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The views of children and young people on the use of silk garments for the treatment of eczema: a nested qualitative study within the CLOTHing for the relief of Eczema Symptoms (CLOTHES) randomized 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 the health and wellbeing of 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 randomized controlled trial, was to qualitatively examine child participants' experiences of using silk garments for the treatment of AE.

Methods Eighteen children aged 5–15 years, who took part in the CLOTHing for the relief of Eczema Symptoms (CLOTHES) trial, participated in age-appropriate individual interviews or focus groups.

Results Thematic analysis generated four themes directly related to the silk garments: (i) expectations of the garments; (ii) wearing the garments; (iii) asking if the garments helped; 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.

Conclusions 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.

What's already known about this topic?

- Eczema affects around 20% of children and can have a detrimental effect on the child and their family.
- Adherence with topical treatments is often poor and can lead to treatment failure.
- Although children are often end-users of eczema treatments, they are rarely engaged in research involving these products beyond completing questionnaires.

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Conflicts of interest
Espère Healthcare Ltd [U.K. and Ireland distributor for DermaSilk®, Alpretec s.r.l. (San Donà di Piave, Italy)] and DreamSkin Health Ltd (Hatfield, U.K.) donated the garments for use in the CLOTHES trial.

The members of the CLOTHES Trial Team are listed in the Appendix.

*Plain language summary available online

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What does this study add?

- Children and young people can be meaningfully engaged in dermatology research and add new dimensions of understanding that would not be gained by proxy data.
- Children told us about their expectations of the garments and their views once they had worn them.
- The added value of child data lies in enhancing understanding of reasons for adherence and nonadherence, in facilitating interpretation of the trial results, and in ensuring selected objective outcome measures include factors important to children.

What are the clinical implications of the work?

- This study illustrates the need to communicate effectively with children and young people to ascertain their thoughts and beliefs about treatment regimens and assess the likelihood of adherence.

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 children 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.[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 to apply and unpleasant to use, and treatment failure is often attributed to nonadherence.[8] Poor control leads to worsening AE, which affects physical and emotional wellbeing.[9] Many parents and children are keen to explore nonpharmacological 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 CLOTHing for the Relief of Eczema Symptoms (CLOTHES) trial comprises randomized controlled trial (RCT) and nested qualitative studies involving children, parents, clinicians, and commissioners of silk clothing. A summary of the elements of the study is provided in Table 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]

Participants and methods

An exploratory qualitative research method[13] was used to explore participating children's and young people's 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 18 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 6 months and those in the standard care group for 2 months after the primary

Table 1 Summary of other elements of the CLOTHing for the relief of Eczema Symptoms (CLOTHES) study

Summary of CLOTHES randomized controlled trial (RCT)	
Design	Parallel group, pragmatic, observer blind, RCT of 6 months' duration
Participants	Three hundred children aged 1–15 years with moderate-to-severe eczema
Setting	Five recruiting centres in the U.K. (recruiting from secondary care, primary care, and advertising)
Intervention	Standard eczema care plus sericin-free, 100% silk garments (long-sleeved top and leggings): either DermaSilk® or DreamSkin®, to be worn as often as possible during the day and night
Control	Standard eczema care; participants who were randomized to standard eczema care received silk clothing after the primary outcome had been collected at 6 months
Primary outcome	Eczema severity assessed by blinded research nurses using the Eczema Assessment Severity Index
Secondary outcomes	Global assessment of eczema severity (investigator and participant), eczema symptoms, use of eczema treatments, health-related quality of life, skin infections, durability and acceptability of the garments, cost-effectiveness
Key results	The CLOTHES trial found no evidence of clinical or economic benefit from use of silk clothing for the management of eczema. These findings were robust after adjusting for baseline imbalances, missing data and levels of adherence in wearing the clothing. Two of the patient-reported secondary outcomes suggested a small benefit favouring silk clothing, but these effects are unlikely to be clinically meaningful, as the effects were small and expectation in the benefits of the clothing was high, leading to potential detection bias
Summary of nested qualitative study with parents	
Design	Exploratory qualitative study with convenience sampling, in-person focus groups and semistructured telephone interviews, and a framework data analysis process
Participants	Twenty-eight mothers and five fathers
Key findings	Nonpharmacological interventions were popular; few parents were familiar with the silk garments. Patterns of wear varied with children under 3 years wearing the garments most. Concern was voiced about quality, fit and cost. Parents reported limited improvement in skin condition although there was some symptomatic relief
Summary of nested qualitative study with clinicians and commissioners	
Design	Exploratory qualitative study with purposive sampling, semistructured telephone interviews and a framework data analysis process
Participants	Twenty-one clinicians and commissioners comprising dermatology specialist nurses (n = 9), dermatologists (n = 4), general practitioners (n = 3), pharmacists (n = 3) and healthcare commissioners (n = 2)
Key findings	Participants generally had limited experience of using silk garments and were aware of a lack of evidence base. On the whole, the garments were viewed as an expensive treatment option although some envisaged they could be cost effective

outcome had been collected at 6 months. Demographic details are provided in Table 2.

Data collection

Ten face-to-face or telephone interviews with children aged 9 years and over (10–40 min in duration) and three focus group discussions, two with 7- to 8-year olds (n = 2 for both groups), and one with 5- to 6-year olds (n = 4) (90–120 min), 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 summarized in Table 3. 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 E.W. spent time with the children getting to know them, making introductions and checking that they were willing to take part. Interviews were conducted by E.W. Focus groups were facilitated by E.W. and an observer was present to take notes and ensure the well-being of participants. Children were not pressurized to join in any activities and we were careful not to interpret a child 'just watching from the side' as nonparticipating. 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 E.W. 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 (Fig. 1), and they used

Table 2 Demographic information of participants

Sex and years of age	Focus group/interview
Girl 5–6	Focus group
Girl 5–6	Focus group
Girl 5–6	Focus group
Boy 5–6	Focus group
Boy 7–8	Focus group
Girl 7–8	Focus group
Boy 7–8	Focus group
Girl 7–8	Focus group
Boy 11	Face-to-face interview
Girl 9	Face-to-face interview
Boy 9	Face-to-face interview
Girl 9	Face-to-face interview
Girl 15	Face-to-face interview
Girl 12	Face-to-face interview
Boy 10	Face-to-face interview
Girl 9	Telephone interview
Girl 10	Telephone interview
Boy 13	Telephone interview

Table 3 Topic guide for data collection

Grand-tour question	Tell me a bit about your eczema: what it's like living with it
Mini-tour questions	How have you got on with the clothing? How much did you wear the clothing? (Day/night/away from home) What was it like wearing the clothing? (Skin condition, comments from others)
Example questions	Can you tell me about any differences you have noticed? (Skin condition/well-being)
Experience questions	Were there particular things you liked or did not like about using the special garments?

drawings, stickers and two-dimensional foam people to share their experiences. Towards the end of each data-collection session, E.W. 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 E.W. to ensure authenticity in data analysis and reporting. Each interaction ended with E.W. 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 5–15 years varied in terms of content and the ways in which they were communicated. However, as seen in the data analysis below some strong and consistent messages were provided.

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

Fig 1. Billy the puppet.

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 that affected the verbal and nonverbal language they used. The analysis process was not linear but moved back and forth between wholes and parts. F.C. and E.W. 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 were 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 that they 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 four themes directly related to the silk garments: (i) expectations of the garments; (ii) wearing the garments; (iii) whether or not they helped; 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 (Table 4)

This theme comprised three subthemes: 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 for, or doubts about, the effect on their eczema.

Theme 2: Wearing the garments (Table 5)

This theme addresses the times at which children chose to wear the garments. There are two subthemes: 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.

Theme 3: Did they help? (Table 6)

This theme has three subthemes: 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, while 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, while 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.

Table 4 Theme 1: Expectations of the garments

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.'	'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.'		

Table 5 Theme 2: Wearing 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.'	'I wore them to school but not PE days . . . people would laugh.'
'Wearing them at night because some people ask like what's that and it's a bit annoying.'	'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 everyone was like "What is that?".'

Theme 4: Thoughts about the garments (Table 7)

Thoughts about the garments comprised three subthemes: 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 (Fig. 2). Older children reported using the garments as advised, allowing creams to 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

Table 6 Theme 3: Did they help?

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

Table 7 Theme 4: Thoughts about the garments

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.'	

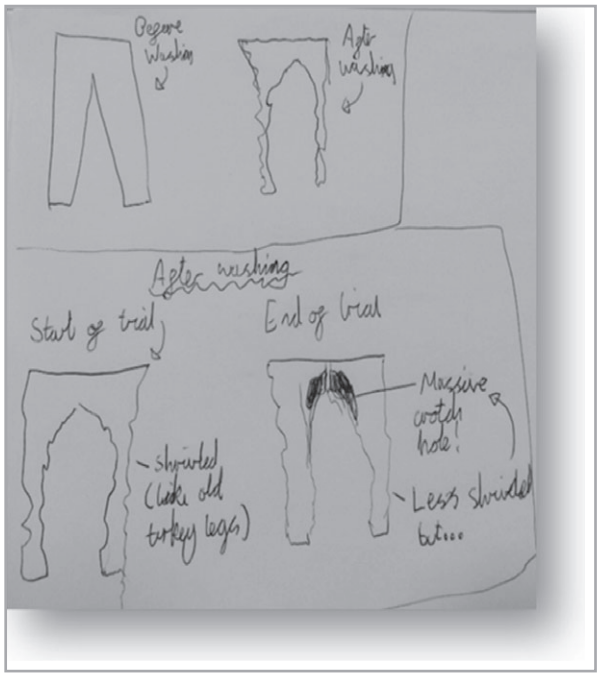

Fig 2. Illustrations of silk garments before and after use and washing.

to buy and should be available on prescription from a general practitioner.

Discussion

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 allowed deeper understanding, particularly about patterns of adherence and reasons for nonadherence.

The child data reported here have uncovered insights that 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 datasets separately and then triangulate ensured no contamination while 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 nonpharmacological 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 have provided a deeper, richer and more detailed understanding of the 'what', 'why' and 'how come' underpinning participants' 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 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 on the 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 adherence.

In terms of relevance to other studies, while many researchers aspire to include children in meaningful ways – for example Hussain[12] – a recent review of 506 peer-reviewed studies conducted between 2009 and 2012 involving children aged 0–8 years analysed child positioning, researcher perspective

and level of respectful culture in each study, concluding that only 3·4% positioned children in inclusive, participatory roles.[5] Our 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.

A strength of this study is that trustworthiness is ensured by documentation of the decision trail[24] and reporting in line with Standards for Reporting Qualitative Research guidance.[25] A limitation is self-selection of participants as they may not be representative of the trial cohort. Also, 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 so 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 the 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. Ours 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.

In 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 garments 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 to prescribed treatment regimens. Therefore there is a need to include children in the evaluation of proposed products from the design phase of trials, and thought should be given as to how best to triangulate data. Broadly, the child and parent data concur, 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 that were not always seasonally influenced. Children's explanations of nonadherence 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 nonadherence in wearing the garments that would not have been revealed from other data.

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Appendix

Members of the CLOTHES Trial Team (contributors): Staff at recruiting centres: Hywel Williams, Principal Investigator; Sandra Lawton, Nurse Consultant; Jo Llewellyn, Research Nurse; Taraneh Dean, Principal Investigator; Jane Grundy, Research Nurse; Ian Pollock, Principal Investigator; Juliet Guinness, Research Nurse; Nigel Burrows, Principal Investigator; Clare Crang, Research Nurse; Andrew Gribbin, Research Nurse. Nottingham Clinical Trials Unit: Lelia Duley, Director of Nottingham Clinical Trials Unit and advisor on trial design; Lucy Bradshaw, Medical Statistician; Rachel Haines, Trial Manager; Eleanor Mitchell, Senior Trial Manager; Alan Montgomery, Professor of Statistics and Clinical Trials; Andrew Jadowski, Trial Administrator; Jennifer White, Trial Coordinator; Sarah Walker, Data Coordinator; Tessa Clarke, Senior Trial Manager; Trish Hepburn, Senior Medical Statistician; Justin Fenty, Senior Statistician; Lucinda Murphy, Data Manager; Daniel Simpkins, IT and Data Manager; Chris Rumsey, IT Programmer. Other support staff at recruiting centres: Hannah Buckley, Principal Investigator; Sharon McCready, Research Nurse Lead; Rachel Watson, Clinical Trials Assistant; Gill Glasbey, Research Study Coordinator. Contributors to the qualitative study: Rachel Harding, Paediatric Nurse; Jo Aspland, Research Associate. Health Economics lead: Tracey Sach. Patient & Public Involvement representative: Amina Ahmed.

Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website:

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BIMZELX is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[1]

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PRESCRIBING INFORMATION

(Please consult the Summary of Product Characteristics (SmPC) before prescribing)

BIMZELX® ▼ (Bimekizumab)

Active Ingredient: Bimekizumab – solution for injection in pre-filled syringe or pre-filled pen: *160 mg of bimekizumab in 1 mL of solution (160mg/mL)*. **Indications:** Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **Dosage and Administration:** Should be initiated and supervised by a physician experienced in the diagnosis and treatment of plaque psoriasis. **Recommended dose:** 320 mg (given as two subcutaneous injections of 160 mg each) at week 0, 4, 8, 12, 16 and every 8 weeks thereafter. For some patients with a body weight ≥ 120 kg who did not achieve complete skin clearance at week 16, 320 mg every 4 weeks after week 16 may further improve treatment response. Consider discontinuing if no improvement by 16 weeks of treatment. Renal or hepatic impairment: No dose adjustment needed. Elderly: No dose adjustment needed. Administer by subcutaneous injection to thigh, abdomen or upper arm. Rotate injection sites and do not inject into psoriatic plaques or skin that is tender, bruised, erythematous or indurated. Do not shake pre-filled syringe or pre-filled pen. Patients may be trained to self-inject. **Contraindications:** Hypersensitivity to bimekizumab or any excipient; Clinically important active infections (e.g. active tuberculosis). **Warnings and Precautions:** Record name and batch number of administered product. *Infection:* Bimekizumab may increase the risk of infections e.g. upper respiratory tract infections, oral candidiasis. Caution when considering use in patients with a chronic infection or a history of recurrent infection. Must not be initiated if any clinically important active infection until infection resolves or is adequately treated. Advise patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a clinically important infection develops or is not responding to standard therapy, carefully monitor and do not administer bimekizumab until infection resolves. *TB:* Evaluate for TB infection prior to initiating bimekizumab – do not give if active TB. While on bimekizumab, monitor for signs and symptoms of active TB. Consider anti-TB therapy prior to bimekizumab initiation if past history of latent or active TB in whom adequate treatment course cannot be confirmed. *Inflammatory bowel disease:* Bimekizumab is not recommended in patients with inflammatory bowel disease. Cases of new or exacerbations of inflammatory bowel disease have been reported. If inflammatory bowel disease signs/symptoms develop or patient experiences exacerbation of pre-existing inflammatory bowel disease, discontinue bimekizumab and initiate medical management. *Hypersensitivity:* Serious hypersensitivity reactions including anaphylactic reactions have been observed with IL-17 inhibitors. If a serious hypersensitivity reaction occurs, discontinue immediately and treat. *Vaccinations:* Complete all age appropriate immunisations prior to bimekizumab initiation. Do not give live vaccines to bimekizumab patients. Patients may receive inactivated or non-live vaccinations. **Interactions:** A clinically relevant effect on CYP450 substrates with a narrow therapeutic index in which the dose is individually adjusted e.g. warfarin, cannot be excluded. Therapeutic monitoring should be considered. **Fertility, pregnancy and lactation:** Women of child-bearing potential should use an effective method of contraception during treatment and for at least 17 weeks after treatment. Avoid use of bimekizumab during pregnancy and breastfeeding. Discontinue breastfeeding or discontinue bimekizumab during breastfeeding. It is unknown whether bimekizumab is excreted in human milk, hence a risk to the newborn/infant cannot be excluded. No data available on human fertility. **Driving and use of machines:** No or negligible influence on ability to drive and use machines. **Adverse Effects: Refer to SmPC for full information.** Very Common *(≥ 1/10)*: upper respiratory tract infection; Common *(≥ 1/100 to < 1/10):* oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis; headache, dermatitis and eczema, acne, injection site reactions, fatigue; Uncommon *(≥ 1/1,000 to < 1/100):* mucosal and cutaneous candidiasis (including oesophageal candidiasis), conjunctivitis, neutropenia, inflammatory bowel disease. **Storage precautions:** Store in a refrigerator (2°C – 8°C), do not freeze. Keep in outer carton to protect from light. Bimzelx can be kept at up to 25°C for a single period of maximum 25 days with protection from light. Product should be discarded after this period or by the expiry date, whichever occurs first.
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Northern Ireland: EU/1/21/1575/002 (2 x 1 Pre-filled Syringes), EU/1/21/1575/006 (2 x 1 Pre-filled Pens) Great Britain: PLGB 00039/0802 (Pre-filled Syringe), PLGB 00039/0803 (Pre-filled Pen). UK NHS Costs: £2,443 per pack of 2 pre-filled syringes or pens of 160 mg each.
Marketing Authorisation Holder: UCB Pharma S.A., Allée de la Recherche 60, B-1070 Brussels, Belgium (Northern Ireland). UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE, United Kingdom (Great Britain).
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References: 1. BIMZELX (bimekizumab) Summary of Product Characteristics. Available from: https://www.medicines.org.uk/emc/product/12834/smpc. Accessed April 2023. **2.** Strober B et al. Poster P1491 presented at the European Academy of Dermatology and Venereology (EADV) meeting, September 7–10 2022; Milan, Italy.

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