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[Intervention Protocol]

Psychological and educational interventions for managing eczema

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

1. To assess the clinical outcomes of psychological and educational interventions in children and adults with eczema
2. To summarise the availability and principal findings of relevant economic evaluations

BACKGROUND

This is an updated version of a previous Cochrane Review (Ersser 2014), extending the population to include adults with atopic eczema, in addition to children (and now with the inclusion of a health economic analysis). A glossary of terms is provided in Table 1.

Description of the condition

Atopic eczema, also called atopic dermatitis, is a long-term inflammatory skin condition. This Cochrane Review relates to atopic eczema throughout; this will be referred to as eczema hereafter. It is a debilitating disease with a multifaceted aetiology and high levels of disease burden for patients (Blakeway 2020; Jabbar-Lopez 2020). The main symptoms are itching, dryness, erythema, weeping, vesicles; and more chronically, skin thickening, hyper/hypo-pigmentation and excoriation. Eczema is usually diagnosed clinically. Serum immunoglobulin E (IgE) levels can sometimes be of diagnostic benefit. Taking a biopsy for histology is rarely needed but can be of use if there is diagnostic uncertainty, particularly in adults. Further investigations in the form of patch testing or 'skin prick' testing (involving putting a drop of liquid onto the forearm that contains a substance the patient may be allergic to) may be indicated if there is a suspicion of co-morbid allergy.

Eczema is the most prevalent longer term inflammatory skin disorder, affecting up to 20% of children and 10% of adults in industrialised countries (Tsakok 2019). A systematic review indicated an increasing prevalence of eczema in Africa, East Asia, Western Europe, and parts of Northern Europe (Deckers 2012). Research has predominantly focused on incidence in childhood, as just under three-quarters of cases begin in children younger than five years of age (Hanifin 2007). Whilst there are fewer adults with eczema, their condition is frequently more severe (Abuabara 2019; Herd 1996). It is unclear whether trends of increasing levels of eczema in adults are due to increasing persistence of disease or new-onset disease later in life.

According to Brunner 2017, eczema is a systemic inflammatory disease with several co-morbidities. With its very high incidence in childhood, chronicity, wide-ranging impact on quality of life for patients and their families, socioeconomic burden, and limited therapeutic possibilities, eczema is challenging for all involved (Eyerich 2019). Its management is complex (Hashimoto 2017) and often requires a well-planned, multidisciplinary approach for optimal care.

Causes

The rising global incidence of eczema has led researchers to question whether environmental factors may be contributing to this public health problem. Studies indicate that the way genes interact with the environment play a role in eczema (Blakeway 2020). Genetic mutations have been associated with eczema (Hongping 2020), with the most consistently reported genetic variant being loss-of-function mutations (resulting in reduced or lost function of the resulting protein) in the gene coding filaggrin (FLG) (Blakeway 2020; Eyerich 2019; Handa 2019; Lau 2019). FLG plays a vital role in aggregating keratin filaments, ordering lamellar lipid bilayers, conserving hydration, and the pH balance of the epidermis. Current understanding focuses on disturbance of the skin barrier, leading to increased permeability of the epidermis,

pathological inflammation, dryness, and percutaneous heightened sensitivity to allergens (Flohr 2010; Tam 2016; Tsakok 2019).

There is growing evidence that micro-organisms on the skin are also indicated in eczema, particularly *Staphylococcus epidermidis* (Tsakok 2019). Disease exacerbations (also called flares) are known to be linked to significant decreases in skin microbiota diversity and an increase in abundance of both *S. aureus* and *S. epidermidis*.

Environmental factors, including skin cleansing, may also contribute to friction damage, and therefore guidance about the optimal frequency of bathing is variable (Tsakok 2019). There is also a positive association between living in a 'hard water' area (water that has high mineral content) and having eczema (Jabbar-Lopez 2020). Animal research evidences that environmental allergens, including but not limited to house dust mites and food protein, can interact with the immune system via antigen-presenting cells (cells that process antigens/allergens and then expose them to the immune system), leading to hypersensitivity (Ersser 2014). This can exacerbate eczema and might also be a precursor for respiratory and food allergies (Fallon 2009). Eczema, particularly in pre-school children, is associated with IgE sensitisation to both food allergens and aeroallergens up to 16 years of age (Johansson 2017).

Impact

Eczema can have significant impact on quality of life for patients and their families, particularly due to sleep disturbance (von Kobyletzki 2017) and itching. Prescription costs can also impact on quality of life for patients with eczema. Impact evaluation on quality of life and mental health is required to provide a rich understanding and optimal management of eczema, particularly as psychosocial factors are foremost in the itch-scratch cycle (Ersser 2014). The fact that eczema is frequently comorbid with other conditions, for example asthma, can also contribute to reduced quality of life for the sufferer and family. Several studies have evidenced that eczema has a greater consequence on quality of life than other dermatological diseases, including acne and psoriasis (Lewis-Jones 2001; Schuster 2019); hence, it is important to measure the impact of interventions on quality of life. This review also aims to capture the experiences of parents' and caregivers', including their wellbeing, where relevant.

There is a high prevalence of depression in people with skin conditions, including eczema (Clarke 2020). Some patients might also fear the stigma associated with the condition (Duncan 2019). Teasdale 2020 cited a lack of recognition by both health professionals and wider society of the wide-ranging impacts on people with eczema and their families. This can include the person with eczema experiencing low mood and self-esteem (Ghio 2021), due to feeling stigmatised and self-conscious about their appearance, and this can affect their relationships. Surveys of patients with moderate-to-severe eczema have revealed a possible impact on academic success. Working life studies have shown that eczema can impact choice of work, though these effects do not continue to have implications upon lifetime productivity (von Kobyletzki 2017). The impact on everyday life can involve people changing their behaviours and modifying everyday routines in response to eczema symptoms, in an attempt to avoid irritants and concord with treatment guidance. Hence, reduction in disease severity and improvement in long-term control are outcomes in this review.

Non-concordance to long-term treatments for eczema is considered to be a barrier to effective eczema management; furthermore, patients and carers can become exasperated with the advice they receive (Santer 2016). People with eczema might also worry about side effects of medication, e.g. potential skin thinning by topical corticosteroids, and risks of skin cancer with topical calcineurin inhibitors (a group of topical medicines which reduce inflammation in the skin by acting on the immune system, often used as an alternative to topical steroids). They may also feel they receive inconsistent advice from medical professionals about the risks of topical treatments and regimens (Teasdale 2020). There may be frustration with the transient benefit of anti-inflammatory topical treatments, especially in people with a relatively new diagnosis of eczema, which may correspond to a lack of understanding or acceptance of eczema as a chronic condition (Teasdale 2020). This may represent an area where psychological and educational interventions will be helpful to enhance concordance.

There are numerous practical burdens involved in treating eczema (Ablett 2016) not only for the individual (and their families) but to wider society (Tsakok 2019). Adherence can be complicated, sometimes involving specific types of clothing and bedlinen, applying greasy emollients, and the avoidance of certain activities for example swimming (van Onselen 2021). Treatments may also sting, feel cold and give an oily appearance to the skin that sufferers may find embarrassing. Findings from a systematic review concluded that low treatment concordance is a multidimensional phenomenon and should not be considered as the patient's fault alone (Eicher 2019). Factors include: patient beliefs, characteristics, efficacy and duration of treatment, route of administration, the chronicity of the disease and the disease itself (Eicher 2019; Capozza 2020). As treatment concordance has been highlighted in the literature, it is important to explore it further as one of the secondary outcomes of this Cochrane Review.

Cost of illness

Eczema places a substantial economic burden on patients in terms of out-of-pocket expenditures, healthcare services in terms of providing treatment, and society in terms of reduced productivity among patients and need to provide informal care for children.

Several studies demonstrate the substantial burden of illness. For example, a retrospective analysis of insurance claims for adults in the USA predicted annual additional costs of USD 3302 (2013 values) per person affected by eczema compared to the general population, with even higher costs for those with more severe disease (Drucker 2018). Another study from the USA estimated median annual out-of-pocket costs associated with eczema to be USD 600 (2019 values), demonstrating the substantial economic burden on patients (Begolka 2021).

A study of 1014 patients with moderate-to-severe eczema across five countries (France, Germany, Italy, Spain, and the UK) estimated direct costs (including contacts with healthcare providers, hospitalisation and emergency room attendance) to range from EUR 2242 to 6924 per person per year. Indirect costs accounting for work impairment leading to productivity losses due to absenteeism ranged from EUR 7277 to EUR 14,236 per person per year. Disease severity was the main driver of both direct and indirect costs (Girolomoni 2021). A cross-sectional study of children in Singapore found that the average societal cost

of illness per child (measured in 2017) was USD 7943, ranging from USD 6651 for mild disease to USD 14,335 for severe disease (Olsson 2020). These studies clearly demonstrate the need for a brief economic commentary, which will be undertaken as part of this review.

Description of the intervention

Although there is currently no cure, various interventions exist to control symptoms of eczema. These interventions tend to target rehydration of the skin, reduction in inflammation, control of itch, and prevention and treatment of infection (Ersser 2014). Standard treatment is with trigger/irritant avoidance and regular application of emollients and topical steroids or calcineurin inhibitors (Wollenberg 2020). Severe cases may also be treated with phototherapy, immunosuppressive treatments or, more recently, dupilumab (a monoclonal antibody/biologic drug that works against chemical messengers called cytokines, specifically interleukin-4 and interleukin-13), and Janus kinase inhibitors (novel therapies which work on the Janus kinase/signal transducers and activators of transcription (JAK-STAT) intracellular signalling pathway of the immune response and can be used both in a topical and oral systemic form) (Mendes 2020). Thorough assessment of the patient's physical and mental wellbeing is also a key to treatment (Duncan 2019). However, there are barriers to providing such support in dermatological practice, including: time pressures, resources and perhaps clinicians' levels of training, hence the need for evaluating the efficacy and economics of both psychological and educational interventions in this patient group.

There are some main eczema treatments that are commonly used but have been shown to be ineffective. These include antihistamines, leukotriene antagonists, probiotics, antibiotics, water softeners, silk clothing, and bath oils (Foisy 2011). In these cases educational and psychological interventions might help to avoid unnecessary expenditure and potential harms.

Sometimes alternative therapies are used to treat eczema, however such therapies will not be explored within the confines of this review. This review will instead focus on the psychological and educational interventions that are sometimes offered in conjunction with conventional treatment (which usually comprises emollients and topical steroids or calcineurin inhibitors). Dermatological educational and psychological behaviour-change approaches are frequently combined (Hashimoto 2017).

Psychological interventions

The itch-scratch cycle is a key consideration when treating a patient with eczema. The psychosomatic approach considers coping behaviours and stress as causal for chronic itch (Wollenberg 2020). Behavioural therapy should also be considered, whereby the scratch reflex is suppressed with intense concentration, habit reversal, or distraction (Rosenbaum 1981; Misery 2021). This can be particularly effective where patients with eczema demonstrate unconscious scratching behaviours. Successful psychology-based programmes include strategies for disrupting the itch-scratch cycle, relaxation, and stress management techniques (Wollenberg 2020). Amongst these approaches, counselling has been found to be one of the most cost-effective (Pickett 2015). Self-management via health services and information delivered or enhanced through the internet and related technologies (eHealth) has also been investigated, mostly with cognitive behavioural interventions,

and has recently been shown to be comparable to face-to-face therapy (Craddock 2018). Mindfulness meditation and relaxation techniques are also promising for reducing itch (Daunton 2016; Heratizadeh 2017).

Guided imagery has been used, to a fairly limited extent. Typically, it takes the form of audio scripts used to divert the imagination away from any stress and the itching sensation (Derrick 1994). Virtual reality is a more immersive approach towards refocusing attention and consequently reducing stress. Whilst there are no published studies (to our knowledge) that have evaluated virtual reality to specifically treat eczema, it has been used to treat anxiety, burns, and pain (Scapin 2018). Since itch and pain can be triggered from the same receptive fields in the skin (Behrang 2020), it is expected that virtual reality could be used as a more potent version of guided imagery. It is worth noting, however, that whilst a range of psychological therapies exist, they are not consistently available in all geographical areas.

Educational interventions

Educational interventions are often used in supporting people with long-term conditions to optimise care (Ingo 2019). For the treatment of eczema, approaches range from one-to-one sessions to group sessions, and from clinician-led to patient-led. They are also presented in a variety of formats which increasingly cater for distanced learning, including online programmes and virtual education sessions. The length of educational intervention is variable and often includes follow-up sessions. The latter are necessary because motivation and intention to change do not always translate into change itself (Thompson 2017). Some behavioural change techniques are also used for educational interventions (Ersser 2014).

How the intervention might work

Psychological interventions

Brain imaging research has shown atypical brain activation patterns in eczema patients after pruritic stimulation, suggesting central sensitisation (Misery 2021). Techniques such as habit reversal work on the notion that scratching can become unconscious and widespread beyond the itch itself (Staughton 2020). Such techniques teach patients how to use different, less harmful, behaviours where the itch perseveres. Other psychological approaches, such as relaxation, might also work by lowering arousal and anxiety or stress that may intensify the awareness of itch.

Currently, the evidence base for mindfulness and relaxation as treatments for eczema is limited. However, it is useful to extrapolate from other similar evidence bases where mindfulness-based interventions have been used successfully. For example, in a small randomised controlled trial (RCT) with 60 participants, Vagnoli 2019 found that relaxation-guided imagery reduced perioperative anxiety and pain in children. A range of different types of well-being podcasts, apps and other media are being developed at speed, and we predict that evaluation of efficacy will follow.

Educational interventions

Educational interventions generally focus on the process of knowledge or skills acquisition through teaching and learning activities (Ersser 2014). Informed patients are able to better

understand the need for any healthcare intervention and how their disease can be managed. Being fully informed can also give patients a sense of empowerment in relation to their condition (Duncan 2019). More recently, it has been demonstrated that the patient must be actively involved in the education process; hence, self-efficacy-based interventions have been promoted (Hashimoto 2017; Thompson 2017) to enable people to self-manage their condition (Ersser 2011).

There is a body of evidence indicating that educational interventions are effective for treating eczema because they support effective self-/parental management. For example, a recent RCT of a parental eczema education programme was evaluated (Cheng 2020); the main conclusion was that nurse-led parental education programmes that provided evidence-based information and encouraged peer support could improve health outcomes in patients with eczema. In addition to nurse-led education clinics there are numerous online programmes and apps available for eczema. However, the quality of such apps is variable, and it is reported that clinicians need guidance that would enable them to make personalised recommendations for patients and caregivers (van Galen 2019).

Why it is important to do this review

Due to eczema being a prevalent disease that has significant impact on patients and their families, educational and psychological interventions are essential. However, there has been little previous research that has evaluated the measurable effects of these interventions. The original version of this review found only limited evidence to support such interventions (Ersser 2007). The updated version of the review (Ersser 2014) also found limited research evidence about the effect of educational and psychological approaches when used alongside medicines for the treatment of childhood eczema; meta-analysis of studies was not possible due to a lack of high-quality evidence and heterogeneity of outcome measurement. In this proposed update we are widening the scope of the review to include adults as well as children and young people. It will be interesting to assess whether there have been more evaluative studies conducted since 2014, and if any evaluation of adults with eczema can help provide insight into the treatment of children and young people who have eczema.

Psychological treatments have been evaluated to a limited extent, despite the fact that the nature of eczema suggests that psychological factors may play a pivotal role in maintenance of the condition (Hedman-Lagerlöf 2019). Trials tend to have small sample sizes which has made it difficult to estimate the effects of treatments (Hashimoto 2017). Studies to evaluate the efficacy of educational interventions have also been sparse or of poor quality, or both (Pustisek 2016). Ridd 2017 found that there is still ambiguity about whether educational interventions are effective in improving quality of life for children and adults with eczema; most studies have been small and of poorer quality, and it is not known which particular components are clinically effective and cost-effective in different clinical settings. Hence, there is a need for this proposed review of the educational and psychological interventions that have been used to help treat adults and children with eczema to date.

From an economics perspective, the rising prevalence of eczema suggests that the economic burden of treating this disease on healthcare services, patients and society can be expected to

grow into the future. However, a common factor among all cost-of-illness studies identified is that the economic burden of eczema is driven by the severity of disease. This suggests that the emergence of new treatment approaches may have substantial potential for cost-effectiveness if they can lead to better disease control for patients, prevention of disease progression to more severe disease stages, and improvement of patients' quality of life.

It is important to conduct this review to assess the cost-effectiveness of eczema interventions. Globally, healthcare systems have insufficient resources (e.g. money or staff) to provide treatment for all of this common health problem and there is a paucity of economic evidence for treatments in comparison to clinical outcomes (Sach 2019). Some interventions now have sufficient evidence to suggest little or no benefit for patients with eczema, such as the application of topical corticosteroids twice daily (rather than once daily); topical corticosteroids containing antibiotics when used for the management of non-infected eczema; the use of ion exchange water softeners; and dietary supplements (probiotics, borage oil, evening primrose oil) (Nankervis 2017). This provides options for disinvestment, ensuring that available funds are channelled to the most effective and efficient treatments. Non-adherence to eczema treatment is widely reported, though the reasons remain poorly understood. Poor treatment adherence results in a complex and sizeable problem for global healthcare, as it has a vast impact on clinical outcomes, health economics, and patient safety (Eicher 2019). Eczema places a substantial economic burden on healthcare providers, patients, and society. Given the need to ensure efficient allocation of scarce healthcare funding resources, it is important to include a summary of the cost-effectiveness evidence base evaluating the use of educational and psychological interventions for the treatment of eczema.

The title of this Cochrane Review has been prioritised by Cochrane Skin in their 2020 prioritisation exercise, which aimed to identify the most important systematic review titles within the group's scope (Cochrane Skin 2020).

OBJECTIVES

1. To assess the clinical outcomes of psychological and educational interventions in children and adults with eczema
2. To summarise the availability and principal findings of relevant economic evaluations

METHODS

Criteria for considering studies for this review

Types of studies

We will include individually randomised, cluster-randomised and cross-over randomised controlled trials (RCTs) that assess educational and psychological interventions for treating eczema in children and adults. Studies will not be excluded based on language or publication status.

Types of participants

We will include participants of any age, with a diagnosis of eczema of any severity (identified using established diagnostic criteria, or diagnosed by a suitable healthcare professional). They may have fulfilled diagnostic criteria such as the Hanifin and Rajka definition

(Hanifin 1980), or the UK modification (Williams 1994); or they may have been diagnosed clinically by a healthcare professional, using the terms 'atopic eczema' or 'atopic dermatitis', for example. For very young children, or for those with certain learning disabilities, the intervention might be family- or carer-based.

Should we identify a study in which only a subset of participants is eligible (e.g. only some of the participants were diagnosed clinically with "atopic" eczema), two mechanisms will be deployed, as follows.

- If the study reports separate data for the eligible participants, we will only include the data for the eligible participants.
- If the study does not report separate data for the eligible participants, then in order to avoid loss of data (i.e. when studies are excluded), we will include studies in which more than 80% of the participants conform to the eligibility criteria.
- If no detailed information is available, an effort will be made to contact the authors of such studies to provide the information required.
- If no reply is attained, or the percentage of relevant participants was less than 80%, the study will be excluded.

Post-hoc inclusion decisions will be avoided as much as possible. However, if a decision is made it will be justified, documented, checked, and agreed by all the review authors. Sensitivity analysis will be conducted if any study with a subset of eligible participants is included in the meta-analysis by a post-hoc inclusion decision, to assess the impact of these decisions on the review's findings.

Types of interventions

We will evaluate all psychological interventions for eczema, delivered to groups or individuals. Eligible interventions include the following.

1. Psychological therapies, including counselling and cognitive behavioural therapy.
2. Behavioural interventions (this may include habit reversal).
3. Self-help interventions.
4. Arousal reduction therapies (this may include mindfulness, meditation, relaxation techniques and guided imagery).

We will evaluate all educational interventions for eczema, delivered to groups or individuals. Eligible interventions include the following.

1. Face-to-face educational interventions, including consultations and workshops.
2. Technology-mediated interventions (this may include online educational packages, videos, animations, social media, and virtual and telephone interactions).
3. Printed educational publications (this may include leaflets, infographics, and comics).

All settings relating to these types of psychological and educational interventions will be included, regardless of whether the intervention is carried out in the community, or within a primary, secondary, or tertiary care setting. All studies will be eligible for inclusion, regardless of mode of delivery, intensity, frequency, or duration of interventions. Interventions are likely to vary in both the mode of delivery (possibly using more than one delivery element)

and the pattern of delivery (with varying duration and frequency). Interventions may also vary in their theoretical underpinning.

Interventions could be simple single interventions; others could be complex interventions that utilise a combination of approaches. We will include studies where the same co-intervention is given in each arm (e.g. conventional treatment such as topical corticosteroids and emollients). The comparators are likely to be standard care (in the study setting), but we will also include studies with active comparators such as different forms of psychological or educational intervention.

Types of outcome measures

Outcome measures for eczema interventions have been addressed by the Harmonising Outcome Measures for Eczema initiative ([HOME 2021](#)). The initiative includes four core outcome domains as follows: a clinical signs tool (Eczema Area and Severity Index (EASI)); patient reported symptoms tools, for example Patient-Oriented Eczema Measure (POEM); quality of life tools; and tools to evaluate long-term control. We will include studies in this review regardless of whether our primary and secondary outcomes were reported.

Primary outcomes

1. Reduction in disease severity, as measured by clinical signs. This includes, but is not restricted to, EASI ([Hanifin 2001](#); [Schmitt 2014](#)), and SCORing Atopic Dermatitis (SCORAD) (with or without subjective component) ([Kunz 1997](#))
2. Reduction in disease severity, as measured by patient-reported symptoms. This includes, but is not restricted to, POEM ([Charman 2004](#); [Spuls 2017](#)), and NRS-11 (Numeric Rating Scale for intensity of itch) ([Yosipovitch 2019](#))
3. Improvement in quality-of-life measures (including, where specified, for family and caregivers), including but not restricted to, Dermatology Life Quality Index (adults) ([Finlay 1994](#)), (children) ([Lewis-Jones 1995](#)), (infants) ([Finlay 2001](#))

In the unlikely event that two scores are used for a single outcome, we will prioritise them based on the outcome measures recommended by [HOME 2021](#).

Secondary outcomes

1. Improvement in long-term control of eczema symptoms. This includes, but is not restricted to, Recap of Atopic Eczema ([Howells 2020](#)), or Atopic Dermatitis Control Test ([Pariser 2020](#))
2. Improvement in psychological well-being measures (including, where specified, for family and caregivers), including but not restricted to, Patient Health Questionnaire ([Kroenke 2001](#)), and Generalised Anxiety Disorder Questionnaire ([Spitzer 2006](#))
3. Improvement in standard treatment concordance
4. Adverse events (i.e. withdrawals due to adverse events)

Timing of outcome assessment

We will group time points into intervals representing 'short-term' (up to 16 weeks after completion of the intervention), and 'long-term' (longer than 16 weeks after completion of the intervention). For 'short-term', we will take the measurement closest to 12 weeks if multiple time points are used. For 'long-term', we will take the measurement closest to 12 months if multiple time points are used.

Search methods for identification of studies

We aim to identify all relevant RCTs, regardless of language or publication status (published, unpublished, in press, or in progress).

Electronic searches

Electronic searches for randomised controlled trials

The Cochrane Skin Information Specialist will search the following databases for relevant trials, with no restriction by date.

1. The [Cochrane Skin Specialised Register 2021](#).
2. The Cochrane Central Register of Controlled Trials (CENTRAL), in the Cochrane Library.
3. MEDLINE, via Ovid (from 1946 onwards).
4. Embase, via Ovid (from 1974 onwards).
5. APA PsycInfo, via Ovid (from 1806 onwards).

The Information Specialist has devised a draft search strategy for RCTs for MEDLINE (Ovid), which is displayed in [Appendix 1](#). This will be used as the basis for the development of search strategies for the other databases listed above.

We (HS, AH, VH, JVO) will search the trials registers listed below.

1. ClinicalTrials.gov (www.clinicaltrials.gov); see search strategy in [Appendix 2](#).
2. The World Health Organization International Clinical Trials Registry Platform (ICTRP) (trialsearch.who.int/); see search strategy in [Appendix 3](#).

Electronic searches for economic evaluations

We will follow the current guidance on searching for a brief economic commentary in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Aluko 2021](#)). The Cochrane Skin Information Specialist will search the [NHS Economic Evaluation Database](#) (NHS EED), available on the UK [Centre for Reviews & Dissemination \(CRD\)](#) website (covering from the earliest record in NHS EED, dating from 1968, up to and including 31 December 2014, when updating of the database ended).

As NHS EED is no longer updated, the Information Specialist will also search the following databases to identify eligible studies added from 1 January 2015 onwards.

1. MEDLINE, via Ovid.
2. Embase, via Ovid.

The Cochrane Skin Information Specialist will adapt our RCT search strategy (see [Appendix 1](#)), replacing the RCT study filter with filters relevant to identifying economic evaluations. The filters used will be those developed by the UK Centre for Reviews and Dissemination (CRD) to identify published reports of economic evaluations for inclusion in the NHS EED database ([CRD 2015](#)) (see [Appendix 4](#)).

Errata and retractions

The Cochrane Skin Information Specialist will run a specific search to identify errata or retractions related to our included studies, and we will examine any relevant retraction statements and errata that are retrieved.

Searching other resources

Additional searches for randomised controlled trials

Searching reference lists

We will check the bibliographies of included studies and any relevant systematic reviews identified for further references to relevant RCTs.

Correspondence with trialists, experts, and organisations

We will contact original trial authors for clarification and further data if trial reports are unclear. We will contact experts/organisations in the field to obtain further information on unpublished, relevant trials.

Adverse effects

We will not perform a separate search for adverse effects of psychological and educational interventions used for managing eczema. We will consider adverse effects described in included studies only.

Additional searches for economic evaluations

We will check the bibliographies of included studies and any relevant systematic reviews identified for references to relevant economic evaluations.

Data collection and analysis

We will use Covidence systematic review software to screen and manage the references. The software will automatically create a PRISMA study flow diagram for us to include in the review.

Selection of studies

We will use Cochrane's Screen4Me workflow to help assess the results of the search for RCTs. Screen4Me comprises three components, of which we will use two: known assessments (a service that matches records in the search results to records that have already been screened in Cochrane Crowd and been labelled as 'RCT' or 'not an RCT'); and the RCT classifier (a machine-learning model that distinguishes RCTs from non-RCTs). For more information about Screen4Me and the evaluations that have been done, please go to the [Screen4Me](#) webpage on the Cochrane Information Specialist's portal. In addition, more detailed information regarding evaluations of the Screen4Me components can be found in [Marshall 2018](#) and [Noel-Storr 2021](#).

Two review authors (HS, AH) will independently screen the titles and abstracts of each record identified in the searches. If a study meets our inclusion criteria, we will analyse the full text to confirm its inclusion. Any disagreement will be resolved by a third review author (VH). We will record reasons for exclusions in the 'Characteristics of excluded studies' table. We will present the process of trial selection in a PRISMA flow diagram ([Moher 2009](#)).

Data extraction and management

Two review authors (HS and AH) will undertake data extraction independently. The data fields we plan to extract include the following.

1. Study information including: study design, study author, year of publication, study duration, study setting, sample size.

2. Participant details (age; severity of condition; ethnicity; patient, carer, or both; etc.).
3. Details of interventions (e.g. behavioural/educational components; co-interventions; length of sessions).
4. Details of comparators (e.g. no treatment or standard care).
5. Details about outcomes (e.g. primary and secondary outcomes; measurement instruments; time points).
6. Outcome data.
7. Conflicts of interest.
8. Funding sources.

These characteristics will be used to complete the 'Characteristics of included studies' tables and extracted outcome data will be entered into meta-analysis or described narratively. We will compare data extractions and any discrepancies will be resolved through discussion. A third review author (VH) will adjudicate where required.

Assessment of risk of bias in included studies

Two review authors (HS and AH) will independently assess the risk of bias of included studies using Cochrane's 'Risk of bias 2' (RoB 2) tool ([Sterne 2019](#)). The following domains will be assessed: bias arising from the randomisation process; bias due to deviations from intended interventions; bias due to missing outcome data; bias in measurement of the outcome; and bias in the selection of the reported result. We will assess the effect of assignment to the intervention. Using the RoB 2 Excel tool to manage the process, we will assess the risk of bias for each outcome shown in the 'Summary of findings' tables. We will use RoB 2 assessments for both short- and long-term outcomes.

We will make judgements in relation to the risk of bias arising from each domain, based on answering a series of signalling questions. An algorithm proposes a bias judgement for each domain based on the answers to signalling questions. Another algorithm proposes an overall 'Risk of bias' assessment for each outcome, based on the judgements for each domain. Domain-level and overall judgements can be 'low' or 'high' risk of bias, or can express 'some concerns'. We will resolve any discrepancies in assessments through discussion between HS and AH, with adjudication by a third review author (VH) if necessary. We will make available our consensus decisions for all signalling questions, for all results assessed for all studies, by placing them on our institutional data repository or in an Appendix.

We will follow the guidance from Cochrane about assessing risk of bias in cluster-RCTs and cross-over RCTs, as follows.

- For cluster-RCTs: we will add an additional domain from the archived version of the tool (Domain 1b - "bias arising from the timing of identification and recruitment of participants") and use the signalling questions from the archived version ([Eldridge 2021](#)).
- For cross-over RCTs: we will use the standard version of the RoB 2 tool for parallel-group randomised trials as it is described (i.e. we will not use the interim variant for cross-over studies as we are only using the first part of the cross-over RCT in the meta-analysis). We will be mindful of the risk of selective outcome reporting for cross-over trials that only report one period ([Higgins 2021](#)).

Our primary analysis will include all eligible studies regardless of whether they are at low risk of bias, high risk of bias, or cause 'some concerns'. We will perform a sensitivity analysis, if feasible, to explore the impact of bias (see: [Sensitivity analysis](#)). The overall 'Risk of bias' judgement will be used to inform one of the GRADE considerations (study limitations); see below.

Measures of treatment effect

As most of our outcomes are likely to be continuous, we will calculate mean differences (MDs) with 95% confidence intervals (CIs). Some of these outcomes may have established minimal clinically important differences (MCIDs), including EASI, SCORAD, pruritis NRS, DLQI and POEM ([CADTH 2018](#)). When studies measure the same outcome using different instruments or scales, we will calculate the standardised mean difference (SMD). If possible, to enable interpretation, we will transform the effect back to the units used in a specific study. Where dichotomous data are expressed (e.g. number of participants with adverse events), risk ratios (RRs) with 95% CIs will be calculated.

Unit of analysis issues

The unit of analysis for parallel-group studies and cross-over trials will be individuals in the treatment arm compared to those in the control arm. Only the first phase of cross-over studies will be included in the meta-analysis because the design is not appropriate for assessing psychological and education interventions, as there are likely to be 'carry-over' effects. In studies with more than two relevant treatment arms, we will analyse pairs of comparisons.

We will address cluster-randomised studies in accordance with methods specified in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2021](#)). The unit of analysis will be the cluster and the sample size for the analysis will be the number of clusters.

We anticipate that many studies will have multi-component interventions from which it may not be possible to estimate the effectiveness of single interventions unless data are presented for comparator groups. We will compare the effectiveness of single and multi-component interventions between studies, and aim to assess whether the effects of combining interventions are additive or multiplicative.

Dealing with missing data

We will attempt to obtain any missing data from the primary study authors. Where it is reasonable, we will attempt to calculate missing data from other numerical data given (e.g. CIs, P values).

Assessment of heterogeneity

Due to anticipated heterogeneity, particularly with respect to studies' participants (i.e. adults versus children), a random-effects model will be applied for the meta-analysis. We will use the following thresholds for interpreting the I^2 value, as outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Deeks 2021](#)).

- 0% to 40%: might not be important.
- 30% to 60%: may represent moderate heterogeneity.*
- 50% to 90%: may represent substantial heterogeneity.*
- 75% to 100%: considerable heterogeneity.*

*The importance of the observed value of I^2 depends on 1) the magnitude and direction of effects, and 2) the strength of evidence for heterogeneity (e.g. P value from the χ^2 test, or a CI for I^2 : uncertainty in the value of I^2 is substantial when the number of studies is small).

Additionally, Cochran's Q test of heterogeneity will be checked to confirm the results of I^2 , as well as visual inspection of the forest plots. To assess whether between-study heterogeneity has been caused by one or more studies with extreme effect sizes, any study with a CI that does not overlap with the CI of the pooled effect will be identified as an outlier and influential study using the Baujat plot approach ([Borenstein 2009](#)).

Assessment of reporting biases

If data allow, we will generate funnel plots and use the Egger test to detect publication bias for meta-analyses that include a minimum of 10 studies ([Egger 1997](#)).

Data synthesis

We will only undertake a meta-analysis if the participants, interventions, comparisons and outcomes are judged to be sufficiently similar, to ensure an answer that is clinically meaningful. If data allow, we will perform meta-analysis, using random-effects models, for each comparison using [Revman Web 2020](#). If it is not feasible to perform meta-analysis due to heterogeneity, we will synthesise the results using the 'Synthesis without meta-analysis (SWIM) in systematic reviews: reporting guideline' ([Campbell 2020](#)).

We plan to separately analyse psychological and educational interventions. Interventions that involve both components (e.g. psycho-educational) will also be analysed. Studies will be pooled together for analysis if they are suitably comparable in relation to their participants, interventions, comparisons, and outcomes.

Where results are estimated for individual studies with low numbers of events (less than 10 in total), or where the total sample size is less than 30 participants and a risk ratio is used, we will report the proportion of events in each group together with a P value from a Fisher's Exact test ([Fisher 1934](#)).

Subgroup analysis and investigation of heterogeneity

If sufficient study information is available, we plan to perform subgroup analysis. The subgroup analysis will aim to identify if intervention effects in the meta-analysis significantly differ by: age, ethnicity, severity of disease, carer versus patient, or group versus individual interventions.

We will use the formal χ^2 test for subgroup differences to test for subgroup interactions. We will compare subgroups using the analysis option of the 'test for subgroup differences' in [Revman Web 2020](#). Will use the P value from the test for subgroup differences in RevMan Web to formally compare subgroups.

Sensitivity analysis

We plan to undertake sensitivity analyses by applying the trim-and-fill method ([Borenstein 2009](#); [Higgins 2021](#)), and removing from the quantitative synthesis studies deemed to be at overall high risk of bias. We will remove studies with a different study design (e.g.

cross-over or cluster-RCTs), or where data have been inputted and calculated differently (e.g. extracted from a figure).

Incorporating economic evidence

Following the search outlined in [Search methods for identification of studies](#), we will develop a brief economic commentary to summarise the availability and principal findings of trial-based and model-based full economic evaluations (cost-effectiveness analyses, cost-utility analyses, cost-benefit analyses) that compare educational and/or psychological interventions with standard treatment for eczema ([Aluko 2021](#)) among children or adults. This commentary will focus on the extent to which principal findings of eligible economic evaluations indicate that an intervention might be judged favourably (or unfavourably) from an economic perspective, when implemented in different settings.

The results of the search will be screened by a health economist (DB) against the same population, intervention and comparator criteria developed for the main review of effectiveness. Evaluations that provide a synthesis of costs and outcomes within a full economic evaluation framework will be included. Evaluations conducted alongside single studies (typically within trial evaluations) and decision analysis models will both be deemed eligible for inclusion. We will extract the following data from eligible studies.

1. Brief study characteristics:
 - a. analysis framework: cost-effectiveness analysis (CEA), cost-utility analysis (CUA), or cost-benefit analysis (CBA);
 - b. type of evaluation (trial- or model-based);
 - c. analysis perspective (e.g. health system, payer, societal);
 - d. time horizon (for costs and effects);
 - e. types of costs included in the evaluation (e.g. health/other/patient and family/productivity);
 - f. costing details (e.g. country, costing year, costing currency, setting (primary/secondary care)).
2. Principal findings:
 - a. base case incremental cost-effectiveness ratio (and range of sensitivity analyses, if reported);
 - b. verbatim text on conclusions drawn by the authors for the main base case analysis;
 - c. verbatim text used by authors to summarise the uncertainty of the results (e.g. any sensitivity analyses conducted, deterministic or probabilistic).

The findings of the brief economic commentary will be incorporated into the Discussion section of the review as a narrative summary of the principal findings of the included economic evaluation studies.

Summary of findings and assessment of the certainty of the evidence

We will prepare 'Summary of findings' tables, using GRADEpro GDT software ([GRADEPro](#)). We plan the following 'Summary of findings' tables (it is anticipated that all interventions will be in addition to standard care, i.e. emollients and topical corticosteroids).

1. Psychological therapies (including counselling and cognitive behavioural therapy) versus standard care only.

2. Behavioural interventions (including habit reversal) versus standard care only.
3. Self-help psychological interventions versus standard care only.
4. Arousal reduction therapies (including mindfulness, meditation, relaxation techniques and guided imagery) versus standard care only.
5. Face-to-face educational interventions versus standard care only.
6. Technology-mediated educational interventions versus standard care only.
7. Printed educational interventions versus standard care only.

We will use the GRADE approach to assess the certainty of evidence for the following primary and secondary outcomes ([Schünemann 2019](#)).

1. Primary outcomes:
 - a. reduction in disease severity, as measured by clinical signs;
 - b. reduction in disease severity, as measured by patient-reported symptoms;
 - c. improvement in quality-of-life measures (including, where specified, for family and caregivers).
2. Secondary outcomes:
 - a. improvement in long-term control of eczema symptoms;
 - b. improvement in psychological well-being measures (including, where specified, for family and caregivers) (measured using [Kroenke 2001](#) or [Spitzer 2006](#) assessments).

As eczema is a chronic condition, long-term outcomes are likely to be more important to patients, therefore they will be prioritised for the 'Summary of findings' tables. For reduction in disease severity as measured by clinical signs (primary outcome 1), we will use EASI alone rather than combining with SCORAD, as the latter also contains a subjective component and is therefore not a comparable outcome.

We will use the five GRADE considerations — study limitations (using the RoB 2 assessments), consistency of effect, imprecision, indirectness, and publication bias — to assess the certainty of the body of evidence for these pre-specified outcomes. We will resolve any discrepancies in the GRADE process through discussion between HS and AH, with adjudication by a third/fourth review author (SOM and OAM) if necessary.

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ADDITIONAL TABLES

Table 1. Glossary of terms

Term	Definition
Aetiology	Refers to the cause of the disease
Allergens	Antigens (see below) which produce an abnormally severe immune response (leading to allergy symptoms) but would otherwise be harmless to the body
Antigens	Substances from outside the body which interact with the immune system, specifically by being bound to an antibody
Biologic drug	A medicine that has been produced from a living organism. Monoclonal antibodies (see below) are a form of biologic drug.
Calcineurin inhibitors	A class of medicines which inhibit the immune system by blocking the action of calcineurin, a chemical which activates T-cells (a type of white blood cell). In eczema, these are commonly used

Table 1. Glossary of terms *(Continued)*

	in a form that can be applied directly to the skin, although ciclosporin is a systemic form (see below) of calcineurin inhibitor which is sometimes used to treat more severe cases.
Chronicity	The propensity for a disease to have a long duration (note: this does not relate to the severity of a disease)
Epidermis	The outermost layer of the skin
Erythema	Red appearance of the skin due to increased blood flow, often a marker of inflammation
Excoriation	Clinical sign of the top layer of the skin having been removed. In the context of eczema, usually due to itching
Filaggrin	A protein within the outermost skin cells which contributes to the flattening and strengthening of cells to create a strong barrier. Its broken-down products also help maintain the water content in the skin.
Hyper/hypo-pigmentation	Increased/decreased appearance of pigment in the skin
Keratin	One of the major constituents of hair, nails and the top layer of the skin. It forms a network within skin cells (keratinocytes)
Lamellar lipid bilayers	A double layer of molecules in the skin which do not dissolve in water and are therefore helpful in maintaining water content of the skin
Leukotriene antagonists	A group of drugs which have an effect on the immune system by blocking leukotrienes, a class of chemicals involved in inflammation and the immune response. They are most commonly used in the treatment of asthma.
Monoclonal antibody	A protein produced in a laboratory from cloning a single white blood cell. The resulting protein can be used to interact with the immune system for a specific purpose.
Pathological inflammation	Inflammation in the body which causes symptoms or is harmful and is due to an overactivity or abnormality with the immune system itself, rather than an external cause such as infection or trauma
Percutaneous	Through the skin
Systemic form	A form of a drug that can be administered into the body, whether by mouth or injection, and therefore has an effect on the whole body not just a specific site
Vesicles	Small blisters of the skin that contain clear fluid

APPENDICES

Appendix 1. Draft search strategy for MEDLINE (Ovid)

1. Eczema/
2. eczema\$.ti,ab.
3. dermatitis, atopic/ or dermatitis/
4. dermatiti\$.ti,ab.
5. Neurodermatitis/
6. neurodermatiti\$.ti,ab.
7. 1 or 2 or 3 or 4 or 5 or 6
8. exp Psychotherapy/
9. exp Behavior Therapy/
10. exp Cognitive Therapy/

11. exp Relaxation Therapy/
12. exp Family Therapy/
13. exp Autogenic Training/
14. exp Counseling/
15. exp Biofeedback, Psychology/
16. psychotherap\$.ti,ab.
17. behavio\$ therap\$.ti,ab.
18. ((cognitive or autogenic) adj2 (therap\$ or counsel\$ or training)).ti,ab.
19. relaxation.ti,ab.
20. family therap\$.ti,ab.
21. (counseling or counselling).ti,ab.
22. Biofeedback.ti,ab.
23. psychotherapy, psychodynamic/
24. psychodynamic therap\$.ti,ab.
25. talking therap\$.ti,ab.
26. behavio\$ management.ti,ab.
27. ((Behavioral or behavioural) adj contracting).ti,ab.
28. behavio\$ change\$.ti,ab.
29. Mindfulness/
30. mindfulness.ti,ab.
31. exp Health Education/
32. exp Patient Education Handout/
33. exp Health Promotion/
34. exp Patient Education as Topic/
35. Eczema Education Programme\$.ti,ab.
36. (health adj (promotion or education or training or teaching)).ti,ab.
37. ((patient\$ or caregiver\$ or carer\$ or parent\$ or dermatolo\$ or communit\$ or group\$) adj (education or training or teaching or learning or information or course\$ or programme\$)).ti,ab.
38. (psychological adj (therap\$ or intervention\$)).ti,ab.
39. arousal reduction technique\$.ti,ab.
40. Imagery, Psychotherapy/
41. (stress adj2 (managing or manage\$)).ti,ab.
42. Empowerment/
43. distraction technique\$.ti,ab.
44. habit reversal.ti,ab.
45. Meditation/
46. or/8-45
47. exp Eczema/px [Psychology]
48. exp Dermatitis, Atopic/px [Psychology]
49. exp Neurodermatitis/px [Psychology]
50. exp Dermatitis/px [Psychology]
51. 47 or 48 or 49 or 50
52. randomized controlled trial.pt.
53. controlled clinical trial.pt.
54. randomized.ab.
55. placebo.ab.
56. clinical trials as topic.sh.
57. randomly.ab.
58. trial.ti.
59. 52 or 53 or 54 or 55 or 56 or 57 or 58
60. exp animals/ not humans.sh.
61. 59 not 60
62. 51 and 61
63. 7 and 46 and 61
64. 62 or 63

Appendix 2. Draft search strategy for ClinicalTrials.gov

We will use the 'advanced search' function and search for:

Condition or disease: eczema OR dermatitis OR neurodermatitis

Other terms:

Psychological and educational interventions for managing eczema (Protocol)

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1. psychotherapy OR biofeedback OR mindfulness OR meditation OR imagery OR empowerment OR “habit reversal” OR stress
2. Eczema Education Programme
3. health AND (promotion OR education OR training OR teaching OR learning OR information OR course OR programme OR program)
4. (behavior OR behaviour OR behavioural OR behavioral) AND (therapy OR therapies OR management OR manage OR managing OR change OR contracting OR counselling OR counseling OR training)
5. (cognitive OR relaxation OR family OR talking OR psychodynamic OR psychological OR autogenic OR stress) AND (therapy OR therapies OR management OR manage OR managing OR change OR contracting OR counselling OR counseling OR training)

Study type: interventional studies (Clinical Trials)

Study results: all studies

Appendix 3. Draft search strategy for WHO ICTRP

We will use the 'advanced search' function and search for:

Eczema* OR dermatiti* OR neurodermatiti* **in condition**

Combined with the following two groups of intervention terms (split due to character limit in the search facility)

1. education* OR psycholog* OR psychother* OR training OR teaching OR learning OR information OR course* OR programme* OR program* OR behavio* OR counsel* OR stress **in intervention**

2. cognitive OR relaxation OR family OR autogenic OR biofeedback OR psychodynamic OR talking OR mindfulness OR health promotion OR empowerment OR meditation **in intervention**

Appendix 4. UK Centre for Reviews and Dissemination filters for identifying economic evaluations in MEDLINE and Embase (Ovid platform)

MEDLINE

- 1 Economics/
- 2 exp "costs and cost analysis"/
- 3 Economics, Dental/
- 4 exp economics, hospital/
- 5 Economics, Medical/
- 6 Economics, Nursing/
- 7 Economics, Pharmaceutical/
- 8 (economic\$ or cost or costs or costly or costing or price or prices or pricing or pharmaco-economic\$).ti,ab.
- 9 (expenditure\$ not energy).ti,ab.
- 10 value for money.ti,ab.
- 11 budget\$.ti,ab.
- 12 or/1-11
- 13 ((energy or oxygen) adj cost).ti,ab.
- 14 (metabolic adj cost).ti,ab.
- 15 ((energy or oxygen) adj expenditure).ti,ab.
- 16 or/13-15
- 17 12 not 16
- 18 letter.pt.
- 19 editorial.pt.
- 20 historical article.pt.
- 21 or/18-20
- 22 17 not 21
- 23 exp animals/ not humans/
- 24 22 not 23
- 25 bmj.jn.
- 26 "cochrane database of systematic reviews".jn.
- 27 health technology assessment winchester england.jn.
- 28 or/25-27
- 29 24 not 28

Embase

1. Health Economics/
2. exp Economic Evaluation/
3. exp Health Care Cost/
4. pharmacoeconomics/
5. 1 or 2 or 3 or 4
6. (econom\$ or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic\$).ti,ab.
7. (expenditure\$ not energy).ti,ab.
8. (value adj2 money).ti,ab.
9. budget\$.ti,ab.
10. 6 or 7 or 8 or 9
11. 5 or 10
12. letter.pt.
13. editorial.pt.
14. note.pt.
15. 12 or 13 or 14
16. 11 not 15
17. (metabolic adj cost).ti,ab.
18. ((energy or oxygen) adj cost).ti,ab.
19. ((energy or oxygen) adj expenditure).ti,ab.
20. 17 or 18 or 19
21. 16 not 20
22. animal/
23. exp animal experiment/
24. nonhuman/
25. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ti,ab,sh.
26. 22 or 23 or 24 or 25
27. exp human/
28. human experiment/
29. 27 or 28
30. 26 not (26 and 29)
31. 21 not 30
32. 0959-8146.is.
33. (1469-493X or 1366-5278).is.
34. 1756-1833.en.
35. 32 or 33 or 34
36. 31 not 35
37. conference abstract.pt.
38. 36 not 37

CONTRIBUTIONS OF AUTHORS

HS and AH were the lead authors.

HS was the contact person with the editorial base.

HS and AH co-ordinated the contributions from the co-authors and wrote the final draft of the protocol.

HS, AH, AT, AR, JVO, ED, VH, SE, OAM, EA, RB and DB worked on the Methods section.

OAM, HS, AH, EA, RB and SOM worked on the statistical sections of the method.

HS and AH drafted the clinical sections of the Background and responded to the clinical comments of the referees.

All authors contributed to writing the protocol.

AR was the consumer co-author and checked the protocol for readability and clarity. She also ensured that the outcomes are relevant to consumers.

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DECLARATIONS OF INTEREST

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Vanessa Heaslip declared that they have no conflict of interest.

Andrew R Thompson reports various occasional media work about lack of psychological interventions for dermatology patients, including *British Journal of Dermatology* editorials, the All Party Parliamentary Group on Skin: APPGS report, and for the British Skin Foundation. AT is a psychological advisor to APPGS.

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