The experiences of children and young people of using silk garments for the treatment of eczema: a nested qualitative study within the CLOTHES randomised controlled trial.

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Summary

Background

Many children suffer with skin diseases, but to date, most dermatological research has been done 'on' rather than 'with' children; in this study we actively sought the experiences of children and young people. Atopic eczema (AE) is a chronic, itchy, inflammatory skin condition that affects around 20% of children and can impact on health and wellbeing for children and their families. The role of specialist clothing in the management of AE is poorly understood.

Objectives

The aim of this study, which was nested in a randomised controlled trial was to qualitatively examine child participants' experiences of using silk garments for the treatment of AE.

Methods

Eighteen children aged 5-15, who took part in the CLOTHES trial, participated in age-appropriate individual interviews or focus groups.

Results

Thematic analysis generated 4 themes directly related to the garments: i) expectations of the garments; ii) wearing the silk garments; iii) did they help? and iv) thoughts about the garments. The conclusions from this nested qualitative study are that: there was some limited improvement in eczema for some children but that the hoped for 'miracle cure' did not transpire. A mixed picture of knowledge, beliefs and experiences of using the silk garments emerged.

Conclusion

Engaging children in the evaluation of the garments provided first hand nuanced insights that enhanced understanding of the CLOTHES study as a whole. This nested study demonstrates that children can and indeed want to be engaged in dermatological research in meaningful ways that add to our understanding of treatment options.

Key words

Eczema, atopic dermatitis, silk garments, children, qualitative

Background

There is growing interest in qualitative research in dermatology[1] and the active engagement of children in dermatology consultations[2], however these ideals are not always realised. Globally there are around 1.8 billion people aged 0-14 years[3]. Historically children have been viewed as dependent and vulnerable objects of study, with primary informants typically being parents or clinicians[4]. There are increasing calls for children to be actively involved in research studies, but evidence suggests that they are frequently not engaged in meaningful ways[5]. Health research is often undertaken *on* rather than *with* children, or their experiences are extrapolated or subsumed within adults' views. Children are rarely heard in dermatology research with the exception of the use of some quantitative measures such as the Children's Dermatology Life Quality Index (CDLQI)[6].

Atopic eczema (AE) is a common inflammatory skin condition affecting around 20% of children[7]. Treatment typically includes emollients and topical corticosteroids or calcineurin inhibitors, and systemic treatments in more severe cases. Topical treatments can be time-consuming and unpleasant to use and treatment failure is often attributed to non-adherence[8]. Poor control leads to worsening AE which affects physical and emotional wellbeing[9]. Many parents and children are keen to explore non-pharmacological interventions for the management of AE, and silk garments have been suggested as one such approach. These garments are available for private purchase or, in some countries on prescription, but the evidence-base for their use is limited. The CLOTHES trial comprises an RCT and nested qualitative studies involving children, parents, clinicians, and commissioners of silk clothing. A summary of the elements of the study are provided in Box 1 and reported in detail in other published works[10, 11]. In this nested study we explored child experiences of using silk garments as they were the users of these products in the CLOTHES trial and therefore their input was essential[12].

Box 1 here

Methods

An exploratory qualitative research method[13] was used to explore child and young people participants' views about the silk garments. In this paper, for ease of reading we use the term children to include all participants.

Ethical considerations

Ethical approval was gained from Health Research Authority East Midlands – Nottingham 1 Research Ethics Committee (reference number 13/EM/0255) and the local research and development department for each participating centre. Parents and children were informed about the qualitative study by their research nurse towards the end of their participation in the RCT. Children were given an age appropriate Participant Information Sheet and invited to sign an assent form[14]. They were told clearly that they did not have to take part and could stop at any time.

Participants

Once children had completed the RCT we recruited a convenience sample[15] of eighteen children aged 5-15 years from both intervention and standard care groups across the five study recruiting sites. We used convenience rather than purposive sampling in light of the challenges of identifying and recruiting children from all sites and, in the case of focus groups, from deliberately narrow age bands. Children in the intervention group had used the garments for six months and those in the standard care group for two months after the primary outcome had been collected at 6 months. Demographic details are provided in Table 1.

Table 1 here

Data collection

Ten face-to-face or telephone interviews with children aged 9 years and over (10-40 minutes in duration) and three focus group discussions, two with 7 to 8 year olds (n=2, n=2), and one with 5 to 6 year olds (n=4) (90-120 minutes), were conducted. All interviews were audio-recorded and transcribed in full. Children in the focus groups were enabled to use developmentally appropriate play activities to maximize opportunity to share their experiences. Key questions are available as supplementary material (supplementary material 1). Data were collected between February and May 2015. Data collected comprised interview transcripts, focus group artefacts with child explanations, for example drawings or sticker pictures, and observer notes)

Prior to data collection, conversations with parents and older children ensured the research team's understanding of the child's developmental stage and current interests and this information was used to plan data collection activity. Some parents chose to be present during the interviews and focus groups but none participated or obviously influenced children's contributions. Venues for data collection were as child-friendly as possible. At the beginning of each episode of data collection EW spent time with the children getting to know them, making introductions and checking that they were willing to take part. Interviews were conducted by EW. Focus groups were facilitated by EW and an observer was present to take notes and ensure the wellbeing of participants. Children were not pressurised to join in any activities and we were careful not to interpret a child 'just watching from the side' as non-participating. Subtle communication was valued as much as the more obvious. Breaks were taken during data collection guided by cues from the children.

A mosaic approach[16] involving multiple participatory and adaptable, creative and fun[17] methods of data collection were used[18]. Elements of the 'least adult' role were adopted to support active child participation and children were enabled to 'take charge' and direct the research agenda[19]. For example EW followed the lead of the children in selecting activities and was fully engaged in these consciously using children's language and testing understanding. Children chose what to do and how to share their feelings and experiences. For example we created a story together with younger children based on a day in the life of Billy the puppet (Image 1), and they used drawings, stickers and 2D foam people to share their experiences. Towards the end of each data collection session EW checked her understanding with the children. They photographed any artefacts as they were keen to take them home. As each photograph was taken the creator explained its significance to EW to ensure authenticity in data analysis and reporting. Each interaction ended with EW briefly recapping what had been said, explaining to the children what would happen to their data and presentation of a certificate acknowledging their contribution. Data gathered using diverse methods, from children aged from 5-15 years, varied in terms of content and the ways in which was communicated. However, as seen in the data analysis below some strong and consistent messages were provided.

Image 1 here

Data analysis

To ensure faithful representation of child data we used three methods of holistic, selective and detailed analysis[20], which involved viewing the data (interview transcripts, artefacts with child explanations and observer notes) as a whole, identifying phrases or ideas that represented the experience under study, and finally studying the data line-by-line in order to identify themes. Throughout analysis we were mindful of the age and developmental stage of participants which affected the verbal and non-verbal language they used. The analysis process was not linear but moved back and forth between wholes and parts. FC & EW reviewed the data alone and then together to ensure authenticity in portraying children's experiences. As data analysis progressed emerging themes were discussed with the qualitative study team until shared understanding was achieved. At this stage the qualitative researchers were independent from the wider study team and findings were not shared until all elements of data analysis was completed.

Reflexivity

Prior to the study the team considered their own beliefs and concluded that they were aware of the detrimental impact that eczema could have on children's lives, but did not have any strong opinions on silk garments as a treatment option. Nevertheless we maintained a level of reflexivity throughout the research process[21].

Findings

The data analysis process generated 4 themes directly related to the garments: i) expectations of the garments; ii) wearing silk garments, iii) did they help? and iv) thoughts about the garments. A description and analysis of each theme is provided below followed by a tabulation of each theme with exemplar data extracts from interviews and focus groups and a photographic example from one focus group. There were no discernible differences in data provided by children from standard care and intervention groups.

Theme 1: Expectations of the garments

This theme comprised three sub-themes: use of other treatments, garments, and hopes. Many children expected the garments to feel 'silky' and hoped that using the garments would reduce the need to use creams. Realising that this was not the case was a source of disappointment. Children were disappointed with the 'rough' texture of the garments and some reported needing to use creams more frequently when wearing the garments. A number of children had expected the silks to be cooling, but for many the effect was the opposite, with the garments making them hotter. Many of the children were excited to try the garments, and spoke of their hopes, or doubts, for the effect on their eczema.

Use of other treatments	**Garments**	**Hopes**
Still have to use cream.	*[silks] made me feel hotter, I thought it would make me cooler*	*I was a bit dubious because nothing's ever really worked that well for me.*
during the day we use the silk suits, put the cream on underneath	*I had a lovely silk long-sleeved top and it was really comfy to wear, forgot you had it on, and I think that was what I thought it would be.~~If it had been pure silk and not with all of these holes…that would have worked for me but.. it was a bit like a washing machine bag~~*	*I had all these expectations built up...I was really hopeful as well. I was really willing to wear them to start with, and then I got them for the start and everything just turned negative for me.*
I have to put cream on every day.		

Theme 2: Wearing the garments

This theme addresses the times at which children chose to wear the garments. There are two sub-themes: day vs night, and school vs home. Few children of any age wore the silks during the day: a majority preferred to wear them at night only. There were many issues with being able to wear them for school, ranging from fit, uniform-requirements, changing for physical education lessons, and the reactions of other children. Peer groups and friendships were very important for children of all ages; only those with very secure friendships felt confident enough to tell their peers openly about their eczema and the garments.

Day vs Night	**School vs home**
I prefer to wear them during the day rather than the night because the silk is really comforting on my skin *Wearing them at night because some people ask like what's that and it's a bit annoying*	*I wore them to school but not PE Days…people would laugh* *Poor fit trousers so not worn to school/don't fit under tights* *Yes I wore them to school but it was a bit weird when like everyone was like 'What is that?'*

Theme 3: Did they help?

This theme has three sub-themes: getting better, getting worse and 'liked anyway'. There was a real mixture of success of the garments, ranging from perceived complete cessation of eczema, to no effect at all, to worsening of symptoms. Some reported that the silks had improved their sleep, whilst others felt it had made them more comfortable but not improved their eczema per se. A few stated that the clothing improved their emotional well-being, whilst others were disappointed in the effect of the garments. Some children reported liking wearing the garments for comfort, even if they had no perceptible effect on their eczema.

Getting better	**Getting worse**	**'Liked anyway'**
Better, the itch goes away *Really helping in the day* *It's kind of helping the eczema go away. Less sore* *More comfortable at night. Certainly quality of sleep and that made a difference*	*I stopped wearing them I realised they were making [my] eczema worse. It did make it all inflamed and more itchy* *[At] night, it wakes you up because it is scraping at my skin..it catches and it rips it*	*It was comfy. Top and bottoms were smooth* *Feels nice on my skin*

Theme 4: Thoughts about the garments

Thoughts about the garments comprised three sub-themes: quality and cost; appearance and design and fit and fabric. Many participants thought the garments were poor quality in terms of appearance, design, fit or the fabric itself. Several children reported that the garments did not wash well, turning baggy and grey and affecting fit over time (see Image 2). Older children reported using the garments as advised, allowing creams soak into the skin before putting them on however they found that garments tended to become sticky and oily, and in some cases smelly. Some thought the texture was rough and actually irritated their skin more and some stated that the silks made them hotter. The fact that the silks were see-through was an issue, particularly for older children, making their use limited to the home. At night, the garments tended to be worn under pyjamas or onesies. The cost, which some children had either looked up or discussed with their parents, was an issue for further purchase for a few, with a couple of participants suggesting that they were too expensive to buy and should be available on prescription from a general practitioner.

Image 2 here

Quality and cost	Appearance and design	Fit and fabric
I've got massive holes gaping wide	*It's not…that private to be wearing something basically see-through…like wearing cling film*	*It was almost like chainmail. They were too rigid*
Get hot and they tear	*They are not very pretty*	*The texture, I put them on and I take them off about an hour later and I know that I'll be scratching so long that it becomes an infection*
If it had been pure silk and not with all of these holes, if it was really thin silk that would have worked for me	*Went grey after washing, stained and grubby and difficult to wash*	*Gap between trouser and top untreated and elastic waistband itchy*
I think the best thing about them is that they are 100% silk and they don't have any…elastic	*No good for summer – long sleeves*	*'Random sizing' poor fit*
We didn't think they were going to be as expensive	*Would like polo neck option. Short sleeved option. Shorts.*	

Discussion

Main findings

Generally children reported some limited improvement in their eczema, but the hoped for 'miracle cure' did not transpire. Several children entered the trial believing that using the garments would lead to a reduction or ceasing of the need to use topical treatments; the requirement to continue use, as set out in the patient instructions, was a source of discontent. Children reported a significant sense of disappointment in relation to effectiveness, and the quality, fit and durability of garments. Including children in the study illuminated deeper understanding particularly about patterns of adherence and reasons for non-adherence.

The child data reported here has uncovered understandings, which help to inform interpretation of the results of the study as a whole. The CLOTHES trial comprised: the RCT, an economic evaluation and qualitative studies with children, parents, clinicians and commissioners. In line with current recommendations, the CLOTHES study was developed as a coherent whole from the design phase[22] with each element contributing to a rounded picture of the impact of silk garments. The decision to analyse data sets separately and then triangulate ensured no contamination whilst maximizing the value of each part[23]. The RCT and economic evaluation found no significant gain in the use of silk garments in treating childhood eczema[11]; parental data revealed a preference for non-pharmacological treatments but a sense of disappointment with the garments, and clinicians and commissioners reported a lack of knowledge and evidence base for the garments particularly given the cost[10] . The child data has provided a deeper, richer and more detailed understanding of the 'what', 'why' and 'how come' underpinning participant's beliefs, behaviours and patterns of adherence.

Parents and children generally had high expectations when entering the trial and this may have led to a degree of detection bias when completing the secondary patient-reported outcome measures (PROMs) with their parents. Inclusion of the quantitative study gave confidence that the selected objective outcomes measure used for the primary outcome in the trial did not miss issues that were important to patients.

The focus groups and interviews at the end of the RCT allowed children to reflect on whether there had been improvement in their condition when their initial high hopes had abated. The children provided detailed and nuanced explanations about why they did and did not wear the garments, which went beyond the views provided by their parents. Some issues were practical in nature, such as the perceived poor fit, rough feeling of the fabric and being hot and uncomfortable. Others were more personal and sensitive and it is these thoughts that were uniquely reported by the children. Several commented about embarrassment of wearing garments and jibes from their peers. Children were also most vocal about ways in which the garments could be improved to increase likelihood of concordance.

Relevance to other studies

Whilst many researchers aspire to include children in meaningful ways, for example Hussain[12], a recent review of 506 peer reviewed studies conducted between 2009-2012 involving children from 0-8 years analysed child positioning, researcher perspective and level of respectful culture in each study concluding that only 3.4 per cent positioned children in inclusive, participatory roles[5]. This study demonstrates that children *can* be included in research even from a relatively young age. Children *wanted* to talk with the researcher and were very able to express their experiences with clarity given age appropriate means of communication.

Strengths and limitations

Documentation of the decision trail[24] and reporting in line with Standards for Reporting Qualitative Research guidance[25] ensures the trustworthiness of this study. Self-selection of participants is a limitation as they may not be representative of the trial cohort. Recruitment of children from study centres in prescribed age-bands was difficult and we would have preferred to recruit more children. We considered recruiting to wider age-bands for the focus groups but made the decision not to do this as it would have compromised the value of using developmental and age-appropriate activities to enable children to convey their thoughts and feelings. Combining qualitative and quantitative approaches from the design stage is a strength but our decision to undertake separate analysis of each dataset could be challenged with some arguing for a more formal approach to data triangulation at analysis stage[22, 26].

There is increasing recognition of the value of including nested qualitative studies within RCTs[27]; however, the rigour and integrative processes in this approach is often lacking[28]. Few nested studies including child participants have been reported. Examples include assessment of a home based exercise programme for children with cystic fibrosis[29] and a home physiotherapy regimen for youngsters with joint hypermobility[30]. Both report valuable child data but this is not explicitly linked with associated RCT data. This is an original study in dermatology to qualitatively seek the experiences of children as part of a larger trial and demonstrates the possibilities for future studies.

Conclusion

This nested study demonstrates that with sufficient planning children can effectively and meaningfully be involved in dermatology research. Given the number of children with skin conditions and the impact this has on their quality of life it is important that we listen to their experiences. Many children were eager to try the garment but were less enthusiastic once they had seen and felt them. The majority of children expressed disappointment about the garments and the impact they had on their eczema. Equally some children expressed a great reluctance to wear the garments and given how much they cost this is an important message for prescribers and commissioners. When combined with other data, the results provide a more robust evidence-base about the value of silk garments in the treatment of childhood eczema.

Effective management of eczema relies on adherence with prescribed treatment regimens. There is therefore a need to include children in the evaluation of proposed products from the design phase of trials and thought should be given to how best to triangulate data. Broadly the child and parent data concurs with agreement that the garments were not of optimum design or quality and that expectations of improvement in condition were not met. Views on comfort were individual with reports of both heating and cooling effects which were not always seasonally influenced. Children's explanations of non-adherence were often different or more subtle from those offered by parents and often included more sensitive subjects such as embarrassment and peer pressure. Inclusion of this qualitative component with children provided additional detail on possible reasons for non-adherence in wearing the garments which would not have been revealed from other data.

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