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Psychological and educational interventions for atopic eczema in children (Review)

Ersser SJ, Latter S, Sibley A, Satherley PA, Welbourne S

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Psychological and educational interventions for atopic eczema in children.
Cochrane Database of Systematic Reviews 2007, Issue 3. Art. No.: CD004054.
DOI: 10.1002/14651858.CD004054.pub2.

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[Intervention Review]

Psychological and educational interventions for atopic eczema in children

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Editorial group: Cochrane Skin Group.
Publication status and date: Edited (no change to conclusions), published in Issue 1, 2010.

Citation: Ersser SJ, Latter S, Sibley A, Satherley PA, Welbourne S. Psychological and educational interventions for atopic eczema in children. *Cochrane Database of Systematic Reviews* 2007, Issue 3. Art. No.: CD004054. DOI: 10.1002/14651858.CD004054.pub2.

ABSTRACT

Background

Psychological and educational interventions have been used as an adjunct to conventional therapy for children with atopic eczema to enhance the effectiveness of topical therapy. There have been no relevant systematic reviews applicable to children.

Objectives

To assess the effectiveness of psychological and educational interventions in changing outcomes for children with atopic eczema.

Search methods

We searched the Cochrane Skin Group Specialised Register (to September 2004), the Cochrane Central Register of Controlled Trials (*The Cochrane Library Issue* 2, 2005), MEDLINE (from 1966-2005*)*, EMBASE (from 1980 to week 3, 2005), PsycINFO (from 1872 to week 1, 2005). On-line: National Research Register, Meta-register of Controlled Trials, ZETOC alerts, SIGLE (August 2005).

Selection criteria

RCTs of psychological or educational interventions, or both, used to manage children with atopic eczema.

Data collection and analysis

Two authors independently applied eligibility criteria, assessed trial quality and extracted data. A lack of comparable data prevented data synthesis.

Main results

Five RCTs met the inclusion criteria. Some included studies required clearer reporting of trial procedures. Rigorous established outcome measures were not always used. Interventions described in all 5 RCTs were adjuncts to conventional therapy. Four focused on intervention directed towards the parents; data synthesis was not possible. Psychological interventions remain virtually unevaluated by studies of robust design; the only included study examined the effect of relaxation techniques (hypnotherapy and biofeedback) on severity. Three educational studies identified significant improvements in disease severity between intervention groups. A recent German trial evaluated long term outcomes and found significant improvements in both disease severity (3 months to 7 years, p=0.0002, 8 to 12 years, p=0.003, 13 to 18 years, p=0.0001) and parental quality of life (3 months to 7 years, p=0.0001, 8 to 12 years p=0.002), for children with atopic eczema. One study found video-based education more effective in improving severity than direct education and the control (discussion) (p<0.001).

The single psychological study found relaxation techniques improved clinical severity as compared to the control at 20 weeks (t=2.13) but this was of borderline significance (p=0.042).

Authors' conclusions

A lack of rigorously designed trials (excluding one recent German study) provides only limited evidence of the effectiveness of educational and psychological interventions in helping to manage the condition of children with atopic eczema. Evidence from included studies and also adult studies indicates that different service delivery models (multi-professional eczema school and nurse-led clinics) require further and comparative evaluation to examine their cost-effectiveness and suitability for different health systems.

PLAIN LANGUAGE SUMMARY

Psychological and educational interventions for atopic eczema in children

Atopic eczema is an itchy inflammatory skin condition which affects the quality of life of children with eczema and their parents; it can affect up to 15% of school children in the UK. Psychological and educational approaches to treating eczema have been used to complement medication in managing eczema by, for example, promoting relaxation and educating parents and children to understand the condition and their role in its successful management. However, the effectiveness of these approaches has not been systematically reviewed.

The main finding of the review is that there is currently only limited research evidence about the effectiveness of educational and psychological approaches when used with medicines for the treatment of childhood eczema. We were only able to include one study on the effectiveness of psychological approaches in the review. We included four educational studies, of which three identified that education decreased the severity of the eczema, and one study found that education improved quality of life for parents of children with eczema. Relaxation methods reduced the severity of the eczema, compared to discussion only, in the psychological study. Two different approaches have been used to deliver education; one led by a nurse and the other by a team of health professionals.

Due to weaknesses in the quality of most of the research studies and the fact that different measures were used to evaluate effectiveness of the approaches, we cannot draw strong conclusions about whether psychological and educational approaches work or which is the best approach to use. More details are needed about the psychological and educational approaches used, to allow a greater understanding of the key factors that might help reduce eczema. Better description of the research methods used are also needed. Research priority should also be given to comparing the relative cost effectiveness of health professionals educating parents either in teams or by nurses alone.

No adverse effects have been reported.

Limitations of the review: We were able to find only five studies eligible for inclusion in the review and we were not able to combine findings from these studies due to the different ways in which effectiveness of the approaches were measured.

BACKGROUND

Description of the condition

Definition, clinical features and epidemiology

Atopic eczema (or atopic dermatitis) is an itchy inflammatory skin disease, which usually involves the skin creases (Williams 2005). It may be acute with redness, scaling, oozing and vesicles or it may be chronic with skin thickening, altered pigmentation and exaggerated surface markings. Itching is a predominant symptom that can lead to a cycle of scratching, causing skin damage and in turn more itching (the itch scratch cycle). Atopic eczema is now the commonest inflammatory skin disease of childhood, affecting around 15% of school children in the UK (Kay 1994; Neame 1995; Schultz Larsen 1996; Emerson 1997). Although only 1 to 2% of adults are affected by atopic eczema, their disease is often more chronic and severe (Herd 1996). Approximately 70% of cases start in children under five years of age (Williams 2000). There is reasonable evidence to suggest that the prevalence of atopic eczema has increased two to three-fold over the last 30 years, for reasons which are unclear (Williams 1992) and in many countries this continues to rise (Asher 2006).

Causes

Studies with twins demonstrate that genetic factors are important in atopic eczema, but other evidence strongly suggests that environmental factors are critical in disease expression (Williams 1995). Allergic factors, such as exposure to house dust mites may be accountable, but non-allergic factors such as exposure to irritants in people with defective skin barrier function and reduced exposure to infectious agents may also be important. Some authorities further divide atopic eczema into extrinsic and intrinsic forms (Wüthrich 2002), the former denotes individuals with evidence of raised circulating antibodies to common allergens, whereas the latter does not. It is also established that psychological factors, such as stress, play a vital role in the course of atopic eczema as a trigger or precipitating factor (Laihinen 1991; Roth 1991; Buske 2001; Buske 2002; Gieler 2002).

Impact

Measurement of the impact of skin disease on quality of life is important for our understanding and management of skin diseases. Several studies suggest that atopic eczema has a more profound effect on quality of life than other skin diseases, such as acne and psoriasis (Lewis-Jones 1995), therefore it is desirable to measure the impact on quality of life as a potential outcome of intervention. The relationship between the severity of atopic eczema in children and adolescents and quality of life has been established (Ben-Gashir 2004). Problematic symptoms such as itching can adversely affect quality of life. Itch leads to scratching and these may have a significant impact on a child's sleep, quality of life (Williams 1997; Lewis-Jones 2001) and family (Johnson 1991; Elliott 1997). Due to the various impacts of atopic eczema, it is necessary to measure changes in disease severity as a key outcome measure. Also, since caregivers, especially parents, are often required to assist with treatments, their ability and confidence are also relevant outcomes to measure. Given that children and adolescents with atopic eczema require special clothing, bedding, frequent applications of greasy ointments and may need to avoid activities such as swimming (Reid 1995), treatment adherence becomes a relevant outcome to measure. There is also a substantial economic cost to the family (Kemp 2003) and the health service (Verboom 2002).

Description of the intervention

Educational and psychological interventions are invariably provided in conjunction with conventional therapy. Such interventions may be directed towards the parent or child, with parents tending to be the primary focus of the educational approaches and children the main target of psychological interventions. The suitability of the intervention will depend on the age and developmental stage of the child and, therefore, the child's ability to participate effectively in an educational and psychological intervention will vary. An example of a psychological (behavioural) intervention is habit reversal, identified as a method of eliminating nervous habits and tics, whereby an alternative or competing behaviour is adopted in place of the undesirable behaviour (Azrin 1973). This has been recently reviewed (Miltenberger 1998).

How the intervention might work

Although there is currently no cure, various interventions do exist to control symptoms, but the effectiveness of many treatments has not been established (Hoare 2000). Conventional treatment consists of the application of emollients and topical corticosteroids, both of which have been in use for over 30 years (Hanifin 1980; Leung 2000). Other treatments include wet wraps (damp, occlusive body bandages either impregnated with a therapeutic substance or applied over topical preparations) and dietary manipulation (Rosenbaum 1981). Other treatments have included complementary therapies such as homeopathy (Ernst 2002). For more severe atopic eczema macrolide immuno-suppressant drugs may be used, for example the oral drug ciclosporin and relatively new treatments called topical calcineurin inhibitors, namely, tacrolimus (Leung 2000) and pimecrolimus (Williams 2005).

Why it is important to do this review

Since atopic eczema affects children and can be disabling for whole families it is generally agreed that psychological support and education of the parent/carer are crucial components of disease management. Little is known, however, of the measurable effects of such interventions and the most recent systematic review of the treatments for atopic eczema to date (Hoare 2000) found only limited evidence to support psychological treatments or educational interventions. Psychological interventions are being incorporated into management strategies to reduce scratching behaviours that exacerbate eczema (Horne 1989; Giannini 1997). Despite the fact that parents are the primary carers for children with atopic eczema, very limited attention has been given to the psychological support of parents (by educational or psychological intervention). As such, the caregiver's ability to manage their child's eczema is an important outcome and therefore the educational or psychological support given to parents is relevant to this review. However, it is recognised that psychological support to both caregiver and child are important. The general case for psychosocial intervention to improve clinical outcomes in organic disease is established (Williams 2002) and in related areas such as asthma (Guevara 2003).

The literature refers to a range of psychological interventions that have been used in atopic eczema, such as behavioural management (Norén 1989; Bridgett 1995; Bridgett 2000) relaxation therapy (de L Horne 1999) and cognitive behavioural therapy

(Ehlers 1995). Clinical observations suggest that behavioural techniques can be a useful adjunct to topical therapy, and breaking the itch-scratch cycle is argued to be a primary clinical aim (Hägermark 1995). However, evaluative research has been limited (Simpson-Dent 1999; Bridgett 2000), especially with children.

Educational interventions have also been used to bring about behavioural change through health/patient education or patient teaching for those with eczema (Niebel 2000). These are important since chronic disease management requires a degree of self management (or caregiver/ parental support) and therefore education and behavioural change (Holman 2000). A limited number of evaluative studies have examined the impact of parental education on the management of atopic eczema in children (e.g. Niebel 2000), although some studies have examined the impact of education on adults with eczema; these studies are informative (e.g.: Ehlers 1995).

OBJECTIVES

To assess the effectiveness of psychological and educational interventions for atopic eczema in children.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs).

Types of participants

Children, adolescents or infants with atopic eczema and their caregivers (including parents).

Types of interventions

We anticipated that most studies would be of conventional treatment alone versus conventional plus psychological/ educational and that we would be unlikely to find trials examining purely psychological/educational approaches. Some interventions which are psychologically or educationally based focused on the parent, the child or both; and depended upon the developmental stage of the child. Whilst some RCTs of therapies have an educational or psychological component, the review only included studies where the educational or psychological intervention was the primary intervention to which the experimental group was exposed were included.

a) Psychological interventions
These included:

1. Autonomic (body) interventions
These are relaxation therapies including:

- progressive relaxation
- autogenic training - a training course during which clients learn a series of simple exercises in body awareness and relaxation designed to switch off the stress-related 'fight and flight' system of the body and switch on the 'rest, relaxation and recreation' system.
- guided imagery: also known as 'visualization', guided imagery utilises imagination and thoughts to improve one's physical, mental and emotional health.
- biofeedback - where the individual learns how to recognise and take control of internal, autonomic, and physiological responses through a mechanism of feedback, imagery or focused thinking.

2. Behavioural interventions

- Behavioural management therapy: the application of behavioural theory (e.g. conditioning, reinforcement) to modify or eradicate undesired behaviours.
- Behavioural contracting: a form of therapy that seeks to change the behaviour of the recipients through a system of contingencies, rewards and consequences. This may include caregiver training programmes and a variety of reward systems (e.g. star or sticker charts).

3. Cognitive interventions

- Cognitive Behavioural Therapy and insight orientated approaches, such as Cognitive Analytical Therapy, are other problem-orientated approaches often used in conjunction with behavioural techniques:

(i) cognitive behavioural therapy is a bio-psychosocial perspective that may involve the promotion of a rational, empiricist or constructivist approach to the individual's understanding of their situation or enhancement of their problem-solving skills and coping strategies;
(ii) cognitive-analytical therapy draws on psychoanalytic as well as cognitive techniques. A structured and focused framework is used to encourage patients to understand the origins of their attitudes and beliefs and the effect they have on present feelings and behaviour in order that change may occur.

4. Combination interventions (involving two or more of the above combined)
These interventions can fall into different and overlapping categories in accordance with their particular theoretical orientation:

- Counselling / talking therapies - usually non-directive, non-judgemental, empathetic and supportive approaches, which enable a client to cope more effectively with their problems or inner states (sometimes referred to as talking treatment). Counselling can be insight-orientated and focus on deeper levels of understanding.
- Hypnotherapy (the intervention is categorised here since it often combines both cognitive and behavioural dimensions).
- Family therapy - views the family, rather than the individual member, as the unit requiring help. Types of family therapy all involve encouraging family members to talk to one another, rather than the therapist, examining inflexibilities, family rules and beliefs, concentrating on relationships within the family and those between the family and the wider systems of health, education, occupation, and social services.

5. Psychodynamic (non-cognitive behavioural therapy)
These approaches emphasise motives and drives, and tend to be used by therapists with an analytical persuasion. The aim of the therapy is the formation of a meaningful relationship between client and therapist, which is then used as the context for exploring psychological defences. This includes focusing on the past which can be recalled and understood (called insight-orientated or exploratory psychodynamic psychotherapy) e.g. Rogerian, Jungian

and psychoanalytic therapies. The approach varies according to the theoretical framework, for example:

- Individual therapy - therapeutic interventions that focus on the internalised working model of the recipient and through a process of reflection and insight reduce unconscious conflicts, or replace them with consciously acknowledged problems in order to reach a different understanding of the situation.
- Group therapy - any therapeutic intervention that is offered to a group of individuals with a shared aim. The approach may be psychoanalytic, psycho educational, cognitive-behavioural, family systems, interpersonal, experiential or didactic and task orientated. Psychoanalytical approaches derive from methods developed by Freud, characterised by a dynamic perspective of all aspects of the conscious and unconscious.

b) Educational Interventions

Educational interventions are focused on the process of acquiring new knowledge and or skills through teaching and learning activities. An approach where information-giving and formal teaching lead the recipients to become more accurately informed about the condition, and therefore, better equipped to understand the need for medical treatments and good disease management. Educational interventions may include as tools, any of the following: lectures, audiotapes, books, booklets, leaflets, handouts, films, videotapes, demonstrations, question and answer sessions. The content of these educational interventions may include information on the disease, treatment instructions, management and prevention strategies. They may be delivered within the hospital setting or in the community via an outreach service mediated through the home or school.

Any educational intervention targeted at children (and/or their caregivers) designed to teach one or more management strategies related to prevention, management, or social skills using any instructional strategy or combination of strategies (problem solving, role-playing, videotapes, computer assisted instruction, booklets, etc.) presented either individually or in group sessions is included in the review (definition derived from Wolf 2002). Dermatological education and psychological behaviour training may be combined to support secondary prevention (Gieler 2000).

Types of outcome measures

The following outcomes were of interest to us as measured by participant, carer, clinician or other trial outcome observer or any combination. Specifically, we were concerned with a clinically significant response in the following outcomes:

Primary outcomes

(i) the participant rated global assessment was the primary outcome measure if available. We refer here to the generic response of the participant deeming the intervention to be effective / helpful or ineffective / unhelpful as an outcome measure. If this was not available, the medical practitioner global rating was used (percentage with good or excellent improvement).
(ii) reduction in disease severity as measured by a trained assessor
(iii) improvement in sleep
(iv) improvement in quality of life of child and parent (caregiver)

Secondary outcomes

(i) reduction in harmful scratching behaviour
(ii) improvement in treatment adherence
(iii) reduction of medication usage (particularly anti-inflammatory / immuno suppressant treatments) *
(iv) enhancement of caregiver ability (actual and perceived) to manage atopic eczema in their child (e.g. self-efficacy (self-confidence), locus of control (distinguishing those who attribute events to either their own control or to external circumstances) and coping measures**

We took into account, in addition to the measures above, adverse affects such as inconvenience and cost. We accepted outcome measures however designed and implemented, although this was accompanied by a critical evaluation of the rigor of the measures used (attention to reliability and validity issues). The conventional treatment used in a trial will be an important characteristic that may influence the effectiveness of the psychological / educational intervention, and this was considered as a possible source of heterogeneity.

* It is recognised that medication usage may go up because of improved adherence or it may go down because the eczema has improved as a result of psychological intervention.

** This outcome allows for the fact that the benefits of psychological support / education may not be primarily 'clinical'.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Skin Group Specialised Register (to September 2004) using the search strategy in Appendix 1.

We searched the Cochrane Central Register of Controlled Trials (*The Cochrane Library Issue* 2, 2005) using the search strategy in Appendix 2.

We searched MEDLINE (1966 - 2005) using the search strategy in Appendix 3.

We searched EMBASE (1980 - week 3, 2005) using the search strategy in Appendix 4.

We searched PsycINFO (1872 - week 1, 2005) using the search strategy Appendix 5.

Searching other resources

References from published studies

We checked these for further trials using the bibliographies of included and excluded studies.

Unpublished literature

We searched SIGLE (System for Information on Grey Literature in Europe) (from 1980 to August 2005) using the following terms: atopic eczema OR dermatitis OR dermat* AND child* AND psy* OR edu* (http://www.stn-international.de/).

We searched for ongoing trials on the National Research Register (http://www.nrr.nhs.uk/) using the terms: atopic eczema AND child* AND psy* OR edu*, the Meta-register of Controlled Trials (www.controlled-trials.com) using the terms:atopic eczema OR dermatitis OR dermat* AND child* AND psy* OR edu* (August 2005).

Conference proceedings

We searched Zetoc alerts for additional conference proceeding that were not expected to be covered by the Cochrane Skin Group Specialist Register (http://zetoc.mimas.ac.uk/) (August 2005).

Adverse effects

We carried out a search for side effects studies by looking at reported events in included studies.

Language restrictions

We did not impose any language restrictions when searching for publications, and translations were sought where necessary.

Data collection and analysis

Selection of studies

Only randomised controlled trials (RCTs) were considered. Two authors checked titles and abstracts identified from the searches and studies that did not refer to an RCT on atopic eczema were excluded. Two authors obtained the full texts of studies for independent assessment to decide which trials fulfilled the inclusion criteria. Any disagreement was resolved by discussion between all the authors. Where randomisation procedures were unclear correspondence was undertaken with the relevant trial authors in an attempt to clarify the procedures used.

Data extraction and management

This was performed independently by two authors who entered data onto a data extraction form. All discrepancies were discussed and a consensus achieved for each paper, with modification of the principal data extraction form. In one paper (Broberg 1990) missing data were derived from data figures/graphs but after subsequent enquiry with the author, the paper was excluded from the study due to inadequate randomisation. All study information and the included RCTs results were entered into RevMan for data management and synthesis. The authors were not blinded to the names of authors, journal or institutions.

Assessment of risk of bias in included studies

The following three areas were addressed, since there is reported evidence that these are associated with biased estimates of treatment effect (Juni 2001):
a) randomisation (method of generation and concealment of allocation)
b) blinding (blinding of observers / participants to the treatment allocation)
c) loss to follow-up (presence of dropouts and withdrawals, and the analysis of these).

The quality assessment included an evaluation of the following components for each included study. Each component was categorised as adequate, unclear, or inadequate on the data extraction form. Criteria for judgement of adequacy are as follows:

Randomisation: studies that employed an unpredictable method of generating the allocation sequence (allocation generation). Methods that lead to adequate generation of a randomised sequence from the details given included those such as computer generated procedures or shuffled envelopes. Those employing alternation were excluded.

Concealment of allocation sequences: if the assignment could not be foreseen (allocation concealment). Adequate included techniques such as use of a third party or use of opaque sealed envelopes. Inadequate techniques included those such as having an open list or in accordance with days of the week.

Blinding / Masking: if taken place after allocation assignment and ensured the outcome assessor, participants and clinicians were unaware of any allocation sequence. In our case, determining adequacy did not relate to all three areas of blinding as this was not practical for our included studies. This is issue is addressed in the methodological quality assessment section.

Loss to follow up: when more than 80% of participants were followed up and then were analysed in the groups to which they were originally randomised (intention to treat). We also included as adequate those studies in which intention to treat (ITT) analysis was undertaken but with minimal missing outcome data. Inadequate loss to follow-up was specified when there was no ITT analysis or substantial missing data, as well as less than 80% follow up.

In addition, assessment was made of the following as required:
d) degree of certainty that participants have atopic eczema
e) baseline comparison for severity of disease
f) comparability at baseline for all primary outcome variables.

Measures of treatment effect

The data available were mainly in the form of means and standard deviations. Standardised mean differences could have been used to calculate an effect measure, should there have been scope for data synthesis.

Unit of analysis issues

The parent-child dyad was the unit of analysis for four included studies, by this we refer to the unit of both the parent and the child (Niebel 2000; Chinn 2002; Staab 2002; Staab 2006) and the fifth focused on the child (Sokel 1993).

Dealing with missing data

There was not substantially enough missing data to affect the findings of the review. Data were extracted from the graphs provided within an excluded study (Broberg 1990) before we became informed it was non-randomised. As a reporting issue, no standard deviations were given in the paper and so we had to calculate these by hand to include in our original plan to undertake data synthesis where possible.

Assessment of heterogeneity

There was no requirement to undertake any formal tests of heterogeneity since there was no scope for data synthesis to take place. However, with the small number of included studies important variations were seen within the four educational studies in terms of the different intervention formats. The different types of intervention format are detailed in the description of studies.

Assessment of reporting biases

No formal assessment of reporting bias was undertaken due to insufficient studies being included in the review. Several studies were reviewed from grey literature sources, but none met the inclusion criteria.

Data synthesis

To undertake data synthesis, data on the same outcome was required from different studies. Although data were available of a similar generic type (e.g. severity, quality of life data) there was insufficient comparative data on the specific measures used (e.g. severity data from the use of SCORAD). The following outlines where similar generic outcomes were available but insufficient comparable data was derived from the specific measures adopted. Comparative analysis was examined in the context of the overall objective to examine the effectiveness of psychological and educational treatments and the specified primary and secondary outcomes of clinical significance, based on the data available.

The main outcome data from the included studies used across more than one study, was that of severity for which different measures were used. SCORAD was used in the studies by Staab 2002; Staab 2006 and Niebel 2000. Despite this, the difference in intervention delivery (whether nurse-led or multidisciplinary led) and the form in which the data was available for each study meant the scope for synthesis was limited. It was thought that little additional information would be gained by drawing together the data from Staab 2002 and Staab 2006 studies. Two within study comparisons were theoretically possible for two of the included studies having two or more intervention groups. One compared different relaxation (psychological) methods - biofeedback and hypnotherapy (Sokel 1993) and the other compared different types of educational delivery - direct and video-mediated (Niebel 2000). In the Sokel 1993 study a newly developed, but unvalidated, severity measure was used in the comparison of the different intervention groups for three parameters of disease severity; this preceded the availability of SCORAD.

There was no scope for data synthesis to be undertaken, since within the educational intervention studies included there were insufficient data available for synthesis. This issue is expanded upon in the discussion.

Subgroup analysis and investigation of heterogeneity

None undertaken, see above.

Sensitivity analysis

Sensitivity analysis could not be undertaken due to the small number of studies included.

RESULTS

Description of studies

A list of included, excluded and ongoing studies is provided at the end of the review. In addition, details of the included studies are tabulated and reasons for the exclusion of studies are provided.

Results of the search

From the searches, 338 studies were identified and their abstracts assessed. The majority of studies identified were in English but other languages encountered included German, Spanish, Italian and French. Translations were conducted as required. Twenty nine relevant studies were selected from the analysis of abstracts for full review. Twenty two of these did not meet the inclusion criteria (see Characteristics of excluded studies). The studies excluded fell into two main categories: non-RCTs or RCTs involving adult participants. Two were later excluded because they were subsequently found to be non-randomised studies (Broberg 1990; Kardorff 2003). Five RCTs were finally selected for inclusion in the review (Sokel 1993; Niebel 2000; Chinn 2002; Staab 2002; Staab 2006). These 5 studies had recruited a total of 1346 parents of children with atopic eczema (1314 within educational studies) and the age of the children ranged from 3 months to 16 years old (see Characteristics of included studies). It is important to mention that conventional topical treatments were used in combination with either educational or psychological intervention in all studies across all groups. It was unlikely that a study would be found whereby psychological or educational interventions were assessed in isolation from conventional therapy; this was evident throughout the review. Stated below are the key characteristics. Details are given in the table of the Characteristics of included studies.

Design

All five studies are a parallel group design.

Sample sizes

The number of participants randomised are as follows: Sokel 1993 (n=44); Niebel 2000 (n=47); Chinn 2002 (n=240); Staab 2002 (n=204); Staab 2006 (n=992)

Setting

Only one study was primary care based (Chinn 2002), the others were hospital based (Niebel 2000; Staab 2002; Staab 2006), although the setting for Sokel's study remains unclear.

Participants

In all the educational studies, the participants were the child-parent dyad, but for the Sokel 1993 study it was the child only.

Interventions

Four studies employed educational interventions (Niebel 2000; Chinn 2002; Staab 2002; Staab 2006). Two studies were nurse-led (Niebel 2000; Chinn 2002), and the other two were delivered by a multidisciplinary team (Staab 2002; Staab 2006). The delivery of the educational interventions varied in relation to their timing and duration of the various elements of delivery. One psychological intervention study met the inclusion criteria (Sokel 1993); it employed relaxation techniques (hypnotherapy and biofeedback).

Outcomes

These varied across studies although there are commonalities, however, these typically employed different measures. The main outcomes measures were quality of life for the child (Chinn 2002; Staab 2002) and the parent (Staab 2002; Staab 2006) and severity (Sokel 1993; Niebel 2000; Staab 2006). No outcomes were employed in the included studies for the following outcomes specified: participant global assessment; improvement of sleep discreetly, although there is an item within the SCORAD severity measure embracing sleep impact; reduction of medication usage and enhancement of caregiver ability to manage atopic eczema in the child.

Included studies

Five RCTs were included in the review, three of which were conducted in Germany (Niebel 2000; Staab 2002; Staab 2006) and

two in the UK (Sokel 1993; Chinn 2002). All five RCTs employed a parallel group design. No adverse effects were reported.

Of the five RCTs included, four focused on educating parents to self-manage their child's atopic eczema (Niebel 2000; Chinn 2002; Staab 2002; Staab 2006). The other examined psychological interventions (hypnotherapy and biofeedback) to improve the quality of life of children with atopic eczema (Sokel 1993). The four RCTs focusing on parental education used a variety of intervention formats. Parents of children with atopic eczema were given multiple training sessions in three of the studies (Niebel 2000; Staab 2002; Staab 2006) but only one training session in the other (Chinn 2002). In relation to the health professionals administering the parental education programmes, two studies were nurse-led (Niebel 2000; Chinn 2002) and three studies were multi-disciplinary (Sokel 1993; Staab 2002; Staab 2006). In terms of health care settings, three studies were based in outpatient clinics (Niebel 2000; Staab 2002; Staab 2006), one in a general practice setting (Chinn 2002) and the other was unclear as to its setting (Sokel 1993).

Excluded studies

Twenty two studies were excluded after failing to meet the inclusion criteria. Of the 22 excluded, 12 were non-RCTs, 8 were RCTs but excluded as the focus of their intervention was on adult participants and 2 were inadequately randomised trials with children.

Of the 12 non-RCTs excluded, 5 focused on educational training for self-management; 4 of which were multi-disciplinary, involving many different health professionals in the intervention (Perdomo-Ponce 1996; Hanifin 1999; Hampel 2001; Chavigny 2002) and one was a nurse-led study (Kalimo 1999). One study used a combined psychotherapeutic and dermatological treatment approach (Peters 1993). Two studies tested psychological interventions for atopic eczema (Haynes 1979; Horne 1989). Another study used psychotherapy to effect lasting change in cutaneous and psychiatric symptoms (Koblenzer 1995). An adult study was conducted on hypnotherapy and severe atopic eczema (Stewart 1995) and two more studies investigated the relationship between psycho-social factors and treatment compliance to educational programmes (Ohya 2001; Cork 2003).

Of the 8 adult RCTs excluded, 3 focused on the psychological interventions of habit reversal (Melin 1986; Noren 1989) and relaxation techniques (Greene 1997). Two more involved educational programmes to improve self-management, of which, one utilised multi-disciplinary training (Coenraads 2001) and one was based on a nurse follow-up session (Gradwell 2002). Another two adult RCTs studied various combined approaches of psychological and educational interventions (Ehlers 1995; Jaspers 2000). Finally, an adult RCT on psychiatric support for participants (Brown 1971) was excluded as a closer inspection revealed only one of the participants involved had atopic eczema. This was confirmed by the findings of the HTA review of interventions for atopic eczema.

Two RCTs designed to educate the parents of children with atopic eczema (Broberg 1990; Kardorff 2003) had originally been deemed suitable for inclusion. The translation of Kardorff 2003 paper and further correspondence with the respective authors provided evidence that forced us to exclude the RCTs since true and and adequate randomisation of the participants had not occurred; this was based on specific criteria (Altman 1999). In each case alteration was used; the participants were alternately allocated to the two study groups in order of their attendance at clinic, one into the control group, then experimental, then control and so on. This is despite Broberg stating in the abstract that the participants were 'randomly assigned' and were 'divided into two random groups'; subsequent evidence demonstrated that this claim was inaccurate.

Ongoing studies

An 'ongoing study' was found on the UK National Research Register based within the Chelsea and Westminster Healthcare NHS Trust (Staughton). The project involved behavioural therapy (habit-reversal) versus conventional medical management with children living with severe atopic eczema. The research question focused on whether a habit-reversal programme might alter the natural history of atopic eczema and whether this is measurable in blood and skin samples. Correspondence with the trial authors revealed the study had been suspended due to the loss of the principal investigator. For details of the ongoing studies, please see Characteristics of ongoing studies.

Risk of bias in included studies

Allocation

Randomisation

According to the published papers, all five of the included studies randomly allocated the participants to either the control or experimental groups. Three studies used sample size computer software to generate random sequences (Chinn 2002; Staab 2002; Staab 2006). The other two studies (Sokel 1993; Niebel 2000) claimed to have randomised the participants but did not state the precise method by which this was achieved.

Allocation concealment

The concealment of participant allocation to groups was considered adequate in two (Staab 2002; Staab 2006) of the five included studies. The remaining three (Sokel 1993; Niebel 2000; Chinn 2002) could not be adequately assessed due to a lack of information in the published reports. Further correspondence with Dr Chinn indicates that a list of subject numbers were generated at the start of the study; participants were allocated according to this list in the order each participant returned their baseline questionnaire. This was conducted independently of their practice or their nurse; the nurse was then informed which group each participant had been assigned.

Blinding

In all five included studies it was impossible to blind the clinician to the allocation of participants to groups. Three studies blinded the outcome assessor (Sokel 1993; Chinn 2002; Staab 2006), the fourth was unclear (Staab 2002) and the fifth did not (Niebel 2000). The Staab 2006 study clearly stated that blinding of the participants was not possible. Participants were not blinded to their group allocation in two studies (Sokel 1993; Niebel 2000) and insufficient information existed to assess this in two studies (Chinn 2002; Staab 2002).

Incomplete outcome data

Loss to follow-up

The Chinn 2002 study was considered adequate in loss to follow-up despite having a lower than 80% follow-up rate, since an

intention to treat (ITT) analysis was completed with minimal missing outcome data. Staab 2002 was unclear in the description of loss to follow-up, but this was much clearer in a different but later study (Staab 2006); no ITT analysis was undertaken and twice as many participants were lost to follow-up in the control arm than the intervention group. However, the study did pass the review quality criterion set of 80% follow-up rate, by reaching 83%, which is favourable for a study of long term clinical outcomes. Sokel 1993 had substantial missing data and no ITT analysis was performed. No participants withdrew from Niebel 2000.

Other potential sources of bias

Topic specific considerations

All five included studies stated their groups were comparable at baseline assessment. However, in the Staab 2002 study at baseline the quality of life of mothers of children with atopic eczema was worse than a control group of mothers with healthy children, with differences reaching significance in all sub-scales. After one year both groups saw significant improvement, but no between group differences were found.

Effects of interventions

Primary outcome measures

(i) Participant rated global assessments

Regrettably, there were no such assessments used in the included studies.

(ii) Reduction in disease severity

In the Sokel 1993 study evaluating biofeedback (BF) and hypnotherapy (HT) no validated measure of eczema severity was used. The dermatologist assessed severity with a scoring sheet showing the front and back of the body divided into 20 zones of approximately equal area. A score of 0 to 3 was given for each zone in respect of erythema (redness), surface damage and lichenification (thickening), the total maximum score being 60.
There are two sets of results: 1) percentage body coverage (area) and 2) mean severity score, the latter are summarised in Table 1. For body coverage, the paper states a key result as 'no significant difference in the percentage body area covered for either erythema, lichenification or surface damage' (p149). It is not clear what the combined (relaxation) results would be for BF (I1) and HT (I2) since this is not tabulated, and whether such results would be significant. Improvements post intervention are seen in the raw data; but there is a high degree of variation (high standard deviation) and the data distribution is skewed; therefore it is difficult to interpret effectively. It may have been better to have employed medians for comparison rather than means from the results to identify the mid point of distribution. Therefore, the focus is on reporting the severity data, which are clearer to interpret (Table 1).
The children in the hypnotherapy and biofeedback groups showed a statistically significant reduction in the severity of surface damage and lichenification compared to the control group. The trial authors employed t-tests comparing time points visit 1 (baseline) with visit 2 (post, 8 weeks) and then baseline with visit 3 (20 weeks). For both surface damage and lichenification the t-test comparisons revealed a significant difference between the groups on visit 3 (t=2.13, p=0.042 and t=2.46, p=0.051, respectively). For the combined relaxation groups there was significant improvement on visit 3 (20 weeks) compared to visit 1 (baseline) for surface damage (t=2.2, p=0.04) and lichenification (t=2.39, p=0.027). There was no improvement over time in the discussion (control) group .

Niebel 2000 (p402) study concludes that atopic eczema symptoms improved overall, but the effectiveness of the treatments differed significantly; they improved with parental education which was most effective via video assisted instruction rather than direct parental teaching. Furthermore, video-assisted approaches (complemented by an instruction book) were less time consuming. Three sets of results are presented in the paper (summarised in Table 2): 1) those related to atopic eczema (AE) symptom severity reported using the Hanifin 1980; Rajka 1989 and SCORAD (summary scores only) methods (the focus here); 2) behavioural changes (e.g.: scratch control) and 3) psychological outcomes (e.g.: the strain of managing the atopic eczema). Therefore, focusing on the disease severity scores; using a composite symptom index based on combined skin severity measures, a statistically significant effect was shown for an educational approach; the video approach (t=5.712, p<0.001) and the direct education approach (without video) (t=8.61, P<0.0001), although this effect was greater than in the control group (t=5.011, p<0.0001). Further analyses revealed the advantage of video education in comparison to the control group was statistically significant; the severity of AE was reduced with itching being alleviated and sleep improved by a factor of three, compared to the control group. The Niebel 2000 study did not report odds ratios. Some non-significant results were reported; this includes the effect on pruritus.

For the Staab 2002 study the difference between the severity score (SCORAD) for each study group was non-significant (p=0.043); limited statistical details are given , with only the mean decrease in score per group being specified other than the p value. Due to the weaknesses in results reporting we have not tablulated the results. The clinical severity results of the Staab 2006 are important since this is a large robust study in which severity (both objective and subjective measurement) is the primary outcome measure. Long term effects were examined 12 months after structured age related multi-disciplinary educational intervention. The results are stratified according to the age banded groupings. Significant improvements in eczema severity (objective and subjective) were seen in all intervention groups compared with controlled groups. The objective measure used was SCORAD, the statistical significance of any change being reported by age group. The analysis of covariance (ANCOVA) was used to assess the impact of the interventions based on assessments after 12 months follow-up. The baseline measures were included as covariates. Adjustment was made for baseline differences between the groups. The subjective severity score was based on parents' assessments of the morphology of their children's skin lesions compared to illustrations evaluated by experts. A third outcome measure was obtained by adding the objective and subjective measures. The total severity scores (combining objective and subjective scores) by age band of the intervention group, with accompanying 95% confidence intervals, versus those of the control group (no intervention minus intervention) are summarised in Additional Table 3. The ANCOVA are summarised here in the comparison of the 'no intervention minus intervention' results for the various age bands (see group difference column). There were statistically significant improvements in severity in each age group. The Staab 2006 study did not report odds ratios.

(iii) Improvements in sleep

None were overtly assessed or recorded in the included studies, however, the impact on sleep is embraced by some severity measures such as SCORAD.

(iv) Quality of life of child and parent

In the assessment of a single nurse consultation on quality of life (Chinn 2002), the Children's Dermatology Life Quality Index (CDLQI), the Infant Dermatitis Quality of Life Index (IDQOL) and the Family Dermatitis Index (FDI) were completed by the parent participants. The results are summarised in Table 4. The scores on these measures were skewed at baseline, 20% of children had a zero score on the FDI, indicating no impact on family life. No significant improvements were found on the CDQOL and IDQOL measures between baseline, 4 and 12 weeks respectively (p>0.05) . There was a suggestion of marginal improvement in FDI score at 4 weeks in the intervention group (p<0.06) (Chinn 2002) (p=0.06).
Staab 2002 used two quality of life outcome measures, a pre-developed and validated disease specific quality of life measure and a generic health related quality of life measure entitled 'Daily Life' that has been used in a wide variety of diseases and healthy populations. The disease specific measure had been subject to an examination of reliability, construct and clinical validity and sensitivity to change. For the generic 'Daily life' measure on the quality of life of mothers of children with atopic eczema it was stated that there was 'significant improvement in the psychic and somatic wellbeing, daily life, joy of life and satisfaction with medical treatment sub-scales, although no data are given nor are the 'p' values reported; furthermore, it is said there were no differences were found between intervention and control groups, but again no data are reported. However, at baseline, the mothers were found to have significant difference in health status compared to a healthy population. The disease-specific quality of life questionnaire showed an improvement in the intervention group regarding a sub-section of the questionnaire relating to confidence in the medical treatment compared to the control group (p=0.016).

The multi-centred study by Staab 2006 also used parental quality of life (of children aged less then 13 years) as a key outcome measure. They used a 26 item German tool 'Quality of life of parents of children with atopic dermatitis' , which has 5 sub-scales: 1) psychosomatic wellbeing; 2) effects on social life; 3) confidence in medical treatment; 4) emotional coping and 5) disease acceptance (Von Rueden 1999). The tool has undergone some validation which reports a high interclass coefficient for test-retest reliability and the reliability of the sub-scales as medium to high (Cronbach alpha between 0.57 and 0.90) (Von Rueden 1999). The summary results presented here reflect the analysis of covariance (ANCOVA) of parental quality of life at baseline and 12 months, comparing no intervention minus intervention, with adjustment for baseline differences between the groups. Details of the difference in the no intervention minus intervention (95% confidence intervals) for the two are bands are given in additional Table 5. Parents of affected children aged under 7 years had significantly better improvements in all the 5 quality of life subscales. Parents of affected children aged 8-12 years experienced significantly better improvements in 3 of the 5 sub-scales; the insignificant changes were psychosomatic wellbeing and effects on social life.

Secondary outcome measures

(i) Reduction of harmful scratching behaviour

No studies were identified meeting the inclusion criteria.

(ii) Treatment adherence

Staab 2002 used an unspecified questionnaire which incorporated treatment behaviour as an item, including the regularity of use of skin medication. Topical steroids used at baseline were comparable in both groups. After the education programme, inflammation of the skin was treated with significantly more steroids than the control group (p=0.001), reflecting that adequate quantities were now being used with the trial authors conveying an improvement in treatment behaviour (the possibility of educational interventions increasing medication use has been acknowledged in the outcome section). Use of logistic regression analyses indicated that the personal regulation of steroids depends mainly on disease severity. Confidence in medical treatment has been referred to earlier as a sub-scale within the parental quality of life tool utilised within the Staab 2006 study; they reported a significant impact on this dimension for parents of affected children under 12 years of age.

(iii) Reduction of medication usage

No studies used this outcome.

(iv) Enhancement of caregiver ability to manage atopic eczema in the child

No studies used this outcome.

(v) Cost

Staab 2002 assessed the direct treatment costs by comparing 6 months prior to the study and 1 year after. Cost reduction was significantly greater in the intervention group than the control group (p=0.043).

DISCUSSION

Summary of main results

The data for this review were limited, comprising of five studies. Four studies focused on parental education interventions (Niebel 2000; Chinn 2002; Staab 2002; Staab 2006), two studies were delivered by nurses (Chinn 2002; Staab 2002) and the other two studies by multidisciplinary delivery (Niebel 2000; Staab 2006). Only one study of psychological interventions met the inclusion criteria, this had two relaxation intervention groups: biofeedback and hypnotherapy (Sokel 1993). All interventions were provided as combined therapy with conventional topical therapy. Only a limited range of the psychological interventions available were employed. Two of the primary outcome measures were utilised (clinical severity and quality of life), although two were not (participant rated global assessment and improvement in sleep), also only one of the secondary measures (treatment adherence). It was surprising not to find the use of sleep improvement as an outcome measure, given the reporting of sleep disruption as a significant consequence of childhood atopic eczema in the literature (Emerson 2000). Data could not be synthesised from these studies due to the following factors; the heterogeneous nature of the outcome measures used, a lack of adequate data (both in quality and accessibility) and methodological weaknesses in study design. The

evidence available to date is therefore derived from individual studies.

For parental educational interventions two studies found statistically significant improvements in clinical severity (SCORAD) in the intervention groups compared to the control (Niebel 2000; Staab 2006) but the difference in SCORAD found between comparison groups was not significant in the Staab 2002 study. In the Staab 2006 study statistically significant improvements in parental quality of life were found in all 5 sub-scales for their affected child within the 7 and under age group and in 3 of these sub-scale for the 8 to 12 group. No differences were found in quality of life outcomes at 4 and 12 weeks in the study by Chinn 2002. A recent multicentre study found significant impact on SCORAD (Staab 2006). However, we support Williams 2006 observation that it remains unclear whether the degree of the final differences observed between groups could be accounted for by the differential use of appropriate treatments (individual therapy remained the responsibility of the patients' doctors). The quality of reporting of SCORAD scores varied in the included studies. The single psychological study (Sokel 1993) identified significant differences in two of three elements of the multi-dimensional clinical severity score (surface damage and lichenification) between the intervention groups (biofeedback and hypnotherapy) and the control group (discussion only).

Overall completeness and applicability of evidence

No studies were identified which could not be subsequently located. Also, one discontinued study Staughton (UK) was identified and confirmed with the principal investigator. It was not clear from the minimal information available if the participants were children or a mixture of both children and adults. A small number of studies met the inclusion criteria, employing a limited range of the potential psychological and educational interventions available. These included educational interventions, parental education (nurse or multi-disciplinary-led), nurse-led individually or with groups of participants, use of technology to support education (video or not) and relaxation-based psychological interventions (hypnotherapy and biofeedback). Although a number of relevant studies were identified in terms of type of intervention, design and disease outcome measures used, the population was made up of adults and as such were recorded as excluded studies, albeit ones of clinical and methodological relevance.

The main methodological weaknesses of the studies examined were:
1) inadequate allocation concealment in half the studies (Sokel 1993; Niebel 2000) due to lack of information from published papers and correspondence;
2) blinding of the outcome assessor remained unclear in one study (Staab 2002) and was not achieved in another (Niebel 2000);
3) loss to follow up was problematic in the Sokel 1993 study which had substantial missing data. No ITT analysis was performed in one study (Staab 2002) and it remained unclear regarding whether there was loss to follow up. Although no ITT analysis was undertaken in the Staab 2006 study, the overall follow up rate (83%) exceeded the threshold criterion of methodological quality specified in the review at the outset;
4) finally, although random allocation was said to be used in all four studies the method by which this was achieved remains unclear in two studies (Sokel 1993; Niebel 2000), despite further correspondence with the trial authors.

Although validated outcome measures were used in the majority of these studies, exceptions include for example, Sokel 1993 who used a non-validated severity measure; Staab 2002 used an untitled disease specific parental quality of life measure and the Trier Scales of Coping (Staab 2002) which are used widely in German studies. Furthermore, most of the included studies focused on parental education, there were few parentally-focused outcomes, other than the use of a parental quality of life measure in two studies (Staab 2002, Staab 2006). It may also be speculated that the clinical outcomes used to measure the impact of the parentally directed interventions (that directly related to the child, eg: clinical severity) may not have been a sufficiently sensitive measure of effectiveness. The issue of studies being underpowered is highlighted in the Chinn 2002 study; the estimation of sample size was unable to detect a significant change in primary care participants. There was reporting problems with some of the individual studies with key quantitative results not being reported; for example in the Niebel 2000 study, SCORAD summary scores were no presented for the parental education group.

Educational interventions are by their nature complex and as such may interact in a complex way with the organisation of health services, which would vary with different cultural settings. By way of illustration, these include the variations that may exist in for example; the availability of specialist dermatology care and the staff to deliver these; the education and scope of practice of health professionals and how services are distributed and delivered across primary and secondary care. In addtition, educational and psychological interventions represent a highly heterogeneous grouping of interventions due to the wide range of methods employed and ways of utilising and delivering them. The range of psychological interventions that could be potentially employed is high - each with different theoretical underpinnings; this is reflected in the intervention summary earlier in the review. Interestingly, no included studies used 'theoretically based' interventions drawing on, for example, behavioural modification or self-efficacy theory.

The capacity of an outcome measure to detect a clinically significant change in a participant remains unclear for the primary outcomes measures used in the included studies. The most renowned severity measure of atopic eczema is SCORAD. This measure has been validated several times on the basis of establishing good inter-rater judgements and recognising the need for prior training (Kunz 1997, Pucci 2005), but it has yet to be assessed against global measures so that it can be correlated with a participant perceived measure of change. A systematic review of named outcome measures for atopic eczema found only SCORAD had been adequately tested for validity, repeatability and responsiveness (Charman 2000). However, it has not been possible to identify published evidence of, and as an argument for, a clinically significant change in the SCORAD score, and such this remains a neglected issue.

Adult and child studies compared

It is useful to briefly compare child studies to relevant adult studies because of methodological insights that may be gained from their discussion and comparison; this may help others when planning future robust studies in children. Four of the included child studies focused on educational interventions, involving either nurse-led or multidisciplinary interventions, directed either at individual parents or groups and located in out-patients or primary care practices as described, (Niebel 2000; Staab 2002; Staab 2006;

Chinn 2002). The three key adult educational studies (Jaspers 2000; Coenraads 2001; Gradwell 2002) involved individual contact (Gradwell 2002) and group education (Coenraads 2001; Jaspers 2000). Significant findings on the effectiveness of the educational intervention were reported in each study, including knowledge of treatment and where to receive help, reduced need for follow-up (Gradwell 2002), improvements in clinical severity and improved self-care ability, highlighted in two studies (Coenraads 2001; Jaspers 2000). There was also further evidence of a reduced need for consultations (Jaspers 2000). Standardised outcomes measures used included the use of severity measures similar to those used in child studies, such as SCORAD (Coenraads 2001), and quality of life measures including DLQI (Gradwell 2002) and SF-36 (Jaspers 2000). The adult studies give a clearer indication of effectiveness than those for the child studies. This would appear to be due to the improved design and clarity about the stages of the research process and in reporting of results, not due to the nature of the interventions. The rigorously designed adult studies by Gradwell 2002 (educational intervention) and Ehlers 1995 (psychological intervention), in terms of use of robust outcome meansures and control, may provide useful pointers toward effective study design for child intervention studies. These studies also highlight the need to give consideration to the scope to combine educational and psychological approaches (based on relaxation and habit reversal) in the management of atopic eczema in children.

Quality of the evidence

The strength and consistency of evidence available is limited due to the lack of robust studies with data and design of a similar nature sufficient to allow data synthesis. The data from individual studies remains inconclusive in terms of the effectiveness of intervention studies given that there is a combination of some clinically significant results on some outcome measures and no differences on others, together with methodological weaknesses in all studies.

Potential biases in the review process

There were no known biases operating in the review process.

Agreements and disagreements with other studies or reviews

Although this is the first systematic review to focus on evaluating the impact of psychological and educational interventions on children with atopic eczema, such strategies were embraced within the HTA generic review of interventions for atopic eczema (Hoare 2000). Four of the five studies included in the current review Niebel 2000; Chinn 2002; Staab 2002; Staab 2006 were published after the HTA report. The HTA report includes Sokel 1993 (hypnotherapy study) in their 'complementary therapies' section; this review has categorised this as a psychologically-based intervention. As with the HTA review, this review reports that Sokel 1993 showed a significant benefit in the reduction in surface damage and lichenification, but not erythema, from hypnotherapy and biofeedback interventions. Sokel's study is the single psychological RCT identified by this review for consideration.

The three psychological studies reviewed in the HTA report (Melin 1986; Noren 1989; Ehlers 1995) are all adult studies and therefore not relevant to the scope of this review. However, the report highlighted that habit-reversal techniques are a useful addition to dermatological treatment in atopic eczema (adult studies) but warns against generalising from these RCTs to other centres with less enthusiastic and adequately trained staff. A key educational intervention study (Broberg 1990) was highlighted in the HTA report (Hoare 2000) as having used a randomised approach, however, subsequent communication with the author has clarified that the allocation technique used (alternation) was not one that led to random allocation. The HTA report included a focus on non-pharmacological treatments for atopic eczema, including 'nurse education' and psychological intervention. The rationale for the review presented here was to examine the sub-set of psychological and educational interventions in greater depth, as well as their nature, quality and impact; embracing the details of the available included studies applicable to children and their methodological critique.

AUTHORS' CONCLUSIONS

Implications for practice

This review draws on evidence from five trials. It is interesting that the studies focused on interventions directed at the parent rather than the child. Three studies reported statistically significant differences between study groups in clinical severity related to psychological and educational intervention respectively, (Sokel 1993; Niebel 2000). Based on the Niebel study there is only very limited evidence that parental education delivered by nurses of those caring for children with atopic eczema may improve the clinical severity of the atopic eczema in such children when used as an adjunct to conventional treatment. Details of the precise nature of educational activity within nurse-led clinics are limited, consideration needs to be given to this issue and its reporting. Evidence from the robust GADIS multicentre study (Staab 2006) of multidisciplinary intervention using an eczema school curriculum indicates that children and their parental carer may benefit from structured education, albeit using a complex intervention. There appear, in consequence, to be two main service delivery models, nurse-led and multi-disciplinary in operation, however, we have no comparative evaluation of their relative effectiveness, either clinically or in terms of cost. Furthermore, reliable conclusions cannot be drawn on the effectiveness of psychological approaches, namely biofeedback and hypnotherapy, from one satisfactory but small study.

Since the management of atopic eczema requires an adaptation in health and illness behaviour and effective actions by the carer, it is logical to develop and evaluate both psychological and educational strategies as an adjunct to conventional therapy. It is surprising that despite the wide range of psychological interventions available few have been subject to limited application and almost no robust evaluation. Educational interventions directed towards parents certainly appear to be worthy of development and robust testing, with attention given to finding both effective and resource efficient models. Current case-based indications of good practice in prominent dermatology departments reveal recognition of the potential of such approaches (eg: Lawton 2005). Educational interventions require careful consideration not only the content of learning but also of the most effective process, including who is best placed to teach affected people, at what frequency and duration and whether or not educational technology should be employed. Four of the five RCTs focused on parental education and used a variety of intervention formats. Parents of children with atopic eczema were given multiple training sessions in three studies (Niebel 2000; Staab 2002; Staab 2006) but only one training session

in the other (Chinn 2002). In relation to the health professionals administering the parental education programmes, two studies were nurse led (Niebel 2000; Chinn 2002) and two were multi-disciplinary (Staab 2002; Staab 2006). In terms of health care settings, three were based in outpatient clinics (Niebel 2000; Staab 2002; Staab 2006) and one in a general practice setting (Chinn 2002).

An important issue for consideration is the scope and limits of the application and effectiveness of psychological interventions that have been used with adults for use with children and their parents. The adult studies provide some additional, useful and relevant information on both interventions and their evaluation not found within the child studies under review. For example, although based on small studies, there are indications that Habit Reversal technique used in conjunction with conventional treatment may improve atopic eczema outcome (Melin 1986; Noren 1989), however, its application to children will depend on the child's developmental stage. Similarly, Ehlers 1995 showed that although a combined approach (patient education and cognitive-behavioural treatment) led to significantly larger improvement in atopic dermatitis than intensive patient education or conventional dermatological treatment, such treatment will be limited to some older children of the appropriate developmental stage. In contrast, those educational studies that have sought to improve effective health behaviour, through adult education, have direct applicability to parental carers of children with atopic eczema. For example, Gradwell 2002 showed that a single 20 minute appointment with a nurse to demonstrate the use of therapies (as well as the standard consultant appointment and follow-up) was useful in improving the participants' understanding of the treatments. Therefore, there may be some limited scope to explore psychological interventions as an adjunct therapy for children of the appropriate developmental stage and opportunities for examining the interventions used to teach adults with atopic eczema and their application for the parents of children with atopic eczema.

The reviewed studies suggest that there is scope for both multi-disciplinary teams and suitably qualified individual clinicians such as nurses, as well as psychologists, to deliver educational interventions in conjunction with conventional therapy. In some countries, such as the UK, nurse-led clinics provide an opportunity for focused intervention. In countries such as Germany, the eczema school multidisciplinary model is more established. There is scope to debate the relative merits of these different service delivery models that both employ different professional groups who are suitably qualified to deliver psychological and educational interventions, their educational activity and how these most effectively integrate with the resource efficient provision of conventional dermatological therapy.

Implications for research

A relatively small number of studies were of adequate methodological quality for inclusion. As such there are significant opportunities to improve research design to evaluate psychological and educational interventions for children with atopic eczema and the reporting standards of such studies. Given the high degree of heterogeneity and complexity in the nature and delivery of educational and psychological interventions, there will need to be many more individual robustly designed trials of adequate power, employing similar intervention formats using validated outcomes measures, before there is any prospect of meta-analysis being undertaken. Employing theory-based interventions of likely effectiveness may enhance the future opportunities for worthwhile individual studies and therefore meta-analyses subsequently.

As to the suitability of the outcomes used for evaluation, the primary indicators selected, clinical severity and disease-related quality of life were prominent across the five included studies. However, in some cases the tools used to measure them were not always robust and were without established validity and reliability. There may be scope to include sleep impact as an outcome measure. Sleep disturbance has received attention in the literature, although it has been little used as an evaluative indicator. Some elements of such impact may be reflected in quality of life measures or those examining family impact. Despite the fact that most of the included studies focused on parental education, there were only limited specific parentally-focused outcomes used (quality of life). It may also be speculated that the child-related clinical outcomes used to measure the impact of the parentally directed interventions may not have been a sufficiently sensitive measure of effectiveness. With all the interventions focusing on the parents rather than the child, consideration needs to be given to whether it is appropriate to utilise child-centred outcomes when trying to achieve internal validity with cause-effect research designs. Parental outcomes, such as treatment adherence or self-efficacy (see Bandura 1997) for example, may offer more realistic opportunities to effectively examine the relationship between the intervention and the dependent variables. Another key issue highlighted by the review is the need for more debate on the clinical significance of the degree of change in eczema severity scores using established measures such as SCORAD. This issue remains relevant for even the more robust studies included in the review and is one that requires more debate.

Amongst the five trials examined, the GADIS study (Staab 2006) evaluated a multi-disciplinary model of service delivery and gives some indication of an effective and robust research design. A missing feature of the GADIS study is a health economic analysis of the elaborate intervention employed; cost comparison studies of different delivery models for educational interventions are an important consideration within the research agenda of this field. Despite the strengths of the Chinn 2002 study evaluating a nurse-led (uniprofessional) model, its main weakness was that the study was under-powered and it focused on one delivery centre. Some useful information to inform the design of more robust trials may be obtained from the review of existing studies and those adult studies examining the delivery of psychological and educational interventions to the parents of children with atopic eczema. These include ensuring: 1) the use of (and reporting of) adequate methods of random allocation and allocation concealment 2) the use of validated outcome measures (for validity and reliability, for use with the appropriate populations under study); 3) and the pursuit of loss to follow-up is addressed within the study design. In addition, given the nature of the interventions and outcomes examined in this review, there is scope to consider a wider range of research designs other than RCTs within any subsequent reviews, since these may help us to better understand the behavioural nature and effects of educational and psychological interventions.

The rationale for the review presented here was to examine in greater depth a sub-set of interventions (educational and psychological) for the management of childhood eczema, specifying their nature, quality, impact and usefulness. Details

of the available included studies applicable to children and their methodological critique, have been included in this review, together with the implications for practice and further research. There was inadequate comparative data available to undertake an effective meta-analysis of existing trials. A key objective of the review was to ascertain if educational and psychological interventions can result in clinically significant changes in outcome for children with atopic eczema. There is insufficient evidence of the effectiveness of psychological interventions, as an adjunct to conventional therapy, to help manage children with atopic eczema - due to a lack of quality and quantity of data from individual studies and therefore an inability to undertake data synthesis subsequently. There is significant scope to undertake robustly designed trials to evaluate theoretically based psychological interventions that may enhance the management of atopic eczema in children; these may be directed at both the parental carer and the child. There is some evidence of the effectiveness of educational interventions, used an adjunct to conventional (topical) therapy, in improving the clinical severity of the child's condition and parental quality of life, however, there are insufficient studies of a robust and comparative data of a homogenous nature to undertake data synthesis as yet. Educational interventions have received limited evaluation using unidisciplinary (largely nurse-led) service delivery model. In addition, more robust evaluation has been undertaken with the other key multidisciplinary model of service delivery. We recognise that different interventions may be delivered using these two contrasting service delivery models. There is a need for a debate on the suitability or fit of these different models for different health systems; furthermore there is also a requirement for a comparative evaluation of their cost effectiveness and wider applicability within different health contexts. Finally, there is a need to give closer attention to the theoretical basis of the educational interventions adopted and for closer investigation of these models to reveal the critical educational processes that are most effective in enhancing the management of atopic eczema in children.

ACKNOWLEDGEMENTS

Ms Katja Schmidt (formerly of University of Exeter), Dr Katja Doerholt and Dr Maja Mockenhaupt (translation assistance, University of Freiberg), Dr Mike Weaver (translation, University of Southampton); Dr Phil Wiffen (Rev-Man assistance, UK Cochrane Centre), Dr Rafael Perera and Dr Peter Nichols (statistical assistance, Universities of Oxford and Southampton respectively), Ms Anne Eisinga (searching strategy audit, UK Cochrane Centre)

Assistance at protocol development phase: Ms Heidi Surridge and Ms Pauline Buchanan. Assistance with study searching from Mr Philip Satherley, Cardiff University.

The constructive comments and guidance of Dr.Tina Leonard, Jo Leonardi-Bee, Phillipa Middleton and Dr Finola Delamere from the Cochrane Skin Group were much appreciated.

The authors are grateful for the comments provided by their lead editor, Dr Sam Gibbs.

The editorial base would like to thank the following people who were the external referees for this review: Elizabeth Moore, Sandra Lawton (content experts), Rosemary Humphreys and Barbara Meredith (consumers).

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CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Chinn 2002

Methods	Design: Parallel group Blinding: Unclear for the participants. Yes for the outcome assessor. Not possible for the clinician. Unit of Randomisation: The child. Unit of Analysis: The child-parent dyad. Quality: Blinding: Unclear.

Chinn 2002 *(Continued)*

	Generation of Randomisation Sequence: Adequate, computer random numbers list generated in blocks of 20. Loss to Follow Up: Adequate, less than 80% follow up but ITT analysis completed. Dropouts differed significantly: Yes, the distribution of baseline IDQOL & FDI scores differed significantly between those who returned all questionnaires & dropouts. The latter had worse QoL FDI scores at baseline.
Participants	Setting: Primary care (general practice) Diagnostic criteria: Yes, BAD guidelines. Disease severity: Children 6 months to 5 years, parents rated severity on a 'five point scale'. Entry criteria: Diagnosis was confirmed by BAD guidelines, new cases and parents requesting repeat prescriptions, 6 months to 16 years old. Participants randomised: 240 total. 120 (intervention) & 120 (control). Participants who took part: 235 total. 115 (intervention) & 120 (control). Age: 6 months - 4 years = younger group (61 intervention) & (54 control). 4 years to 16 years = 58 (intervention) & 62 (control). Sex: not stated. Duration of Condition: new cases and parents requesting repeat prescriptions (intervention & control). Severity of Condition: At baseline, parent completed a 'five-point scale for severity'. The majority of cases were 'fairly good' (29%) or 'average' (43%). 25% of parents reported their child's eczema as 'severe' or 'extremely severe'. Withdrawals Number of: 1 (intervention) & 4 (control). Reason for: 'Moved out of the area' or otherwise withdrawal (intervention & control). Loss to follow up: 14 (intervention) & 24 (control). ITT analysis: Yes
Interventions	Intervention Nature: nurse led parental education consultation. Format: face to face session with a trained dermatology nurse. Theoretical basis: Duration: 30 minutes. Frequency: One-off session. No extant theoretical base.
Outcomes	Primary: (a) Quality of Life using the Children's Dermatology Life Quality Index (4-16yrs) or Infant Dermatitis Quality of Life questionnaire(<4yrs). (b) Family Dermatitis Index
Notes	Group comparability at baseline: Yes Conventional topical treatment Allocation concealment: I generated a list of subject numbers (1-240??) at the beginning of the study and those that volunteered were allocated according to this list in the order each patient returned their baseline questionnaire. I did this independent of the practice or their nurse. The nurse was informed which group each patient had been assigned and she then arranged the nurse interview for those in the intervention group.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Niebel 2000

Methods	Design: Parallel group Blinding: Not for participants and outcome assessor. Not possible for clinicians. Unit of Randomisation: the parent Unit of Analysis: the child-parent dyad Quality: Masking: Inadequate, the assessor was aware of allocation Generation of Randomisation Sequence: Yes, stated in the text but no mention of a randomisation method. Loss to Follow Up: No dropouts from study. Dropouts differed significantly: N/A
Participants	Setting: Dermatology clinic (secondary) Age ranges not stated in paper. Diagnostic criteria: Yes (Hanifin & Rajka, 1980). Disease severity: medium to severe level of AE. Entry criteria: no Participants randomised: 47 total. 14 (C) 18 (I1) 15 (I2). Mean Age: Children = 8m 6f (C) 4.7yrs (I1) 8m 7f (I2) Sex: 8M, 6F (C) 12M, 6F (I1) 8M, 7F. (I2) Mean Duration of Condition: 1.58yrs (C) 1.6yrs (I1) 1.25yrs (I2) Severity of Condition: SCORAD baseline = 4 (C) 3.9 (I1) 4.2 (I2) Withdrawals: N/A
Interventions	Intervention 1: Nature: parental educational training program delivered in groups (details given of the topic content). Format: nurse led sessions on theoretical and practical information. Theoretical basis: Frequency: 10 X 2hr sessions. Duration: Maximum of 16 weeks. Intervention 2: Nature: parental educational training program Format: Video film (100mins) and booklet with information on theoretical and practical information. Theoretical basis: theory element and practical element, designed to promote more therapeutically effective self-help. Frequency duration: Maximum 16 weeks. Control group: conventional dermatology consultation with no other intervention.
Outcomes	(a) Disease severity (SCORAD-summary scores given only) Timing: pre & post assessment (b) Psychological problems with mothers
Notes	Group comparability at baseline: The parents (mothers) age and socio-demographic features were comparable (except for level of school education). Children, comparable age and severity distribution across groups. Conventional topical treatment: For both groups, when an exacerbation occurred -topical steroids were used for approx. 1 week. Wet lesions were treated with antiseptic compressions.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Sokel 1993

Methods	Design: Parallel group Blinding: Participants, no. Outcome assessor, yes. Not possible for the clinician. Unit of Randomisation: The child Unit of Analysis: The child Quality: Blinding: Adequate, the dermatologist was unaware of which treatment each child was receiving and took no part in the psychological treatments. Generation of Randomisation Sequence: Yes, but no mention of a randomisation method. Loss to Follow Up: substantial missing data and no ITT analysis. Dropouts differed significantly: There were 13 dropouts from the 44 initial participants but no reasons are offered within the paper. No intention to treat analysis was performed so it is not clear what affect the high number of dropouts had on the results.
Participants	Setting: unclear Diagnostic criteria: no, but 'all had AE that was inadequately controlled'. Disease severity: not for recruitment standardisation, only as an outcome measure. Entry criteria: Children with inadequately controlled atopic eczema (despite the use of emollients, topical corticosteroids, paste bandages or antihistamines), however, the age range for inclusion were not explicitly stated. Informed consent was obtained via the parent of the child. Participants randomised: 44 total. 16 (C) 18 (I1) 10 (I2) Mean Age (months): 117.25 (C) 111.38 (I1) 108.8 (I2) Sex: 8M,8F (C) 9M,9F (I1) 6M,4F (I2) Duration of Condition: not specified Severity of Condition: not specified Withdrawals Number of: 12 total. 6 (C) Reason for: not stated. ITT analysis: not stated.
Interventions	Intervention 1 Nature: Relaxation technique: Hypnotherapy Format: Focused specifically on reducing itching through guided imagery face-to-face with a clinical psychologist. Theoretical basis: Precise technique based on Karle & Boys (1987) and Olness & Gardner (1988). Duration: 30min sessions Frequency: 4 sessions at 2,3,5 & 8 weeks after enrolment. Intervention 2 Nature: Relaxation technique: Biofeedback Format: A relaxometer gave feedback to participants about their level of relaxation using skin conductance. Theoretical basis: Biofeedback techniques can engage the participant to actively manage the stress-response initiated by anxiety about their health problem. Duration: 30 min sessions Frequency: 4 sessions at 2,3,5 & 8 weeks after enrolment. Discussion only group (control): Children were encouraged to keep an eczema diary which would be discussed at the next session. Parents were encouraged to help the children complete this. No specific psychological therapy was given. Duration: 30 min sessions Frequency: 4 sessions at 2,3,5 & 8 weeks after enrolment.
Outcomes	(a) Mean % of body coverage for (i) erythema (ii) surface damage (iii) lichenification. (b) Mean severity score for (i) erythema (ii) surface damage (iii) lichenification.
Notes	Group comparability at baseline: Yes, no differences between the three groups for age or vocabulary test at enrolment.

Sokel 1993 *(Continued)*

	Conventional topical treatment: all participants were stabilised on conventional topical and oral treatments for two weeks before being randomly allocated to one of the groups.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Staab 2002

Methods	Design: Parallel group design. Blinding: Unclear for both the participants and outcome assessor. Not possible for the clinician. Unit of Randomisation: The child. Unit of Analysis: The child-parent dyad. Quality: Masking: Unclear and insufficient details provided. Generation of Randomisation Sequence: Yes, a computer generated sequence was used. Loss to Follow Up: This was unclear from the text. Dropouts differed significantly: No.
Participants	Setting: Secondary care evening sessions. Diagnostic criteria: Yes (Hanifin & Rajka, 1980). Age range: 5 months to 12 years. Disease severity: participants had moderate to severe symptoms (SCORAD scale > 20 points). Entry criteria: the physician confirmed diagnosis and severity of atopic dermatitis. Participants were to have a SCORAD scale >20 points and duration of at least 4 months. Participants randomised: 204 (I group n=93 c group n=111). Mean Age: child 2.7yrs (treatment group) & child 3.4yrs (control group). Sex: Not stated. Duration of Condition: 2.1yrs (treatment group) & 2.4yrs (control group). Severity of Condition: SCORAD 44 SD+/- 17 (treatment group) & 42 SD+/- 15 (control group). Withdrawals Number of: not stated Reason for: not stated. Number lost to follow up: 21 (control) & 38 (intervention). ITT analysis: not stated.
Interventions	Intervention Nature: parental educational training program. Format: group sessions with presentations from various experts. Theoretical basis: Frequency: once a week and for two hours in an evening session. Duration: 6 weeks.
Outcomes	Primary outcomes: (a) disease severity (SCORAD- NB: does not distinguish between objective and subjective scores) (b) disease specific (atopic eczema) parental QoL (untitled). (c) generic parental QoL (Daily Life Questionnaire). (d) coping strategies (Trier Scales of Coping). Secondary outcomes: (a) Questionnaire (unspecified) two key items (1) treatment behaviour: regularity of use of skin medication [topical steroids] & help seeking from unconventional treatments & [indoor allergy reduction]

Staab 2002 *(Continued)*

	[& initiated dietary restrictions] (2) direct cost of treatment - calculated costs for previous 6 months and after 1 year.
Notes	Group comparability at baseline: Yes. Conventional topical treatment Allocation concealment: The families in this study were randomly assigned to education or waiting control group. We did not stratify for age or severity. They were enrolled in the randomisation program in the computer by the time of their first evaluation visit. After this visit they were told in what group they have been allocated.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Staab 2006

Methods	Design: Parallel group design. Blinding: No (not possible for participants or trainers), Unit of randomisation: child. Unit of analysis: child-parent dyad Quality: Blinding: see above. Scoring of AD severity scale involving staff not involved in intervention. Generation of randomisation sequence: Adequate: Independent study centre, computer generated random numbers, randomisation code concealed in closed envelopes from those entering the study. Loss to follow-up: Adequate: No ITT analysis was undertaken- but overall follow-up rates of 83% met review threshold (good rate for long term study). Drop out rate 17% (10% I group, 24% C group). LFU - twice as many in control arm than intervention group.
Participants	Setting: 7 centres hospital out-patients, 3 from children's hospitals, 3 from hospitals specialising in dermatology and one Dept of Psychosomatic Medicine. Diagnostic criteria: Yes (Hanifin & Rajka 1980). Disease severity: eczema duration, minimum of 3 months & severity of =/> 20 points on SCORAD. Entry criteria: children / young people 3 months to 18 years in 3 age bands (<7 years, 8 to 12, 13 to 18 years). Diagnosed by dermatologist or paediatrician. Participants randomised: 992, with 496 allocated to each group). (645 <7 band, 214, 8 to 12 band & 151, 13 to 18 band). Mean Age (& SD): <7 band = I gp: 2.4 (1.8), C gp: 2.4 (1.9); 8 to 12 band =I gp: 9.5(1.6), C gp: 9.5 (1.5); 13 to 18 band I gp: 14.9 (1.7), Cgp: 14.8 (1.7). Sex (% male): <7 band: 52 both gps, 8 to 12 band: I gp: (40), C gp: (48); 13 to 18 band: I gp (41), C gp (36). Condition (duration): not specified other than minimum of 3 months. Withdrawls Number (LFU): 169 (I= 50, C=119) Reasons: tabulated, most gave 'no sufficient response'.
Interventions	Intervention: Nature: Standarised (structured) educational programme delivered by a multiprofessional team (dermatologists, paediatricians, psychologists, dieticians) who had undergone 40 hours of training. Format: The content and structure of the programme and teaching methods were agreed by an inderdisciplinary consensus group. Details tabulated (table 1) Parents of children aged 8 to 12 attended seperate sessions. Adolescents aged 13 to 18 attended tailored sessions. A manual & handouts were used. nb: did not contain a therapy mandate, remained responsibility of patients' doctors. Theoretical basis: Not specified. Duration: 6 once weekly sessions lasting 2 hours each. Control conditions: no education.
Outcomes	Primary outcomes: a) Severity of eczema:

Staab 2006 *(Continued)*

	i) SCORAD ii) subjective severity score (the 'Skin detective' tool) iii) Itch questionnaires: used 2 standardised tools JUCKKI 15 item tool for 8 to 12 age group and JUCK-JU of 18 items for the 13 to 18 group. b) Quality of life of parents of children aged <13 years: Tool (German): 'Quality of life in parents of children with AD'. 26 item validated tool structured by factor analysis into 5 sub-scales (with abbreviations) psychosomatic wellbeing, (pw); wellbeing, (w), effects on social life, (esl), confidence in medical treatment, (cmt), emotional coping, (ec), acceptance of disease, (aod).
Notes	Group comparability at baseline: Yes. In all age groups the severity of eczema or parental quality of life (of children aged <13 years) did not differ significantly between the intervention and control groups at baseline.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Legend: Gender: QoL = Quality of life, F = female, M = male. Age: Yr = year, m = months, LFU = Loss to follow-up, ITT = Intention to treat analysis, Rx = treatment, Study groups: C = control, I = Intervention, CI = Confidence interval. BAD = British Association of Dermatologists, B = Baseline. FU = Follow up (time point). Outcome measures: IDQOL = Infant Dermatitis Quality of life Index, CDQOL = Children's Dermatology Life Quality Index, FDI = Family Dermatitis Index. SCORAD = Scoring Index of Atopic Dermatitis. N/A: not applicable. SD = Standard Deviation
References: Hanifin & Rajka (1980). Kardoff & Schnelle-Parker (2001), Karle & Boys (1987), Olness & Gardner (1988).

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Broberg 1990	Inadequate randomisation
Brown 1971	Adult participants (RCT) & HTA report states that only one participant has atopic eczema.
Chavigny 2002	Non-RCT
Coenraads 2001	Adult participants (RCT)
Cork 2003	Non RCT
Ehlers 1995	Adult participants (RCT)
Gradwell 2002	Adult participants (RCT)
Greene 1997	Adult participants (RCT)
Hampel 2001	Non-RCT
Hanifin 1999	Non-RCT
Haynes 1979	Non-RCT
Horne 1989	Non-RCT
Jaspers 2000	Adult participants (RCT)

Study	Reason for exclusion
Kalimo 1999	Non-RCT
Kardorff 2003	Inadequate randomisation
Koblenzer 1995	Non-RCT
Melin 1986	Adult participants (RCT)
Noren 1989	Adult participants (RCT)
Ohya 2001	Non-RCT
Perdomo-Ponce 1996	Non-RCT
Peters 1993	Non-RCT
Stewart 1995	Non-RCT

Characteristics of ongoing studies *[ordered by study ID]*

Staughton

Trial name or title	Atopic eczema and Habit Reversal
Methods	
Participants	Severe atopic patients
Interventions	Behavioural therapy versus conventional medical management.
Outcomes	Subjective and objective clinical improvement according to benchmarked disease severity indices.
Starting date	After correspondance with author, the study is currently discontinued.
Contact information	Dr Richard CD Staughton Dermatology Dept Chelsea & Westminster Hospital 369 Fulham Road London SW10 9NH Telephone: 0181 746 8170 richard.staughton@chelwest.nhs.uk or sharon.singh@chelwest.nhs.uk
Notes	Does Habit Reversal Programme alter natural history of Atopic Dermatitis? Is this measurable in blood and skin samples?

ADDITIONAL TABLES

Table 1. Mean severity scores: children completing 3 assessment sessions (Sokel 1993)

Severity dimension	Discussion gp (C)	BF & Hypno gp (I)	Biofeedback gp (I)	Hypnotherapy gp (I)

Table 1. Mean severity scores: children completing 3 assessment sessions (Sokel 1993) *(Continued)*

(A) Erythema				
Baseline	19.6 (SD 11.6)	15.3 (SD 8.4)	13.4 (SD 7.5)	16.7 (SD 9.2)
8 weeks	19.1 (SD 11.2)	16.9 (SD 11.8)	17.5 (SD 11.9)	16.5 (SD 12.2)
20 weeks	23.7 (SD 10.8)	15.5 (SD 11.7)	13.1 (SD 11.7)	17.4 (SD 11.9)
(B) Surface damage				
Baseline	18.4 (SD 13.5)	18.8 (SD 8.4)	16.1 (SD 4.2)	20.8 (SD 10.2)
8 weeks	16.9 (13.6)	15.7 (SD 9.5)	13.4 (SD 7)	17.5 (SD 10.9)
20 weeks	22.5 (SD 12.5)	14.2 (SD 8.7)	12 (SD 9.5)	15.9 (SD 8.1)
(C) Lichenification				
Baseline	25.2 (SD 10)	23 (7.9)	23.8 (SD 5.5)	22.4 (SD 9.5)
8 weeks	22.4 (SD 12.1)	21.4 (SD 9.2)	23.4 (SD 9.1)	19.9 (SD 9.3)
20 weeks	27.1 (SD 7.5)	18.3 (SD 9.9)	18.9 (SD 7.9)	18 (SD 11.5)

Table 2. Childrens' skin condition (severity) after dermatology consultation (Niebel 2000

Severity score	Direct teach (pre)	Direct teach (post)	Video teach (pre)	Video teach (post)	Control (pre)	Control (post)	ANOVA / ANCOVA	P
(A) Rajka & Langeland criteria								
1. General severity	3.9 (SD 1.19)	3.2 (SD 1.47)	4.2 (SD 0.94)	3 (SD 1.25)	4 (SD 1.1)	3.71 (SD 2.43)	Z:F(1/36)=5.76	p<0.022
2. Surface area	1.9 (SD 0.88)	1.7 (SD 0.82)	2 (SD 0.53)	1.47 (SD 0.64)	1.71 (SD 0.61)	1.36 (SD 0.63)	Z:F(1/36)=10.87	p<0.002
3. Pruitus	2 (SD 0.67)	1.5 (SD 0.71)	2.2 (SD 0.56)	1.53 (SD 0.64)	2.29 (SD 0.61)	2.36 (SD 2.34)	Z:F(1/36)=2.09	P<0.15
(B) Hanifin criteria								
1. Erythema	1 (SD 0.65)	0.58 (SD 0.61)	2.4 (SD 0.66)	1.53 (SD 1.06)	1.71 (SD 0.8)	1.36 (SD 1.15)	Z:F(1/39)=11.34	p<0.002
2. Excoriation	1.61 (SD 0.98)	0.65 (SD 0.85)	2.13 (SD 0.95)	1.3 (SD 1.06)	1.86 (SD 0.95)	1.07 (SD 1.21)	Z:F(1/39)=15.6	p<0.0001
3. Lichenification	1.54 (SD 0.96)	0.75 (SD 0.84)	2.27 (SD 0.96)	2 (SD 1.25)	2.14 (SD 0.86)	1.86 (SD 1.03)	Z:F(1/38)=7.12	p<0.01
4. Flaking	1.73 (SD 0.83)	1.04 (SD 0.9)	1.57 (SD 0.75)	1.3 (SD 0.98)	2.07 (SD 0.92)	1.77 (SD 0.96)	Z:F(1/39)=5.73	p<0.022
5. Induration	0.83 (SD 0.94)	0.42 (SD 0.7)	1.7 (SD 0.78)	0.93 (SD 1.16)	1.11 (SD 1.08)	0.68 (SD 0.72)	Z:F(1/38)=14.48	p<0.0001
6. Inflammation	1.13 (SD 0.86)	0.5 (SD 0.56)	1.53 (SD 1.13)	0.67 (SD 1.13)	0.93 (SD 0.99)	0.29 (SD 0.61)	Z:F(1/38)=13.48	p<0.001
(C) SCORAD (summary)	N/A	N/A	55.91 (18.45)	36.91 (25.95)	48.66 (SD 15.43)	32.33 (SD 17.75)	Z:F(1/27)=22.42	p<0.0001

Table 3. Total severity scores - Mean (SD) Baseline & 12mth ANCOVA (Staab 2006)

Age group	Baseline (I)	12 months (I)	Mean diff..95%CI (I)	Baseline (C)	12 months (C)	Mean diff. 95%CI (C)	Group diff (95% CI)	p value
3-7 months	41.4 (16.6)	23.7 (16.7)	-17.5 (-19.6 to 15.3)	40.6 (15.2)	28.4 (16.5)	-12.2 (-14.3 to -10.1)	-5.2 (-8.2 to -2.2)	0.0002
8-12 years	41.8 (16.6)	25.8 (17.7)	-16.0 (-20.0 to-12.0)	40.4 (15.1)	32.6 (16.5)	-7.8(-11.4 to -4.3)	-8.2 (-13.6 to -2.8)	0.003

Table 3. Total severity scores - Mean (SD) Baseline & 12mth ANCOVA (Staab 2006) *(Continued)*

13-18 years	43.1 (14.7)	23.4 (12.6)	-19.7 (-23.7 to -15.7)	40.4 (13.9)	35.2 (15.2)	-5.2 (-10.5 to 0.1)	-14.5 (-21.2 to -7.9)	0.0001

Table 4. Change in quality of life scores across comparison groups (Chinn 2002)

QOL measure	Study group	N	Mean	SD	Range	Mean difference	95% CI difference	P
(A) CDLQI								
Baseline - 4 weeks	Control	50	-0.96	5.4	-22 to 13			
	Intervention	50	-2.26	3.8	-16 to 6			
	Difference					-1.3	-3.2 to 0.6	0.17
Baseline - 12 weeks	Control	50	-2.08	5.1	-20 to 12			
	Intervention	50	-1.84	3.5	-10 to 9			
	Difference					0.24	-1.5 to 2.0	0.7
(B) IDQOL								
Baseline - 4 weeks	Control	42	-0.09	3.6	-11 to 10			
	Intervention	55	-0.14	2.8	-7 to 6			
	Difference					-0.05	-1.3 to 1.2	0.9
Baseline - 12 weeks	Control	42	-0.71	4.4	-12 to 13			
	Intervention	55	0.46	5.1	-15 to 19			
	Difference					1.2	-0.8 to 3.1	0.24
(C) FDI								
Baseline - 4 weeks	Control	92	0.09	3.3	-15 to 8			
	Intervention	105	-0.7	2.6	-11 to 5			

Table 4. Change in quality of life scores across comparison groups (Chinn 2002) *(Continued)*

	Difference					-0.79	-1.62 to 0.04	0.06
Baseline - 12 weeks	Control	92	-0.41	4	-16 to 10			
	Intervention	105	-0.07	4.1	-10 to 15			
	Difference					0.34	-0.8 to 1.5	0.5

Table 5. Parental QOL (no intervn- intervn) by age group using ANCOVA Staab 06

Outcome by age group	No intv-intv 95% CI	p value
3mth-7yr		
Psychosomatic wellbeing	1.4 (0.2 to 2.5)	0.0040
Effects on social life	0.8 (0.2 to 1.4)	<0.0001
Confidence on medical treatment	2.1 (1.4 to 2.8)	<0.0001
Emotional coping	1.9 (1.3 to 2.5)	<0.0001
Acceptance of disease	0.6 (0.2 to 0.9)	<0.0001
8-12 years		
Psychosomatic wellbeing	0.6 (-1.2 to 2.4)	0.360
Effects on social life	0.2 (-0.8 to 1.2)	0.940
Confidence on medical treatment	2.9 (1.7 to 4.1)	<0.0001
Emotional coping	1.8 (0.9 to 2.8)	0.002
Acceptance of disease	0.6 (0 to 1.2)	0.031

APPENDICES

Appendix 1. Cochrane Skin Group Specialised Register search strategy

We searched the Cochrane Skin Group Specialised Register (to September 2004) using the search strategy below:
(eczema* or (atopic and dermatitis)) AND (psychotherap* or ((psychodynamic or cognitive or famil*) and therap*) or (behav* and (cognitive or manag* or contracting or therap*)) or (autogenic and train*) or counsell* or relaxation or imagery or biofeedback or (patient* and compliance) or (health and promot*) or (health and educat*) or (patient* and (education or teaching)) or (famil* and practice*) or (parent and child) or (skin and care))

Appendix 2. Cochrane Central Register of Controlled Trials search strategy

We searched the Cochrane Central Register of Controlled Trials (*The Cochrane Library Issue* 2, 2005) using the search strategy below:
(child and (dermatitis next atopic) and ((patient next education) or imagery or (behavior next therapy) or (psychoanalytic next therapy) or (autogenic next training) or (relaxation next techniques) or (cognitive next therapy))).

Appendix 3. MEDLINE search strategy

(i) Search strategy to locate RCTs
Search terms 1-29 , as given in the Cochrane Handbook (Alderson et al 2004), appendix 5b.2

(ii) Search strategy to locate atopic eczema in children
30. exp DERMATITIS, ATOPIC/
31. dermatitis, atopic.mp.
32. eczema, atopic.mp.
33. atopic eczema.mp.
34. atopic dermatitis.mp.
35. (infan$ eczema or eczema infan$).mp.
36. (child$ eczema or eczema child$).mp.

37. (adolescen$ eczema or eczema adolescen$).mp.
38. exp NEURODERMATITIS/
39. Besniers prurigo.mp.

(iii) Search strategy to locate interventions & misc terms.
40. exp PSYCHOTHERAPY/
41. psychodynamic therapy.mp.
42. exp Behavior Therapy/
43. behaviour$ therapy.mp.
44. behavior$ management.mp.
45. behaviour$ management.mp.
46. exp Autogenic Training/
47. autogenic training.mp.
48. SUGGESTION/
49. exp HYPNOSIS/
50. exp Cognitive Therapy/
51. exp COUNSELING/
52. counsel$.mp.
53. exp RELAXATION TECHNIQUES/ or exp "MIND-BODY AND RELAXATION TECHNIQUES"/ or exp RELAXATION/
54. relaxation.mp.
55. exp "Imagery (Psychotherapy)"/
56. imagery.mp.
57. exp "Biofeedback (Psychology)"/
58. biofeedback.mp.
59. family therapy.mp. or exp Family Therapy/
60. patient compliance.mp. or exp Patient Compliance/
61. health promotion.mp. or exp Health Promotion/
62. health education.mp. or exp Health Education/
63. patient education.mp. or exp Patient Education/
64. patient teaching.mp.
65. family practice.mp. or exp Family Practice/
66. parent-child relations$.mp. or exp Parent-Child Relations/
67. skin care.mp. or exp Skin Care/
68. or/30-39
69. or/40-67
70. 29 and 68 and 69

Appendix 4. EMBASE search strategy

1. random$.ti,ab.
2. factorial$.ti,ab.
3. (crossover$ or cross over$ or cross-over$).ti,ab.
4. placebo$.ti,ab.
5. (doubl$ adj blind$).ti,ab.
6. (singl$ adj blind$).ti,ab.
7. assign$.ti,ab.
8. allocat$.ti,ab.
9. volunteer$.ti,ab.
10. CROSSOVER PROCEDURE.sh.
11. DOUBLE-BLIND PROCEDURE.sh.
12. RANDOMIZED CONTROLLED TRIAL.sh.
13. SINGLE-BLIND PROCEDURE.sh.
14. or/1-13
15. exp ANIMAL/ or NONHUMAN/ or exp ANIMAL EXPERIMENT/
16. exp HUMAN/
17. 16 and 15
18. 15 not 17
19. 14 not 18
20. dermatitis, atopic.mp.
21. exp ATOPIC DERMATITIS/
22. eczema, atopic.mp.
23. exp ECZEMA/

24. atopic eczema.mp.
25. atopic dermatitis.mp.
26. (infan$ eczema or eczema infan$).mp.
27. (child$ eczema or eczema child$).mp.
28. (adolescen$ eczema or adolescen$).mp.
29. neurodermatitis.mp.
30. exp NEURODERMATITIS/
31. Besniers prurigo.mp.
32. psychotherapy.mp. or exp PSYCHOTHERAPY/
33. exp Psychodynamics/ or psychodynamic therapy.mp.
34. behavior$ therapy.mp. or exp BEHAVIOR THERAPY/
35. behaviour$ therapy.mp.
36. behavior$ management.mp.
37. behaviour$ management.mp.
38. (behavioral contracting or behavioural contracting).mp. [mp=title, original title, abstract, name of substance, mesh subject heading]
39. Autogenic training.mp. or exp AUTOGENIC TRAINING/
40. Suggestion.mp. or exp SUGGESTION/
41. Hypnosis.mp. or exp HYPNOSIS/
42. Cognitive therapy.mp. or exp COGNITIVE THERAPY/
43. (Cognitive behavioral therapy or cognitive behavioural therapy).mp. [mp=title, original title, abstract, name of substance, mesh subject heading]
44. counseling.mp. or exp COUNSELING/
45. counselling.mp.
46. relaxation.mp.
47. (mind and body).mp. [mp=title, original title, abstract, name of substance, mesh subject heading]
48. relaxation therapy.mp. or exp RELAXATION TRAINING/
49. progressive relaxation.mp.
50. imagery.mp. or exp IMAGERY/
51. guided imagery.mp.
52. biofeedback.mp. or exp FEEDBACK SYSTEM/
53. family therapy.mp. or exp FAMILY THERAPY/
54. patient compliance.mp. or exp PATIENT COMPLIANCE/
55. health promotion.mp. or exp HEALTH PROMOTION/
56. health education.mp. or exp HEALTH EDUCATION/
57. patient education.mp. or exp PATIENT EDUCATION/
58. patient teaching.mp.
59. family practice.mp.
60. parent-child relations$.mp. or exp CHILD PARENT RELATION/
61. skin care$.mp. or exp SKIN CARE/
62 or/20-25
63 or/26-28
64 or/29-61
65 19 and 62 and 63 and 64

Appendix 5. PsycINFO search strategy

1 exp Skin Disorders/ or exp Dermatitis/ or exp Neurodermatitis/ or atopic dermatitis.mp.
2 eczema.mp. or exp ECZEMA/
3 or/1-2
4 (child$ or infan$ or adol$).mp. [mp=title, abstract, subject headings, table of contents, key concepts]
5 (trial$ or random$ or placebo$).mp. [mp=title, abstract, subject headings, table of contents, key concepts]
6 3 and 4 and 5

WHAT'S NEW

Date	Event	Description
2 October 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 1, 2003
Review first published: Issue 3, 2007

Date	Event	Description
5 November 2007	New search has been performed	Minor update
23 May 2007	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

The following contributions will be made by the reviewers stated:
Link with editorial base - SE
Review the correspondence - ALL
Draft the protocol -SE, PS, SL, SW
Search for trials - PS, AS
Obtain copies of trials - PS, AS
Select which trials to include - SE, SL, AS
Extract data from trials - SE,SL
Enter data into RevMan - AS
Carry out the analysis - SE, AS, SL
Interpret the analysis - SE, SL, AS
Draft the final review - SE, SL, AS
Update the review - ALL

DECLARATIONS OF INTEREST

None

SOURCES OF SUPPORT

Internal sources

- University of Southampton, UK.

External sources

- British Dermatological Nursing Group (Research award), UK.