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Ingrid Muller, Beth Stuart, Tracey Sach, Lucy Yardley, Kate Greenwell, Taeko Becque, Paul Leighton, Laura Howells, Jane Harvey, Julie Hooper, Mary Steele, Katy Sivyer, Daniela Ghio, Emma Teasdale, Emma Axon, Stephanie Lax, Holly Clarke, Mary Onoja, Amina Ahmed, Gareth Griffiths, Hayden Kirk, Sinead Langan, Sandra Lawton, Paul Little, Matthew Ridd, Amanda Roberts, Hywel C Williams, Kim S Thomas and Miriam Santer

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Extended Research Article

Supporting self-care for eczema in the community: the Eczema Care Online research programme including two RCTs

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This article

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Abstract

Background: Eczema is a common condition with significant impact on quality of life. The main cause of treatment failure is non-use of prescribed treatments because treatments are time-consuming to apply; they may sting when first applied to inflamed skin; there are concerns about the safety of some treatments; and because people often receive conflicting advice about how and when to use them.

Objectives: Objectives of the present study are to: (1) explore the self-care support needs of children with eczema and their parents/carers, and young people with eczema, (2) review current best evidence about the safest and best ways to use topical corticosteroids for eczema, (3) develop theory-, evidence- and person-based online interventions to support eczema self-management in young people with eczema and parents/carers of children with eczema, (4) evaluate the clinical and cost-effectiveness of the interventions in two randomised controlled trials and (5) conduct a process evaluation and implementation planning.

Design: Five qualitative studies, four systematic reviews (one qualitative) and two parallel randomised controlled trials with nested process evaluation and economic evaluation.

Setting: Primary care.

Participants: Children and young people aged 13–25 years with eczema, and parents/carers of children aged 0–12 years with eczema. Participants with very mild or inactive eczema were excluded.

Interventions: We developed and evaluated two online behavioural interventions to support eczema management in: (1) young people and (2) parents/carers of children. Participants were not blinded to group allocation.

Main outcome measures: Primary outcome measure in the randomised controlled trials was participant-reported eczema severity measured by the patient-oriented eczema measure over 24 weeks. Secondary outcomes included patient-oriented eczema measures over 52 weeks, quality of life and patient enablement.

Results: Qualitative reviews and interviews provided in-depth understanding of the views, experiences and contexts within which young people and families manage eczema and identified barriers and facilitators to key behaviours. Systematic literature reviews on topical corticosteroid safety and effectiveness found no evidence of harm when topical corticosteroids were used intermittently to treat or prevent eczema flares. Our Cochrane review, which included 104 trials (8443 participants), found that potent and moderate topical corticosteroids are probably more effective than mild topical corticosteroids for treating moderate or severe eczema and that effectiveness is similar between once and twice daily use.

Findings informed development of two online interventions, which were evaluated in two randomised controlled trials comparing intervention plus usual care to usual care only. Three hundred and forty parents/carers (169 usual care; 171 intervention) and 337 young people (169 usual care; 168 intervention) were randomised [mean baseline patient-oriented eczema measure 12.8 (standard deviation 5.3) and 15.2 (standard deviation 5.4), respectively]. An intention-to-treat analysis approach to the analysis was taken. Follow-up rates were: 92.4% (314/340) parents/carers and 90.2% (304/337) young people at 24 weeks.

Compared with usual care over 24 weeks, eczema severity (patient-oriented eczema measure) improved in the intervention groups: adjusted mean difference −1.5 (95% confidence interval −2.5 to −0.6) for parents/carers, and −1.9 (95% confidence interval −3.0 to −0.8) for young people. Effects were sustained for 52 weeks in both groups. Enablement showed an important difference favouring the intervention group in both trials [adjusted mean difference at 24 weeks −0.7 (95% confidence interval −1.0 to −0.4) for parents/carers and −0.9 (95% confidence interval −1.3 to −0.6) for young people]. No harms were identified in either group. Economic analysis found both interventions were low cost and cost-effective with almost all analyses (with the exception of the complete-case cost–utility analysis for the parent/carer trial) estimating the interventions to be dominant (cost saving and effective).

Process evaluation demonstrated that both groups found the interventions usable, relatable and trustworthy, and perceived that they helped to manage their eczema. The interventions have been redeveloped into an English and Welsh product ready for dissemination and an implementation strategy has been developed.

Limitations: This research was conducted during the COVID-19 pandemic. While this did not have a major impact on our research plans or delivery, it may have had impacts (positive and negative) on people's eczema, their eczema management and access to health care.

Conclusions: Eczema Care Online is effective and acceptable to its target groups. Findings from this programme support the wide-scale implementation of the interventions, available at www.eczemacareonline.org.uk.

Future work: Future work may explore how Eczema Care Online can be implemented in different settings and contexts and adapted for severe eczema. More research is also needed on the long-term safety of topical corticosteroids.

Trial registration: This trial is registered as Current Controlled Trials ISRCTN79282252.

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Report Supplementary Material 2	Template for Intervention Description and Replication checklist
Report Supplementary Material 3	National Institute for Health and Care Excellence evidence summary
Report Supplementary Material 4	Questionnaire booklet of RCT measures

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/10.3310/FNHD8546).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

AMSTAR	A MeaSurement Tool to Assess systematic Reviews
CEA	cost-effectiveness analysis
CEAC	cost-effectiveness acceptability curve
CHU-9D	Child Health Utility Nine Dimensions
CONSORT	Consolidated Standards of Reporting Trials
CUA	cost–utility analysis
EASI	Eczema Area and Severity Index
ECO	Eczema Care Online
EOS	Eczema Outreach Support
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
GP	general practice or general practitioner
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HOME	Harmonizing Outcome Measures for Eczema
HTA	Health Technology Assessment
ICER	incremental cost-effectiveness ratio
MCID	minimum/minimal(ly) clinically important difference
NES	National Eczema Society
NIHR	National Institute for Health and Care Research
NMB	net monetary benefit
NPT	normalisation process theory
PEI	patient enablement instrument
PETS	Problematic Experiences of Therapy Scale
PGfAR	NIHR Programme Grants for Applied Research
POEM	patient-oriented eczema measure
PPI	patient and public involvement
QALY	quality-adjusted life-year
RCT	randomised controlled trial
RECAP	recap for atopic eczema patients
SA	sensitivity analysis
SAP	statistical analysis plan
TCI	topical calcineurin inhibitor
TCS	topical corticosteroids
WTP	willingness to pay

Plain language summary

Eczema is a very common skin condition and can reduce quality of life for various reasons including itching and poor sleep. Eczema treatments include regular moisturisers (emollients) and flare-control cream (usually steroid cream). People often do not use these for a range of reasons, including uncertainty about how to use them and concerns about their safety.

We spoke to over 130 young people, children and families to get an in-depth understanding of their views and experiences around eczema management. We also looked at all the evidence about the best and safest ways to use flare control creams. These findings were brought together in websites to support (1) young people with eczema and (2) parents/carers of children to help them manage their eczema. The two websites were tested in two large trials where young people and parents/carers of children with eczema were recruited by general practices in England. If they chose to take part, half were randomised to be given access to the website. Everyone still accessed their usual eczema care and got treatments in the same way. Participants were asked to fill in questionnaires for a year to ask about their eczema. We found that the websites helped improve eczema over 24 weeks when compared to usual care on its own. This improvement could still be seen after 1 year. The websites represent good value for money, and interviews with people who used them found that the websites were highly valued.

Our eczema websites lead to small but long-lasting improvements in eczema. We have redeveloped these into a single website, available in English and Welsh, and developed plans to promote the website in the National Health Service and in the community. The website can be found at www.eczemacareonline.org.uk and is free to use with no registration.

Scientific summary

Background

Eczema is a common itchy skin condition with a significant impact on quality of life. For most people with eczema, treatments include flare-control creams [topical corticosteroids (TCSs) and topical calcineurin inhibitors] to manage disease exacerbations and daily emollient moisturisers. The main cause of treatment failure is non-use of prescribed treatments for reasons such as treatments being time-consuming to apply; that they may sting when first applied to inflamed skin; concerns about the safety of some treatments; and because people often receive conflicting or insufficient advice about how and when to use them.

Objectives

1. To understand facilitators and barriers to effective eczema management for patients and parents/carers.
2. To update and combine existing evidence around the safety of TCSs and develop knowledge tools for patients and healthcare professionals.
3. To develop online behavioural interventions to support eczema self-care for patients and parents/carers.
4. To determine the clinical and cost-effectiveness of online behavioural self-care interventions compared to standard clinical care.
5. To formulate and initiate an implementation plan for integrating interventions into clinical practice and facilitating their uptake, informed by process evaluation.

Methods

This programme consists of five related workstreams.

1. Understanding barriers and facilitators to effective eczema management

We carried out extensive qualitative work to inform intervention development.

1. We conducted a systematic review and thematic synthesis of qualitative studies to explore the views and experiences of people with eczema and parents/carers of children with eczema.
2. We conducted a secondary analysis of 23 transcripts of interviews with young people aged 16–25 years with eczema collected as part of the HealthTalk.org SKINS project.
3. Primary qualitative research was conducted with (1) children aged 6–12 with eczema, (2) young people aged 13–25 with eczema and (3) parents/carers of children aged 0–12 with eczema. Participants were recruited through primary care and secondary care. Interviews were analysed using thematic analysis.

Analyses in all three of these studies explored views and experiences of topics such as living with eczema, eczema treatments, perceived causes and triggers and experiences of transitioning to co-management or self-management.

2. Evidence for the best and safest way of using topical corticosteroids

We reviewed the scientific evidence of the best and safest ways of using TCSs for eczema through three systematic reviews of the literature.

1. We conducted an umbrella review of systematic reviews of studies using topical steroids for eczema to summarise what is already known about the safety of using TCSs from published systematic reviews.
2. We conducted a Cochrane review of randomised controlled trials (RCTs) evaluating different strategies for using TCSs to examine the safety and effectiveness of different strategies.
3. We conducted a systematic review of the longer-term safety of TCSs for eczema when used for more than a year.

Key findings informed knowledge support tools for patients and health professionals to support the appropriate use of eczema treatments and ensure consistent messaging and signpost to Eczema Care Online (ECO).

3. Developing interventions to support eczema self-care

Two complex behavioural interventions were developed to support eczema management: one for young people aged 13–25 years and other for parents/carers of children aged 0–12 years with eczema. The interventions were online and developed using theory-based, evidence-based and person-based approaches. The interventions were co-produced with an intervention development group which comprised patient and public contributors, dermatologists, nurses, general practitioners (GPs), psychologists and skin researchers. Intervention planning was carried out alongside workstreams 1 and 2 to guide our programme theory and provide us with an in-depth understanding of the key issues, needs and behavioural challenges of our two target groups.

Programme theory was developed for each intervention, including guiding principles, behavioural analysis and an intervention logic model. Intervention materials and prototype interventions were optimised using qualitative think-aloud interviews with participants recruited through database search and mail-outs from eight GP practices. Interviews were analysed using the person-based approach table of changes.

4. Clinical and cost-effectiveness of our online behavioural interventions

Two independent, pragmatic, parallel-group, online RCTs were conducted to determine the clinical and cost-effectiveness of the two online behavioural interventions developed in workstream 3. Participants were recruited through database search and mail-outs from 98 general practices in England. Participants were eligible to take part if they were a young person aged 13–25 years with eczema (trial 1) or a parent/carer of a child aged 0–12 years with eczema (trial 2). People were excluded if they reported very mild or inactive eczema [scoring 5 or less on the patient-oriented eczema measure (POEM)].

Eligible participants were randomised (1 : 1) to receive usual eczema care, or to an online behavioural intervention for eczema plus usual care. Participants in the usual care group were given access to the intervention at the end of the trial period. The primary outcome in both trials was eczema symptoms reported using POEM every 4 weeks for 24 weeks. POEM includes seven questions about the frequency of eczema symptoms over the previous week that are summed to give a score from 0 (no eczema) to 28 (worst possible eczema). Secondary outcomes included POEM scores every 4 weeks over 52 weeks, quality of life, eczema control, itch intensity (young people only), patient enablement, treatment use, adherence problems and intervention use (intervention group only). Service and treatment use data were collected through medical notes review. Separate analyses were carried out for each of the two trials, and according to intention-to-treat principles. Health economic evaluations were conducted from an NHS perspective and included cost–utility and cost-effectiveness analyses.

5. Integrating interventions into clinical practice and facilitating uptake

A qualitative and quantitative process evaluation was nested within the two trials to understand likely causal mechanisms for the interventions, how effects may vary between user groups and settings, and to inform implementation of the interventions. Semistructured qualitative interviews were conducted with a sample of trial participants selected using purposive sampling to ensure a range of ages, gender, ethnicity, eczema severity, socioeconomic status, recruitment site, trial group and intervention usage. Interviews explored views of the website content, delivery features, changes that resulted from the intervention, the impact of the COVID-19 pandemic and reasons for any low intervention usage. Interviews from both groups were analysed together using thematic analysis. Intervention modifications for dissemination were identified using the person-based approach table of changes method.

Intervention usage data were collected to describe patterns of intervention usage for all participants in the intervention arm. Mediation analysis was used to determine whether patient enablement, treatment use or barriers to adherence mediate the intervention effect on eczema severity. Subgroup analysis was carried out to explore whether the intervention effect was different among pre-specified categories of baseline variables. Logistic regression explored associations between higher intervention use and various demographic and baseline factors.

We developed an implementation strategy in consultation with a wide range of stakeholders.

Results

1. Understanding barriers and facilitators to effective eczema management

Database searches and screening identified 39 papers reporting 32 qualitative studies for review. Thematic synthesis of the data identified four overarching analytical themes: (1) eczema not viewed as a long-term condition; (2) significant psychosocial impact of eczema not acknowledged by others; (3) hesitancy (patient/carer uncertainty) about eczema treatments; and (4) insufficient information and advice about eczema. Review findings informed workstream 3 intervention planning and guided our primary qualitative research.

Qualitative data from 72 participants were analysed in this workstream. The sample included 30 parents of children aged 0–12 years, 14 children aged 6–12 years, 5 young people aged 13–16 years, plus secondary analysis of data collected from 23 young people aged 16–24 years (SKINS project). Findings enabled us to develop an in-depth understanding of the views and experiences of young people and families managing eczema. Key barriers and facilitators were identified, which support the development of our programme theory and behavioural interventions in workstream 3.

2. Evidence for the best and safest way of using topical corticosteroids

Database searches for the umbrella review identified 38 systematic reviews of the safety of TCS in eczema which included 106 studies (77 RCTs and 29 observational studies). No evidence was found that TCSs cause harm when used intermittently 'as required' to treatment eczema flares or as 'weekend therapy' to prevent flares. Adverse events were uncommon with short-term use of TCSs, but high-quality evidence was limited.

The Cochrane systematic review of safety and effectiveness of different strategies of using TCSs for eczema included 104 RCTs with a total of 8443 participants. Key findings included evidence that moderate and potent TCS are better than mild TCSs, that once-daily use of TCSs is as effective as twice daily and that 'weekend therapy' is effective and safe for preventing flares. Reported adverse events were infrequent.

Our systematic review of the long-term safety of TCS for eczema included two RCTs (n = 2570, including 1288 receiving TCS), two cohort studies (all participants received some form of TCS n = 148) and three case-control studies (cases n = 10,322, controls n = 12,201). Overall, the limited body of evidence provides some indication that TCSs used intermittently for eczema are safe over periods of up to 5 years, but gaps remain in our understanding of the lifelong effects of TCS use.

Key findings from this programme were developed into a knowledge tool following extensive stakeholder engagement. The tool signpost to EczemaCareOnline.org.uk and focuses on the primary message of the main interventions, 'two treatments used well', to support consistent messaging around treatment use among health professionals and people and families with eczema.

3. Developing interventions to support eczema self-care

Findings from workstreams 1 and 2 informed the programme theory and evidence base for intervention development. The interventions were developed to target the following key behaviours:

- Improve emollient use.
- Improve the use of TCSs for flare-ups.
- Improve management of irritants and triggers.
- Improve emotional management.
- Reduce scratching.

The online interventions were developed and optimised through qualitative think-aloud interviews with 25 parents/carers of children with eczema and 30 young people aged 13–25 years with eczema. Interviews lasted 45–90 minutes and were recorded and transcribed verbatim. Participants found the information and advice clear, easy to follow, helpful and relatable, particularly the quotes and tips from others like them. Participants found the information on TCSs reassuring. Young people found most content interesting and helpful, whereas parents/carers found the initial prototype

intervention lengthy and repetitive, which led to the content being streamlined and made more interactive, which participants valued and found acceptable and engaging.

4. Clinical and cost-effectiveness of our two online behavioural interventions to support eczema management

Three hundred and forty parents/carers of children (169 usual care; 171 intervention) and 337 young people (169 usual care; 168 intervention) were randomised into the trials. All randomised participants were included in the analyses. Retention was excellent: 92.4% (314/340) parents/carers and 90.2% (304/337) young people at 24 weeks.

Our two brief online behavioural interventions to support eczema management for parents/carers of children and for young people provided a useful benefit in eczema severity at 24 weeks. After controlling for baseline severity and confounders, compared with usual care over 24 weeks, eczema severity (POEM) improved in the intervention groups: −1.5 [95% confidence interval (CI) −2.5 to −0.6] for parents/carers, and −1.9 (95% CI −3.0 to −0.8) for young people. Effects were sustained for 52 weeks in both trials. No harm or unintended effects were identified in either group.

We did not detect a difference in the use of eczema treatments between groups, yet did find statistically significant differences between groups in patient enablement instrument scores. Enablement showed an important difference favouring the intervention group in both trials [adjusted mean difference at 24 weeks −0.7 (95% CI −1.0 to −0.4) for parents/carers and −0.9 (95% CI −1.3 to −0.6) for young people].

Economic analysis found that both interventions were low cost and cost-effective with almost all analyses estimating the interventions to be dominant (that is cost saving and more effective than usual care). The exception was the cost–utility analysis for the parent/carer trial where the incremental cost per quality-adjusted life-years was < £20,000.

5. Process evaluation and implementation to integrate interventions into clinical practice and facilitate uptake

Qualitative process evaluation included interviews with 17 parents/carers and 17 young people who took part in the RCTs. Feedback was mostly positive. Participants found the intervention trustworthy and valuable, and participants felt the intervention websites helped them manage their or their child's eczema. Participants reported that ECO helped them to understand and feel confident in managing eczema; improve their use of treatments; avoid irritants and triggers; engage in productive treatment conversations with health professionals; and involve their child in eczema management (parents).

Quantitative process evaluation found that, for parents/carers, about 30% of the intervention effect on the POEM score at 24 weeks was mediated by increasing patient enablement. For young people, about 50% of the intervention effect was mediated by increasing enablement.

Process evaluation showed that the interventions were commonly accessed on smartphones, suggesting the need for an adaptable product and that we needed a stable platform over a few years where software would be updated. As part of our implementation strategy, we therefore decided to redevelop the interventions into a product for dissemination. We worked with a commercial software provider to develop the two interventions into one mobile adaptive website www.eczemacareonline.org.uk. Theory-informed analysis of the qualitative work in this programme and stakeholder consultations also enabled us to identify value propositions (unique identified benefits of the product within the marketplace), target audiences, key stakeholders and avenues for implementation.

Conclusions

We have developed, tested and implemented online interventions to support the self-management of eczema. The benefits on clinical outcomes of using the ECO intervention have been demonstrated in two RCTs, targeting two key user groups: parents of children with eczema and young people learning to manage their own eczema. A within-trial cost-effectiveness analysis suggests that use of the intervention represents value for money for the NHS, resulting in potential cost savings and improved outcomes.

In eczema, self-management support is particularly important due to the complexity and high burden of treatment adherence. By promoting the use of ECO, as well as providing evidence that the interventions improve eczema outcomes, we hope that signposting to self-management support will become increasingly embedded in routine care.

Our two interventions have been redeveloped into one website www.eczemacareonline.org.uk. This resource is freely available in English and Welsh.

Trial registrations

The trial is registered as Current Controlled Trials ISRCTN79282252.

- Workstream 1: systematic review of qualitative studies PROSPERO registration number CRD42018110496.
- Workstream 2: umbrella review PROSPERO registration number CRD42018079409.
- Workstream 2: Cochrane review CD013356.
- Workstream 2: long-term safety review PROSPERO registration number CRD42021286413.
- Workstream 4: trials are registered ISRCTN79282252.

Funding

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Synopsis

Research summary

Eczema is very common and can cause substantial impact on quality of life for many reasons including sleep disturbance and itch.[1,2] Families of children with eczema express frustration that they receive insufficient or conflicting information about how to manage the condition,[3] as do adults with eczema.[4] People with eczema have highlighted the need for tailored information that explains underlying principles in order to motivate treatment adherence.[5,6] Reasons for non-adherence include:[2]

- Therapy being time-intensive.[7,8]
- Poor understanding of treatments and how to use them.[7]
- Underuse of topical corticosteroids (TCSs) related to fear of side effects.[9]
- Conflicting advice from different health professionals regarding how to use TCSs.[10]
- Child refusal.[8]

Self-care includes all the health behaviours that people take to look after their condition, including treatment adherence. Non-adherence is related to people's understanding of their condition and its treatment, as well as perceived need for treatments and concerns about adverse consequences of treatments.[11] Self-care is particularly complex in eczema as it involves regular application of topical treatments (mainly emollients for maintenance and TCSs for inflamed eczema) and avoidance of triggers (e.g. dust). Presently, many people with eczema or their parents/carers receive little advice on how to manage their condition or obtain advice of variable quality from the internet.[12] There is a need for high-quality interventions accessible for all, as well as evidence of whether they work so that clinicians can signpost towards these as an essential part of routine care.[2]

Importance and relevance of the Eczema Care Online programme

Childhood eczema is very common, affecting over 20% of children aged 5 or less[13,14] and 10% of adults.[15] Research among children with eczema in secondary care suggests that the impact on quality of life from severe eczema is second only to cerebral palsy, with greater impact than for asthma or diabetes[16] and adults with eczema can also suffer severe impact.[17] Although the majority of eczema is 'mild', this can still cause substantial impact on quality of life.[18] Although there is a common perception that eczema mainly affects young children, approximately 40% continue to experience symptoms into adulthood. Teenagers and adults often experience more severe disease and a substantial impact on quality of life, healthcare costs and work/school absence.[19]

Qualitative research has illustrated the impact on both children and adults:

> *She hardly got any sleep, she scratched herself, and she was at a point where she couldn't keep up at school, she was totally exhausted.*[3]

For some families of children with eczema, regularly applying topical treatments can become distressing:

> *She's kicking and going and screaming, people must think that we are really sort of hurting her …*[10]

Eczema has considerable socioeconomic impact,[20] and, on the basis of trial data (Softened Water Eczema Trial[21] and CLOTHES[22]), we estimate the current annual cost of eczema to the NHS to be between £3.48B and £4.43B. Previous research has demonstrated the potential value of education-based interventions for eczema. One trial has demonstrated improved eczema outcomes following 12-hour group training for eczema,[23] but international data suggest that availability of eczema education is limited in most countries.[24]

This programme of work addressed priority areas for eczema research as identified by a James Lind Alliance Eczema Priority Setting Partnership:[25]

- What is the best way of delivering eczema care and support?
- What is the long-term safety of TCSs?

These priorities are linked, as uncertainty about TCS safety appears to lead to inconsistent advice from health professionals and is a barrier to self-care among people with eczema or their parents/carers.

Original aims and objectives

The programme of work set out to improve the lives of people with eczema by developing and testing online behavioural interventions (websites) that will support self-care and address common barriers to eczema self-care, including concerns around TCSs.

The objectives of the programme are shown in *Figure 1*. These are:

1. To understand facilitators and barriers to effective eczema management for patients and parents/carers.
2. To update and combine existing evidence around the safety of TCSs and develop knowledge tools for patients and healthcare professionals.
3. to Develop online behavioural interventions to support eczema self-care for patients and parents/carers (informed by findings from workstreams 1 and 2).
4. To determine the clinical and cost-effectiveness of online behavioural self-care interventions compared to standard clinical care.
5. To formulate and initiate an implementation plan for integrating interventions into clinical practice and facilitating their uptake (if clinically and cost-effective), informed by process evaluation.

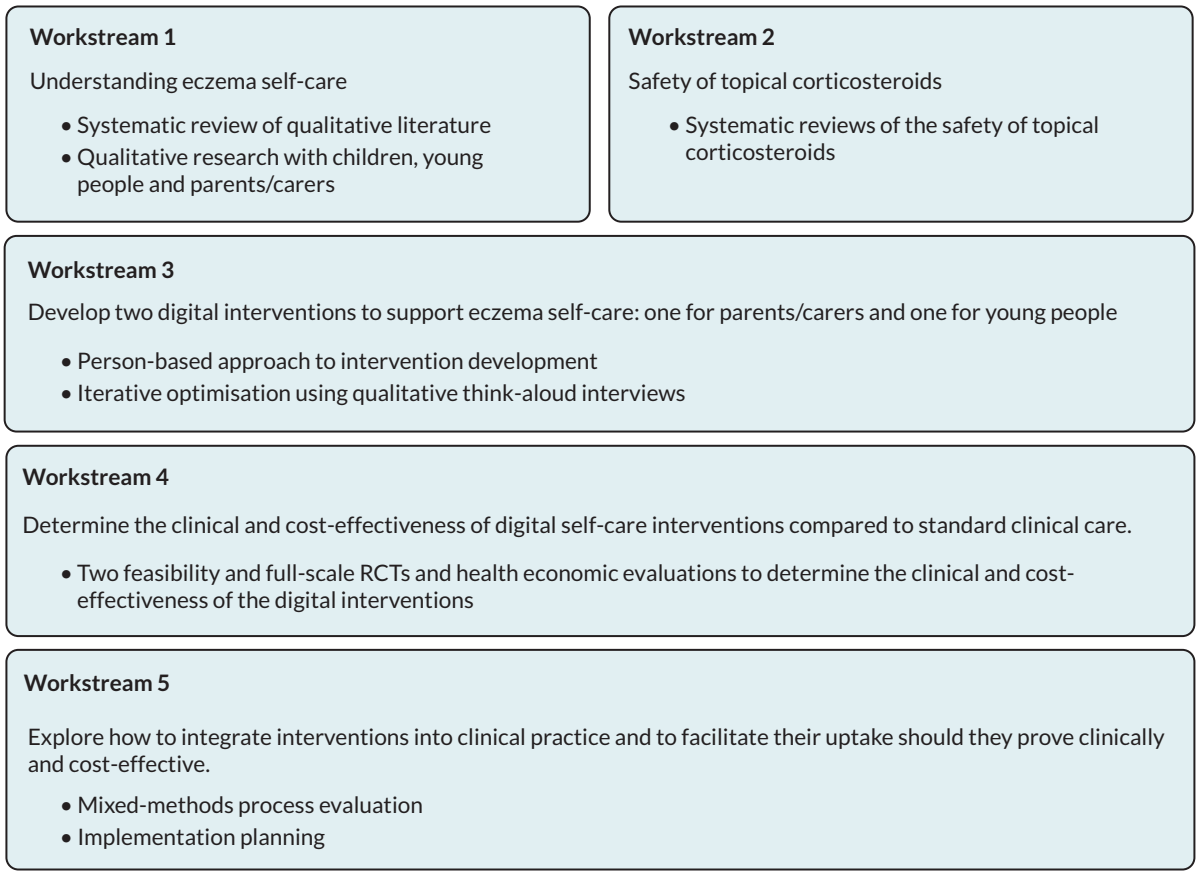

FIGURE 1 Overview of ECO workstreams.

Modifications to original aims

Changes to workstream 2

We originally planned to conduct two systematic reviews on the safety of TCSs: one of randomised controlled trial (RCT) data and one of observational study data. Feedback from patients and carers challenged that it is not sufficient to look at the safety of TCSs in isolation, as safety is closely linked to the concept of 'appropriate use' of TCSs. In response, we enlarged the scope of our planned review of RCTs to include effectiveness outcomes as well as safety outcomes, and to explicitly examine different strategies for using TCSs (e.g. once daily vs. twice daily, reactive vs. proactive therapy). We delivered three systematic reviews as part of workstream 2:

1. Umbrella review of published systematic reviews on the safety of TCSs in eczema.
2. Cochrane systematic review of the best and safest ways of using TCSs in eczema (RCT evidence only).
3. Systematic review of the longer-term safety of TCSs (RCT and observational studies with more than 1 year of follow-up).

Changes to workstream 4

Minor modifications were made to the designs of the two RCTs to improve their efficiency and in response to the COVID-19 pandemic. We originally planned to conduct two feasibility RCTs, but through our robust intervention development work, and iterative feedback from users, we were able to establish that changes to the intervention would be very unlikely between feasibility and main trial and we decided to change the feasibility trials to internal pilot trials, retaining the stop/go criteria originally planned before commencing the main trials. This enabled the pilot trial data to be used in the main trials, increasing programme efficiency. We also changed our recruitment strategy to recruit through primary care only, rather than primary and secondary care as originally planned. This was partly in response to our experience in workstream 1 where we encountered challenges with secondary care recruitment, but we also found that we were recruiting sufficient numbers of people with moderate to severe eczema through primary care. Recruiting through primary care only for the RCTs enabled us to conduct medical notes review for all participants, which was important for collection of secondary outcomes.

Changes were made to the secondary outcome measures of the RCTs following the final meeting of the Harmonising Outcome Measures for Eczema initiative (www.homeforeczema.org) in 2019. The finalised Core Outcome Set includes long-term control measured by recap for atopic eczema patients (RECAP) and itch intensity single item for adults. These were added and did not substantially add to questionnaire burden. Following discussion with our independent programme steering group and funder, we decided not to include Eczema Area and Severity Index (EASI) as a secondary outcome, which was originally included only at follow-up so as not to 'dilute' the online-only intervention at baseline. EASI is not recommended to be used at follow-up only. Excluding EASI as an outcome measure meant the trial could be delivered fully online and therefore in more geographical regions which boosted the diversity of our study population and reduced our carbon footprint as people did not have to travel for in-person assessment.

Further changes were made to the RCT design in response to the COVID-19 pandemic. We made minor changes to ensure all trial processes were online. We also increased the trial sample size from 200 to 303 participants per trial to detect a smaller minimal clinically important difference (MCID) in our primary outcome patient-oriented eczema measure (POEM) of 2.5 instead of 3 as new evidence emerged suggesting this is meaningful in certain contexts. Finally, we published an additional qualitative study of the impact the pandemic had on people's management of eczema which emerged from our process evaluation interviews.

Changes to workstream 5

Changes to the trial design and successful recruitment through primary care meant that the programme had a significant underspend and was ahead of schedule. Following discussion with the programme management group, the independent programme steering group and funder, we were given permission to repurpose funds to redevelop the trial version of the interventions into a marketable product in English and Welsh ready for dissemination. This product is freely available at www.eczemacareonline.org.uk.

Patients and public involvement throughout the programme

Patient and public involvement (PPI) co-applicants Amanda Roberts and Amina Ahmed have been actively involved in all aspects of programme planning, project management, intervention development, systematic reviewing, protocol development, trial management and implementation work. Wider patient and public engagement were gained through stakeholder workshops and work with the Centre of Evidence Based dermatology patient panel. Eczema Outreach Support (EOS) and the National Eczema Society (NES) worked closely with the Eczema Care Online (ECO) team throughout this programme. EOS and NES representatives were members of our Programme Steering Committee and attended various ECO stakeholder events. More detail on the PPI approach can be found in Patient, public and practitioner involvement in the programme.

Programme achievements

The ECO programme has achieved its intended objectives to develop and evaluate two interventions to support young people and families with eczema (workstreams 3 and 4). In addition, we have improved understanding of the experiences, barriers and facilitators of eczema management in children, young people and parents/carers (workstreams 1 and 5), and an understanding of how the intervention could be implemented in practice (workstream 5). We have also produced a comprehensive synthesis of the evidence on the safety and effectiveness of TCSs for eczema (workstream 2).

The work has been disseminated via academic, professional and public involvement routes, including publication in academic journals, presentations and public engagement events. Highlights include:

- Twenty-three peer-reviewed journal publications.
- Lay summaries and/or blogs to accompany publications.
- Twenty peer-reviewed conference presentations.
- Eight stakeholder engagement workshops.
- Two effective and cost-effective interventions to support management among people and families with eczema ready for implementation.

Workstream 1: understanding facilitators and barriers to effective eczema management among patients and parents/carers

Workstream 1 addresses objective 1 of the programme: to understand facilitators and barriers to effective eczema management for patients and parents/carers.

Publications relating to this section and workstream are listed in *Publications* and cited throughout this section.

Workstream 1.1: views and experiences of managing eczema – systematic review and thematic synthesis of qualitative studies

This work has been published:

https://doi.org/10.1111/bjd.19299.[26] PROSPERO registration number CRD42018110496.

It was published alongside a supportive commentary written by a prominent eczema advocate[27] and also contributed to a National Institute for Health and Care Research (NIHR) evidence signal.[28]

Aims

To review and synthesise qualitative studies exploring the views and experiences of eczema and eczema management among people with eczema and parents/carers of children with eczema.

Methods of qualitative data synthesis

A systematic review and thematic synthesis of the qualitative literature of people's experience of eczema and treatments for eczema was conducted to inform the development of the two behavioural interventions. The review focused primarily on the views and experiences of eczema and eczema treatments, and barriers/facilitators to eczema self-management. To be eligible for inclusion, studies must have used qualitative data collection and analysis methods. Mixed-methods studies were included if they had a substantive qualitative component. Papers that focused solely on health service provision models or the views/experiences of health professionals were excluded.

Results

Four electronic databases were searched using a comprehensive search strategy: MEDLINE, EMBASE, PsycInfo and Cumulative Index to Nursing and Allied Health Literature. Searches yielded 2241 records (1569 after duplicates removed). Eligibility screening identified 39 papers reporting 32 studies for inclusion. Studies included in this review explored the views and experiences of 1007 participants including 405 parents/carers of children with eczema, 252 people with eczema and 350 online forum users. Thematic synthesis of the data identified four overarching analytical themes: (1) eczema not viewed as a long-term condition; (2) significant psychosocial impact of eczema not acknowledged by others; (3) hesitancy (patient/carer uncertainty) about eczema treatments; and (4) insufficient information and advice about eczema. See *Figure 2* for a summary of key findings.

Key findings from this evidence synthesis highlight that people living with eczema, particularly young people and parents of children with eczema, often do not see eczema as a long-term condition. People are cautious about topical treatments for eczema, especially TCSs, and this appears to be exacerbated by experiences of conflicting and inconsistent advice from health professionals and others. Several barriers and facilitators to treatment use were identified in this review and they helped inform the intervention development in workstream 3.

People with eczema and their carers feel frustrated when others view eczema as mundane, insignificant or 'easy', while it has significant psychosocial impact. People were often seeking an underlying cause for their eczema. Interestingly

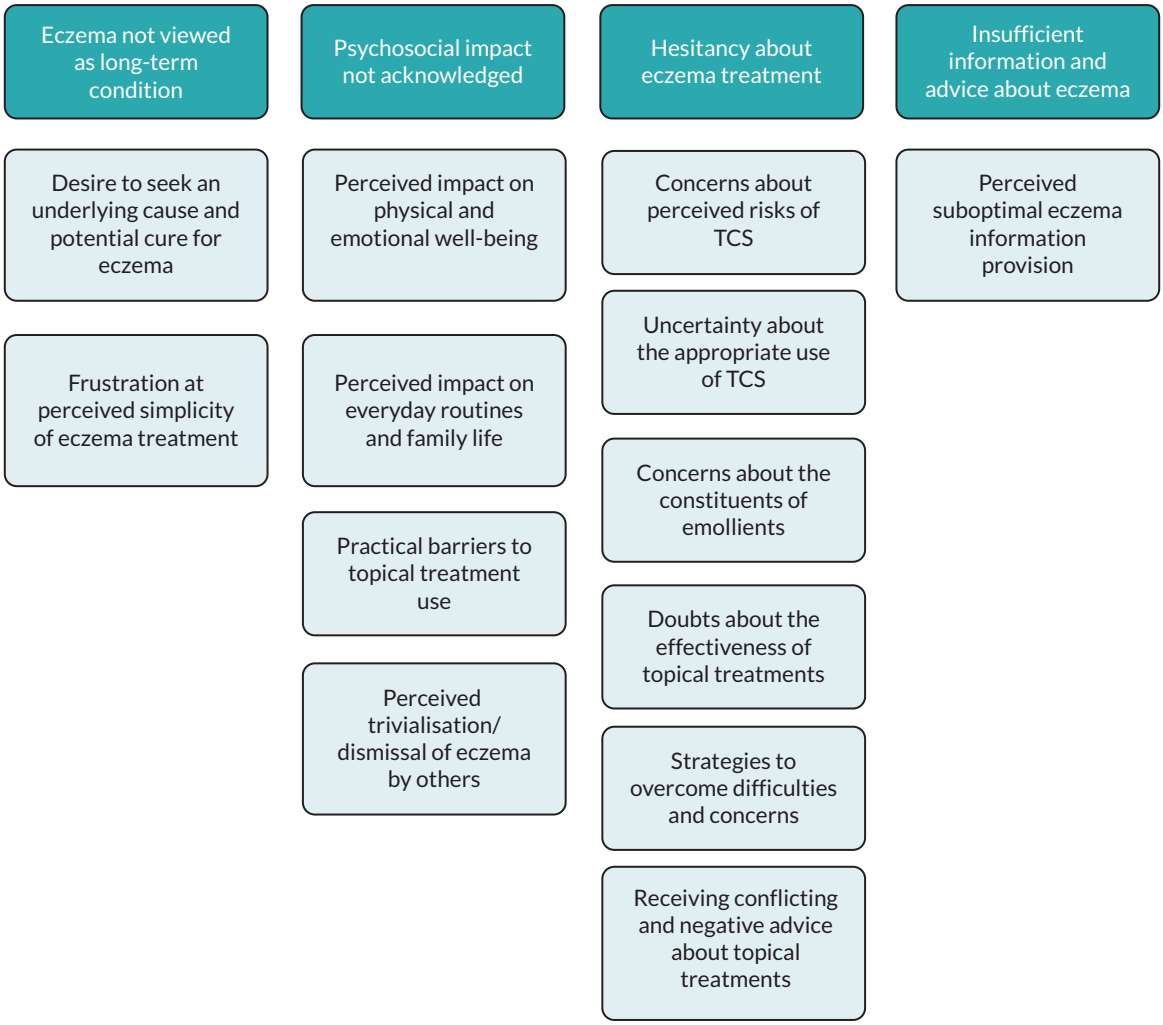

FIGURE 2 Components of key themes.

it was often parents and young people who focused on a 'cure' for eczema. It is likely that adults with eczema had been living with the condition for longer and had more experience of its long-term and fluctuating nature. Commonly reported messages around 'you or your child will grow out of it' can feel like dismissal, especially when mismatched with actual experiences. These findings helped shape the guiding principles and key messages around the impact of eczema and eczema treatment use in the interventions in workstream 3. This review identified an evidence gap and a need for further research in children's and young people's experiences of eczema. The second part of this workstream aimed to address these unanswered questions through further qualitative research with children, young people and parents/carers.

Workstream 1.2: views and experiences of managing eczema – qualitative research with children, young people and parents/carers

This work has been published:

https://doi.org/10.1111/bjd.18046.[29]

https://doi.org/10.1111/bjhp.12467.[30]

https://doi.org/10.1136/bmjopen-2020-044005.[31]

https://doi.org/10.3390/children8020158.[32]

Aims

To further explore the views and experience of children and young people with eczema, and parents/carers of children with eczema, and to further understand the facilitators and barriers to effective eczema management to inform intervention development in workstream 3.

Methods

Qualitative interviews were conducted to supplement the systematic review findings reported in workstream 1.1. Potential participants were invited to take part in this study through database searches and mail-outs from 16 general practices (GPs) in England and through opportunistic recruitment from 3 secondary care sites in England. Participants were invited to take part in this study if they were aged 6–25 years with a diagnosis of eczema or were the parent/carer of a child aged 6–12 with eczema. Children under the age of 16 were invited to the study via their parents/carers. Those who were interested in taking part in the study returned a reply slip to the study team who purposively sampled participants based on age, gender, eczema severity and geographical location to achieve a maximum variation sample.

Written consent was obtained from participants over 16 years of age and parents/carers of children aged under 16, and written assent from children aged under 16 prior to the interview. Interviews were semistructured, and all interviews were carried out face-to-face in participants' homes or University premises between March and August 2018. Key topics explored in interviews were:

- Eczema experiences and impact on daily life.
- Perceived causes of eczema.
- Views and experiences of eczema treatments/eczema self-care.
- Views about transitioning to co-management and self-management.
- Experiences of eczema information provision.
- Views about websites/web-based inventions.

Secondary analysis was carried out on transcripts of 23 interviews collected as part of the HealthTalk.org SKINS project. As participants from the SKINS project were aged between 16 and 24 years (mean age 19 years), we supplemented the data with five additional interviews that we conducted with young people aged 13–16 to ensure their views and experiences are represented in the findings.

Child interviews

During child interviews, parents were invited to be present to support their child, but we explained that we wanted to find out about the child's perspective, and we ensured that all questions were directed to the child. A range of developmentally appropriate and individualised techniques were used to help the child feel at ease and feel able to share their experiences including adopting a conversational style and focusing on what the child was doing. At the start of the interview, a conversation was started about the child's interests, which often prompted them to show the researchers their favourite toys, books, stories they had written and certificates/awards they had won. We adopted a Mosaic approach[33] to data collection that involved using multiple creative and fun participatory activities such as using picture cards related to the interview questions to guide the conversation and general play activities. Children were given an ECO whale toy (study mascot), colouring pencil set and ECO whale drawing and colouring sheets. They were also offered stickers and Lego bricks to play with. We aimed to adopt the 'least adult role' to encourage active participation in the interview.[34] We did this by sitting on the floor with the children and engaging in their chosen activities (e.g. helping build Lego, choosing stickers or colouring pencils) and allowing the children to 'direct the research agenda'. Children did this through choosing picture cards to guide the conversation, starting the digital recorder themselves, or by expressing their views through drawing their responses to some questions. We were flexible in our approach and found that with younger participants (6–9 years), we often talked about their eczema while they continued with their chosen activity. Children aged 10–12 years were happy to be asked questions in a more traditional interview format and did not feel the need to stay engaged in another activity.

Results

Qualitative data from 72 participants were analysed in this workstream to inform the development of the two ECO interventions. Our participant sample comprised:

- Fifteen parents of children aged 0–5 years.
- Fifteen parents of children aged 6–12 years.
- Eight children aged 6–9 years.
- Six children aged 10–12 years.
- Twenty-three young people aged 16–24 years (SKINS project).
- Five young people aged 13–16 years.

Purposive sampling ensured we included participants with a range of ages, eczema severity and gender. Child interviews typically lasted around 30 minutes (range 19–46 minutes) and adult interviews lasted around 45 minutes (range 30–65 minutes). SKINS project interviews with young people lasted up to 2 hours. Interviews were transcribed verbatim and analysed using inductive coding and thematic analysis.[34]

Key findings

As reported in Sivyer *et al.*,[35] we found that children do not typically view eczema as a long-term condition, and topical treatments (predominately emollients) were seen to provide effective symptom relief. Uncertainty around co-managing at home was expressed as children typically felt that parental reminders and assistance with applying different types of topical treatments were still needed. For some children, eczema can be difficult to manage at school due to a lack of convenient access and appropriate spaces to apply creams and psychosocial consequences such as attracting unwanted attention from peers and feeling self-conscious. Treatment adherence could be supported by reinforcing that eczema is a long-term episodic condition, providing clear information about regular emollient use, practical advice such as setting reminders to support co-management at home, and working with schools to facilitate topical treatment use when necessary.

Among young people, participants reported a mismatch between information received about eczema and their experiences. They did not expect eczema to be a long-term condition, and this had implications for self-care, making it challenging to identify eczema triggers and evaluate the success of treatment regimens.[29] Participants also struggled to adapt and to find a balance between accepting eczema as long term and hoping it would go away. This linked to a gradual shift in treatment expectations from 'cure' to 'control' of eczema.

Young people described both visible symptoms (such as flaky, dry and inflamed skin) and invisible symptoms (such as itch, pain, exhaustion and mental distress) that elicit different psychosocial needs. These psychosocial needs are to (1) be understood; (2) be perceived as normal; and (3) receive emotional support. This has implications on behaviours, such as seeking support, avoiding going out and hiding their skin, as well as emotional implications, such as social isolation and feeling anxious and low.

Although topical treatments were generally perceived as effective, young people expressed doubts about their long-term effectiveness, and concerns around the safety and an over-reliance on TCSs. Participants welcomed the opportunity to take an active role in their eczema management, but new roles and responsibilities also came with initial apprehension and challenges, including communicating their treatment concerns and preferences with health professionals and obtaining treatments.[31] Decisions regarding whether to engage in behaviours that would exacerbate their eczema (e.g. irritants/triggers, scratching) were influenced by young people's beliefs regarding the negative consequences of these behaviours, and perceived control over the behaviour and its negative consequences.

Conclusion

The qualitative work concluded that for young people who continue to experience eczema beyond childhood, a greater focus on self-care for a long-term condition may be helpful. Greater awareness of the impact of early messages around 'growing out of' eczema and the provision of high-quality information may help patients manage expectations and support adaptation to treatment regimens.[29]

Furthermore, having a better understanding of young people's experiences and psychosocial needs will provide a framework on how best to support adolescents and young adults when managing symptoms related to eczema.

In children, treatment adherence could also be supported by reinforcing that eczema is a long-term episodic condition, providing clear information about regular emollient use, practical advice such as setting reminders to support co-management at home, and working with schools to facilitate topical treatment use when necessary.

Behavioural change interventions must also address the treatment concerns of children and young people and equip them with the knowledge, skills and confidence to take an active role in their own eczema management.

Impact on intervention development

The systematic review of qualitative literature and primary qualitative research carried out in workstream 1 resulted in an in-depth understanding of the needs of our intervention target users (young people aged 13–25 with eczema and parents/carers of children aged 0–12 with eczema). Key findings were used to develop our programme theory, which included an intervention logic model (see *Appendix 1*, *Figures 7* and *8*) and detailed guiding principles (see *Appendix 2*, *Tables 2* and *3*). Findings were also used to inform our behavioural analysis (see *Appendix 3*, *Tables 4* and *5*). Full details are reported in *Workstream 3: development of online behavioural interventions to support eczema self-care*.

Workstream 2: summary of evidence for the best and safest ways of using topical corticosteroids

Workstream 2 addresses objective 2 of the ECO programme: to update and combine existing evidence around the safety and effectiveness of TCSs and develop knowledge tools for patients and healthcare professionals.

This section includes four studies.

- Workstream 2.1: an umbrella review of existing systematic reviews of studies using topical steroids for eczema.
- Workstream 2.2: a Cochrane systematic review of the safety and effectiveness of different strategies for using TCSs.
- Workstream 2.3: a systematic review of the long-term safety of TCSs in eczema.
- Workstream 2.4: creation of knowledge tools to support patients and healthcare professionals.

Workstream 2.1: an umbrella review of existing systematic reviews of studies using topical steroids for eczema

This work has been published:

https://doi.org/10.1136/bmjopen-2020-046476.[36] PROSPERO registration number CRD42018079409.

Aims

- To summarise what is known about the safety of using TCSs from published systematic reviews.
- To inform the development of the ECO intervention (workstream 3).

Methods

Design

A systematic review of published systematic reviews. The last search date was 2 March 2021. Reviews were included if they assessed the safety of TCSs in atopic eczema and searched > 1 database using a reproducible search strategy. Review quality was assessed using version 2 of 'A MeaSurement Tool to Assess systematic Reviews' (AMSTAR 2 tool).[37]

The intervention of interest was any TCS strategy used to treat eczema. The comparisons of interest were any other TCS, the same TCS used in a different way, another topical anti-inflammatory treatment, vehicle, no treatment, or a combination of any of these. Comparisons with non-topical treatments were excluded as we were interested in clinical practice decisions regarding alternatives to TCSs.

Safety outcomes were extracted where reported in the reviews on immediate cutaneous adverse events (e.g. burning sensation/stinging), other cutaneous adverse events (e.g. skin thinning, telangiectasia, skin infections, folliculitis), systemic adverse events (e.g. effects on the endocrine system, impact on growth) and rebound symptoms/steroid withdrawal.

Results

This review included 38 systematic reviews (35 in English, 2 in Chinese and 1 in German). The reviews included 106 studies (77 RCTs and 29 observational studies).

Key findings

- We found no evidence that TCSs cause harm when used intermittently 'as required' to treatment eczema flares or as 'weekend therapy' to prevent flares.

- Adverse events of greatest concern to patients and clinicians, such as skin thinning, were uncommon with short-term use of TCSs. However, high-quality evidence was limited.
- Resolution of adverse events was rarely reported. For adverse events such as skin thinning or biochemical signs of adrenal suppression, it is important to know if the effect is transient and if levels return to normal once the TCS is stopped.
- Treatment decisions are a balance of benefits and harms. See workstream 2.2 for a Cochrane review of the effectiveness and safety of different strategies for using TCSs.

Conclusion

Conclusions were limited by the content of the included reviews and safety was frequently reported in less detail than effectiveness. It is not clear whether this is because the original trials did not report adverse events in sufficient detail or whether the review authors did not include all the available safety data, perhaps only focusing on a restricted group of adverse events.

Most of the included reviews were rated low or critically low quality using AMSTAR 2.[37] Where the quality of evidence assessments [e.g. Grading of Recommendations Assessment, Development and Evaluation (GRADE)] were reported in the reviews, most individual studies included in the reviews indicated a high or unclear risk in at least one domain. Many RCTs did not include follow-up beyond 2–4 weeks of treatment and therefore data on long-term safety are limited. Although short-term TCS use reflects an appropriate treatment duration for treating an individual flare, it does not reflect the chronic nature of eczema and the need for TCS use over the long term. Longer-term prospect observational studies are better placed to explore the longer-term safety of TCS and should be designed with years rather than months of follow-up (see workstream 2.3 for an overview of long-term studies).

Impact on intervention development

This review informed development of the ECO intervention prior to testing in the online RCTs (workstream 4).

Workstream 2.2: a Cochrane systematic review of the safety and effectiveness of different strategies for using topical corticosteroids

This work has been published:

https://doi.org/10.1002/14651858.CD013356.pub2.[38]

Aim

- To summarise what is known about the safety and effectiveness of different strategies for using TCSs.

Methods

This Cochrane systematic review of RCTs evaluated different strategies for using TCSs (last searched January 2021). Trials including people with a diagnosis of eczema of any severity were included. The interventions were any TCS used in a trial where a clinically relevant strategy of TCS use was compared to another (*Figure 3*).

Effectiveness and safety outcomes were assessed using the international Harmonizing Outcome Measures for Eczema (HOME) initiative's recommended core outcome domains of clinician-reported signs and patient-reported symptoms of eczema.[39] The safety outcomes were clinically relevant local (e.g. skin thinning) and systemic adverse events (e.g. adrenal suppression). Outcomes were GRADE assessed for quality.

Results

The review included 104 RCTs in children (n = 43), adults (n = 16), both (n = 17), or unspecified ages (n = 28), with a total of 8443 participants (range 3–409 per trial). Most were parallel-group (n = 63) or within-participant studies (n = 39) conducted in high-income countries (n = 81) and were largely conducted in outpatient or other hospital settings. See *Appendix 4*, *Table 6* for table of included studies.

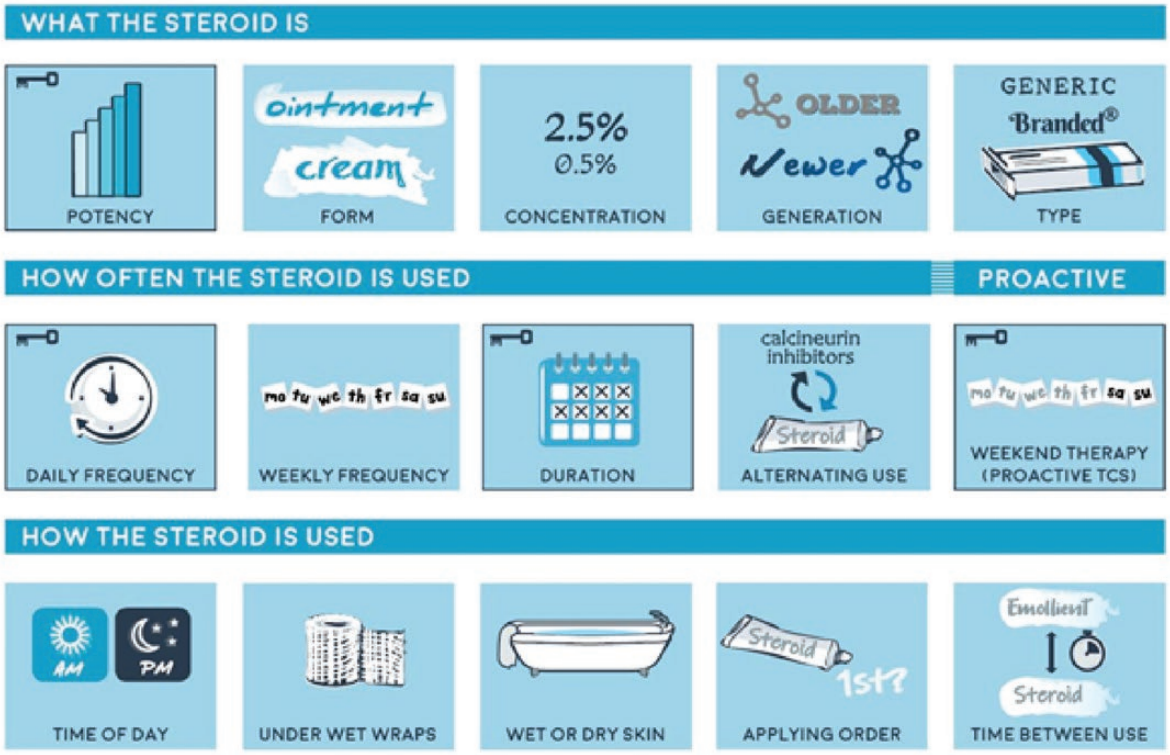

FIGURE 3 Summary of strategies for using TCSs included in the review.

Eighteen treatment strategies were evaluated in the review. The pre-specified strategies of main interest were

- different potencies of TCSs;
- frequency of applications of TCSs;
- duration of use for treatment of a flare;
- weekend (proactive) therapy for the prevention of flares.

Conclusions were based largely on the number of cleared or marked improvements in Investigator Global Assessments at 1–5 weeks in flare treatment trials, and the number of relapses by 16–20 weeks in weekend (proactive) therapy trials.

Key findings

- To *treat* flares of moderate to severe eczema, there is evidence that moderate and potent TCSs are better than mild TCSs; and once-daily potent TCS is as effective as twice daily, but the optimal duration of TCS use is unknown.
- There is evidence that 'weekend therapy' (prophylactic use of TCS 2 consecutive days every week) with potent TCSs may prevent flares of moderate to severe eczema.
- Adverse events were infrequent (e.g. skin thinning in < 1%), but reporting was poor.
- Evidence for other strategies was lacking.

Details of the key findings are summarised in *Report Supplementary Material 1*.

Conclusions

Treatment regimens could be simplified by recommending the use of TCS once per day.

While these findings provide some reassurance that using TCSs intermittently to treat eczema flares is safe, there were several strategies of interest that had not been addressed in adequately powered clinical trials. Outcome measurement and reporting were suboptimal in many of the included trials, with a lack of HOME core outcome set outcomes. Where

safety outcomes were reported, they often lacked detail, were inconsistently reported and had insufficient duration of follow-up.

A further challenge to interpretation is that the classification of potency is viewed differently worldwide, making comparisons of TCS potency as used in the reported trials more difficult.[40]

There is a growing interest in TCS withdrawal within people with eczema, but no trials specifically addressed this.

Impact on the Eczema Care Online intervention

This review informed the final content of the ECO intervention (workstream 3) and the development of the clinical practice knowledge tool (workstream 2.4).

Workstream 2.3: a systematic review of the long-term safety of topical corticosteroids in eczema

This review is published.

https://doi.org/10.1002/ski2.268.[41] PROSPERO registration number CRD42021286413.

Aim

- To conduct a systematic review of adverse effects associated with the long-term use of TCS for eczema.

Methods

This was a systematic review of RCTs, cohort studies and case-control studies that reported adverse effects of TCSs when used in patients with eczema (search date December 2021). Included studies had > 1 year of follow-up, a minimum cohort size of 50 participants, or a minimum of 50 per arm for RCTs. Risk of bias (ROB) was assessed using Cochrane ROB2, Cochrane Risk Of Bias In Non-randomized Studies – of Interventions (ROBINS-I) and Newcastle Ottawa Scales (as appropriate). Evidence was GRADE-assessed. Results were presented narratively.

Results

Two RCTs (n = 2570, including 1288 receiving TCS), two cohort studies (n = 148) and three case-control studies (cases n = 10,322, controls n = 12,201) were identified. The studies reported on local adverse effects (skin thinning), and systemic adverse effects (type 2 diabetes, lymphoma, growth abnormalities, bone mineral density reduction, signs of adrenal insufficiency, non-skin infections, impaired vaccine response and other non-lymphoma malignancies). No long-term studies concerning topical steroid withdrawal or eye problems were identified.

Key findings

- Overall, the limited body of evidence provides some reassurance that TCSs used intermittently for the management of eczema are safe over periods of up to 5 years.
- A 5-year RCT reported only one episode of skin atrophy in 1213 patients treated with intermittent mild or moderate TCSs (GRADE-assessed as 'moderate' certainty), and no cases of clinical adrenal insufficiency were reported in 75 patients in a RCT of intermittent mild or moderate TCSs used for 3 years (GRADE-assessed as 'moderate' certainty).
- There was moderate certainty evidence to suggest no increased risk of growth abnormalities, non-skin infections, impaired vaccine response or lymphoma/non-lymphoma malignancies.
- Some 'very low' certainty data have provided a potential link between TCSs and lymphoma and type 2 diabetes. These associations warrant further investigation.
- Gaps remain in our understanding of the lifelong effects of TCS use that are difficult to address in high-quality studies.

Conclusions

This review provides some reassuring data for the limited impact of TCS on growth and skin thinning when used intermittently to treat eczema flares over several years. This contrasts with the public perception that these side effects are common and widespread.

Although broadly reassuring, it should be noted that the longest RCT was 5 years in duration and studies were generally underpowered to identify rare events.

There were certain adverse effects that were not reported on in either RCTs or the observational studies, for example topical steroid withdrawal and the effects of TCSs on the eyes. For the adverse effects reported, there was very little information provided regarding the consequences of the adverse effects and whether they resolved after discontinuation of treatment.

Impact on other aspects of the programme

This review did not directly inform other aspects of the programme, as it was completed after the ECO toolkit was completed and tested. However, people with eczema have prioritised the need for better-quality research on the long-term safety of TCSs as a research priority and we hope that this review will stimulate interest in this area.

Workstream 2.4: creation of knowledge tools to support patients and healthcare professionals

This knowledge tool is freely available at www.eczemacareonline.org.uk/en/printables.

Aims

- To develop a knowledge support tool for use in primary care that supports appropriate use of eczema treatments.
- To ensure consistent messaging with and signpost to the ECO toolkit.

Methods

A summary of the key messages from the ECO programme of research (arising from intervention development and summaries of known evidence supporting treatment decisions) was collated into a series of 'key messages' for sharing with wider stakeholders and for use in knowledge mobilisation activities.

These key messages were developed with stakeholder input through a series of workshops including:

- A 1-day face-to-face meeting with 34 attendees including researchers (*n* = 11), healthcare professionals (*n* = 13), patient partners/organisations (*n* = 10) (September 2019).
- Five 90-minute online meetings where particular stakeholder views were invited from primary care (*n* = 4), secondary care (*n* = 7), pharmacy (*n* = 5), people with eczema/patient organisations (*n* = 7) and parents of children with eczema/patient organisations (*n* = 7) (March 2021).
- A 2-hour online meeting with 18 individuals or patient organisation representatives particularly concerned about a safety concern of eczema treatments termed 'topical corticosteroid withdrawal' (May 2021).

The workshops served to clarify the purpose of the key messages, ensure appeal to end users, establish the most appropriate setting for their use, and how they might be used to support clinical care in that setting. Feedback was reviewed through a normalisation process theory (NPT) lens and the key messages were refined and tailored to the target audience, followed by further modification through user testing where members of the public/patients provided feedback.

The final version of the knowledge support tool is shown in *Figure 4*.

FIGURE 4 Knowledge support tool for using eczema treatments.

Key outcomes

- This knowledge tool focuses on the concept of 'Two Treatments Used Well' to support people in managing their eczema and understanding how to use their emollients and flare control creams (TCS).
- The infographic will be shared widely with healthcare professionals and through professional societies.
- It serves as an opportunity to ensure consistent messaging between different healthcare professionals and reflects the style and content of the messages in the ECO toolkit.
- It serves as a useful signposting tool for the full ECO website.

Conclusion

We hope this tool will provide a useful tool to support clinical practice and to support patients in navigating their self-care needs. It also provides and alternative avenue for promoting the ECO website.

This knowledge tool is tailored specifically for a UK audience, but the messages it contains are likely to be applicable to most healthcare settings.

Impact on Eczema Care Online intervention and implementation

This knowledge tool has been incorporated into the ECO website and provides a concise, printable version of the key messages contained in the website. It also serves as a signposting tool for the ECO website as it contains the web address and a QR-code link.

Workstream 3: development of online behavioural interventions to support eczema self-care

Workstream 3 addresses the third objective of the programme: to develop online behavioural interventions to support eczema self-care for patients and parents/carers.

This work has been published:

https://doi.org/10.1136/bmjopen-2021-056867.[42]

https://doi.org/10.3399/BJGP.2021.0503.[35]

https://doi.org/10.1186/s40900-019-0169-8.[43]

Workstream 3.1: intervention planning

Aim

- To develop online behavioural interventions to support eczema management in (1) young people aged 13–25 and (2) parents/carers of children aged 0–12 with eczema using theory-, evidence-, and person-based approaches.

Methods

Two complex behavioural interventions were developed to support eczema management: one for young people aged 13–25 with eczema (intervention – young people) and one for parents and carers of children aged 0–12 with eczema (intervention – parent/carer). The interventions were online and developed using theory-, evidence- and person-based approaches.[44,45] Full details of the development of our programme theory and interventions have previously been published.[35,42]

Intervention planning was carried out alongside our systematic review of the qualitative literature and qualitative studies reported in workstream 1 and the systematic reviews of TCS safety and effectiveness reported in workstream 2 to guide our programme theory, identify relevant intervention components and characteristics and ensure treatment information was evidence-based. This evidence guided decisions regarding the intervention's target behaviours and provided us with an in-depth understanding of the key issues, needs and behavioural challenges of our two target groups (young people and parents/carers).

Intervention development group

As reported in Greenwell *et al.*,[42] intervention planning and development were guided by a multidisciplinary intervention development group, which comprised 18 members including PPI contributors, dermatologists, a nurse consultant, researchers with an interest in eczema, GPs, health psychologists and experts in intervention development, writing patient-friendly health information and long-term conditions in adolescents. Through regular meetings and reviewing documents, this group guided the design of the research, helped with the interpretation of the research findings, and provided detailed feedback on the intervention plans, written content, website design and prototypes for both online interventions. Two mothers of children and young people with eczema (one of whom had eczema herself and helps run an eczema support group) were part of our multidisciplinary intervention development group. We also sought additional PPI feedback on the intervention content and design from two young people with eczema and a panel of PPI contributors with an interest in skin research, most of whom had experience of eczema, and some were aged 18–25. Further details of how contributions from public contributors and other stakeholders complemented the person-based approach have been published.[43]

Defining intervention target behaviours

The multidisciplinary intervention development group agreed that ECO would aim to reduce eczema severity by supporting young people with eczema and parents/carers of children with eczema to:

1. increase their use of emollients to maintain skin hydration and prevent flare-up
2. improve their use of TCSs or topical calcineurin inhibitors (TCIs) through reactive applications of these treatments in response to flare-ups or, where appropriate, regular intermittent ('weekend') preventative applications of TCSs or TCIs if emollients are insufficient as maintenance therapy
3. improve their management of irritants and triggers
4. improve their emotional management
5. reduce scratching.

The use of emollients and TCSs/TCIs was identified as core behaviours that would likely have the greatest effect on eczema severity. Therefore, intervention content relating to these behaviours was deemed the most important.

Developing an intervention plan

Consistent with the person-based approach,[44] our in-depth understanding of young people with eczema and parents/carers of children with eczema informed the development of guiding principles (see *Appendix 2*, *Tables 2* and *3*), which outlined key intervention objectives and the design features that will address these.[46] A list of potential barriers and facilitators to the target behaviours was also identified from this evidence base and from consultation with the multidisciplinary intervention development group and additional PPI representatives. A behavioural analysis (see *Appendix 3*, *Tables 4* and *5*) outlined the intervention components that were added to address each of the identified barriers and facilitators for each target behaviour and these components were mapped onto behaviour change theoretical frameworks to describe the planned intervention content and identify hypothesised mechanisms of action. The behaviour change techniques taxonomy classifies intervention content by their behaviour change techniques, the smallest component for changing behaviour.[47] The behaviour change wheel was used to classify the source (a component of the COM-B model hypothesised to influence behaviour; capability, opportunity, motivation) and function (e.g. 'education', 'persuasion') of each individual or group of behaviour change techniques.[48] We also mapped the behaviour change techniques onto their theoretical constructs (e.g. 'knowledge', 'skills') using the theoretical domains framework,[49] which is recommended for use alongside the behaviour change wheel. To illustrate key elements of the intervention's programme theory, two logic models (see *Appendix 1*, *Figures 7* and *8*) were developed to illustrate how the intervention components, theoretical constructs (intervention processes) and key behaviours (purported mediators) influence the intervention outcomes (eczema severity).

Workstream 3.2: intervention development

As published in Sivyer *et al.*[35] and Greenwell *et al.*,[42] once intervention planning was complete, we started developing two interventions: one for young people with eczema and one for parents/carers of children with eczema. Creating the intervention prototype was done in several stages. Guided by our target behaviours, guiding principles and qualitative research, the multidisciplinary intervention development group agreed the topics of the intervention modules and videos to be created. We then wrote page content and video scripts, and circulated them to the multidisciplinary intervention development group for comment to ensure it was evidence-based and medically accurate, and the advice was clear and feasible. Positive and negative feedback was entered into the person-based approach table of changes,[50] and potential changes were discussed, agreed and prioritised. We tested either the video scripts, audio recordings of the scripts or a storyboard or prototype of the video with young people and parents/carers using think-aloud interviews, and these were also reviewed by a PPI panel. Once the written intervention content and videos were finalised, we created a working prototype of the intervention using the LifeGuide software (University of Southampton, Hampshire, UK),[51] which was reviewed by our PPI contributors and further optimised through qualitative think-aloud interviews with young people with eczema and parents/carers of children with eczema. The final videos were created by an external video creator.

Description of interventions

We developed two online behavioural interventions using LifeGuide software (www.lifeguideonline.org). Interventions were thoroughly tested to ensure functionality across different types of devices (computers, mobile phones, tablets). A modular intervention was developed with sections focusing on topics related to eczema including treatment use, lifestyle and environment and psychosocial issues (e.g. stress). Users were initially guided through a short introductory module, which had three key purposes:

1. To establish credibility of the intervention.
2. To explain eczema and the skin barrier.
3. To briefly explain key treatments (emollients and TCSs) and how to use them.

This aimed to ensure users had the basic knowledge/skills for managing eczema. A key aspect of the intervention was the terminology developed for describing emollients, which we called 'moisturising creams', and TCSs, which we called 'flare control creams'. These terms were explored throughout the qualitative research and with PPI in this programme to reflect parents'/carers and young people's own terminology for eczema treatments, often referring to all treatments as 'creams' and not understanding the difference between emollients and TCSs. The intention behind using the terminology 'moisturising creams' and 'flare control creams' was to help make clear their different purposes, particularly the role of TCS and TCIs in treating eczema flare-ups.

At the end of the introduction, users could take a brief eczema assessment to assess their or their child's eczema, the results of which then recommended one of two core modules: 'getting control using flare control creams' or 'keeping control using moisturising creams'. These provided more information about treatments, addressed common concerns, and provided information and photos/video demonstrations of how best to use treatments. Additional modules were provided through drop-down menus to allow users to access a range of topics. These included managing irritants and triggers ('what can make eczema worse'), managing the impact of eczema ('itch, stress, and sleep'), and other treatments and related issues ('more about treatments'). While similar topics were covered in the young people and parent/carer interventions, their content often deferred to include information relevant and meaningful to that age group. For parents/carers, these also included information on co-management ('help your child manage eczema'), and for young people, we included additional content on cosmetics, make-up and shaving and finances.

A key design principle of both interventions was that users may not have a lot of time to spend on the intervention and so the content was designed to be helpful, relatable and interesting even if someone only had a few minutes to spend on it. Another key design feature was the use of quotes from other young people or parents/carers sharing their experiences of eczema and eczema management advice throughout the intervention. To ensure inclusivity, images and descriptions of eczema included different skin tones. See *Appendix 2*, *Tables 2* and *3* for full details of guiding principles for intervention design. Template for Intervention Description and Replication checklist is given in *Report Supplementary Material 2*.

Intervention optimisation

Qualitative think-aloud interviews were carried out with a wide range of target users to ensure the interventions were accessible, easy to use, relatable and meaningful. We also used the think-aloud interviews to elicit feedback on aspects like new terminology (moisturising creams and flare control creams) and design features like the quiz for recommending topics.

Face-to-face think-aloud interviews were conducted between October 2018 and April 2019. Participants were recruited through mail-outs from eight GP practices in the South of England. Participants needed to be aged 13–25 years or have a child aged 0–12 years with diagnosed eczema and with one or more eczema prescriptions in the previous 12 months. Participants (or legal guardians of 13- to 15-year-olds) received an invitation pack, including an information sheet, and a reply slip to express interest in the study. To gather a diverse range of views and cover a range of developmental stages, participants were purposively sampled on the child or young person's age, gender, eczema severity and geographical location. Selected participants were invited to a face-to-face and consented before the interview.

Key findings

Think-aloud interviews were conducted with 25 parents and carers and 28 young people that lasted 45–90 minutes and involved think-aloud techniques where participants were asked to use sections of the intervention as they usually would while saying all their thoughts out loud. Interviews were audio-recorded and transcribed verbatim. Data were analysed concurrently to the interviews using a table of changes,[50] in which all positive and negative comments were collated, and potential changes identified and prioritised in terms of feasibility and importance of changes in increasing acceptability and feasibility of the intervention. Minor changes to the intervention were agreed within the intervention development team with key issues discussed with stakeholders to support reflexivity and medical accuracy of modified intervention content. Interviews were carried out iteratively, with feedback from earlier interviews informing modifications to optimise the intervention, and later interviews using revised prototype interventions to seek feedback on modifications.

Views of the prototype were generally positive, particularly the new terminology for eczema treatments, the wide variety of topics covered, and the videos, and tips. Participants found the information and advice clear, easy to follow, helpful and relatable. They particularly found the quotes and advice from others like them helpful. Young people and parents/carers found the information about the safety of TCSs reassuring.

Young people found the facts about how common it is to still have symptoms at their age reassuring, personal and it made them feel less alone. Young people valued that the advice focused on living well with eczema, rather than focusing solely on medical treatments. Most young people explained how they learnt something new about eczema and its management from the part of the website they used, with some explaining that intervention helped address the knowledge gaps from childhood.

Parents/carers however felt the content was lengthy and repetitive, and wanted quicker access to the main modules. A key issue was that many parents/carers initially felt the content was not relevant to them if they had been looking after their child's eczema for a while. Despite this, when going through the content participants still identified things that they had not known, such as why and how emollients help keep eczema under control and how to correctly apply treatments (e.g. using TCS until 2 days after the eczema flare-up clears, applying topical treatments in the direction of hair growth). Parents/carers also felt they had gained useful practical tips they had never tried before, such as putting creams in the fridge to make them cool to soothe itching or setting reminders on phones.

Modules were streamlined and made more interactive to increase user choice and autonomy using optional click-outs and pop-ups. In particular, the core content in the introductory module was cut from 21 to 9 short pages. Readability was improved on individual pages by: (1) highlighting key messages using bold text; (2) using bullet points; and (3) separating text using boxes. Signposting, quotes and tips were added to the introductory module and first page of the core modules to emphasise that:

1. the website provided up-to-date information about eczema and its treatments
2. core modules would be basic at the start but then progress
3. even parents/carers who had been caring for their child's eczema for a while had learnt new things.

Conclusion

Two interventions were rigorously developed following complementary theory-, evidence- and person-based approaches to intervention development helped ensure the intervention was acceptable and engaging to a sample of young people with eczema and parents and carers of children with eczema. Our multidisciplinary intervention development group, including PPI, ensured that the content was evidence-based, that advice was feasible, and that the perspectives of families and people living with eczema were considered throughout the whole development process.

The interventions were subsequently evaluated for their clinical and cost-effectiveness, as described in *Workstream 4*.

Workstream 4: determine the clinical and cost-effectiveness of the Eczema Care Online interventions

Workstream 4 addresses the third objective of the programme: to determine the clinical and cost-effectiveness of online behavioural interventions compared to standard clinical care.

This work has been published:

https://doi.org/10.1136/bmjopen-2020-045583.[2]

https://doi.org/10.1136/bmj-2022-072007.[52]

https://doi.org/10.1007/s10198-023-01649-9.[53]

The trial was registered with the International Standard Randomised Controlled Trial Number registry (ISRCTN79282252) on 28 November 2019, prior to enrolling the first participant. The trials were approved by South Central–Oxford A Research Ethics Committee (19/SC/0351).

Multicentre randomised controlled trials

Two separate, pragmatic, multicentre, unmasked individually randomised superiority trials were conducted to evaluate the clinical and cost-effectiveness of the two ECO interventions developed in workstream 3: ECO for parents/carers of children with eczema, and ECO for young people with eczema.

The trials were conducted within GP in the UK NHS. Most trial processes were online from the start, with the exception of consent forms from parents/carers of 13- to 15-year-olds which were originally paper-based. In response to COVID-19, these consent forms were digitised, making all trial processes fully online. Participants were invited via search of electronic health records and postal invitation from participating practices around four regional centres: Wessex, West of England, East Midlands, and Thames Valley and South Midlands. Potential participants were sent an invitation pack containing a participant information sheet and the study uniform resource locator (URL) to register if they wished to take part. After registering, participants were asked to provide informed consent and complete screening and baseline measures online. For children under 16, the invitation was sent to their parents/carers. In the trial for parents/carers, informed consent and questionnaires were completed by the parent/carer. In the trial for young people, parental consent and young person's assent were sought for participants aged under 16 and young person's consent was sought for participants aged 16 and over. Young people aged 13–25 years were asked to complete their own questionnaires.

Participants were eligible if they were a young person aged 13–25 with eczema or the parent/carer of a child aged 0–12 years with eczema, had a GP electronic record code for eczema and had a prescribed eczema treatment in the past 12 months. On baseline screening, participants were excluded if they had a baseline POEM[54] score of < 5 to exclude very mild or inactive eczema. Participants were also excluded if they were unable to give informed consent; were unable to read and write English (as the intervention content and outcome measures were in English); had taken part in another eczema study in the past 3 months; or had no internet access. Only one person per household could take part in either trial, as the intervention content was similar. This has been reported in Santer *et al.*[52]

Outcome measures

All participant-reported outcome measures were collected online via LifeGuide software.[51] Automated reminder texts and e-mails were sent by the software, and non-responders were followed up by the trial team via text message, e-mail or telephone call.

The primary outcome for both trials was the difference in patient-reported eczema severity between the usual care and intervention group, measured by POEM every 4 weeks over 24 weeks.[54,55] POEM includes seven questions about the frequency of eczema symptoms over the previous week that give a total score from 0 (no eczema) to 28 (worst possible eczema).

Secondary outcomes included POEM scores 4-weekly over 52 weeks, eczema control at 24 and 52 weeks, measured by RECAP,[56] itch intensity[57] at 24 and 52 weeks (young people only), patient enablement at 24 and 52 weeks,[58] quality of life at 24 and 52 weeks: measured by Child Health Utility Nine Dimensions (CHU-9D)[59] for children aged 2–12 years and EuroQol-5 Dimensions, five-level version (EQ-5D-5L)[60] among young people aged 13–25. Health service use and medication use were measured by medical notes review for the 3-month period prior to baseline and the whole 52-week trial period.

We also measured prior beliefs about the effectiveness of the intervention and other online resource use (websites or apps for eczema). Process measures included self-reported barriers to adherence to eczema treatments measured at 24 and 52 weeks using the Problematic Experiences of Therapy Scale (PETS) and frequency of eczema treatment use (treatment adherence) was measured by self-report at 24 and 52 weeks. Intervention usage data (e.g. time spent on the intervention, number of logins, pages viewed) for each participant were recorded by LifeGuide software for the duration of the 52-week trial period. See *Report Supplementary Material 4* for the questionnaire booklet of outcome and process measures.

Sample size and randomisation

The sample size calculation was based on 4-weekly POEM scores using repeated measures from baseline to 24 weeks, seeking to detect a MCID of 2.5 points between groups [standard deviation (SD) 6.5]. Assuming a correlation between repeated measures of 0.70, with 90% power and 5% significance, this gave a target sample size of 121 per group in each of the two trials. Allowing for 20% loss to follow-up resulted in a target sample size of 303 in each of the two trials. Participants were randomised online via LifeGuide software to either (1) usual eczema care or (2) online intervention plus usual care. Randomisation was carried out in random permuted blocks (size 4 and 6) and stratified by age (children 0–5 vs. 6–12 years; young people 13–17 vs. 18–25 years), baseline eczema severity [POEM categories[55] 6–7 (mild); 8–16 (moderate); 17–28 (severe)] and recruitment region (4 regions, as above).

Key findings

Analysis was conducted following a statistical analysis plan (SAP) agreed in advance with the independent Trial Steering/Data Monitoring Committee and reported according to Consolidated Standards of Reporting Trials (CONSORT) guidelines,[61,62] and the two trials were analysed separately. Full results have been reported elsewhere.[52]

Three hundred and forty parents/carers of children (169 usual care; 171 intervention) and 337 young people (169 usual care; 168 intervention) were randomised into the trials. The mean baseline POEM was 12.8 (SD5.3) for children and 15.2 (SDd5.4) for young people. Three young people withdrew from follow-up but did not withdraw their data. All randomised participants with available outcome data were included in their randomised arm, in the intention-to-treat analyses. Follow-up rates were excellent: 92.4% (314/340) parents/carers and 90.2% (304/337) young people at 24 weeks. CONSORT diagrams for the trials can be found in *Appendix 5*, *Figures 9* and *10* (see *Appendix 6*, *Tables 7* and *8* for full baseline characteristics).

We found that our two brief online behavioural interventions to enable self-management for eczema for parents/carers of children and for young people provided a useful benefit in eczema severity at 24 weeks. After controlling for baseline severity and prespecified covariates (age, recruiting centre, sex, ethnicity, prior belief in the intervention, previous use of a website for eczema, and parental education in the parent and carer trial), compared with usual care over 24 weeks, eczema severity (POEM) improved in the intervention groups: −1.5 [95% confidence interval (CI) −2.5 to −0.6] for parents/carers, and −1.9 (95% CI −3.0 to −0.8) for young people. Effects were sustained for 52 weeks in both trials. The magnitude of the treatment effects ranges from a small improvement to larger than the MCID of 2.5 points. No harm or unintended effects were identified in either group.

We did not detect a difference in the use of eczema treatments between groups, yet did find significant differences between groups in patient enablement instrument (PEI) scores. Enablement showed an important difference favouring the intervention group in both trials [adjusted mean difference at 24 weeks −0.7 (95% CI −1.0 to −0.4) for parents/carers and −0.9 (95% CI −1.3 to −0.6) for young people].

Economic evaluation

Aim

To undertake a within-trial economic evaluation of the two online interventions from an NHS perspective.

Methods

We conducted two primary cost–utility analysis (CUA), using individual-level data collected within the trials, to estimate the cost-effectiveness for each of the interventions plus usual care compared to usual care alone in terms of incremental cost per QALYs at 52 weeks. A secondary cost-effectiveness analysis (CEA) was conducted for each of the two trials, and the two trials combined, using the trial primary outcome measure POEM.

The interventions were developed using research funding and therefore the 'development costs' were not included in the economic evaluations but are reported separately.[63] However, 'maintenance costs' likely to be incurred to keep the intervention running were included in the analysis. This included e-mail support, server-to-host interventions, server updates and domain names. The maintenance costs were split equally among participants, although when implemented on a larger scale, the per participant cost would likely be smaller.

Wider NHS resource use for eczema (primary and secondary care medication and service use) was captured via medical notes from GP practices. This was for a 52-week period plus a 3-month pre-baseline period to allow for adjustments for baseline costs in the adjusted analyses. All resource use was valued using UK published unit costs (in Great British pounds 2020–1).[64,65]

In terms of outcomes, quality-adjusted life-years (QALYs) were estimated via utility scores elicited using the proxy CHU-9D for parents/carers and the EQ-5D-5L instrument for young people. Utility measurements were collected at baseline, 24 and 52 weeks via online questionnaire. The responses received were converted to utility scores using the Stevens[59] value set for the CHU-9D and using UK preference weights in line with recommendations at the time of analysis for the EQ-5D-5L.[66,67] These utility values were used to estimate the number of QALYs generated over the 52-week trial period, using both linear interpolation and area under the curve analysis with and without baseline adjustment.[68] Separate CUAs were conducted to estimate the incremental cost per QALY for each trial.

The CEA was undertaken using the primary outcome for the trial, the POEM, where a lower score represents less severe eczema. Since a two-point difference in POEM score is deemed to be a difference that would be noticeable and important to people with eczema,[69] we use this to estimate the incremental cost per success.

The mean (SD) cost per participant was estimated for each randomised group in order to estimate the mean difference (95% CI) in cost per participant between groups. Alongside this, the mean (SD) utility and mean (SD) QALYS per participant per randomised group are presented along with the mean difference (95% CI) in utility and QALYs between groups.

A regression-based approach[70] using complete-case data was used in the base-case CUAs. Both unadjusted and adjusted results are presented, but the adjusted analyses constitute the main base-case analysis adjusting for baseline POEM/utility/cost (as appropriate), recruitment region and the covariates which were pre-specified in the SAP as possible confounders: age, gender, ethnicity, prior belief in the intervention, carer education if appropriate, and prior use of a website or app for eczema information or advice. Secondary CEA is presented for each trial and both trials combined as POEM was used in both trials (unlike utility which was captured using a different instrument in each trial to reflect the age of participants). Incremental cost per success is presented. Generalised linear models were used to

estimate adjusted incremental costs and effects in the CEAs given the binary outcome; this assumes that costs and benefits are not correlated.

Since costs and outcomes were likely to be skewed, non-parametric bootstrapping was used to determine the level of sampling uncertainty surrounding the mean incremental cost-effectiveness ratios (ICERs) by generating 10,000 estimates of incremental costs and benefits. Cost-effectiveness acceptability curves (CEACs) were produced, which show the probability that the interventions are cost-effective for different values of willingness to pay (WTP). The National Institute for Health and Care Excellence threshold of £20,000–30,000 per QALY is used.[66]

Sensitivity analyses (SAs) to explore the impact of missing data on results were undertaken using multiple imputation.[71]

Key findings

The trial interventions were low cost in terms of maintenance and ongoing delivery costs, with a mean cost per participant of £1.32 in the parent/carer trial and £1.36 in the young person's trial.

Incremental results are presented in *Appendix 7*, *Table 9*. In the base-case complete-case CUAs for the parents/carers trial, the adjusted analysis had an incremental cost of −£34.15 (95% CI−104.54 to 36.24) and was associated with incremental QALYs of −0.003 (95% CI −0.021 to 0.015). The ICER was £12,466 per QALY, which, since it falls in the Southwest quadrant of the cost-effectiveness plane (i.e. the intervention is cost-saving but has a slightly worse outcome), is unlikely to be considered cost-effective because the ICER is not greater than the WTP threshold. Another way of presenting this is as a net monetary benefit (NMB; estimated as incremental benefit × WTP threshold − incremental cost) which is positive (suggesting interventions are cost-effective) in all analyses except for the adjusted complete-case analysis where the NMB is negative (see *Appendix 7*, *Table 9*) at both a £20,000 and £30,000 WTP threshold indicating that the intervention would not appear cost-effective. For the interested reader who wishes to understand the vagaries of estimating and interpreting ICERs and NMBs, please see Paulden.[72] For the trial including young people, the intervention was dominant in both the adjusted and unadjusted analyses. The adjusted analysis had an incremental cost of −£20.82 (95% CI −71.77 to 30.13) and was associated with incremental QALYs of 0.012 (95% CI −0.017 to 0.041). In the SA to estimate the impact of missing data, the intervention was dominant for both trials, with at least a 65% probability of being cost-effective at the £20,000 WTP threshold. Given the level of missing data, particularly in trial 1, the SA using multiple imputation is likely to give a more valid estimate of cost-effectiveness.

In the complete-case CEAs, the parent/carers trial's adjusted analysis estimated an incremental cost of −£27.66 (95% CI −79.63 to 24.31) and an incremental success of 8.6% (95% CI −3.0% to 20.2%). In the young person's trial, the adjusted incremental cost was −£23.57 (95% CI −74.22 to 23.07) with an incremental success of 10.4% (95% CI −2.4% to 23.2%). The CEA analysis combining both trials showed an adjusted incremental cost of −£20.35 (95% CI −55.41 to 14.70) with an incremental success of 10.3% (95% CI 2.3% to 18.1%). In all CEA analyses, the intervention was dominant (cheaper and more effective than usual care).

Conclusions

Eczema Care Online interventions for parents/carers of children with eczema and for young people with eczema are robustly developed evidence-based resources which were found to be low cost and cost-effective.

A small amount of benefit at low cost, with no identifiable harms, for a condition that impacts many people can lead to substantial health benefits for the public in absolute terms. The findings reinforce the importance of health professionals signposting people with eczema to self-management support.

Workstream 5: explore how to integrate interventions into clinical practice and facilitate their uptake

Workstream 5 addresses the third objective of the programme: to formulate and initiate an implementation plan for integrating interventions into clinical practice and facilitating their uptake (if clinically and cost-effective), informed by process evaluation. It also includes the redevelopment of the online behavioural interventions into a marketable product ready for dissemination. We examined two aspects of implementation: (1) how people and families with eczema might use ECO outside a trial, and (2) how health professionals and organisations may signpost to ECO.

Workstream 5.1: process evaluation

This work has been published or is currently under review:

https://doi.org/10.1093/bjd/ljac115.[73]

https://doi.org/10.1002/ski2.59.[74]

Aim

- To understand likely causal mechanisms for the interventions, how effects might vary between user groups and settings, and inform the implementation of the interventions.

Methods

Design

Qualitative and quantitative process evaluation embedded in the two RCTs (workstream 4) using three data sources:

1. Qualitative interviews with young people and parents/carers participating in the RCTs.[73]
2. Objective intervention usage data collected across a 52-week study period.
3. Quantitative process questionnaires.

Recruitment

The methods of recruitment for the RCT are described in *Workstream 4: determine the clinical and cost-effectiveness of the Eczema Care Online interventions*. For the qualitative interview study, all trial participants were asked if they consented to be contacted by the research team on study sign-up. Those who consented were recruited via purposive sampling to recruit a range of ages, gender, ethnicity, eczema severity, socioeconomic status, recruitment site, trial groups and intervention usage. Participants were contacted by the research team and invited to take part. Consenting participants were sent an information sheet and completed an online consent form. For young people aged 13–15 years, their parents or legal representatives provided online consent for them to take part. These young people were sent an information sheet and provided verbal assent at the outset of the interview. Participants were given a £10 voucher for taking part.

Data collection and analysis

Qualitative: Semistructured telephone interviews were carried out at least 3 months after randomisation by four researchers. A topic guide was developed with feedback from a PPI representative and included questions exploring people's views of the website content and delivery features, any cognitive or behavioural changes that resulted from using the website, impact of the COVID-19 pandemic on eczema management or intervention usage, and reasons for

any low intervention usage. Interviews from both groups were analysed together using inductive thematic analysis.[75] Intervention modifications were identified using the person-based approach table of changes method.[50]

Quantitative: There were two hypothesised behavioural mechanisms: emollient use and TCS/TCI use, for which no differences were observed in the trials. There were also two psychological mechanisms: patient enablement (the self-perceived ability to understand and cope with health issues) and perceived barriers to treatment. Intervention usage data were collected to describe patterns of intervention usage for all intervention participants in the intervention arm (young people *n* = 168; parents/carers *n* = 171) for both trials across the 52-week study period. Data were analysed using descriptive statistics. Per-protocol and complier-average causal effect analyses were carried out to examine the effect of high intervention use on eczema severity (POEM questionnaire). High intervention use included users who had finished at least one of the treatment modules (moisturising creams or flare control creams) or an optional module. Mediation analysis was used to determine whether patient enablement, treatment use or barriers to adherence mediate the intervention effect on eczema severity. Subgroup analysis was carried out to explore whether the intervention effect was different among pre-specified categories of baseline variables. Logistic regression explored associations between higher intervention use and various demographic and baseline factors.

Key findings

Participants

Seventeen parents/carers and 17 young people from the two intervention groups took part in the qualitative interviews. Thereafter, 314/340 (92.4%) parents/carers completed the 24-week POEM and 304/337 (90.2%) young people completed the 24-week POEM (primary timepoint). See *Appendix 8*, *Table 10* for participant characteristics.

Qualitative interviews

Generally, both parents/carers and young people found the interventions easy to use and relatable, were able to engage with them competently, believed they were trustworthy and provided value to them and believed they helped them manage eczema. Our analysis suggested that the interventions may reduce eczema severity by facilitating empowerment among its users. Parents/carers and young people reported that ECO helped them to understand and feel confident in managing eczema; improve their use of topical treatments; avoid irritants and triggers that make eczema worse; engage in productive treatment conversations with their health professional; and involve their child in eczema management (parents/carers). Many parents and young people valued how the interventions helped them, or their child, normalise or accept eczema. Although many reported how the intervention relieved concerns they had about the safety of eczema treatments, two young people still held negative beliefs about TCSs, views that were not influenced by the intervention. Some participants believed they were already knowledgeable about eczema, had a good treatment regimen, or had their eczema under control and, therefore, felt that the interventions were not valuable to them. Several minor modifications were made to the intervention including improving the website design to make it more visually appealing, improving navigation to locate specific informational content more easily within a module, and adding information on TCS withdrawal. See *Appendix 9*, *Table 11* for an excerpt from the Table of Changes.

Intervention usage

Most intervention participants in the parent/carer trial (88%; *n* = 151) and the young people trial (93%; *n* = 156) reached the minimal engagement threshold within the trial period, which was defined as having viewed the core introductory content containing all the key content that we felt was necessary for behaviour change. Users spent a relatively short amount of time on the interventions (median = 21–27 minutes). See *Appendix 10*, *Table 12* for details.

Quantitative process analysis

For parents/carers, about 30% of the intervention effect on the POEM score at 24 weeks was mediated by increasing patient enablement. For young people, about half of the intervention effect was mediated by increasing enablement. However, as enablement and POEM were measured at the same time point, as is common in trials, these results need to be interpreted with caution. There was no evidence of a mediating effect of treatment use or perceived barriers to treatment in either trial. See *Appendix 11*, *Table 13* for details.

Most of the associations between user characteristics and outcomes were not statistically significant, but these are exploratory analyses which are likely to be underpowered for the tests undertaken. However, those in the parent/carer trial with severe eczema at baseline had a significantly larger treatment effect than those with mild eczema (−4.0 vs. 0.8, adjusted interaction term −4.0, 95% CI −7.7 to −0.2). This difference is larger than the MCID of 2.5 points for the POEM outcome. Higher baseline eczema severity (young people; combined parents/carer and young people data), greater baseline emollient use (combined parents/carer and young people data), having a degree (parent/carer), having uncertainty about how to carry out treatment and having doubts about treatment efficacy (parent/carer) were significantly associated with higher use of the online intervention, although higher intervention usage was not linked to improved outcomes. See *Appendices 12–14* for details.

Conclusions

In summary, the process evaluation suggests that these interventions were acceptable to our parents/carers and young people and provided benefits with little time commitment. It is likely that all people with eczema will benefit from using the intervention. Together with the RCT findings, these studies provide additional support for the wider implementation of ECO.

Redevelopment of interventions

We worked with a commercial software provider to redevelop the trial versions of the online interventions into marketable products ready for dissemination and implementation. The intervention content that was trialled remained the same, but minor changes were made in response to findings from the process evaluation. Minor changes included:

- Removal of questionnaires and study e-mails/texts.
- We combined 'ECO for families' and 'ECO for young people' so you now choose if you are there 'for my child' or 'for myself' when you first enter, and the content is tailored accordingly.
- The website was built using the latest adaptive technology to ensure it can be accessed from a range of devices.
- Adding information about 'topical steroid withdrawal'.
- Redesign of the navigation/layout to improve usability.
- Translate website content into Welsh.

The intervention is freely available in both English and Welsh at www.eczemacareonline.org.uk.

Workstream 5.2: implementation and engagement planning

This work has been published:

https://doi.org/10.1136/bmj.o2973.[76]

Our ambition has always been for ECO to improve the lives of people living with eczema. However, innovations and ideas from research do not always easily translate into changes in healthcare systems outside of the research setting.[77–79] Therefore, from the outset of the programme, we have given thought to how ECO, and more widely the knowledge that it aims to share, can reach people with eczema.

Normalisation process theory is an implementation theory that explains what processes are required for an intervention to be taken up in practice.[79] NPT has guided our implementation strategy. Our aim was to develop an implementation strategy for ECO; to do so, we needed to understand barriers and facilitators to implementation. The implementation strategy will allow us to understand the best mode of delivery for ECO beyond a trial setting, understand how ECO fits within the marketplace for online information about eczema, and identify the target audience, key stakeholders and target avenues to help prioritise implementation efforts.

Methods

We used the following sources of information to inform our implementation strategy:

- We mapped the process evaluation interview data (reported in workstream 5.1) to the NPT constructs, to help identify barriers and facilitators to implementation.
- We undertook a series of stakeholder consultation meetings throughout the programme. See *Patient, public and practitioner involvement in the programme* and *Workstream 2.4: creation of knowledge tools to support patients and healthcare professionals* for details. We mapped the insight from these stakeholders to the NPT constructs, to help identify barriers and facilitators to implementation.
- We used data on how individuals within the RCTs used the interventions (reported in workstream 5.1) to inform the layout and emphasis we put onto sections of the intervention when re-designing ECO for implementation.

We used the process evaluation interviews and stakeholder feedback to help inform our value propositions (i.e. what is the unique value of ECO). We also examined how our value propositions compared to how other online sources of information for eczema were presented.

Eczema Care Online implementation strategy

Our implementation strategy is outlined in the Table 1 below. We worked with professional networks UK Dermatology Clinical Trials Network, British Association of Dermatologists, British Dermatological Nursing Group, Primary Care Dermatology Society and Allied Health Sciences Network to inform and implement our strategy.

TABLE 1 Eczema Care Online implementation strategy and actions to date

Strategy outline	Summary of rationale	Actions to date
Delivery: redesign the two interventions into one mobile adaptive website	To improve user experience and accessibility. To simplify maintenance. To meet different user access and preferences (desktops and mobile phones). To include a Welsh language version to enhance accessibility in Wales.	Created and launched a newly developed website: www.eczemacareonline.org.uk
Marketplace: ECO value propositions: 1. proven to help people with eczema 2. created in partnership 3. independent 4. comprehensive 5. evidence based and theory informed, and 6. accessible and appropriate to a UK audience.	Comparison to other websites shows some value propositions are unique to ECO (proven to help people with eczema) and others are comparable with other websites (accessible and appropriate to a UK audience). Each has been emphasised as important by different stakeholders, so all are to be maintained, but certain ones may be more relevant to highlight in different contexts.	Emphasising value propositions in all our communications. Examples include: A short animation that describes the value propositions: https://youtu.be/B99_BKaoncs (see *Figure 5*) Social media advertisements emphasising value propositions (see *Figure 6*) E-mails to key stakeholders emphasising the value propositions. Summary document that describes the value propositions and evidence for ECO to share with organisations interested in adopting the resource (*Report Supplementary Material 3*)
Target audience: anyone with eczema, but mainly people with newly diagnosed eczema or people managing their own eczema for the first time.	Stakeholder consultation and interviews with potential users suggest newly diagnosed may experience the most benefit.	Communications with all stakeholders and advertisements have all emphasised the relevance to anyone with eczema or caring for a child with eczema. Website redesign allows for use for either myself or my child.
Key stakeholders: patient organisations, healthcare professional organisations and healthcare delivery organisations.	Raising awareness among organisations with influence to reach wider numbers of both healthcare professionals who may share the website with patients and individuals who may use the website.	Published academic papers, press releases, and presented at academic conferences that will reach some key stakeholders.

continued

TABLE 1 Eczema Care Online implementation strategy and actions to date (*continued*)

Strategy outline	Summary of rationale	Actions to date
		Contacted some key stakeholders directly via e-mail explaining how they might benefit from ECO. In discussions with both the two UK leading charities and an Australian eczema charity about how they can make use of the resources.
Avenues for implementation: a wide variety of avenues to be explored, but efforts prioritised on embedding weblinks to the interventions into resources that support clinical practice and training, as well as working with eczema charities to embed and promote the resource. We are also exploring direct promotion through social media advertising.	Eczema charity websites are engaged with the intervention and a less resource-intensive avenue than others.	Provided materials and information to eczema charities so they could promote the website.
	Integration into primary care electronic systems and resources has more barriers to access, but stakeholder consultation and interviews with users suggest could be the most successful route once embedded.	Contacted multiple training and clinical practice organisations to ask them to embed ECO into systems or resources.
	Secondary care users are receptive to the intervention and can be key influencers for primary care via advice and guidance.	Written articles about ECO for organisations to communicate with their network/members.
	Pharmacy involvement growing in eczema management, so a longer-term goal is to improve pharmacy implementation avenues.	Key clinical champions promoting ECO at national and international meetings, on podcasts, and among their networks.
	Social media advertisements are relatively inexpensive and may help increase traffic and reach a different target audience to other routes.	Created 'two treatments used well pads' and business cards that were shared with all practices participating in the trial, some pharmacies and some secondary care departments. A targeted social media campaign was initiated in November 2022 including paid advertising on Facebook and Instagram, and collaboration with charities and support groups.

FIGURE 5 Screenshot of the ECO YouTube animation video.

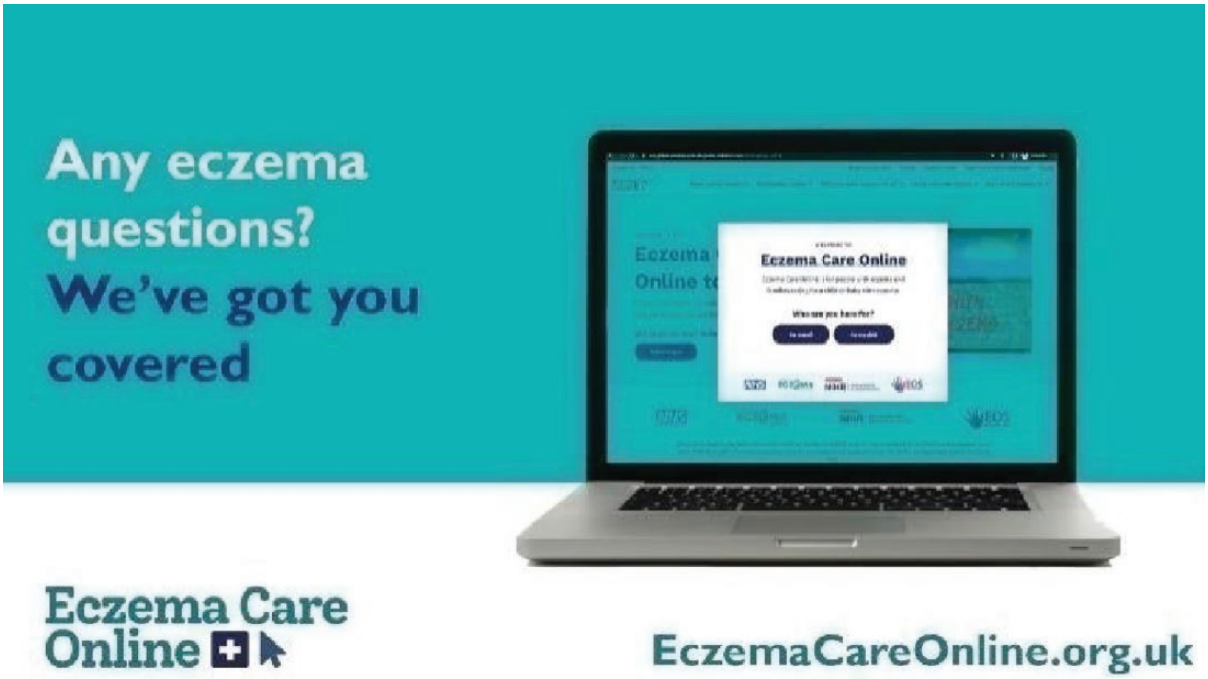

FIGURE 6 Example of materials used in social media advertisements emphasising value propositions 'comprehensive' and 'accessible'.

Further work is required to fully action the strategy and to evaluate its effectiveness, but the section below outlines key implementation successes to date.

Implementation successes to date

Since launch of the website in June 2022, the website has been accessed by over 13,450 unique visitors from 138 countries. At least 12 organisations have agreed to share in communications with their network, embed into resources or clinical systems, or include in training courses.

Feedback from a range of stakeholders indicates that ECO has been well received:

> *Very helpful resources indeed. Since it has become available, I have tried to include it in every Advice & Guidance that I do!*
>
> *Paediatric Dermatologist, UK*

> *I have been disseminating around my clinical networks as this will be a really useful, national, harmonised resource for people affected by eczema.*
>
> *Paediatric Allergist, UK*

> *Our Family Workers regularly signpost families to ECO so hopefully there is a steady stream of families benefiting from the information.*
>
> *Eczema Outreach Support, UK*

> *Looked brilliant because you can just send it away to [patients] and say look, this is what it's all about*
>
> *General Practitioner, UK*

Challenges for implementation of our strategy

National Health Service policy is to expand NHS-accredited health apps/websites to support people in managing their own health, but progress on accrediting apps/websites has been slow and online infrastructure is needed to signpost to reliable resources. The Digital Technology Assessment Criteria for health apps produced to give staff and patients confidence that digital health tools meet clinical safety, data protection, accessibility and cyber security standards has been very difficult for research teams to undertake, requiring substantial additional investment of time that is often

beyond the scope of the original funding. This is in addition to licensing and technology transfer arising at the end of a programme where contracts may be ending and research teams therefore having difficulty finding capacity to complete these tasks. Costs of hosting the intervention over the coming 5 years have been secured, but longer-term sustainability that allows content, digital infrastructure and format to be kept up to date remains uncertain. We have explored private, public and charity sector partnerships. Participants in the ECO trials reported that knowing the intervention is free from commercial influence was important to them in trusting messages and public contributors have also pushed us to maintain a focus on independence and keeping the interventions free to use. We would therefore like to maintain 'ownership' (i.e. content control) of the ECO interventions with a commitment to making sure content is evidence-based, while also disseminating in partnership with eczema charities to raise awareness. NIHR funding enabled us to co-produce engaging and effective interventions, but it is not completely clear yet how these will remain free to use for the NHS in the long term.

Conclusion

Focusing on the barriers and facilitators to implementation of the ECO website throughout this programme has ensured that our product is market-ready and able to be implemented widely, both in the UK (as our primary target audience) and internationally.

The website will be free to access for 5 years; it is free from commercial influence and does not require registration. It has been extremely well received by charity partners, healthcare professionals and people with eczema. To ensure longer-term sustainability, we are exploring various options for partnerships but are mindful of the impact that commercial influence or changes to the content may have on effectiveness.

Patient, public and practitioner involvement in the programme

Patient and public contributors have been central throughout the programme. This research topic was prioritised by patients and health professionals in a James Lind Alliance Priority Setting Partnership and builds on years of experience in providing information to families with eczema from the Nottingham Support Group of Carers of Children with Eczema, co-led by public contributor Amanda Roberts plus co-applicants Hywel Williams and Sandra Lawton.

Public contributor co-applicants have been involved in all aspects of research design, programme management, intervention development, systematic reviewing, protocol development, trial management, and implementation and dissemination work. Specific examples include the following:

- Provided advice and input on participant recruitment strategies.
- Reviewed all participant information sheets and consent forms to determine whether wording was likely to be appropriate for the target population.
- Pushed the research team to ensure that a plan was in place to ensure the sustainability of the intervention beyond the end of the grant.
- Contributed to the interpretation of study findings in all workstreams.
- Involved in co-authoring all publications and other outputs such as blogs and press releases from the programme.
- PPI co-applicant Amanda Roberts co-wrote a blog in the *BMJ* in October 2019 titled 'Diverging views on eczema treatments – promoting shared understanding between doctors and patients'.
- PPI co-applicant Amina Ahmed co-wrote a blog in the *BMJ* in July 2019 titled 'Patient partnership in an academic research unit'.
- Attended and facilitated stakeholder events.

We also undertook wider PPI throughout the programme. Additional public involvement was sought through the Nottingham Centre of Evidence-Based Dermatology patient panel who provided input at various stages of the programme. The online interventions were co-produced with a diverse group of public contributors and other key stakeholders. We worked closely with our PPI co-applicants, another public contributor Kate Henaghan-Sykes who is the parent of a child with eczema, and two young people with eczema who joined the development group.

Several stakeholder events were held throughout this programme. In September 2019, we held a stakeholder meeting in London, attended by 34 people including representation from people with eczema, parents/carers of children with eczema, health professionals and representatives from eczema charities. This meeting primarily focused on sharing and discussing findings from our systematic reviews on the best and safest ways to use TCSs for eczema, which is a potentially sensitive topic due to common concerns people have about the safety of TCSs. In 2021 we held a series of smaller, virtual stakeholder meetings with patients, parents, primary care clinicians and secondary care clinicians to discuss and refine key messages from the Cochrane review on TCS safety and efficacy and approaches to dissemination. Thirty people attended these meetings. As a result of discussions in the workshops, we also organised a dedicated workshop targeted to those individuals with an interest in TCS withdrawal; 18 people attended this additional workshop.

Throughout this programme we worked closely in partnership with the two main UK eczema charities, NES and EOS. The chief executive officers of both NES and EOS were members of our Programme Steering Committee and charity representatives attended our stakeholder events. NES and EOS have also endorsed www.eczemacareonline.org.uk and have been active partners in disseminating the intervention by promoting and linking to it from their websites.

Public contributors have attended and presented findings from the ECO programme at academic conferences. PPI contributor Kate Heneghan-Sykes has gone on to a role as core PPI in the Primary Care Research Centre, University of Southampton, and PPI contributor Amanda Roberts has successfully secured a NIHR Programme Grant as co-lead with Professor Kim Thomas to conduct rapid citizen science-led trials for eczema [Rapid Eczema Trials programme grant (NIHR PGfAR 31466)], which aims to address the balance of power between researchers and public contributors in eczema research.

Equality, diversity and inclusion

At all stages of the programme, we sought diversity among both research participants and public contributors. During intervention development, feedback was sought from a diverse group of 55 young people and parents/carers of children with eczema. We sampled participants from a wide range of ethnic and socioeconomic backgrounds, ages, gender and eczema severity. During our clinical trial, we monitored participant characteristics and noticed early on that we were recruiting significantly fewer men aged 13–25 compared to women. In response, we carried out a review of invitation materials to help improve appeal to young men. We showed our study documents to five young men to obtain feedback which led to a series of changes, including adding a QR code to the invitation and making information about gift vouchers more prominent. While this resulted in a small increase in uptake among young men, they remained under-represented in the sample. This highlights the need to engage under-represented groups (in this case young men) more systematically in the earlier phases of intervention development. The INCLUDE Ethnicity Framework[80] will be helpful in designing future trials and seeking to maximise inclusion and applicability to underserved groups, although was not available at the start of designing this trial. We are taking this practice forward in our ongoing programme grant Acne Care Online (NIHR PGfAR 202852).

We ensured that all programme materials used inclusive language (e.g. 'parents and carers' to include a range of family structures) and used inclusive imagery in all study materials (e.g. ethnic diversity). We iterated all public-facing materials with public contributors to maximise accessibility in terms of language and layout.

In implementing the interventions, we prioritised making the resources freely available to be used by any member of the public who needs them. This was emphasised as a priority throughout the programme by public contributors and is key to ensuring that the benefits of the intervention can be disseminated in a way that minimises the risk of increasing inequalities in health. We have achieved this in the short term by negotiating a 5-year web-hosting term with our commercial partners.

Reflections on what was and was not successful

Overall, the ECO programme was a success, and we delivered a large programme of work ahead of schedule and to budget. Early work suggested that a feasibility trial was not necessary, and we commenced with an internal pilot. This contributed to completing ahead of time, allowing for the intervention to be redeveloped using commercial software within the life of the programme, such that it is already being rolled out and widely used.

We maintained good working links between the research teams in Nottingham, Southampton and our other partner institutions and strengthened links and collaborations with our host Solent NHS Trust and charity partners NES and EOS. Many of the research team are now working on related programme grants Rapid Eczema Trials and Acne Care Online and all continue to work in research.

Throughout the programme we used rigorous methodology and multidisciplinary subgroups, including PPI, to ensure high-quality research. We have produced 23 papers throughout the programme, including publishing our main trial paper in the *BMJ* with an accompanying *BMJ* opinion piece about ECO implementation. All our publications have been published on our programme website (www.nottingham.ac.uk/ECO) and Twitter (Twitter, Inc., San Francisco, CA, USA) (@ECO_eczema) with accompanying plain English summaries and/or a blog. Seven videos have also been disseminated and are available on our programme website.

Our clinical trial (workstream 4) started at the end of 2019 and when the COVID-19 pandemic started we had to adapt quickly to amend some trial processes and adjust to remote working. Online trials worked well, particularly in the COVID-19 era, but also for reducing the carbon footprint of research. We worked with a commercial provider to create www.eczemacareonline.org.uk in both English and Welsh to enable dissemination throughout the UK. There are ongoing challenges to keeping ECO freely available in the future.

Limitations relating to the methods or execution of the research

We have identified several limitations to the methods or execution of the research in this programme. Workstream 2 delivered three robust systematic reviews, including a Cochrane review. While many novel and useful findings came from the reviews, safety data were often under-reported and follow-up periods were often short, which limited the conclusions we were able to draw from the reviews.

During the trial in workstream 4, young men and fathers were under-represented despite our efforts to tailor recruitment materials to be inclusive and accessible to men. More process measures may have allowed us greater insight into the mechanisms of action of the interventions but may also have adversely affected follow-up due to the questionnaire burden.

The ECO interventions were developed mainly for people with mild-moderate eczema managed in primary care. Modifications may be needed to enhance the relevance to people with severe eczema or those managed in secondary care. Similarly, the interventions were developed and trialled in young people up to 25 years. While this is likely to be relevant to most adults, further research may be needed to optimise and tailor the intervention to the needs of older adults.

In the workstreams 4 and 5 qualitative process evaluation, we were able to purposively sample participants across a range of demographics and geographical areas, with different eczema severities and different levels of intervention usage. We recruited people from a range of ethnic minority groups and people from areas with greater levels of deprivation; however, parents had educational attainment above population averages, so the findings may be less applicable to those with lower education levels.

There were also limitations to the quantitative process evaluation. We encountered challenges with how best to measure time spent on the intervention as it is not known whether people were actively engaging in the intervention page or whether the page was open while they did something else. For the mediation analysis, the primary outcome and potential mediators were measured at the same time point. Ideally, the mediators should have been measured at an intermediate time point, after the use of the intervention and before the measurement of the outcome at 24 weeks.

Conclusions from the whole programme

This programme award has developed, tested and implemented an online intervention to support the self-management of eczema. The benefits of using the ECO interventions have been demonstrated in two RCTs, targeting two key user groups, and a within-trial CEA suggests that the use of the intervention can result in potential cost savings to the NHS.

There have been many calls for health professionals, and the NHS, to take a greater role in signposting patients towards evidence-based digital resources to support self-management. However, this is not widely practised in the increasingly pressurised context of routine care. In eczema, self-management support is particularly important due to the complexity and high burden of treatment adherence.[81] By providing resources that allow health professionals to promote these resources easily, as well as providing evidence that the interventions improve eczema outcomes, we hope that promoting self-management support will become increasingly the new standard of care.

Continuing dissemination following publication of the RCTs in December 2022 and monitoring the uptake of interventions will allow us to track routes to implementation and further build on these. We are pursuing dissemination via charity partners in addition to via health professional signposting, in order to diversify and aim for the intervention to be promoted by multiple routes. The imperative now is for effective implementation of ECO. This is where programmatic funding has been crucial in allowing time to develop the product from research-focused software into highly usable software.

Recommendations for future research

This programme has demonstrated the effectiveness of well-developed online behavioural interventions to support self-management of skin conditions. Future research could develop and evaluate similar resources to target the needs of people with other chronic skin conditions, particularly those that require complex treatment regimens and lifestyle support.

Implementation research into the best ways of sustaining and delivering the intervention in different settings, including GP, community pharmacy and through charities, will also be important.

Our systematic reviews of the best and safest ways of using TCS highlighted the paucity of evidence to inform usual practice, with many evidence gaps, including:

- How long should TCS be used for an eczema flare-up?
- How long to leave between the application of TCS and emollients?
- What is the safety of TCS use beyond 12 months?
- What is topical steroid withdrawal and how can it be avoided?

Future research may enhance research participation by engaging with under-represented groups and considering their needs from the outset.

Implications for practice and lessons learnt

We have developed evidence-based online interventions for eczema self-management and shown that these provide a useful, sustained benefit in eczema severity over 12 months. Although the improvement in eczema resulting from access to interventions is modest, this benefit is low cost and with no identifiable harms. If this was a drug treatment, we would prescribe it. For now, we are maintaining 'ownership' (i.e. control of content) of the ECO interventions. Our dissemination strategy is in partnership with eczema charities to raise awareness and to embed intervention weblinks into clinical practice. There will be an ongoing challenge of sustainability after the research funding is finished, but we are committed to keeping the interventions freely available for as long as possible.

Process evaluation suggests that these benefits arise in part due to enabling young people and parents/carers of children to feel more confident in managing their eczema and probably also because of understanding around the different treatments and trigger avoidance.

The core intervention message of 'two treatments used well', that is, 'flare control creams' (topical anti-inflammatories) to get control of eczema and 'moisturising creams' (emollients) to keep control of eczema, seems likely to have contributed to the success of the interventions and can be promoted in a variety of contexts, such as within consultations as well as in the intervention. For people with repeated flares, weekend therapy to prevent flare-ups is a safe and effective strategy.

Additional information

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Members of the Eczema Care Online programme steering committee: Tara Dean, Suzie Holland, Andrew Proctor, John Norrie and Gail Hayward; and former steering committee members Magali Redding and Margaret Cox.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

This study was conducted in compliance with the ethical principles of the Declaration of Helsinki and in compliance with all International Council for Harmonisation Good Clinical Practice guidelines. Study protocols were reviewed and approved by the Institutional Review board and/or Independent Ethics Committees. All participants provided written informed consent.

Ethical approval for the trial was given by South Central-Oxford A Research Ethics Committee (19/SC/0351).

Information governance statement

The University of Southampton is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, the University of Southampton is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here www.southampton.ac.uk/hr/services/data-protection/data-protection.page

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/FNHD8546.

Primary conflicts of interest: Beth Stuart was on the HTA Commissioning Committee 15 September 2020 –30 November 2024.

Tracey Sach was a member of NIHR Health Technology Assessment (HTA) Efficient Study Designs – 2 1 November 2015–31 July 2016, HTA Efficient Study Designs Board 13 October 2014–7 December 2014, HTA End of Life Care and Add-on-Studies 1 September 2015–9 February 2016, HTA Primary Care Themed Call Board and the HTA Commissioning Board between 2013 and December 2019. She is a steering committee member of the UK Dermatology Clinical Trials Network and Chair of the NIHR Research for Patient Benefit Regional Advisory Panel for the East of England, HTA General Committee 1 August 2016–31 July 2017, HTA Commissioning Committee 19 June 2017–31 January 2020. Tracey had no part in the decision-making for funding this study.

Lucy Yardley is NIHR Senior Investigator, Theme lead for NIHR ARC-West and NIHR HPRU in Behavioural Science and Evaluation and was cross-cutting theme lead for NIHR BRC at University of Southampton (2017–22). She is a member of the MRC/NIHR Better Methods Better Research funding panel and was a member of NIHR HTA Efficient Designs research 1 November 2015–31 July 2016 and NIHR Public Health Research funding panels but had no part in the decision-making for funding this study.

Laura Howells has received consultancy fees from the University of Oxford on an educational grant funded by Pfizer, unrelated to the submitted work.

Sinead Langan is on the medical advisory board for the NES.

Matthew Ridd was a member of an NIHR HTA committee (2016–9), NIHR Systematic Reviews Programme Advisory Group (2019–20) and continues on the NIHR In-Practice Fellowship Selection Committee (since February 2020).

Amanda Roberts was a member of HTA General Committee 1 June 2017–30 November 2021, and HTA fast Track Committee – June 2021 and had no part in the decision-making for funding this study.

Hywel C Williams was director of the NIHR Health Technology Assessment Programme from 2015 to 2020, and the PGfAR EOIs – HTA projects Remit meeting. HTA Commissioning Sub-Board (EOI) 1 April 2016–31 March 2017, HTA Efficient Study Designs Board 8 August 2014–7 December 2014, HTA PG Skype, NIHR Journals Library Board 1 April 2012–1 April 2018, HTA Board Recruitment, HTA Remit and Competitiveness Group 26 May 2010–30 September 2020, HTA General Committee – 1 January 2016–2 November 2020, HTA Post-Funding Committee teleconference (POC members to attend 26 May 2010–30 September 2020, HTA Funding Committee Policy Group (formerly CSG) 1 January 2010–30 September 2020, HTA Commissioning Committee 1 January 2010–30 September 2020. Hywel had no part in the decision-making for funding this study.

Miriam Santer was a panel member of NIHR Programme Grants for Applied Research 2018–23, and Academic PPIE lead and Board Member NIHR School for Primary Care Research 2022 to present day. Miriam had no part in the decision-making for funding this study.

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Appendix 1 Eczema Care Online intervention logic models

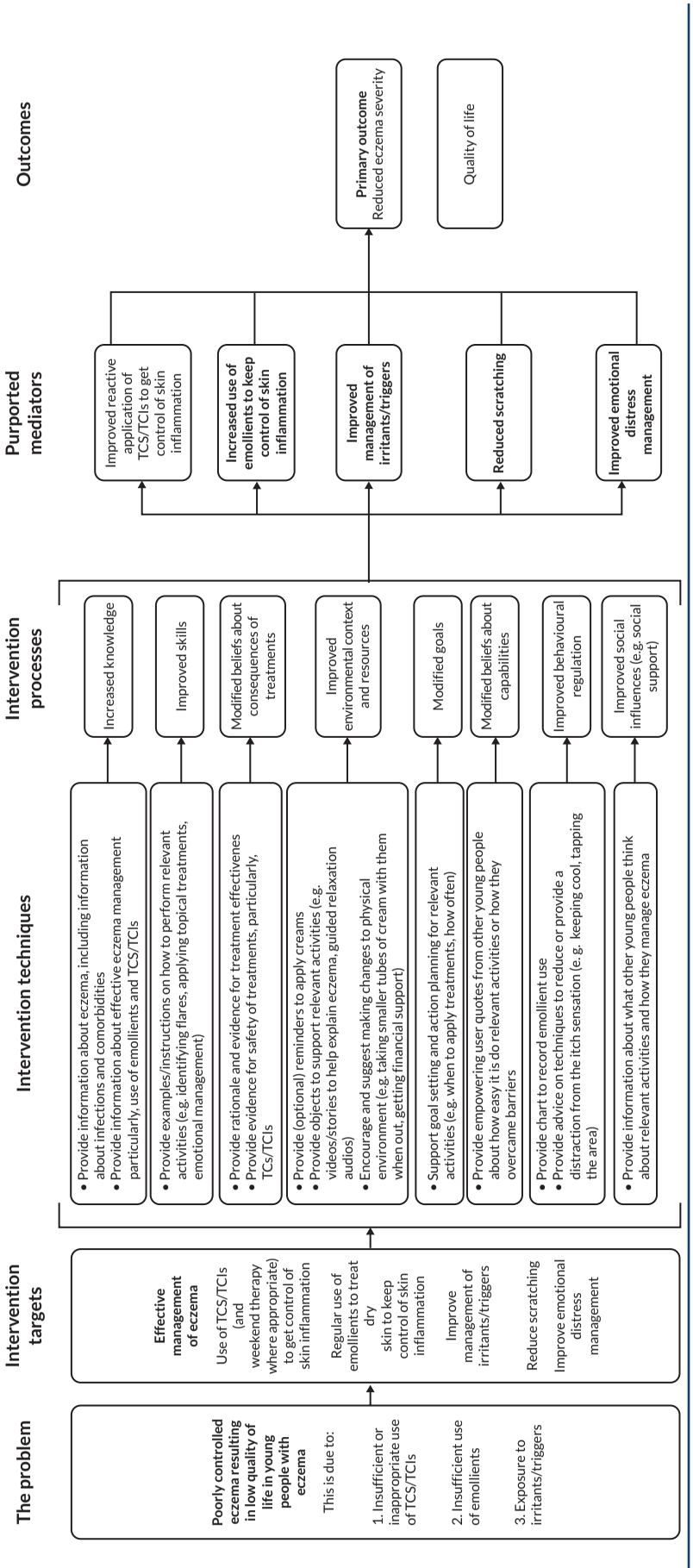

FIGURE 7 Eczema Care Online intervention logic model for young people.

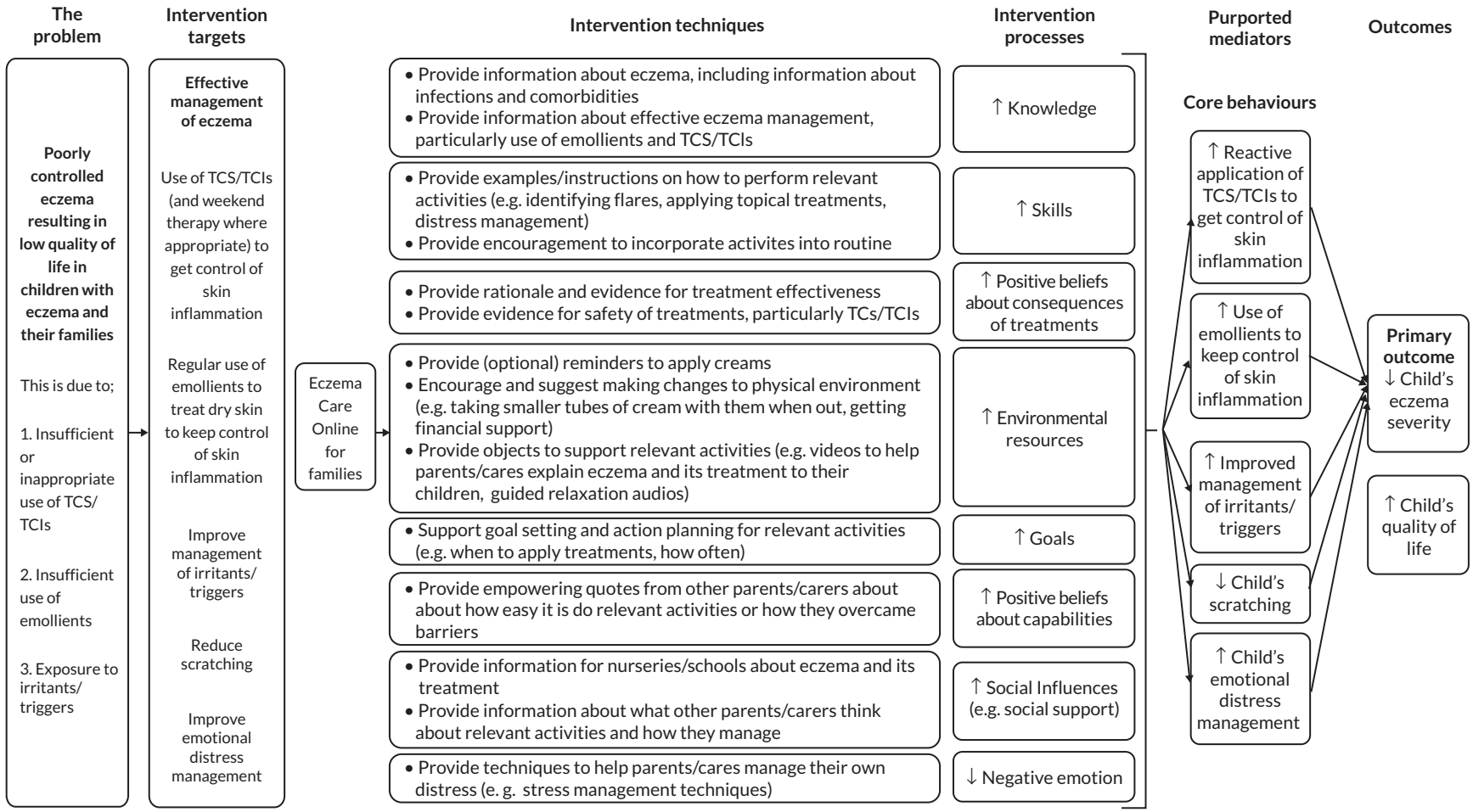

FIGURE 8 Eczema Care Online intervention logic model for parents/carers.

Appendix 2 Eczema Care Online guiding principles

TABLE 2 Eczema Care Online guiding principles for young people

User context	Intervention design objectives	Key intervention features
Young people (YP) with eczema have an increasing desire for autonomy regarding their eczema management but may feel apprehensive about their new roles and responsibilities. YP may have gaps in their understanding of eczema. YP may perceive barriers to using topical treatments.	To support YP to gain autonomy and competence in their eczema management	Ensure YP have a complete understanding of eczema and the rationale behind their treatment. To build YP's self-efficacy for the target behaviours (e.g. information on how to apply treatments, avoid irritants/triggers, reduce scratching). Stories and tips from other YP on what helped them take control of their own eczema and how to overcome barriers to treatments. Use autonomy-promoting language, provide choice wherever possible and avoid condescending or 'child-like' language/graphics. Provide advice on how to communicate with health professionals and make the most out of appointments.
YP have a desire to live as 'normal' a life as possible. YP may be told in childhood that they would 'grow out of' eczema, which is at odds with their own experiences.	To enable YP to maintain a sense of normalcy when managing their eczema	Provide age-appropriate advice on living with eczema (e.g. shaving, wearing make-up, and managing eczema at work/university/school). Provide relatable stories and advice from other YP with eczema. Acknowledge that, for some, eczema persists into adolescence and adulthood. Provide images and descriptions of eczema for different skin types. Avoid providing overly restrictive advice on irritants/triggers, instead offering advice on how to minimise the negative consequences of exposure irritants and triggers or provide alternatives (e.g. using emollients in place of soap).
YP may have doubts about the long-term effectiveness of topical treatments, and concerns around their safety and becoming over-reliant on TCSs YP may find topical treatments unpleasant in texture and/or smell and they worried about applying treatments in public in case others.	To build YP's beliefs in the positive effects of their topical treatments	Provide information to address topical treatment concerns and barriers, and persuade YP of the long-term effectiveness of these treatments.
YP may dislike reading large amounts of text, preferring content that is easy to scan, visual and peer-created. YP want interventions that are accessible on their smartphones and computers.	To provide engaging and accessible intervention content	Provide interactive content (e.g. quizzes), videos and pictures, and reduce reading burden by keeping the amount of text per page to a minimum. Break the content down into lots of short sections/modules. Intervention to be mobile-friendly. Provide peer-created content (e.g. stories, videos)

TABLE 3 Eczema Care Online guiding principles for parents/carers

Issues	Source	Intervention design objectives to address issues	Key features to address issues
Parents/carers may not have a lot of time; eczema treatment can be time-consuming and may be challenging to fit into their daily routines.	SR; EO	To create an intervention that is engaging and easy to navigate, in which parents/carers can quickly find the relevant information	• Make most intervention content optional so it can be accessed when/if it is needed • Add filtering questions to help signpost parents/carers to relevant modules • Use a modular layout so that parents/carers can quickly identify and select relevant topics • Ensure information is concise, presented in short chunks • Provide information in a range of formats to improve accessibility (e.g. audio–visual features, interactive features).
Parents/carers may feel distressed by the impact eczema has on their child. They may be struggling to manage their child's eczema, may be sleep-deprived or may worry about the long-term impact of eczema on their child. They may also feel distressed by their child's reaction to treatments (e.g. if the child finds it uncomfortable or painful), which may lead them to avoid, delay, stop, or to use treatments less often than needed	PPI; SR; I	To reduce parents/carers' feelings of helplessness, frustration, self-blame and guilt about their child's eczema	• Validate and normalise parents/carers' feelings around eczema and its management • Emphasise things that parents/carers can do to help manage their child's eczema, including tips and quotes from other parents/carers • Acknowledge that there are precipitating factors that are out of their control and identify what parents/carers can do to manage flare-ups • Avoid messages that may be viewed as blaming parents/carers for eczema flare-ups • Provide emotional management techniques that can help parents/carers manage difficult emotions
Young children may resist treatments because they dislike them and may not understand why they need them. As children get older, they increasingly encounter situations where they need to take more responsibility for managing their eczema (e.g. starting school, socialising outside the home). They may also want to start to self-manage, so will need to develop their own knowledge and skills for managing eczema.	PPI; SR; I	To facilitate co-management of eczema between parents/carers and their child to support their child's treatment adherence, and support their child's transition towards self-management	• Provide suggestions for ways parents/carers can involve their child in managing their treatment • Provide age-appropriate materials to help children learn about eczema and its management
Children may find eczema painful, itchy, unpleasant, or distressing. They may not understand what eczema is, or why they need to do the things that help them manage their eczema. They may find topical treatments painful, unpleasant, frustrating or boring, which may lead them to avoid using treatments or use them less than is needed.	PPI; SR; I	To reduce children's feelings of distress, anxiety, hopelessness and frustration around eczema and its treatment	• Help parents/carers to understand children's feelings • Provide age-appropriate tools/activities to help children manage difficult emotions related to eczema and its treatment to use on their own or with parents/carers • Provide age-appropriate explanations about eczema and its treatments to help children make sense of eczema and its treatment

EO, expert opinion; I, stage 1 interviews; PPI, patient–public involvement representatives; SR, systematic review.

Appendix 3 Eczema Care Online behavioural analysis using the Behaviour Change Wheel, theoretical domains framework and Behaviour Change Techniques Taxonomy

TABLE 4 Behavioural analysis for young people

Barriers/facilitator to target behaviour	Intervention components	Target construct (BCW)	Theoretical domain (TDF)	Intervention function (BCW)	Behaviour change technique (using BCTv1)
Target behaviour: increased emollient use					
Belief that emollients (in general or a specific brand) do little to control eczema (QSR; QI) *Belief that emollients are useful for preventing dry/cracking skin (QI)*	• Provide persuasive and credible information about the effectiveness of emollients, including scientific evidence, user quotes, and videos • Provide rationale for how emollients control eczema	Psychological capability; reflective motivation; social opportunity	Beliefs about consequences; knowledge; social influences	Education; persuasion; modelling	5.1 Information about health consequences 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source
	The 2-week challenge • Provide an emollient chart to allow YP to record how their skin is after applying emollients	Reflective motivation	Beliefs about consequences	Education; persuasion	5.1 Information about health consequences 2.4 Self-monitoring of outcomes of behaviour
	• Provide advice on how to choose an effective emollient (e.g. list of available emollients, disadvantages of using cosmetic moisturisers)	Psychological capability	Skills	Training	4.1 Instructions on how to perform the behaviour
Concerns about the safety and side effects (e.g. stinging, dependency) of emollients smell, feel and appearance of emollients (QSR; QI)	• Provide persuasive and credible information about the safety of emollients and risk of side effects (including their flammability), including scientific evidence, user quotes and videos	Psychological capability; reflective motivation; social opportunity	Beliefs about consequences; knowledge; social influences	Education; persuasion; modelling	5.1 Information about health consequences 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source
	• Provide advice on how to choose the right emollient (e.g. using different emollients at different times of the day, highlighting that different emollients have different constituents, smells and feel) • Provide advice on disguising emollients when around others/away from home (e.g. putting emollient in smaller containers)	Psychological capability	Skills	Training	4.1 Instructions on how to perform the behaviour
	The 2-week challenge • Provide an emollient chart to allow YP to record how their skin is each day after applying emollients and how they have found the emollients (e.g. side effects, texture)	Reflective motivation	Beliefs about consequences	Education; persuasion	5.1 Information about health consequences 2.4 Self-monitoring of outcomes of behaviour
Concerns about the psychosocial impact of emollients (e.g. feeling self-conscious) (QSR; QI)	• Provide strategies to reduce the psychosocial impact of emollients (e.g. feeling less self-conscious) • Provide quotes from YP explaining how they overcame some of the psychosocial consequences of emollients	Psychological capability; reflective motivation; social opportunity	Beliefs about consequences; beliefs about capabilities; knowledge; skills; social influences	Education; persuasion; training; modelling	5.3 Information about social and environmental consequences 5.6 Information about emotional consequences 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source

Barriers/facilitator to target behaviour	Intervention components	Target construct (BCW)	Theoretical domain (TDF)	Intervention function (BCW)	Behaviour change technique (using BCTv1)
Inconvenience of using emollients when away from home (QSR; QI)	• Provide advice on using emollients when away from home (e.g. requesting smaller tubes from health professional)	Physical opportunity	Environmental context and resources	Environmental restructuring	12.1 Restructuring the physical environment
Inconvenience of emollients rubbing off (e.g. on clothes and bed sheets) (QSR; QI)	• Provide advice on how to choose the right emollient and avoiding them rubbing off (e.g. put on loose clothing, allowing adequate time for absorption, leaving it to dry in a warm room)	Psychological capability	Skills	Training	4.1 Instructions on how to perform the behaviour
Belief that emollients are time-consuming to apply and to find the right one/competing time pressures (QSR; QI) Forgetting to apply emollients (QI) *Having an emollient routine* (*QI*)	• Provide information on how to integrate emollient use into everyday life • Reassure YP that applying emollients should not be time-consuming • Advise YP to plan when they will apply their emollients (i.e. ensure they allocate time)	Psychological capability; reflective motivation	Knowledge; skills; goals	Education; training; enablement	1.4 Action planning 4.1 Instructions on how to perform the behaviour 5.3 Information about social and environmental consequences
	The 2-week challenge • Suggest YP to apply their emollient daily • Suggest YP plan when they will apply their emollients • Suggest YP apply their creams at the same time in the same context each day • Allow YP to choose how many times per day they aim to apply their emollients and suggest they choose a particular time of the day or situation (e.g. after showering) to apply • Provide an emollient chart to record whether they have used their emollients at their agreed times	Reflective motivation; psychological capability	Goals; skills; behavioural regulation	Enablement; training	1.1 Goal setting (behaviour) 1.4 Action planning 2.3 Self-monitoring of behaviour 8.1 Behavioural practice/rehearsal 8.3 Habit formation
	• Allow users to set up regular reminders to apply emollients by e-mail or text messages and decide on the frequency of these reminders • Provide an emollient chart that acts as a reminder by suggesting YP record whether they have used their emollients at their agreed times (2-week challenge)	Physical opportunity	Environmental context and resources	Environmental structuring	7.1 Prompts/cues
Belief that finding an emollient that works best for you is inconvenient, confusing and time-consuming (QSR; QI)	• Acknowledge how frustrating and time-consuming this process can be • Provide quotes from YP emphasising the importance of finding the right emollient	Psychological capability; reflective motivation; social opportunity	Beliefs about consequences; beliefs about capabilities; knowledge; social influences	Education; persuasion; modelling	5.1 Information about health consequences 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source
Belief that you don't need to apply the emollient every day or only when you need it/eczema is bad (QI)	• Provide information on how often to apply emollients and the rationale for doing this	Psychological capability; reflective motivation	Knowledge; skills	Education; training	4.1 Instructions on how to perform the behaviour 5.1 Information about health consequences

continued

TABLE 4 Behavioural analysis for young people (*continued*)

Barriers/facilitator to target behaviour	Intervention components	Target construct (BCW)	Theoretical domain (TDF)	Intervention function (BCW)	Behaviour change technique (using BCTv1)
Lack of skills regarding how to apply emollients/low self-efficacy (QSR)	• Provide instructions on how to correctly apply emollients, including how much emollient to apply	Psychological capability	Skills	Training	4.1 Instructions on how to perform the behaviour
Ran out of emollients (EO) *Stocking up on emollient* (QI)	• Provide advice on how to obtain more emollients/ avoid running out	Physical opportunity	Environmental context and resources	Environmental structuring	12.5 Adding objects to the environment
Cost of emollients (QI)	• Provide advice about financial benefits YP can apply for or strategies for reducing the cost of emollients	Physical opportunity; psychological capability; reflective motivation	Environmental context and resources; knowledge; beliefs about consequences	Environmental structuring; education; persuasion	5.3 Information about social and environmental consequences 12.5 Adding objects to the environment
Difficulties in getting health professionals to prescribe different emollients (QI) *Preparing and researching for consultations* (QI)	• Provide advice on how to prepare for appointments with health professionals	Psychological capability	Skills	Training	4.1 Instructions on how to perform the behaviour
Target behaviour: improved use of TCSs or TCIs					
Belief that TCSs/TCIs are not effective enough for managing flare-ups (e.g. provide only temporary relief before their eczema returned) (QI)	• Provide persuasive and credible information about the effectiveness of TCS/TCIs, including scientific evidence, user quotes and videos • Provide rationale for how TCS/TCIs control eczema • Provide advice on whether emollients are also needed	Psychological capability; reflective motivation; social opportunity	Beliefs about consequences; knowledge; social influences	Education; persuasion; modelling	5.1 Information about health consequences 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source
	• Provide advice on how to choose an effective TCS/TCIs	Psychological capability	Skills	Training	4.1 Instructions on how to perform the behaviour
Concerns about the long-term safety of TCSs (QSR; QI; EO)	• Provide persuasive and credible information about the safety of TCSs/TCIs (e.g. skin thinning, wrinkling, dependency), including scientific evidence, user quotes and videos	Psychological capability; reflective motivation; social opportunity	Beliefs about consequences; knowledge; social influences	Education; persuasion; modelling	5.1 Information about health consequences 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source
Concerns about the immediate side effects (e.g. stinging) of TCSs/TCIs (QI)	• Provide reassuring advice about the temporary nature of side effects (e.g. stinging) and how to choose the right TCS/TCIs (i.e. no side effects)	Psychological capability; reflective motivation;	Skills; beliefs about consequences; knowledge	Education; persuasion; training	4.1 Instructions on how to perform the behaviour 5.1 Information about health consequences
Uncertainty regarding when to start and finish TCSs/TCIs (QI)	• Provide information on when to apply TCSs/TCIs and for how long	Psychological capability	Skills	Training	4.1 Instructions on how to perform the behaviour

Barriers/facilitator to target behaviour	Intervention components	Target construct (BCW)	Theoretical domain (TDF)	Intervention function (BCW)	Behaviour change technique (using BCTv1)
Lack of skills regarding how to apply TCSs/TCIs/low self-efficacy (EO)	• Provide instructions on how to correctly apply TCSs/TCIs, including how much to apply	Psychological capability	Skills	Training	4.1 Instructions on how to perform the behaviour
Belief that using more TCS than prescribed will conceal their eczema or make their eczema flare-up pass quicker (QI)	• Provide information on how much TCS/TCIs to apply	Psychological capability	Skills	Training	4.1 Instructions on how to perform the behaviour
Uncertainty regarding the difference between steroids (QI)	• Provide information on what type of steroids are available and which ones they should use on different body parts and why	Psychological capability	Skills	Training	4.1 Instructions on how to perform the behaviour
Ran out of TCSs/TCIs/not being able to get hold of their preferred TCS (e.g. out of stock) (QI) *Stocking up on TCS/TCIs (QI)*	• Provide information on how to obtain more TCS/TCIs and avoid running out	Physical opportunity	Environmental context and resources	Environmental structuring	12.5 Adding objects to the environment
Belief that health professionals (including pharmacists) are reluctant or hesitant to prescribe TCSs/the right potency (QI)	• Provide advice on how to talk to health professionals • Provide advice on how to choose an effective TC/TCI (e.g. list of available TCSs/TCIs) • Provide explanation of how the health professional decides on the TCS/TCI prescription	Psychological capability	Skills	Training	4.1 Instructions on how to perform the behaviour
Cost of TCSs/TCIs (QI)	• Provide advice about financial benefits YP can apply for or strategies for reducing the cost of TCSs/TCIs.	Psychological capability; reflective motivation	Beliefs about consequences; knowledge	Education; persuasion	5.3 Information about social and environmental consequences
Target behaviour: management of irritants and triggers					
Lack of knowledge regarding common irritants and triggers (EO)	• Provide information on common irritants and triggers • Provide information on misconceptions (e.g. food allergies)	Psychological capability; reflective motivation	Beliefs about consequences; knowledge; skills	Education; persuasion; training	4.1 Instructions on how to perform the behaviour 5.1 Information about health consequences
Belief that you can't avoid some triggers (e.g. stress)/belief that the benefits of avoidance (e.g. avoiding a brief flare-up) do not outweigh the costs (e.g. not being able to go swimming) (QI)	• Where appropriate, provide advice on how to minimise the effects of irritants/triggers (e.g. apply emollients before and/or afterwards) • Where appropriate, provide advice on how to avoid or reduce contact with certain irritants/triggers (e.g. soaps, high temperatures, sweat), including when away from home	Psychological capability; reflective motivation	Beliefs about consequences; knowledge; skills	Education; persuasion; training	4.1 Instructions on how to perform the behaviour 5.1 Information about health consequences

continued

TABLE 4 Behavioural analysis for young people (*continued*)

Barriers/facilitator to target behaviour	Intervention components	Target construct (BCW)	Theoretical domain (TDF)	Intervention function (BCW)	Behaviour change technique (using BCTv1)
Target behaviour: reduce scratching					
Belief that scratching is not that bad (EO)	• Explain itch–scratch cycle and that scratching makes itch/eczema worse	Psychological capability; reflective motivation	Beliefs about consequences; knowledge	Education; persuasion	5.1 Information about health consequences 5.6 Information about emotional consequences
Feeling of itchiness and desire for instant relief (QI) *Wearing appropriate clothes* (*QI*); *Keeping cool* (*QI*); *Emollient use* (*QI*); *Antihistamine* (*QI*); *Tapping* (*QI*); *Keeping nails short/wear gloves* (*QI*)	• Provide information on the factors that make scratching more likely (e.g. hot temperature, lack of sleep) • Provide advice on reducing itchiness (e.g. keeping cool, emollient use, tapping the area, clench fist, wearing clothes with long arms and legs, put emollient in fridge to keep cool) • Provide advice on sleep management • Provide techniques to prevent the negative consequences of scratching (e.g. keep nails short, wear gloves) and how to deal with the annoyance of others telling them to stop scratching (e.g. ask people to suggest things they can do, like tap skin, instead)	Physical capability; psychological capability	Environmental context and resources; skills; behavioural regulation	Training; education; enablement; environmental restructuring	4.1 Information on how to perform a behaviour 4.2 Information about antecedents 12.3 Avoidance/reducing exposure to cues for behaviour 12.5 Adding objects to the environment 12.6 Body changes
Scratching is a habit (QI) *Distraction techniques* (*QI*)	• Provide techniques to raise awareness of scratching (e.g. record instances of scratching) • Provide techniques to stop scratching (e.g. distraction, relaxation techniques, replace scratching with an alternative behaviour such as clenching fists)	Psychological capability; automatic motivation; physical opportunity	Environmental context and resources; skills; behavioural regulation	Training; enablement; environmental restructuring	2.3 Self-monitoring of behaviour 4.1 Information on how to perform a behaviour 8.2 Behaviour substitution 8.4 Habit reversal 12.4 Distraction 12.5 Adding objects to the environment
Target behaviour: engaging in emotional management techniques					
Belief that emotional management techniques will do little to control their eczema or help with difficult emotions (EO)/belief that stress (e.g. during exam time) can't be avoided (QI) *Belief that emotions affect eczema* (*QI*)	• Explain the necessity of emotional management techniques for promoting engagement with the other behaviours and provide evidence that they are effective for dealing with difficult emotions	Psychological capability; reflective motivation	Beliefs about consequences; knowledge	Education; persuasion	5.1 Information about health consequences 5.6 Information about emotional consequences
	• Provide user quotes demonstrating how emotional management techniques helped other users to take control of their eczema	Psychological capability; reflective motivation; social opportunity	Beliefs about consequences; knowledge; social influences	Education; persuasion; modelling	5.1 Information about health consequences 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source

Barriers/facilitator to target behaviour	Intervention components	Target construct (BCW)	Theoretical domain (TDF)	Intervention function (BCW)	Behaviour change technique (using BCTv1)
Lack of understanding regarding how to do the emotional management techniques (EO)	• Provide guidance on how to do the emotional management techniques	Psychological capability	Skills	Training	4.1 Instructions on how to perform the behaviour
	• Provide guided audio recordings of emotional management exercises	Physical opportunity	Environmental context and resources	Environmental structuring	12.5 Adding objects to the environment
Lack of confidence in ability to practise emotional management techniques (EO)	• Provide YP quotes demonstrating how easy it was for other users to practise the emotional management techniques	Psychological capability; reflective motivation; social opportunity	Beliefs about consequences; beliefs about capabilities; knowledge; social influences	Education; persuasion; modelling	6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source

BCTv1, Behaviour Change Techniques Taxonomy; BCW, Behaviour Change Wheel; EO, barrier emerged from expert opinion; QI, barrier/facilitator emerged from qualitative interview research with young people; QSR, barrier/facilitator emerged from systematic review of qualitative literature with adults with eczema and parents/carers of children with eczema; TDF, theoretical domains framework; YP, young people.

TABLE 5 Behavioural analysis for parents/carers

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
Target behaviour: increase use of emollients/moisturisers					
Lack of knowledge around what emollients to use, how to use them, when, how often, and how much (SR; EO)	Parents/carers • Provide information about how emollients might differ (e.g. in thickness, visibility on skin, length of time between applications, smell, dispensers), when different types of emollients might be used, how often they need to be applied and how much to apply, including information about potential triggers in commonly used non-prescription moisturisers (e.g. scented moisturisers, olive oil) • Acknowledge that it is common to find eczema treatment confusing • Provide advice about identifying when emollients are needed for a range of different skin types and severities Children • Explain how emollients help eczema using videos	↑ Knowledge; skills	Psychological capability; social opportunity; reflective motivation	Education; training; modelling; persuasion	4.1 Instructions on how to perform the behaviour 7.1 Prompts/cues 9.1 Credible source
Lack of skills regarding how to apply emollients/low self-efficacy (SR)	Parents/carers • Use videos to demonstrate how emollients should be applied and how much • Encourage parents/carers to involve their child in applying emollients so they can learn how to do it themselves Children • Use videos to demonstrate how emollients should be applied and how much	↑ Skills; social influence	Physical capability; social opportunity; reflective motivation	Training; modelling; persuasion	4.1 Instructions on how to perform the behaviour 6.1 Demonstration of the behaviour 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
Belief that the emollients won't work (PPI; SR)	Parents/carers • Provide a rationale for how emollients help to manage eczema and why emollient treatments may require trial and error emphasising that there is no quick cure and that treatments may need to be adjusted depending on their child's eczema changes over time • Provide persuasive and credible information about the effectiveness of emollients, including scientific evidence, user stories, quotes and videos • Acknowledge that the process of finding the right emollient can be frustrating/overwhelming/disheartening • Provide user stories/quotes demonstrating how they found the right emollient and their feelings around this process • Provide advice about trying out new emollients and finding an emollient that works, including information about types, dispensers, storage and time to see effects • Encourage use of a 2-week challenge to evaluate how regular use of an emollient improves eczema symptoms (redness, soreness, itching), and prompt trying a different emollient if it doesn't • Provide a log that can be used to record emollient use and experiences (e.g. printable paper chart, electronic log)	↑ Positive beliefs about consequences; environmental context and resources; social influence; goals	Psychological capability; reflective motivation; social opportunity; training; physical opportunity; automatic motivation	Education; persuasion; modelling; environmental restructuring; enablement	1.1 Goal setting (behaviour) 1.4 Action planning 2.3. Self-monitoring of outcomes of behaviour 3.1. Social support (unspecified) 4.1. Instructions on how to perform the behaviour 5.1. Information about health consequences 6.2. Social comparison 6.3. Information about others' approval 8.1 Behavioural practice/rehearsal 8.3 Habit formation 9.1. Credible source 12.5. Adding objects to the environment

continued

TABLE 5 Behavioural analysis for parents/carers (*continued*)

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
Belief that emollients aren't necessary if eczema is mild or you can't see it (PPI; I)	Parents/carers • Provide a rationale for how emollients help to manage eczema, including when eczema is only mild or not visible on the skin • Provide information on how often to apply emollients and the rationale for doing this • Provide persuasive and credible information about the effectiveness of emollients, including scientific evidence, user stories and videos Children • Explain how emollients help eczema using videos • Provide easy-to-understand information about how and why emollients should be used even when you can't see it using videos	↑ Knowledge; social influence	Psychological capability; reflective motivation	Education; persuasion; modelling	4.1. Instructions on how to perform the behaviour 5.1. Information about health consequences 6.2 Social comparison 9.1. Credible source
Distrust of HCP advice about emollient use due to previously receiving contradictory messages, or feeling dismissed or fobbed off by their HCP (SR)	Parents/carers • Provide information about what can reasonably be expected from their HCP • Provide advice about when they should go to their HCP (e.g. when trying to find the right emollient) • Provide advice about communicating with their HCP about eczema and its treatment • Provide online facilities to document what treatments they have used and how they have found them (including options for this to be printed and taken to appointments)	↑ Knowledge; skills; environmental context and resources	Psychological capability; physical opportunity	Training; environmental restructuring; enablement	4.1 Instructions on how to perform the behaviour 12.5 Adding objects to the environment

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
Lack of consensus between parents/carers on emollient use and how to treat the child's eczema or pressure from others to try alternative treatments (e.g. dietary restriction, complementary and alternative medicine) (PPI; SR)	Parents/carers • Provide a rationale for how emollients help to manage eczema • Provide persuasive and credible information about the effectiveness of emollients, including scientific evidence, user stories and videos • Provide information about alternative treatments and relative evidence for them • Provide printouts about eczema and its treatment that can be given to important others (i.e. schools) to help them understand the need for regular emollient use	↑ Knowledge; environmental context and resources; social influence	Psychological capability; reflective motivation; social opportunity	Education; persuasion; environmental restructuring; enablement	3.1. Social support (unspecified) 5.3 Information about health consequences 6.2 Social comparison 9.1 Credible source 12.5 Adding objects to the environment
Concerns around emollients being unpleasant for their child (e.g. burning, stinging) or about other potential side effects of emollients (e.g. stinging) (EO; PPI)	Parents/carers • Provide persuasive and credible information about the safety of emollients and risk of side effects, including scientific evidence, user stories and videos • Provide advice about trying out new emollients and finding an emollient that works, including advice on when an emollient should be abandoned to try a new one • Provide advice on how to support child to tolerate the treatments better (e.g. distraction, relaxation) • Provide user stories/quotes about how they dealt with unpleasant reactions in their child • Reassure parents/carers that it is ok to ask to change emollients if their child cannot tolerate their current emollient • Provide a chart for parents/carers to monitor how their child's skin is after applying emollients as part of '2-week challenge' • Provide a log that can be used to record emollient use and experiences (e.g. printable paper chart, electronic log)	↑ Knowledge; positive beliefs about consequences; skills; social influence; environmental context and resources	Psychological capability; reflective motivation; social opportunity; training;	Education; persuasion; modelling; enablement; environmental restructuring	2.3 Self-monitoring of outcomes of behaviour 3.1. Social support (unspecified) 4.1 Instructions on how to perform the behaviour 5.1 Information about health consequences 6.2 Social comparison 6.3 Information about others' approval 7.1 Prompts/cues 9.1 Credible source 12.5 Adding objects to the environment

continued

TABLE 5 Behavioural analysis for parents/carers (*continued*)

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
	Children • Provide easy-to-understand information about how emollients differ and how different creams may feel different on the skin using videos				
Disliking the smell, feel or appearance of emollients, or finding treatments like wet wrapping anxiety provoking (PPI; SR)	Parents/carers • Emphasise the benefits of applying emollients to outweigh these negative consequences • Provide advice on how to explain to children about emollients • Provide advice on how to support child to tolerate the treatments better (e.g. distraction, relaxation) • Provide advice about when/where to apply emollients to minimise impact • Provide advice on how to decide if the child's reaction to the emollient suggests that the emollient should be abandoned and a new one tried • Highlight that different emollients have different ingredients and therefore different smells and feel, which could help them find a new emollient to try or indicate which might smell/feel similarly • Reassure parents/carers that it is ok to ask to change emollients if their child cannot tolerate their current emollient • Provide a chart for parents/carers to monitor how their child's skin is after applying emollients as part of '2-week challenge' Children • Provide techniques to help child relax	↑ Knowledge; positive beliefs about consequences; skills; social influence; environmental context and resources ↓ Emotion	Psychological capability; reflective motivation; training; social opportunity;	Education; persuasion; modelling; enablement; environmental restructuring	2.3 Self-monitoring of outcomes of behaviour 3.1. Social support (unspecified) 4.1 Instructions on how to perform the behaviour 5.1 Information about health consequences 6.2 Social comparison 6.3 Information about others' approval 7.1 Prompts/cues 9.1 Credible source 11.2. Reduce negative emotions 12.5 Adding objects to the environment

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
Difficulty fitting emollient treatments into family schedules, particularly if there are siblings [e.g. if there are different routines for different siblings (SR; PPI)]	Parents/carers • Provide information on how to integrate emollient use into everyday life • Advise parents/carers to plan when they will apply their emollients (i.e. ensure they allocate time) • Reassure parents/carers that making emollient treatments part of their daily routine can make it feel like they take less time, and may even reduce the time the treatments take as it becomes an automatic habit rather than an effortful activity	↑ Knowledge; skills; social influence, goals	Psychological capability; automatic motivation	Education; enablement	1.4. Action planning 4.1. Instructions on how to perform the behaviour 5.3. Information about social and environmental consequences 8.1 Behavioural practice/rehearsal 8.3 Habit formation
Forgetting to apply emollients (I);	Parents/carers • Provide information on how to integrate emollient use into everyday life • Advise parents/carers to plan when they will apply the emollients (i.e. ensure they allocate time) • Provide advice on how to plan a routine for school days that their child/child's teacher can follow • Suggest trying to apply creams at the same time in the same context each day • Teach the person to identify environmental cues that can be used to remind them to perform a behaviour, including times of day or elements of contexts • Provide an emollient chart to record whether they have used their emollients at their agreed times • Allow users to set up regular reminders to apply TCSs by e-mail or text messages and decide on the frequency of these reminders Children • Provide an emollient reward chart to take to school to record whether they have used their emollients at their agreed times	↑ Skills; environmental context and resources; goals	Reflective motivation; automatic motivation; psychological capability; physical opportunity	Enablement; training?	1.1 Goal setting (behaviour) 1.4 Action planning 2.3 Self-monitoring of behaviour 7.1. Prompts/cues 8.1 Behavioural practice/rehearsal 8.3 Habit formation

continued

TABLE 5 Behavioural analysis for parents/carers (*continued*)

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
Difficulties getting their child to stay still when applying emollients, refusing to have the treatments or avoiding them (PPI)	Parents/carers • Encourage parents/carers to involve their child in doing the emollients (e.g. putting creams on their doll, putting creams on their parents/siblings, putting creams on themselves) and provide a rationale for doing so • Provide suggestions for other activities around emollient use to make emollient times more fun and interesting for children (e.g. imaginary games, singing, special toys for emollient times) • Provide reward charts parents can use to 'reward' the child for doing their emollients Children • Explain how emollients help eczema using videos • Use videos to demonstrate how emollients should be applied and how much	↑ Knowledge; skills; environmental context and resources; social influence	Psychological capability; reflective motivation; physical opportunity	Education; persuasion; environmental restructuring; modelling	4.1 Instructions on how to perform the behaviour 6.2 Social comparison 10.4 Social reward 12.5 Adding objects to the environment
Distress around child's negative reactions to having the emollients applied (e.g. crying, refusing)	Parents/carers • Acknowledge that caring for a child with eczema can be challenging and that children's reactions to treatments can be distressing • Provide materials that parents can use with their child to increase their understanding about eczema and its treatment to change the dynamic from parent vs. child, to parent and child vs. eczema, for example videos • Provide advice on how to involve their child in treating eczema so that they work together to treat eczema • Provide advice on how to manage doing the treatments when their child is upset/refusing • Provide emotional/stress management techniques and resources (e.g. relaxation audios)	↑ Knowledge; skills; social influence ↓ Emotion	Psychological capability; physical opportunity	Training; enablement; modelling	3.1. Social support (unspecified) 4.1 Instructions on how to perform the behaviour 6.2 Social comparison 11.2 Reduce negative emotions 12.5 Adding objects to the environment

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
Difficulties managing emollients outside the family home (e.g. at school, being out and about) (SR; I)	Parents/carers • Encourage action planning for specific events, for example holidays • Provide advice on how to manage common difficulties (e.g. going on holiday, transition to school, managing severe eczema in school) • Provide user stories about how other parents/carers have managed these difficulties (particularly the transition to school) • Provide printouts about eczema and its treatment that can be given to important others (i.e. schools, nurseries) to help them understand the need for regular emollient use • Provide advice on using emollients when away from home (e.g. requesting some smaller tubes from their HCP, advice about different emollients that are good for using 'on-the-go' (e.g. lotions vs. ointments)	↑ Knowledge; skills; environmental context and resources; social influence; goals	Psychological capability; physical opportunity	Environmental restructuring; enablement; modelling	1.4 Action planning 3.1. Social support (unspecified) 4.1 Instructions on how to perform the behaviour 6.2 Social comparison 12.1 Restructuring the physical environment 12.5 Adding objects to the environment
Running out of emollients (PPI)	Parents/carers • Advise parents/carers to keep a supply of emollients in the house • Provide advice about how to obtain more emollients, including what is/isn't available over the counter • Encourage action planning for specific events, for example holidays	↑ Knowledge; goals	Psychological capability	Education; enablement	1.4. Action planning 4.1 Instructions on how to perform the behaviour
Belief that finding an emollient that works best for you is difficult (TA)	• Acknowledge how frustrating and time-consuming this process can be • Provide stories from carers/parents emphasising the importance of finding the right emollient	↑ Beliefs about capabilities; social influence	Psychological capability; reflective motivation; social opportunity	Education; persuasion; modelling	5.1 Information about health consequences 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source
Inconvenience of emollients rubbing off (e.g. on clothes and bed sheets) (I)	Parents/carers • Provide advice on how to choose the right emollient and avoiding them rubbing off (e.g. put on loose clothing, leaving it to dry in a warm room)	↑ Knowledge	Psychological capability	Training	4.1 Instructions on how to perform the behaviour

continued

TABLE 5 Behavioural analysis for parents/carers (*continued*)

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
Target behaviour: improve use of topical steroids (TCSs)					
Lack of knowledge regarding what are TCSs, how to use them, when, how often, and how much (I)	Parents/carers • Provide information about different types of TCSs (creams/ointments), their different potencies, and differences in how they should be used (e.g. different creams for different body parts) • Provide information on when to apply TCSs and when they should use them, and for how long, including advice on identifying the start and end of flare-ups • Provide information about how they differ from emollients in terms of what they are and their function • Provide advice about how emollients and TCSs should be used together (e.g. a minimum 20 minutes between applications) • Provide instructional video/photos of how to correctly apply TCSs Children • Explain what TCSs are in simple language, how they need to be used and when using videos	↑ Knowledge; social influence	Psychological capability; physical capability; social opportunity; reflective motivation	Education; training; modelling; persuasion	4.1 Instructions on how to perform the behaviour 5.1 Information about health consequences 6.1 Demonstration of the behaviour 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source
Lack of skills regarding how to apply TCSs/low self-efficacy (EO, L[1])	Parents/Carers • Provide instructions about how to apply TCSs • Provide instructional video about how to correctly apply TCSs	↑ Skills; social influence	Physical capability; social opportunity; reflective motivation	Training; modelling; persuasion; enablement	4.1 Instructions on how to perform the behaviour 6.1 Demonstration of the behaviour 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
Belief that TCSs do little to control eczema, make eczema worse (e.g. makes skin itchier, causes rebound flares), or provide only temporary relief before their eczema returned (SR)	Parents/carers • Provide rationale for how TCSs control eczema as an adjunct to emollients, including their role in dealing with flare-ups and infections • Provide persuasive and credible information about the effectiveness of TCSs, including scientific evidence, user stories and videos • Acknowledge that the process of finding the right TCS can be frustrating/overwhelming/disheartening • Provide user stories demonstrating how they found the right TC and their feelings around this process • Provide advice on how to choose an effective TCS • Provide a chart for parents/carers to monitor how their child's skin is after applying TCSs Children • Explain how TCSs help eczema using videos or stories • Explain that it can take time for TCSs to work via stories/videos • Provide stories demonstrating how they found the right emollient and feelings around this process	↑ Environmental context and context and resources; positive beliefs about consequences; social influence	Psychological capability; reflective motivation; social opportunity	Education; persuasion; modelling; training	2.3 Self-monitoring of outcomes of behaviour 5.1 Information about health consequences 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source
Concerns about the long-term safety of TCSs (SR; I)	Parents/carers • Provide persuasive and credible information about the safety of TCSs, including scientific evidence, user stories and videos Provide rationale for how TCSs control eczema	↑ Positive beliefs about consequences; social influence	Psychological capability; reflective motivation; social opportunity	Education; persuasion; modelling	5.1 Information about health consequences 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source
Concerns about the immediate side effects (e.g. stinging) of TCSs (SR; I)	Parents/Carers • Provide advice on how to choose the right TCS (i.e. no side effects), including how to identify a preferred cream/ointment	↑ Knowledge;	Psychological capability	Training	4.1 Instructions on how to perform the behaviour

continued

TABLE 5 Behavioural analysis for parents/carers (*continued*)

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
Running out of TCSs (e.g. staying away from home, at school) (PPI)	Parents/carers • Advise parents/carers to keep a supply of TCS in the house • Provide advice about how to obtain more TCSs, including what is/isn't available over the counter • Encourage action planning for specific events, for example holidays, going to school	↑ Environmental context and resources; goals	Psychological capability; physical opportunity	Environmental restructuring	1.4. Action planning 12.5 Adding objects to the environment
Difficulty getting topical steroids if health professionals are reluctant to prescribe them, distrust of HCP advice due to previously receiving contradictory messages, or feeling dismissed or fobbed off by their HCP (SR, PPI) *Preparing for consultations* (*TA*)	Parents/carers • Provide information about current guidelines in eczema treatment and what can be reasonably be expected from their HCP • Provide advice about when they should go to their HCP (e.g. when there is a flare-up or they need to change TCSs) • Provide advice about communicating with their HCP about eczema and its treatment • Provide online facilities to document what treatments they have used and how they have found them (including options for this to be printed and taken to appointments)	↑ Knowledge; skills; environmental context and resources	Psychological capability; physical opportunity	Training; environmental restructuring	4.1 Instructions on how to perform the behaviour 12.5 Adding objects to the environment
Concerns about psychosocial impact of TCSs (e.g. judgements from others about giving their child steroids and feeling ashamed) (PPI)	Parents/carers • Provide persuasive and credible information about the safety of TCSs, including scientific evidence, user stories and videos • Provide rationale for how TCSs control eczema	↑ Knowledge; skills; social influence; environmental context and resources	Psychological capability; reflective motivation; social opportunity	Education; persuasion; modelling (and enablement?)	5.3 Information about social and environmental consequences 5.6 Information about emotional consequences 6.2 Social comparison 9.1 Credible source 11.2 Reduce negative emotions
Difficulty fitting topical steroids into family schedules on top of emollient use (EO)	Parents/carers • Provide information on how to integrate TCS use into existing routine • Advise parents/carers to plan when they will apply their TCSs (i.e. ensure they allocate time)	↑ Knowledge; skills; goals; environmental context and resources	Psychological capability; automatic motivation	Education; enablement; environmental restructuring	1.4. Action planning 4.1. Instructions on how to perform the behaviour 5.3. Information about social and environmental consequences

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
Forgetting to apply TCSs (EO);	Parents/carers • Advise parents/carers to plan when they will apply the TCSs (i.e. ensure they allocate time) • Advise users to regularly apply TCS in the same context (e.g. after breakfast) • Provide advice on how to plan a routine for school days that their child/child's teacher can follow	↑ Skills; environmental context and resources; goals	Reflective motivation; automatic motivation; psychological capability; physical opportunity	Enablement; training; environmental restructuring	1.1 Goal setting (behaviour) 1.4 Action planning 2.3 Self-monitoring of behaviour 7.1. Prompts/cues 8.1 Behavioural practice/rehearsal 8.3 Habit formation
Difficulties managing TCSs outside the family home (e.g. at school, being out and about) (EO)	Parents/carers • Encourage action planning for specific events, for example holidays • Provide advice on how to manage common difficulties (e.g. going on holiday, transition to school, managing severe eczema in school) • Provide user stories about how other parents/carers have managed these difficulties (particularly the transition to school) • Provide editable printouts to give to important others to help them understand the need for using TCSs and when they need to be applied • Provide advice on using emollients when away from home	↑ Knowledge; skills; environmental context and resources; social influence	Psychological capability; physical opportunity	Training; environmental restructuring; modelling	3.1. Social support (unspecified) 4.1 Instructions on how to perform the behaviour 6.2 Social comparison 12.1 Restructuring the physical environment 12.5 Adding objects to the environment
Belief that TCSs are time-consuming to apply (EO)	Parents/carers • Provide information on how to integrate TCS use into everyday life • Reassure parents/carers that applying TCSs should not be time-consuming • Advise parents/carers to plan when they will apply TCSs (i.e. ensure they allocate time)	↑ Knowledge; social influence; goals	Psychological capability	Education; enablement	1.4 Action planning 4.1 Instructions on how to perform the behaviour 5.3 Information about social and environmental consequences
Target behaviour: improve management of irritants and triggers					
Lack of knowledge regarding irritants and triggers (EO)	Parents/carers • Provide information on common irritants and triggers • Provide information on misconceptions (e.g. food allergies)	↑ Knowledge;	Psychological capability; reflective motivation	Education	5.1 Information about health consequences

continued

TABLE 5 Behavioural analysis for parents/carers (*continued*)

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
Difficulty avoiding irritants, accidental exposure to irritants or planned exposure to irritants when benefits of avoidance (e.g. avoiding a brief flare-up) do not outweigh the costs (e.g. not being able to go swimming) (I)	Parents/carers • Where appropriate, provide advice on how to avoid or reduce contact with certain irritants/triggers (e.g. soaps, high temperatures, sweat, pets), including when away from home • Where appropriate, provide advice on how to minimise the effects of irritants/triggers (e.g. apply emollients in advance or immediately afterwards)	↑ Knowledge; skills	Psychological capability	Training	4.1 Instructions on how to perform the behaviour
Child refusing to avoid irritants when costs of exposure (e.g. bad flare-ups, chance of infection) outweigh perceived benefits (e.g. the fun of playing in the sandbox) (EO)	Parents/carers • Where appropriate, provide advice on how to support/encourage their child to avoid irritants (e.g. use of distraction, substituting the activity they are missing out one with a 'safer' activity that they also enjoy)	↑ Knowledge; skills	Psychological capability	Training	4.1 Instructions on how to perform the behaviour
Target behaviour: reducing scratching					
Belief that scratching is not that bad (EO)	Parents/carers • Explain itch–scratch cycle and that scratching makes itch/eczema worse Children • Explain itch–scratch cycle and that scratching makes itch/eczema worse and makes you feel out of control using videos	↓ Emotion	Psychological capability; reflective motivation	Education	5.1 Information about health consequences 5.6 Information about emotional consequences
Child scratch automatically (I; SR)	Parents/carers • Provide information on the factors that make scratching more likely (e.g. hot temperature, lack of sleep) • Provide advice on reducing itchiness (e.g. keeping cool, emollient use, tapping the area, antihistamine use, wearing clothes with long arms and legs) • Provide a link to content on sleep • Provide techniques to prevent the negative consequences of scratching such as bleeding (e.g. keep nails short, wear gloves)	↑Environmental context and resources	Physical capability; psychological capability	Training; education; enablement; environmental restructuring	4.1 Information on how to perform a behaviour 4.2 Information about antecedents 12.3 Avoidance/reducing exposure to cues for behaviour 12.5 Adding objects to the environment 12.6 Body changes

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
Low confidence in ability to stop child scratching, especially when scratching is a habit (I) *Distraction techniques* (*I*)	Parents/carers • Provide techniques to stop scratching (e.g. distraction, replace scratching with an alternative behaviour such as clenching fists and think of something calm/pleasant) • Provide user stories/quotes about how other parents/carers have managed to stop their child scratching	↑ Knowledge; skills; social influence; environmental context and resources	Psychological capability; automatic motivation; physical opportunity; social opportunity	Training; enablement; environmental restructuring; modelling	2.3 Self-monitoring of behaviour 3.1 Social support (unspecified) 4.1 Information on how to perform a behaviour 6.2 Social comparison 8.2 Behaviour substitution 8.4 Habit reversal 9.1 Credible source 12.4 Distraction 12.5 Adding objects to the environment
Child distress – parents/carers may feel guilty if they tell their child off for scratching if it upsets their child (PPI)	Parents/carers • Provide user stories about how other parents/carers have managed to stop their child scratching • Provide emotional/stress management techniques to help carers manage difficult emotions, and to support their child to manage theirs	↑ Knowledge; skills; social influence	Psychological capability; social opportunity	Enablement; modelling	3.1 Social support (unspecified) 6.2 Social comparison
Target behaviour: improve emotional/stress management					
Belief that emotional management techniques are not relevant to them (EO)	Parents/carers • Provide a rationale for using emotional management techniques (including its role in supporting parents/carers to look after their child, and it role for supporting the child to tolerate eczema and its treatments) • Acknowledge that eczema and its treatment can be challenging for both parent and child • Acknowledge that it can be different managing concerns about how eczema and its treatment affect their child	↑ Knowledge ↓ Emotion	Psychological capability; reflective motivation	Education; persuasion	5.1 Information about health consequences 5.6 Information about emotional consequences

continued

TABLE 5 Behavioural analysis for parents/carers (*continued*)

Barriers/facilitators[a] to target behaviours	Intervention ingredient	Theoretical domains framework (TDF)	Target construct (BCW)	Intervention function (BCW)	BCT (using 93 BCT taxonomy v1)
Belief that emotional management techniques will do little to control eczema or help with difficult emotions (EO)	Parents/carers • Provide evidence that emotional management techniques are effective for dealing with difficult emotions • Provide user stories/quotes demonstrating how emotional management techniques helped other users to manage the challenges that eczema brings • Provide user stories/quotes demonstrating how emotional management techniques have helped their child	↑ Positive beliefs about consequences; social influence ↓ Emotion	Psychological capability; reflective motivation; social opportunity	Education; persuasion; modelling	5.1 Information about health consequences 5.6 Information about emotional consequences 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source
Lack of understanding regarding how to do the emotional management techniques (EO)	Parents/carers • Provide guidance on how to do the emotional management techniques • Provide guided audio recordings of emotional management exercises Children • Provide age-appropriate materials (e.g. stories, videos, podcasts) that children can use to help them with emotional management	↑ Skills; environmental context and resources	Psychological capability; physical opportunity	Training; environmental restructuring	4.1 Instructions on how to perform the behaviour 12.5 Adding objects to the environment
Difficulties engaging in emotional management techniques in the long term/ Lack of confidence in ability to practise emotional management techniques (EO)	Parents/carers • Provide user stories/quotes demonstrating how easy it was for other users to practise the emotional management techniques	↑ Beliefs about capabilities; social influence; goals	Reflective motivation; social opportunity	Persuasion; modelling; enablement	1.1 Goal setting (behaviour) 1.4 Action planning 1.5 Review behaviour goal(s) 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source

BCTv1, Behaviour Change Techniques Taxonomy; BCW, Behaviour Change Wheel; EO, expert opinion; HCP, healthcare professional; I, stage 1.2 qualitative interviews; SR, systematic review; TA, stage 2.1 think-aloud interviews.

a Intervention components and BCTs identified through deductive analysis.

Appendix 4 Cochrane review description of included studies

TABLE 6 Description of included studies

Comparison	Number of studies (participants)		
	Number of studies (participants)	By age group	By eczema severity
Which TCS to use?			
Moderate vs. mild potency TCS	12 (1184)	1 (249) in children and adults 7 (306) in children 4 (629) unspecified	1 (113) mild to moderate 4 (372) moderate to severe 7 (699) unspecified
Potent vs. mild potency TCS	22 (1010)	2 (71) in children and adults 11 (582) in children 2 (45) in adults 8 (312) unspecified	3 (251) mild to moderate 12 (418) moderate to severe 9 (341) unspecified
Potent vs. moderate potency TCS	25 (1515)	3 (201) in children and adults 7 (567) in children 3 (172) in adults 12 (575) unspecified	3 (145) mild to moderate 11 (817) moderate to severe 11 (553) unspecified
Very potent vs. potent TCS	6 (730)	3 (207) in adults 3 (523) unspecified	1 (30) mild to moderate 2 (87) moderate to severe 1 (117) severe 2 (496) unspecified
TCS cream vs. TCS ointment	7 (677)	1 (376) in children and adults 2 (136) in children 3 (105) in adults 1 (60) unspecified	2 (121) mild to moderate 2 (90) mild to severe 2 (406) moderate to severe 1 (60) unspecified
Different concentrations of the same TCS	2 (401)	1 (376) in children and adults 1 (25) in adults	2 (401) moderate to severe
'Second generation' TCS vs. older TCS	15 (1248)	3 (296) in children and adults 7 (639 in children 5 (313) in adults	1 (24) mild to moderate 12 (1120) moderate to severe 2 (97) unspecified
Branded TCS vs. generic TCS	No trials.		
How often to apply TCS?			
Twice or more vs. once daily TCS[a]	25 (2862)	6 (1075) in children and adults 12 (864) in children 7 (676) in adults 2 (247) unspecified	5 (244) mild to moderate 1 (19) moderate 13 (1803) moderate to severe 8 (796) unspecified
Daily vs. less frequent TCS	4 (327)	1 (44) in children and adults 3 (283) in children	3 (243) mild to moderate 2 (84) moderate to severe
Longer- vs. shorter-term duration of TCS use for induction of remission	No trials.		
TCS alternating with TCI vs. TCS alone	1 (30)	1 (30) in children	1 (30) moderate to severe
Weekend therapy (proactive TCS) vs. no TCS/reactive use of TCS	9 (1344)	3 (945) in children and adults 5 (287) in children 1 (112) in adults	2 (156) mild to moderate 7 (1188) moderate to severe

continued

TABLE 6 Description of included studies (*continued*)

Comparison	Number of studies (participants)		
	Number of studies (participants)	By age group	By eczema severity
How to use the TCS?			
Timing of application of TCS	2 (158)	1 (137) in children and adults 1 (21) in children	1 (137) moderate to severe 1 (21) unspecified
Wet wrap vs. no wet wrap	6 (221)	1 (24) in children and adults 5 (197) in children	2 (75) mild to moderate 2 (56) moderate 2 (90) moderate to severe
TCS applied to wet vs. dry skin	1 (45)	1 (45) in children	1 (45) in mild to severe
TCS before vs. after emollient	1 (46)	1 (46) in children	1 (46) moderate to severe
Time between emollient and steroid	No trials		

Appendix 5 Consolidated Standards of Reporting Trials diagram of recruitment to Eczema Care Online trials

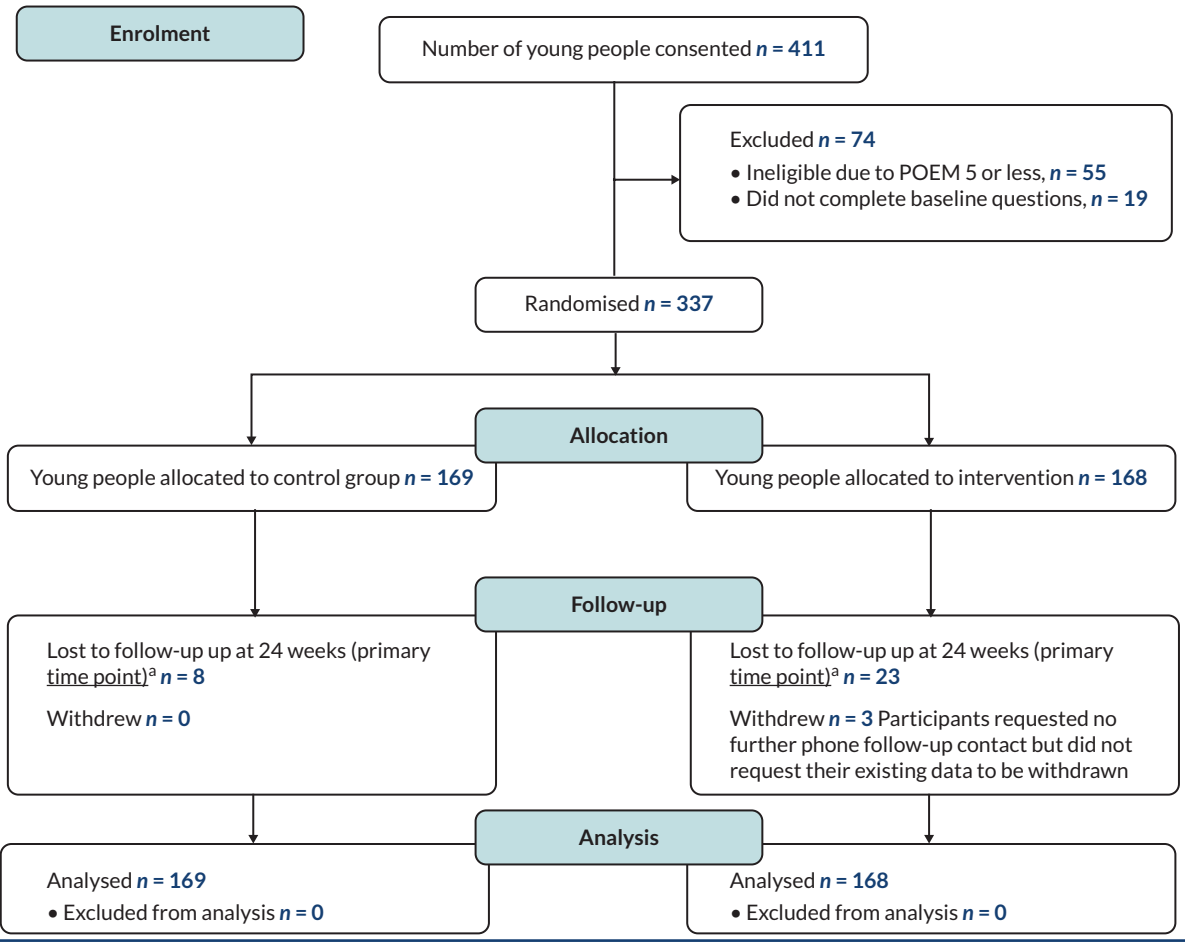

FIGURE 9 Consolidated Standards of Reporting Trials diagram of trial for young people. Reproduced with permission from Greenwell *et al.*[42] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original figure. a, Lost to follow-up where 24 week questionnaire (primary time point) not received.

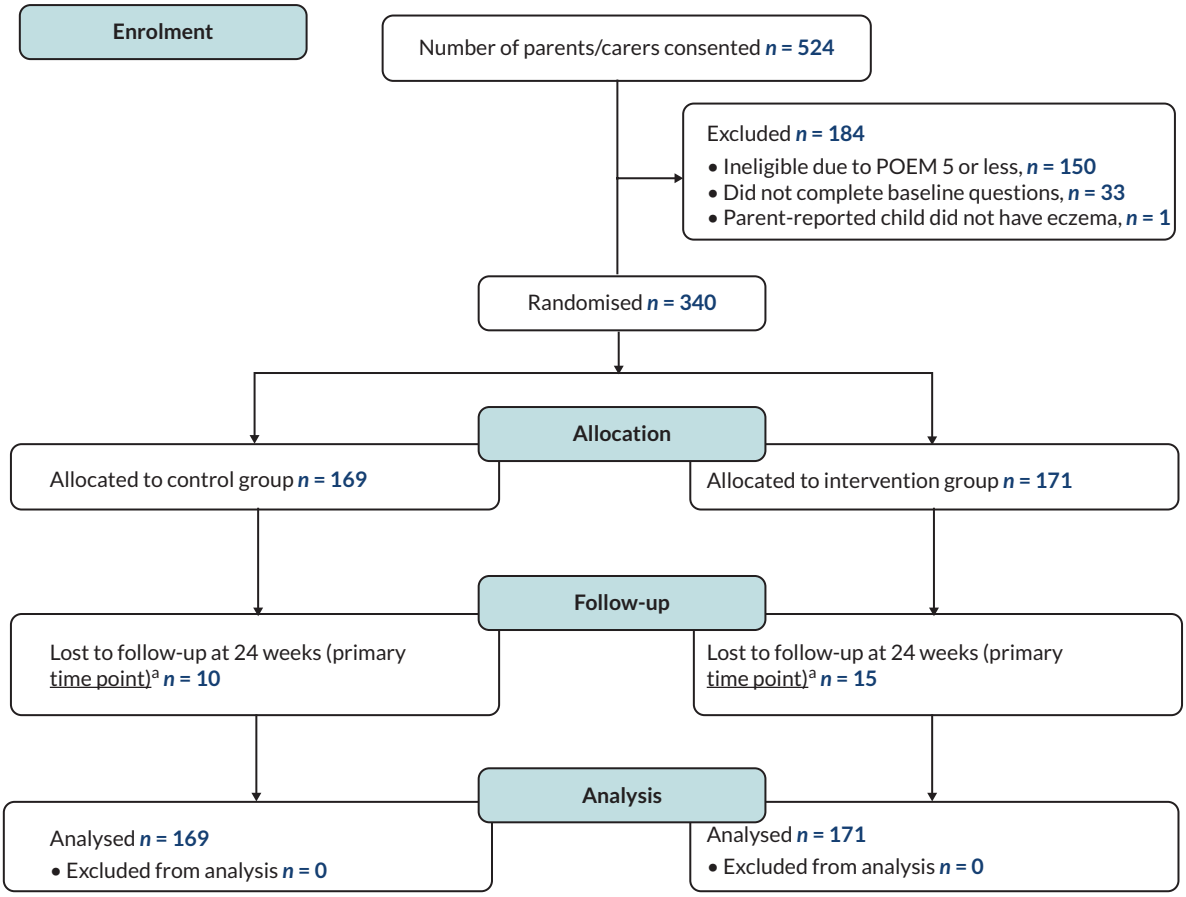

FIGURE 10 Consolidated Standards of Reporting Trials diagram of trial for parents/carers. a, Lost to follow-up where 24-week questionnaire (primary time point) not received.

Appendix 6 Baseline characteristics of Eczema Care Online trial participants

TABLE 7 Baseline characteristics of participants in trials for young people with eczema

	Usual care YP (*n* = 169)	Intervention YP (*n* = 168)	Total YP (*n* = 337)
Respondent's age (years) Mean (SD)	19.0 (3.3)	19.5 (3.5)	19.3 (3.4)
Respondent's sex Female *n* (%)	134 (79%)	125 (74%)	259 (77%)
Respondent's self-reported ethnic group			
White	142 (86%)	143 (86%)	285 (86%)
Asian	9 (5%)	7 (4%)	16 (5%)
Black	2 (1%)	4 (2%)	6 (2%)
Mixed	10 (6%)	9 (6%)	19 (6%)
Other	3 (2%)	3 (2%)	6 (2%)
Prefer not to answer	–	–	–
Prior belief in intervention[a] [1 (low) to 10 (high)]			
Median (IQR)[b]	6 (5–8)	6 (5–8)	6 (5–8)
Use of other websites for eczema in last 6 months *n* (%)	24 (14%)	26 (16%)	50 (15%)
Eczema severity (POEM)[a] score (0–28)			
Mean (SD)	15.3 (5.5)	15.1 (5.3)	15.2 (5.4)
POEM category[a] n (%)			
Mild (6–7)	11 (7%)	10 (6%)	21 (6%)
Moderate (8–16)	92 (54%)	92 (55%)	184 (55%)
Severe (17–28)	66 (39%)	66 (39%)	132 (39%)
Eczema control (RECAP)[c] Median (IQR)			
Median (IQR)	13 (8.5–17)	13 (10–16)	13 (9–17)
Itch intensity[d] [1 (low) to 10 (high)]			
Median (IQR)	6 (4–7)	6 (4–7)	6 (4–7)
Health-related quality of life (EQ-5D-5L) (mean, SD)	0.80 (0.18)	0.80 (0.14)	0.80 (0.16)

IQR, interquartile range; YP, young people.
a POEM measure of eczema severity scores 0 (low) to 28 (high).[54,55]
b Where 1 is 'not at all effective' and 10 is 'very effective'.
c RECAP measure of eczema control scores 0 (low) to 28 (high).[56]
d Itch intensity 'How would you rate your itch at the worst moment during the previous 24 hours?' was asked for young.

TABLE 8 Baseline characteristics of participants in trial for parent/carer of children with eczema

	Usual care PC (*n* = 169)	Intervention PC (*n* = 171)	Total PC (*n* = 340)
Respondent's age (years) Mean (SD)	37.5 (6.4)	37.7 (6.8)	37.6 (6.6)
Respondent's sex Female *n* (%)	155 (92%)	156 (91%)	311 (92%)
Child's age (years) Median (IQR)	4 (2–7)	4 (2–7)	4 (2–7)
Child's sex Female *n* (%)	79 (47%)	85 (50%)	164 (48%)
Respondent's self-reported ethnic group			
White	138 (82%)	144 (84%)	282 (83%)
Asian	13 (8%)	10 (6%)	23 (7%)
Black	7 (4%)	2 (1%)	9 (3%)
Mixed	6 (4%)	7 (4%)	13 (4%)
Other	2 (1%)	6 (4%)	8 (2%)
Prefer not to answer	2 (1%)	2 (1%)	4 (1%)
Highest qualification n (%)			
Degree or equivalent	87 (53%)	80 (48%)	167 (50%)
Diploma or equivalent	22 (13%)	29 (17%)	51 (15%)
A-level	10 (6%)	6 (4%)	16 (5%)
GCSE/O-level	14 (9%)	19 (11%)	33 (10%)
None	3 (2%)	5 (3%)	8 (2%)
Other	24 (15%)	23 (14%)	47 (14%)
Prefer not to answer	4 (2%)	6 (4%)	10 (3%)
Prior belief in intervention[a] [1 (low) to 10 (high)]			
Median (IQR)[a]	7 (5–8.5)	7 (5–8)	7 (5–8)
Use of other websites for eczema in last 6 months *n* (%)	31 (19%)	41 (24%)	72 (22%)
Eczema severity (POEM)[b] score (0–28)			
Mean (SD)	12.8 (5.4)	12.9 (5.2)	12.8 (5.3)
POEM category[c] n (%)			
Mild (6–7)	25 (15%)	28 (16%)	53 (16%)
Moderate (8–16)	110 (65%)	102 (60%)	212 (62%)
Severe (17–28)	34 (20%)	41 (24%)	75 (22%)
Eczema control (RECAP)[c] Median (IQR)			
Median (IQR)	11 (8–16)	12 (9–17)	12 (8–16)
Health-related quality of life (CHU-9D) (mean, SD)	0.86 (0.10)	0.87 (0.09)	0.87 (0.10)

GCSE, General Certificate of Secondary Education; IQR, interquartile range; PC, parent/carer.
a Where 1 is 'not at all effective' and 10 is 'very effective'.
b POEM measure of eczema severity scores 0 (low) to 28 (high).[54,55]
c RECAP measure of eczema control scores 0 (low) to 28 (high).[56]

Appendix 7 Incremental cost–utility analysis and cost-effectiveness analyses results, including sensitivity analyses

TABLE 9 Incremental CUA and cost-effectiveness analyses results, including SA

Analysis (n_i, n_{uc})	Incremental cost (£) (95% CI)	Incremental QALYs (95% CI)	ICER (£)	CEAC at £20,000 threshold	NMB at £20,000 threshold	CEAC at £30,000 threshold	NMB at £30,000 threshold
Base case, CCA, unadjusted (89, 96)	3.08 (59.20 to 65.36)	0.014 (−0.009 to 0.037)	227.49	87%	£276.92	87%	£416.92
Base case, CCA, adjusted (73, 71)	−34.15 (−104.54 to 36.24)	−0.003 (−0.021 to 0.015)	12,465.86	69%	−£25.85	68%	−£55.85
SA1, MI unadjusted (171,169)	−21.03 (−67.24 to 25.18)	0.016 (−0.003 to 0.035)	Dominant	87%	£341.03	87%	£501.03
SA2, M1 adjusted (171,169)	−23.60 (−68.59 to 21.40)	0.007 (−0.007 to 0.021)	Dominant	65%	£163.60	63%	£233.60
Analysis (n_i, n_{uc})	**Incremental costs (95% CI)**	**Incremental proportion achieving success (95% CI)**	**ICER**	**CEAC at £20,000 threshold**	**NMB at £20,000 threshold**	**CEAC at £30,000 threshold**	**NMB at £30,000 threshold**
Secondary analysis, CEA, unadjusted (149,153)	−22.88 (−72.27 to 26.52)	7.6% (−3.4% to 18.6%)	Dominant				
Secondary analysis, CEA, adjusted (97, 88)	−27.66 (−79.63 to 24.31)	8.6% (−3.0% to 20.2%)	Dominant				
Analysis (n_i, n_{uc})	**Incremental cost (£) (95% CI)**	**Incremental QALYs (95% CI)**	**ICER**	**CEAC at £20,000 threshold**	**NMB at £20,000 threshold**	**CEAC at £30,000 threshold**	**NMB at £20,000 threshold**
Base case, CCA, unadjusted (122,140)	−25.56 (−74.68 to 23.56)	0.010 (−0.023 to 0.044)	Dominant	75%	£225.56	74%	£325.56
Base case, CCA, adjusted (88,118)	−20.82 (−71.77 to 30.13)	0.012 (−0.017 to 0.041)	Dominant	81%	£260.82	81%	£380.82
SA1, MI unadjusted (168,169)	−13.66 (−59.05 to 31.73)	0.016 (−0.017 to 0.476)	Dominant	84%	£333.66	83%	£493.66
SA2, M1 adjusted (168,169)	−11.77 (−54.27 to 230.71)	0.008 (−0.015 to 0.031)	Dominant	81%	£171.77	80%	£251.77
Analysis (n_i, n_{uc})	**Incremental costs (95% CI)**	**Incremental proportion achieving success (95% CI)**	**ICER**	**CEAC at £20,000 threshold**	**NMB at £20,000 threshold**	**CEAC at £30,000 threshold**	**NMB at £30,000 threshold**
Secondary analysis, CEA, unadjusted (131,147)	−19.24 (−68.50 to 30.02)	11.3% (−0.2% to 22.8%)	Dominant				
Secondary analysis, CEA, adjusted (96,123)	−23.57 (−74.22 to 23.07)	10.4% (−2.4% to 23.2%)	Dominant				

continued

TABLE 9 Incremental CUA and cost-effectiveness analyses results, including SA (*continued*)

Analysis (n_i, n_{uc})	Incremental costs (95% CI)	Incremental proportion achieving success (95% CI)	ICER	CEAC at £20,000 threshold	NMB at £20,000 threshold	CEAC at £30,000 threshold	NMB at £30,000 threshold
Secondary analysis, CEA, unadjusted (280,300)	−20.36 (−55.38 to 16.66)	9.4% (1.4% to 17.3%)	Dominant				
Secondary analysis, CEA, adjusted (270,289)	−20.35 (−55.41 to 14.70)	10.3% (2.3% to 18.1%)	Dominant				

CCA, cost–consequence analysis; MI, multiple imputation analysis.
For incremental proportion achieving success (> 2-point change on POEM) adjusted analysis, 'Prior belief in effectiveness of website' was removed from the analysis due to the model being unable to converge if it was included. Where n_i is the number of participants with data available in the intervention arm and n_{uc} is the number of participants in the usual care arm with data available.

Appendix 8 Qualitative process evaluation participant characteristics

TABLE 10 Qualitative process evaluation participant characteristics

	Parents/carers (*n* = 20)	Young people (*n* = 20)
Age (years)		
Mean	38.53	18.24
Range	29–62	13–25
Gender		
Female *N* (%)	14 (82.35)	9 (52.94)
Male *N* (%)	3 (17.65)	8 (47.06)
Child's age (years)		
Mean	4.47	*N*/A
Range	0–12	*N*/A
Child's gender		
Female *N* (%)	8 (47.06)	*N*/A
Male *N* (%)	9 (52.94)	*N*/A
Child/young person eczema severity (defined by POEM)[a]		
Mild *N* (%)	3 (17.65)	2 (11.76)
Moderate *N* (%)	9 (52.94)	7 (41.18)
Severe *N* (%)	5 (29.41)	8 (47.06)
Ethnicity (self-reported)		
White British *N* (%)	13 (76.47)	11 (64.71)
Chinese *N* (%)	2 (11.76)	0
Indian *N* (%)	1 (5.88)	3 (17.65)
African *N* (%)	0	1 (5.88)
White and black Caribbean *N* (%)	1 (5.88)	1 (5.88)
White and Asian *N* (%)	0	1 (5.88)
Socioeconomic status (Index of Multiple Deprivation score)[b]		
Mean	6.47	6.94[c]
Range	1–10	2–10[c]
Highest level of qualification		
Degree (or equivalent or higher)	9 (52.94)	*N*/A
Diploma (or equivalent)	4 (23.53)	*N*/A
'A' Level	2 (11.76)	*N*/A

continued

TABLE 10 Incremental CUA and cost-effectiveness analyses results, including SA (*continued*)

	Parents/carers (*n* = 20)	Young people (*n* = 20)
GCSE/'O' level	0	*N*/A
None	0	*N*/A
Other	1 (5.88)	*N*/A
Prefer not to say	1 (5.88)	*N*/A
Completed the introductory module at the time of interview		
Yes	15 (88.24)	14 (82.35)
No	2 (11.76)	3 (17.65)

GCSE, General Certificate of Secondary Education.
a Mild eczema defined as POEM 6–7; moderate eczema POEM 8–16; severe eczema POEM 17–28. Respondents with very mild eczema (a POEM score of 5 or lower) were excluded from the research.
b Calculated from postcode, 10 is the highest socioeconomic status.
c *N* = 16.

Appendix 9 Example excerpts from the Eczema Care Online Table of Changes

TABLE 11 Example excerpts from the ECO Table of Changes

Intervention component	Summary of issue identified	Changes implemented	Reason for change (or lack of change)
Information architecture	A minority of participants spoke of information overload, there being too much reading, or it being hard to find what information they need.	Improved navigation, ensuring users can skip irrelevant content and easily access the content they need. Broke up text with videos. Included additional summaries of key information.	REP; IMP
Visual design	Some participants found the visual design impersonal, bland, unattractive and dated.	Improved visual design to look more attractive and modern	REP
Delivery methods	A minority found it difficult to use on a smartphone.	Website made available as a webapp, thus improving smartphone usability.	REP
Information depth	A few participants found the information to be pitched at too low a level and would have liked more information on the evidence base supporting the advice provided	Added links to associated research publications, where appropriate.	EAS
Advice on of TCSs	Some participants were cautious about the use of TCSs due to concerns and experiences relating to TCSs withdrawal.	Added brief reassuring information on TCSs withdrawal.	IMP; EAS
Information on antihistamines	One parent/carer was surprised by and disagreed with the information that said that antihistamines do not help itch, which was the opposite of his experience.	Added an acknowledgement that different things work for different people to avoid people feeling disengaged by any evidence that contradicts their experience	EAS

EAS, easy and uncontroversial change; IMP, important for engagement or behaviour change; REP, issue raised repeatedly by multiple participants.
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Appendix 10 Eczema Care Online intervention usage

TABLE 12 Eczema Care Online intervention usage

Variable	Parents/carers (*n* = 171)		Young people (*n* = 168)	
	24 weeks		52 weeks	
Intervention visits per participant[a]				
Median (IQR)	3 (3)	5 (7)	3 (4)	4 (7)
Range	0–10	1–17	1–17	1–25
Duration of intervention usage (between first and last use) (days)[a]				
Median (IQR)	N/A	252 (201)	N/A	195 (167)
Range	N/A	1–364	N/A	10–364
Total time spent on intervention[a] ***(minutes)***				
Median (IQR)	20 (36)	27 (41)	18 (32)	21 (36)
Range	2–154	2–157	3–201	3–208
Modules started per participant[b]				
Median (IQR)	3 (4)	4 (5)	3 (4)	3 (4)
Range	0–15	0–15	0–18	0–18
Modules finished per participant[b]				
Median (IQR)	2 (2)	2 (3)	2 (2)	2 (2)
Range	0–10	0–10	0–21	0–21

IQR, interquartile range.
a Excluding visits to complete research questionnaires and users who visited only once.
b Total modules for parents/carers is 16; total modules for young people is 14.

Appendix 11 Process evaluation mediation models for patient-oriented eczema measure score at 24 weeks

TABLE 13 Process evaluation mediation models for POEM score at 24 weeks

Mediator		Unadjusted effect (95% CI)	Adjusted[a] effect (95% CI)
Parent carer trial			
Patient enablement (PEI) at 24 weeks	Indirect (mediating) effect	−0.7 (−1.1 to −0.2)	**−0.6 (−1.0 to −0.2)**
	Direct effect	−1.3 (−2.8 to 0.2)	−1.3 (−2.6 to −0.1)
	Total effect	−2.0 (−3.4 to −0.5)	−1.9 (−3.2 to −0.7)
Total treatment use[b] at 24 weeks	Indirect (mediating) effect	−0.2 (−0.9 to 0.5)	−0.01 (−0.6 to 0.6)
	Direct effect	−2.0 (−3.5 to −0.5)	−1.5 (−2.9 to −0.1)
	Total effect	−2.2 (−3.8 to −0.6)	−1.5 (−3.0 to 0.003)
PETS score at 24 weeks	Indirect (mediating) effect	0.1 (−0.3 to 0.5)	0.1 (−0.1 to 0.4)
	Direct effect	−1.8 (−3.2 to 0.4)	−1.9 (−3.1 to −0.7)
	Total effect	−1.7 (−3.1 to 0.2)	−1.8 (−3.0 to −0.5)
Young people trial			
PEI at 24 weeks	Indirect (mediating) effect	−1.4 (−2.1 to −0.6)	**−1.2 (−1.9 to −0.5)**
	Direct effect	−1.2 (−2.9 to 0.5)	−1.2 (−2.8 to 0.4)
	Total effect	−2.6 (−4.2 to −0.9)	−2.4 (−4.0 to −0.9)
Total treatment use[b] at 24 weeks	Indirect (mediating) effect	−0.01 (−0.5 to 0.5)	−0.2 (−0.7 to 0.3)
	Direct effect	−2.0 (−3.7 to −0.4)	−1.7 (−3.3 to −0.2)
	Total effect	−2.0 (−3.7 to −0.3)	−1.9 (−3.5 to −0.3)
PETS score at 24 weeks	Indirect (mediating) effect	−0.1 (−0.5 to 0.3)	−0.1 (−0.4 to 0.2)
	Direct effect	−2.0 (−3.6 to −0.5)	−1.7 (−3.3 to −0.2)
	Total effect	−2.2 (−3.8 to −0.5)	−1.8 (−3.4 to −0.2)

a Adjusted for baseline POEM score and baseline value of the potential mediator (PEI, total treatment use or PETS).
b Total treatment use is weekly combined emollient, TCS and TCI use.
Note
Bold indicates statistical significance.

Appendix 12 Trial predictors of high intervention usage

TABLE 14 Young people trial predictors of high intervention usage

	High user – no	High user – yes	Odds ratio (95% CI)
Gender – female (*n*, %)	53 (73.6%)	72 (75%)	1.1 (0.5 to 2.2)
Age group – 18–25 years (*n*, %)	46 (65.3%)	63 (65.6%)	1.0 (0.5 to 1.9)
Index of Multiple Deprivation – lowest quintile (most deprivation) (*n*, %)	7 (10.1%)	5 (5.3%)	0.5 (0.2 to 1.6)
Baseline POEM score (mean, SD)	13.8 (5.5)	16.1 (4.9)	**1.09 (1.02 to 1.16)**
Baseline emollient use score (mean, SD)	9.3 (6.4)	11.5 (7.2)	1.04 (0.99 to 1.10)
Baseline total treatment use score[a] (mean, SD)	12.2 (7.3)	14.8 (8.5)	1.04 (0.99 to 1.08)
PETS (n, %)			
Symptoms too severe	46 (64.8%)	65 (69.2%)	1.2 (0.6 to 2.3)
Uncertainty how to carry out treatment	33 (45.8%)	41 (43.6%)	0.9 (0.5 to 1.7)
Doubt treatment efficacy	54 (75.0%)	74 (77.9%)	1.2 (0.6 to 2.4)
Practical problems	62 (87.3%)	80 (84.2%)	0.8 (0.3 to 1.9)

a Total treatment use is weekly combined emollient, topical corticosteroid and topical calcineurin inhibitor use.
Note
Bold indicates statistical significance.

TABLE 15 Parent/carer trial predictors of high intervention usage

	High user – no	High user – yes	Odds ratio (95% CI)
Gender – female (*n*, %)	37 (51.4%)	48 (48.5%)	0.9 (0.5 to 1.6)
Age group – 5–12 years (*n*, %)	25 (34.7%)	37 (37.4%)	1.0 (0.9 to 1.1)
Education – degree (*n*, %)	27 (38.0%)	53 (54.6%)	**2.0 (1.1 to 3.7)**
Index of Multiple Deprivation – lowest quintile (most deprived) (*n*, %)	8 (11.3%)	10 (10.1%)	0.9 (0.3 to 2.4)
Baseline severity (mean, SD)	12.3 (5.2)	13.3 (5.1)	1.04 (0.98 to 1.10)
Baseline emollient use (mean, SD)	12.1 (6.7)	11.7 (6.8)	1.04 (0.99 to 1.09)
Baseline total treatment use[a]	13.6 (8.6)	14.5 (7.8)	1.01 (0.97 to 1.06)
PETS (n, %)			
Symptoms too severe	36 (50.0%)	61 (62.9%)	1.7 (0.9 to 3.1)
Uncertainty how to carry out treatment	18 (25.0%)	44 (44.9%)	**2.4 (1.3 to 4.8)**
Doubt treatment efficacy	31 (43.7%)	60 (60.6%)	**2.0 (1.1 to 3.7)**
Practical problems	33 (46.5%)	59 (59.6%)	1.7 (0.9 to 3.1)

a Total treatment use is weekly combined emollient, topical corticosteroid and topical calcineurin inhibitor use.
Note
Bold indicates statistical significance.

Appendix 13 Patient-oriented eczema measure at 24 weeks by online intervention use (complier-average causal effect analysis)

TABLE 16 Patient-oriented eczema measure at 24 weeks by online intervention use

Trial	Intervention engagement	*n*	Observed mean POEM at 24 weeks intervention arm	Unadjusted mean difference CACE (95% CI)	Adjusted[a] mean difference CACE (95% CI)
Parents/ carers	High	91	9.4	−2.9 (−5.3 to −0.5)	**−3.1 (−5.5 to −0.7)**
	Low	62	8.6		
Young people	High	84	12.2	−3.8 (−6.5 to −1.0)	**−2.8 (−5.5 to −0.1)**
	Low	59	10.8		
Combined	High	175	10.7	−3.4 (−5.3 to −1.6)	**−3.1 (−5.5 to −0.7)**
	Low	121	9.7		

a Adjusted for baseline POEM, recruitment region, ethnicity, prior belief in intervention, use of other eczema websites and education (parents/carers only). High engagement indicates finishing the core introductory content and at least one optional module.

Note
Bold indicates statistical significance.

Appendix 14 Subgroup analyses

TABLE 17 Parent/carer trial subgroup analyses

Subgroup	*n*	Mean difference in POEM score over 24 weeks (95% CI)	Unadjusted interaction term (95% CI)	Adjusted[a] interaction term (95% CI)
Age group				
0–4 years	216	−0.7 (−2.1 to 0.6)		
5–12 years	122	−1.6 (−3.6 to 0.3)	−1.0 (−3.3 to 1.4)	−1.6 (−3.7 to 0.4)
Education				
No degree	163	−1.0 (−2.6 to 0.5)		
Degree	167	−1.1 (−2.7 to 0.6)	0.1 (−2.2 to 2.3)	−0.3 (−2.3 to 1.6)
Index of Multiple Deprivation				
2nd–5th quintiles (least)	303	−1.0 (−2.2 to 0.1)		
1st quintile (most)	33	−2.3 (−6.1 to 1.5)	−0.8 (−4.6 to 3.0)	−0.9 (−4.2 to 2.4)
Baseline POEM				
Mild	53	0.8 (−0.8 to 2.4)		
Moderate	211	−0.6 (−1.8 to 0.5)	−1.5 (−4.2 to 1.2)	−1.0 (−4.1 to 2.1)
Severe	74	−4.0 (−6.7 to −1.4)	−5.0 (−8.1 to −1.8)	**−4.0 (−7.7 to −0.2)**
Combined emollient use				
0–14 times per week	143	−0.1 (−1.7 to 1.4)		
14+ times per week	156	−1.9 (−3.6 to −0.2)	−1.8 (−4.1 to 0.6)	−0.8 (−2.8 to 1.3)
Total treatment use[b]	271		−0.13 (−0.27 to 0.02)	−0.03 (−0.16 to 0.10)
PETS				
Symptoms too severe				
No	126	0.2 (−1.3 to 1.7)		
Yes	210	−1.6 (−3.1 to −0.1)	−1.8 (−4.1 to 0.5)	−1.1 (−3.1 to 0.9)
Uncertainty how to carry out treatment				
No	213	−0.7 (−2.1 to 0.7)		
Yes	124	−1.7 (−3.5 to 0.1)	−0.9 (−3.2 to 1.4)	−1.1 (−3.1 to 1.0)
Doubts about treatment efficacy				
No	150	−1.1 (−2.8 to 0.6)		
Yes	185	−1.0 (−2.5 to 0.5)	0.1 (−2.1 to 2.4)	0.5 (−1.4 to 2.4)

TABLE 17 Parent/carer trial subgroup analyses (*continued*)

Subgroup	*n*	Mean difference in POEM score over 24 weeks (95% CI)	Unadjusted interaction term (95% CI)	Adjusted[a] interaction term (95% CI)
Practical problems				
No	148	−2.0 (−3.9 to −0.2)		
Yes	188	−0.3 (−1.7 to 1.1)	1.8 (−0.5 to 4.0)	−0.8 (−2.7 to 1.2)

a Adjusted for baseline POEM, recruitment region, ethnicity, prior belief in intervention, use of other eczema websites and education (parent/carer trial only).
b Total treatment use is weekly combined emollient, TCS and TCI use; interaction term is the difference in treatment effect between subgroups.
Note
Bold indicates statistical significance

TABLE 18 Young people trial subgroup analyses

Subgroup	*n*	Mean difference in POEM score at 24 weeks (95% CI)	Unadjusted interaction term (95% CI)	Adjusted[a] interaction term (95% CI)
Gender				
Male	67	−1.5 (−4.5 to 1.5)		
Female	237	−2.3 (−4.1 to −0.4)	−0.8 (−4.5 to 3.0)	−3.5 (−7.3 to 0.4)
Age group				
13–17 years		−1.3 (−3.1 to 0.6)		
18–25 years		−1.6 (−3.0 to −0.2)	−0.4 (−2.8 to 2.0)	−0.6 (−2.7 to 1.5)
Index of Multiple Deprivation				
2nd–5th quintile (least)	293	−1.1 (−2.3 to 0.0)		
1st quintile (most)	23	−5.6 (−10.2 to −1.0)	−4.6 (−9.1 to −0.1)	−2.8 (−6.6 to 1.0)
Baseline POEM				
Mild	92	−1.6 (−4.9 to 1.7)		
Moderate	179	−0.9 (−2.1 to 0.3)	1.0 (−2.9 to 5.0)	1.3 (−2.9 to 5.4)
Severe	129	−2.3 (−4.0 to −0.6)	−0.5 (−4.5 to 3.6)	0.8 (−3.4 to 5.1)
Combined emollient use				
0–14 times per week	150	−0.9 (−2.5 to 0.6)		
14+ times per week	131	−2.9 (−4.7 to −1.0)	−2.0 (−4.4 to 0.5)	−1.1 (−3.2 to 1.0)
Total treatment use[b]	267		−0.1 (−0.2 to 0.1)	−0.1 (−0.2 to 0.1)
PETS				
Symptoms too severe				
No	112	−1.9 (−3.7 to −0.1)		
Yes	214	−1.4 (−2.8 to 0.1)	0.5 (−1.9 to 2.8)	0.5 (−1.6 to 2.6)

continued

TABLE 18 Young people trial subgroup analyses (*continued*)

Subgroup	*n*	Mean difference in POEM score at 24 weeks (95% CI)	Unadjusted interaction term (95% CI)	Adjusted[a] interaction term (95% CI)
Uncertainty how to carry out treatment				
No	190	−1.4 (−2.9 to 0.1)		
Yes	137	−1.6 (−3.3 to 0.1)	−0.2 (−2.5 to 2.1)	−0.4 (−2.4 to 1.7)
Doubts about treatment efficacy				
No	89	−1.6 (−3.6 to 0.5)		
Yes	239	−1.6 (−2.9 to −0.2)	0.2 (−2.4 to 2.7)	0.8 (−1.5 to 3.1)
Practical problems				
No	58	−2.2 (−4.8 to 0.3)		
Yes	268	−1.5 (−2.7 to −0.2)	0.7 (−2.3 to 3.7)	−0.1 (−2.7 to 2.5)

a Adjusted for baseline POEM, recruitment region, ethnicity, prior belief in intervention, use of other eczema websites.
b Total treatment use is weekly combined emollient, TCS and TCI use. Interaction term is the difference in treatment effect between subgroups.

EME
HSDR
HTA
PGfAR
PHR

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