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Research

Age related, structured educational programmes for the management of atopic dermatitis in children and adolescents: multicentre, randomised controlled trial

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Abstract

Objective To determine the effects of age related, structured educational programmes on the management of moderate to severe atopic dermatitis in childhood and adolescence.

Design Multicentre, randomised controlled trial.

Setting Seven hospitals in Germany.

Participants Parents of children with atopic dermatitis aged 3 months to 7 years (n = 274) and 8-12 years (n = 102), adolescents with atopic dermatitis aged 13-18 years (n = 70), and controls (n = 244, n = 83, and n = 50, respectively).

Interventions Group sessions of standardised intervention programmes for atopic dermatitis once weekly for six weeks or no education (control group).

Main outcome measures Severity of eczema (scoring of atopic dermatitis scale), subjective severity (standardised questionnaires), and quality of life for parents of affected children aged less than 13 years, over 12 months.

Results Significant improvements in severity of eczema and subjective severity were seen in all intervention groups compared with control groups (total score for severity: age 3 months to 7 years − 17.5, 95% confidence intervals − 19.6 to − 15.3; v − 12.2, − 14.3 to − 10.1; age 8-12 years − 16.0, − 20.0 to − 12.0; v − 7.8, − 11.4; − 4.3; and age 13-18 years − 19.7, − 23.7 to − 15.7; v − 5.2, − 10.5 to 0.1). Parents of affected children aged less than 7 years experienced significantly better improvement in all five quality of life subscales, whereas parents of affected children aged 8-12 years experienced significantly better improvement in three of five quality of life subscales.

Conclusion Age related educational programmes for the control of atopic dermatitis in children and adolescents are effective in the long term management of the disease.

Introduction

Atopic dermatitis is a chronically relapsing, inflammatory skin disease affecting up to a fifth of schoolchildren. Recent studies suggest that this prevalence is increasing in industrialised countries. Atopic dermatitis commonly begins in infancy or early childhood, and the symptoms of itching, scratching, and sleeplessness can place a burden on the whole family. Lack of information, overstrain, helplessness, and lack of confidence in medical treatment lead to suboptimal management of the disease and increasing use of healthcare resources, including alternative therapies.

Educational programmes aim to empower patients and carers in solving the problems arising from chronic diseases, and meta-analysis of results has highlighted the need for standardised methods so that improvements in self management of chronic disease can be more accurately assessed. Although several educational interventions have been developed for adults with atopic dermatitis, the literature on educational programmes for children and their parents is sparse. In addition, studies have not used the type of standardised, structured intervention that is proving highly beneficial in the management of other chronic atopic conditions in children, such as asthma.

Our study, the German atopic dermatitis intervention study, was set up to develop standardised interventions for the self management of atopic dermatitis and to assess their effects. We have used our collective experience and the input from three consensus conferences to define the content and structure of such a programme, including study design and choice of evaluation instruments. Here we report data, stratified into three age groups, collected from 992 families with children aged 3 months to 18 years with atopic dermatitis, within a multicentre, randomised controlled study. We determined the long term effect of age related, structured educational programmes on the control of moderate to severe atopic dermatitis in childhood and adolescence by assessing changes in disease severity, itch, and parents’ quality of life over 12 months.

Participants and methods

The three participating groups were parents of children with atopic dermatitis aged 3 months to 7 years and 8-12 years and adolescents with atopic dermatitis aged 13-18 years (table 1). Participants were recruited from seven centres in Germany: three children’s hospitals (Berlin, Osnabrück, and Cologne), three hospitals specialising in dermatology (Munich, Erlangen, and Hannover), and one department of psychosomatic medicine (Giessen). Atopic dermatitis was diagnosed by dermatologists or paediatricians. The inclusion criteria were diagnosis of atopic dermatitis according to the criteria of Hanifin and Rajka, eczema duration a minimum of at least three months, and a severity of eczema of at least 20 points according to the scoring of atopic dermatitis scale. Exclusion criteria were other acute or...
chronic illnesses or psychiatric disorders requiring treatment. A total of 992 patients were eligible and agreed to participate in the study. All participants (parents and adolescents) gave written informed consent.

After one year, 823 participants could be reached for evaluation: dropout rate of 17% (10% in the intervention group, 24% in the control group).

Study design
The study was designed as a randomised, controlled intervention study. Randomisation was carried out anonymously by an independent study centre in Heidelberg using computer generated random numbers. The randomisation code was concealed in closed envelopes from those entering patients into the study. The treatment programme consisted of six, weekly group sessions (5-8 participants), lasting two hours each. Patients were drawn consecutively from the seven study centres. The patients and their parents in the intervention and control groups were followed up at six (data not shown) and 12 months. The sample size estimation and power calculation was based on the severity of eczema (total on scoring of atopic dermatitis scale) as the primary outcome. With an effect size $d$ of 0.40, $a = 5\%$, and $\beta = 20\%$, we calculated that we would need 125 participants in each group, assuming a 20% loss during follow-up. No interim analysis was carried out, no stopping rules.

The participants could not be blinded as they were aware that they were receiving education, and it was also not possible for the trainers to be blinded. The scoring of atopic dermatitis scale was measured by investigators who were not actively involved as trainers.

Interventions
The educational programme was standardised to provide theme centred group training and comprised six, once weekly sessions, lasting two hours each. Parents of affected children aged 3 months to 7 years received education, with the contents of the sessions based on previously reported work. The parents of affected children aged 8-12 years attended separate educational sessions. Adolescents aged 13-18 years attended educational sessions tailored to their needs. These sessions covered medical, nutritional, and psychological issues, and were carried out by a multiprofessional team of dermatologists or paediatricians, psychologists, and dietitians, who had undergone a 40 hour training programme to qualify as trainers (see table 1). The contents and structure of the programme and didactic methods were discussed and worked out by an interdisciplinary consensus group over two years before starting the programme.

A manual specified the content of each session, and participants were given handouts summarising the timetable and the most important points of the sessions. The sessions also encouraged participants to share personal experiences and to try out newly learned skills.

The educational programme did not contain a therapy mandate, and any topical or systemic individual therapy (for example, prescriptions or specific diets) remained the responsibility of the patients’ doctors.

Outcome measures
The primary end points were the differences in severity of eczema and parents' quality of life between the start of the study (baseline) and follow-up at 12 months.

Severity of eczema
We graded the severity of eczema using the scoring of atopic dermatitis scale. This scale is based on the extent of eczema, the morphology of the lesions, and the two subjective items of sleep disturbance during the night and itch. The objective scoring of atopic dermatitis is the total score on the scoring of atopic dermatitis scale minus the scores related to both subjective items.

Subjecive severity score
The subjective severity of eczema was measured using the “skin detective,” a subjective score for severity related to part of the scoring of atopic dermatitis scale. The parents compared the morphology of their child's skin lesions with those of illustrations evaluated by experts.

Itch questionnaires
We used two standardised questionnaires to measure itching behaviour: JUCKKI, which contains 15 items and is aimed at 8-12 year olds, and JUCKJU, which comprises 18 items and is aimed at 13-18 year olds. The final versions of these two questionnaires were tested after preliminary studies in a group of 204 children and 168 adolescents. Two-factorial scale solutions resulted for both questionnaires. The two factors covered the areas catastrophisation (negative thoughts on pain that have got out of control) and coping. The internal consistence can be rated satisfactory to good, with values between 0.72 and 0.91. The questionnaires on itching cognitions provide two age appropriate procedures for children and adolescents with which differential aspects of these constructs can be reliably measured.

Quality of life for parents of children aged less than 13 years
Parents’ quality of life was measured with the German questionnaire “Quality of life in parents of children with atopic dermatitis.” This questionnaire was developed as part of the Berlin public health study “Evaluation of an educational programme for parents of children with atopic dermatitis,” and has been validated; it consists of 26 items, which can be divided by factor
analysis into five interpretable subscales: psychosomatic well-being, effects on social life, confidence in medical treatment, emotional coping, and acceptance of the disease. Convergent validity of this instrument has been tested. The questionnaire also highlights differences between parents of children with varying degrees of disease severity, which is a prime indicator of clinical relevance. The questionnaire has shown high intraclass coefficients for test retest reliability. The reliability for the subscales was medium to high, which was expressed by a Cronbach's \( \alpha \) of between 0.57 and 0.90. The intercorrelations of the dimensions are moderate (0.20-0.63), which shows that each dimension gives independent information on the respective aspects of quality of life.

**Statistical analysis**

All statistical analyses were carried out using SAS. For statistical tests we used non-parametric methods. We used analyses of co-variance to compare values at baseline with those at 12 months between the study arms.

**Results**

In total, 1010 patients were assessed for eligibility to take part in the study: 645 parents of children with atopic dermatitis aged 3 months to 7 years, 214 parents of affected children aged 8-12 years, and 151 adolescents aged 13-18 years. Of these, 992 participants were randomised (figure). In all age groups the severity of eczema did not differ significantly between the intervention and control arms at baseline (table 2). Additionally, no statistically significant differences were found between the intervention and control participants for all other outcome measures at baseline. After losses during follow-up, the number of participants in the intervention arms was 274 for children aged 3 months to 7 years; 102 for children aged 8-12 years; and 70 for adolescents aged 13-18 years. Comparable numbers in the control groups were 244, 83, and 50. The clinical characteristics and results of all outcome measures at baseline did not differ significantly between participants lost to follow-up and those remaining.

**Severity of eczema according to scoring of atopic dermatitis scale**

At baseline the mean score for severity of eczema was greater than 40 points in the intervention and control groups. At 12 months' follow-up the severity of eczema had decreased in all groups, but the decrease was significantly greater in the intervention arms (table 3).

**Subjective severity score**

Self evaluation of atopic dermatitis by children and adolescents has been shown to be similar to evaluation by experts. In our study the subjective severity score for eczema decreased significantly more in the intervention groups (table 3).

**Itching behaviour in 8-12 year olds and 13-18 year olds**

Table 3 shows the results of the subscales of the itch questionnaires in children aged 8-12 years and the adolescents at baseline and 12 months’ follow-up. In the 8-12 year olds, significantly greater improvements were shown in the intervention group for the subscales catastrophisation (intervention group, −7.0, 95% confidence interval −8.9 to −5.1; control group, −1.8, −3.5 to −0.2: \( P < 0.0001 \)) and coping (1.0, −0.3 to 2.3 \( v = −0.4, −1.6 \) to 0.8; \( P < 0.05 \)). In adolescents only the subcale catastrophisation showed a significantly greater improvement (table 3).

**Quality of life for parents of children aged less than 13 years**

Improvement in quality of life for parents of children aged 3 months to 7 years was significantly greater in the intervention group for all five subscales of the quality of life questionnaire (table 4). Improvement in quality of life for parents of children aged 8-12 years was significantly greater in the intervention group for three of the five subscales. The improvement in the subscales for confidence in medical treatment, emotional coping,
Discussion

Age related educational programmes for the control of atopic dermatitis in children and adolescents are significantly more effective in the long term management of the disease than is conventional treatment. Over a 12 month period statistically significant benefits were seen in the intervention groups for severity of eczema, subjective severity, and effect on parents' quality of life. One important feature of our study was the inclusion of a control group, since improvements in outcomes are also observed in the absence of parental or patient education. The educational intervention is probably complex as it can have a range of specific and non-specific effects and interactions between such effects. The benefit may not be attributable solely to the educational interventions in the absence of a controlled group that has simple non-directive group work with no educational programme. We assumed that patients in the control group that has simple non-directive group work with no education would have seen no benefit compared to the intervention group.
groups were highly motivated and tried to optimise their thera-
pies. Any treatment interventions were not restricted in either
intervention or control groups. We monitored treatments by
questionnaire and found no major imbalances between study
arms. The effect of education on long term improvements of
disease severity was noticeable and compares favourably with the
improvement in disease management achievable by drug
intervention alone.

It is well known that patients with an identical composite
score on the scoring of atopic dermatitis scale may differ greatly
in the measures of individual items. To our knowledge, however,
even a 5 point improvement in the score might be clinically
relevant for an individual patient.

The design of the programme, developed by the German
atopic dermatitis intervention study, differs from previous
psychosocial interventions. The educational programme
comprises a 40 hour training workshop for teachers qualified in
atopic dermatitis. The programme is offered by institutions with
national certification for the education of children and
adolescents with the disease. A facility that provides education in
atopic dermatitis must have at least one certified trainer, as well
as further team members, for the programme to be correctly
administered by doctors and psychologists, in combination with
nutritionists or dietitians. One new and notable aspect of the
educational programme is the promotion of cooperation
between different professionals, despite the highly diverse
approaches of the different disciplines.

In Germany, although almost all established inpatient
departments specialising in atopic dermatitis offer patient
education, the ideal situation is one in which educational
facilities are associated with a college that has long term experi-
ence in patient education and is able to offer supervision and
instructed seminars (so called “train the trainer” workshops). In
2000 the Association for Atopic Eczema Education established
eight colleges in Germany to fulfil these needs.

Our study expands on the positive results seen with adult
educational programmes and shows that such an approach
works well in the control of atopic dermatitis in children and
adolescents. Our results support those observed in previous
single centre studies with smaller numbers of patients, which
showed a beneficial effect of education in children with atopic
dermatitis and their parents. In particular, Staab et al showed
that parents’ quality of life improved significantly in the interven-
tion groups compared with a control group, using a programme
that provided the basis for the intervention presented here.

A strategy that maximises patient and parent education can
complement a symptom oriented therapeutic approach. Such
an approach is appropriate for atopic dermatitis, when
psychological and nutritional factors and a combination of topi-
cal and systemic therapies may need to be considered to tackle
the underlying multifactorial pathophysiology of this chronic
disease. In addition to treating the symptoms of atopic derma-
titis in childhood and adolescence, giving parents educational
support is an important factor in achieving a positive long term
outcome.

Although the value of programmes for the prevention of
atopic dermatitis is recognised, this approach is usually used
when basic therapy and expert medical attention have failed, and
is not used as a primary means of disease management. We
included in our study only families of children diagnosed as
having moderate to severe atopic dermatitis (>20 on scoring of
atopic dermatitis scale). However a study that evaluated
educating adult patients about atopic dermatitis showed that
those patients with less severe symptoms derived greater
benefit. Future studies should tackle the target groups that
would benefit most from education.

In conclusion we found that age related educational
programmes for the control of atopic dermatitis in children and
adolescents are significantly more effective in the long term
management of the disease than is conventional treatment. Such
programmes should be considered for integration into routine
care.

Contributors: DS was study coordinator. She was responsible for the educa-
tional programme in one of the study centres and was involved in the study
design, evaluation of the instruments, and development of the programme.
TLD was responsible for the evaluation centre and data management, was
involved in the study design, evaluation of the instruments, and the
development of the medical content of the programme, and wrote
the paper with UG and DS. MF was responsible for one of the study centres and
was involved in the development of the medical content of the programme.
JR was involved in the development and testing of the evaluation
instruments. TL-C was involved in the development of the child educational
part of the programme, JR was responsible for one of the study centres and
was involved in the development of the medical content of the programme.
SS was responsible for the inpatient study centre and was mainly involved
in the development of the adolescent part of the programme and didactic
topics. RS was involved in the study design, data management, and evalua-
tion. GS-O was involved in the development of the psychological content of
the programme and in the evaluation. CS was responsible for the
educational programme in one of the study centres and was involved in the
development of the medical content of the programme. RSch was responsi-
ble for one of the study centres and was involved in the development of
the medical content of the programme. TW was responsible for one of the
study centres and was involved in the development of the medical content
of the programme and the didactic presentation of the manuals. MW was
responsible for the educational programme in one of the study centres and
was involved in the didactic development of the programme. UW was the
principal investigator, initiated the proposal and was involved in the study
design. UG was involved in the study design and was head of the evaluation
group. All authors approved the final draft. DS, TLD, MF, JR, RSch, TW, and
UG are guarantors.

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Research


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