) |
| Humidity during treatment | 64·9 (1·9) | 66·9 (4·0) |
| Humidity during control | 66·8 (3·7) | 65·5 (2·4) |

IQR, interquartile range; SCORAD, SCORing Atopic Dermatitis; ADSI, Atopic Dermatitis Severity Index; IDQOL, Infants’ Dermatitis Quality Of Life Index. aCalculated as the mean daily temperature or humidity [(daily minimum + daily maximum)/2] for the 6-week intervention or control period.
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Table 2. Median [interquartile range (IQR)] and mean (SD) change in objective SCORing Atopic Dermatitis (SCORAD), Atopic Dermatitis Severity Index (ADSI) and Infants’ Dermatitis Quality Of Life Index (IDQOL) from baseline according to group of assignment.

| Group                                      | 3 weeks       | 6 weeks       | 9 weeks       | 12 weeks      |
|--------------------------------------------|---------------|---------------|---------------|---------------|
| Cotton-first standard-wool SCORAD         | Median (IQR)  | Mean (SD)     | Median (IQR)  | Mean (SD)     |
| n                                         | 16            | 16            | 15            | 17            |
| P-value                                    | 0.20          | 0.56          | < 0.01        | < 0.01        |
| Wool-first wool-standard SCORAD            | Median (IQR)  | Mean (SD)     | Median (IQR)  | Mean (SD)     |
| n                                         | 19            | 17            | 17            | 17            |
| Cotton-first ADSI                         | Median (IQR)  | Mean (SD)     | Median (IQR)  | Mean (SD)     |
| n                                         | 15            | 12            | 11            | 13            |
| Wool-first ADSI                           | Median (IQR)  | Mean (SD)     | Median (IQR)  | Mean (SD)     |
| n                                         | 13            | 11            | 11            | 10            |
| Cotton-first IDQOL                        | Median (IQR)  | Mean (SD)     | Median (IQR)  | Mean (SD)     |
| n                                         | 13            | 7             | 13            | 13            |
| Wool-first IDQOL                          | Median (IQR)  | Mean (SD)     | Median (IQR)  | Mean (SD)     |
| n                                         | 15            | 9             | 11            | 10            |
| P-value                                    | 0.89          | 0.90          | 0.12          | < 0.01        |

Area in grey indicates active treatment with wool ensemble.

groups, a reduction in mean and median scores during wool intervention remained (median $-1$, IQR $-4.5$ to $-0.5$ at 3 weeks; $P = 0.03$ and median $-2$, IQR $-4.5$ to $-0.5$ at 6 weeks; $P = 0.01$). Again, the wool-first group showed a rise in IDQOL scores when participants changed over to cotton (Table 3).

Topical steroid use (Table 4) Daily use of TS on the body was reduced when wearing wool, particularly for the cotton-first group. When combined across the time periods, children wearing wool approximately halved their daily body steroid use (odds ratio 0.44, 95% CI 0.23–0.83), compared with those who wore cotton. Facial TS use was inconsistently associated with wool garment wear. By contrast, moisturizer use, measured by daily frequency of applications, did not significantly change overall or consistently correlate with wool garment use.

Adverse events

No untoward medical occurrence was observed in this study, regardless of its causal relationship to study treatment, except...
Wool-first ADSI Median (IQR) 4 (2–5) 2 (1–4) 2 (1–3) 0 (0–2) 0 (0–0.5)
Mean (SD) 2.4 (1.9) 2.4 (2.2) 1.1 (2.2) 0.7 (1.8)
 n 19 19 17 17 14
Wool-first ADSI Median (IQR) 2 (2–4) 0 (0–3) 1 (0–3) 1.5 (0–3) 2 (0–3)
Mean (SD) 1.9 (2.7) 1.6 (2.3) 2.1 (2.5) 2.3 (2.4)
 n 15 15 14 14 16
Cotton-first IDQOL Median (IQR) 8.5 (5–10) 5.5 (4–8) 4 (3–5) 4 (3–5) 2 (1–5)
Mean (SD) 8.2 (3.6) 6.7 (4.2) 4.4 (2.2) 4.3 (2.6) 3.0 (3.3)
 n 15 14 16 11 13 15
Wool-first IDQOL Median (IQR) 7 (4–11) 4 (2–6) 2 (2–8) 7 (3–10) 5 (2–8)
Mean (SD) 7.6 (4.5) 4.8 (3.5) 4.5 (4.1) 6.8 (4.6) 5.8 (4.5)
 n 15 19 13 13 15 14

Area in grey indicates active treatment with wool ensemble.

Fig 3. Mean (95% confidence interval) objective SCORing Atopic Dermatitis (SCORAD) according to group of assignment. Vertical lines indicate change over from cotton to wool or wool to cotton.

Discussion

In this randomized crossover trial, wearing superfine merino wool garments reduced oSCORAD with statistical significance and reduced TS use in mild and moderate AD. Children with severe AD were excluded owing to complications that could affect compliance and clothing effects in a short study. Eczema reduction was more pronounced in the cotton-first group, but remained significant when both groups were combined. No observed difference in garment use explained this possible difference between groups; compliance was high in both groups.

Various reasons may explain why wool garment effects appeared to be more substantial in the cotton-first group. Firstly, the median age of children in the cotton-first group was 12 months older than those in the wool-first group. While AD severity naturally decreases with increasing age, any age-related improvement in eczema generally takes years to occur and is unlikely to impact a study with a 3-month follow-up period significantly.

Secondly, patients in the cotton-first group completed more visits by the time they changed to wool, compared with the wool-first group. This may have created a run-in effect. Thus, the benefits of wool may possibly be greater when there is less skin inflammation. Children in the cotton-first group benefited from a longer period of age-related improvement in eczema generally takes years to occur and is unlikely to impact a study with a 3-month follow-up period significantly.
optimizing routine management before wool was introduced.

Thirdly, environmental factors may have confounded results. Temperature variations may trigger AD flares. As the study ran from winter to summer, the wool-first group would have tended to wear wool in warmer months; this may have influenced differences in the effects observed between the two groups. However, the mean daily temperatures between the groups were similar and could not explain the differences observed (Table 1). By contrast, children in the cotton-first group, who improved the most during treatment, had lower mean daily temperatures (Table 1). The Harmonizing Outcome Measures for Eczema (HOME) group consensus recently advocated the Eczema Area and Severity Index score to assess AD severity, having potential to help prevent childhood AD. Therefore, future studies should use this scale.34,35 Fifthly, while the trend to a clinically significant reduction in SCORAD was clear, our sample size was small, resulting in imprecise estimates of the wool’s potential to help prevent childhood AD. Further areas to study include the interaction of environmental conditions and the effects of wool should be explored in future studies.

Notably, during the second phase, children in the wool-first group showed a worsening of AD, which regressed to baseline values when they switched from wool to cotton, from 6 to 12 weeks. This may indicate that cessation of wool use and reverting to cotton clothing results in a relative worsening of eczema, which was the reverse of the findings for the group that changed from cotton to wool.

This study demonstrated not only a statistically significant reduction in AD severity with the use of superfine merino wool ensembles, compared with cotton over a 6-week period, but also a reduction in oSCORAD that may be of clinical significance. The estimated effect of woolen garments after 6 weeks of use was a reduction in oSCORAD of $-7.6$ units ($95\%$ CI $-10.4$ to $-4.8$); a clinically important reduction in the SCORAD has been estimated to be $8.2$ units.32

This study had some limitations. Firstly, children with severe AD were not included. Secondly, minimum wear time was short, based on realistic wear patterns in Melbourne, where dramatic changes in climate can occur anytime. There may have been differences in the duration of wear, and longer wear may have had a greater impact; this was not captured in the data. Thirdly, we cannot totally exclude recall bias. Diary cards were mostly well completed to verify garment use, but were not used to quantify topical treatments, which is a limitation to address in future studies. Fourthly, weaknesses of the SCORAD, the primary outcome measure, include inter- and intra-rater variability, which lowers accuracy and reproducibility, particularly in assessing disease extent.29 The Harmonizing Outcome Measures for Eczema (HOME) group consensus recently advocated the Eczema Area and Severity Index score to assess AD severity, having potentially higher inter-rater and intrarater reliability. Future studies should use this scale.34,35 Fifthly, while the trend to a clinically significant reduction in SCORAD was clear, our sample size was small, resulting in imprecise estimates of the wool clothing effect on oSCORAD. In retrospect, inclusion of seven children (five wool-first, two cotton-first) with oSCORAD $<8$ possibly also compromised the power to show a clinically important oSCORAD reduction. A larger trial is required to confirm our findings. Sixthly, the follow-up period was relatively short. A longer period may clarify the greater effect observed in the cotton-first group. Seventhly, geographical climatic variations may limit the generalizability of results to other countries.

In this study, superfine merino wool clothing reduced the severity of paediatric mild-to-moderate AD compared with cotton clothing, suggesting a potential place for superfine merino wool in the management of childhood AD. Therefore, traditional management guidelines classifying all wool-based clothing as irritants should be modified to include superfine merino wool as a recommended clothing choice in childhood AD. Further areas to study include the interaction of environment and wool in paediatric AD and comparison studies with different textiles and fibre specifications. Future studies of superfine merino wool should consider children with severe AD, effects of longer wear times, other geographical climates and wool’s potential to help prevent childhood AD.

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**Table 4** Proportion treated at least daily with topic steroids according to group of assignment

| Steroid use on body | Group     | 3 weeks | 6 weeks | 9 weeks | 12 weeks |
|---------------------|-----------|---------|---------|---------|----------|
| Cotton first, % (a/N) | 53 (10/19) | 31 (5/16) | 24 (4/17) | 6 (1/16) |
| Wool first, % (a/N)   | 28 (5/18)  | 33 (6/15) | 41 (7/17) | 33 (5/15) |
| P-value              | 0.18      | 1       | 0.47    | 0.08    |

| Steroid use on face | Group     | 3 weeks | 6 weeks | 9 weeks | 12 weeks |
|---------------------|-----------|---------|---------|---------|----------|
| Cotton first, % (a/N) | 5 (1/19)  | 12.5 (2/16) | 18 (3/17) | 0 (0/16) |
| Wool first, % (a/N)   | 11 (2/18) | 27 (4/15)  | 41 (7/17) | 27 (4/15) |
| P-value              | 0.60      | 0.40    | 0.26    | 0.04    |
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