

Effects of a Short-Term Parental Education Program on Childhood Atopic Dermatitis: A Randomized Controlled Trial

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Abstract: Parental education is important in managing childhood atopic dermatitis (AD). We evaluated the long-term effects of a 2-day parental education program (PEP) on childhood AD. In an investigator-blinded, randomized controlled trial, 59 children age 6 months to 6 years with moderate to severe AD and their mothers were recruited in Japan. Participants were given a booklet about AD and received conventional treatment alone or in combination with a 2-day PEP comprising three lectures, three practical sessions, and a group discussion. The primary outcome was evaluation of eczema severity using SCORing Atopic Dermatitis (SCORAD) at 6 months. Secondary outcomes included changes in symptom scores, amount of corticosteroid used, parental quality of life as determined according to the Dermatitis Family Impact questionnaire, and change in parental anxiety regarding the use of corticosteroids in their children. Participants in the PEP group had a significantly lower SCORAD score than those in the control group at 6 months (mean difference 10.0, 95% confidence interval [CI] = 2.3–17.7, $p = 0.01$) and objective SCORAD score (mean difference 7.1, 95% CI = 0.8–13.5, $p = 0.03$). The sleeplessness symptom score (mean difference 1.6, 95% CI = 0.0–3.1, $p = 0.048$) and corticosteroid anxiety score ($p = 0.02$) in the PEP group were significantly better than in the control group at 6 months. There was no significant difference between groups in the amount of corticosteroid used or quality of life. The PEP had positive long-term effects on eczema severity and parental anxiety about corticosteroid usage.

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Atopic dermatitis (AD) is a chronic skin disease that has a significant effect on the lives of pediatric sufferers, affecting patients' and parents' quality of life (1). The education of parents of children with chronic diseases is important in their long-term management, particularly AD (2), in which poor adherence is a major cause of treatment failure (3). Previous studies have demonstrated the benefit of parental education in the management of childhood AD (4–9). Physicians and nurses play a central role in the education of AD (10), but because of busy clinical schedules, they often spend a limited amount of time with parents teaching appropriate skin care and topical application methods. A hospital stay is one way in which time can be made to fully educate patients and their parents. Considering the financial burden of hospitalization (11), we have designed a 2-day parental education program (PEP) (12). The aim of this study was to use validated measurements in a randomized controlled trial (RCT) to evaluate longer-term effects of our program on childhood AD.

MATERIALS AND METHODS

Study Design

The ethics committee of Aichi Children's Health and Medical Center approved this parallel-group RCT. Details of the trial were prospectively lodged in the University Hospital Medical Information Network clinical trials registry (trial number UMIN000000794).

Participants and Setting

Pediatric allergists saw all recruited patients (children age 6 mos to 6 yrs with moderate to severe AD (13) who required topical corticosteroid application daily) and their caregivers in an outpatient clinic at Aichi Children's Health and Medical Center, Aichi, Japan, from June 2007 to September 2008. Patients were excluded if they needed emergency admission, were undergoing psychological therapy, had a serious comorbidity that might interfere with the management of their AD, were unable to afford the one-night hospital stay, were not capable of caring for themselves, or were otherwise not eligible according to the pediatric allergists' judgment. All participants gave informed consent to participate in the study.

Normal Care

In this trial, topical corticosteroids of an appropriate potency and emollients were used according to the

guidelines (13). Mixtures of different ointments and use of topical calcineurin inhibitors were not allowed. A switch to a different topical corticosteroid or use of antibiotics or antihistamines was permitted according to the pediatric allergists' judgment, although a change in other oral medications was not allowed. Topical corticosteroids were applied daily until the eczema resolved completely, and the application interval increased by 1 day per month thereafter to decrease steroid application gradually. Daily application of the same topical corticosteroid was reinstituted if AD relapsed.

Intervention

After recruitment, parents in the PEP group were given a booklet containing information with similar themes to the formal education in addition to oral instruction and advice on skin care.

They participated in the formal education program with their children within 2 weeks of randomization (Table 1). The program was conducted over 2 days (from Friday to Saturday) (12). We held the program in the hospital for parents to watch the behavior of other children and parents through the night. Parents paid <800 Japanese yen (about US\$10) total for hospital charges. After completion of the education program, conventional treatment was continued for 6 months.

In the control group, patients received conventional treatment and the same information booklet as the PEP group.

Pediatric allergists reviewed each group at 3 and 6 months in an outpatient clinic. Additional visits were allowed if it was consistent with conventional treatment.

TABLE 1. *Structure and Content of the Parental Education Program*

Session (trainer)	Duration (number)	Topics
Lecture (PA)	60 minutes (1)	Epidemiology, diagnosis, pathophysiology, treatment, genuine side effects of topical corticosteroid
Lecture (NP)	30 minutes (1)	Skin care including method of application
Lecture (NP) Group discussion (NP)	30 minutes (1) 120 minutes (1)	Allergen avoidance Care for children with atopic eczema; skin management in the home
Practical session (NP)	About 20 minutes (3)	Care for child's skin in the bathroom

PA, pediatric allergist; NP, nurse practitioner.

Outcome Measures

The primary outcome was change in the severity of eczema determined using SCORing Atopic Dermatitis (SCORAD) (14) at 6 months. The objective SCORAD index, which is the SCORAD modified by excluding the subjective symptoms, was calculated to remove responder bias as a post hoc additional analysis. A single scorer blinded to group allocation determined objective SCORAD on the basis of digital photographs taken of the patients' lesions. The photographs were taken of the whole body and individual lesions. Picture quality was confirmed as being sufficient to evaluate the eczema before the child left the clinic. The scorer chose one lesion as the representative site.

Secondary outcome parameters included changes of symptom scores (i.e., 0–10) for pruritus and sleeplessness, parental quality of life scores according to the Dermatitis Family Impact (DFI) questionnaire (15), anxiety scores with respect to the use of corticosteroids from baseline, and assessment of corticosteroid usage at 3 and 6 months. Independent bilingual translators translated the original DFI into Japanese and back into English. The Japanese version was then validated in Japanese families. The corticosteroid anxiety score was assessed by asking parents "How much are you worrying about applying corticosteroids to your children's skin?" (1 = no anxiety, 5 = very anxious). Topical corticosteroid use was estimated by counting the number of used tubes and calculating the total weight of ointment used.

Randomization and Blinding

Participants were allocated 1:1 to the PEP or the control group using a computer-generated randomization list with a block size of eight. For each patient, parents performed randomization by picking a paper from a total of eight pieces of paper, half of which were labeled PEP and half Control in a sealed box. Treatment allocation was concealed from the objective SCORAD scorer. All analyses were performed before unblinding of treatment allocation.

Statistical Analysis

The mean difference in changes from baseline to 6 months between interventions was 14 ± 30 points on the SCORAD index based on our unpublished clinical data. We determined that 82 children per group were needed to achieve 80% power with an alpha of 0.05 in a two-tailed analysis, allowing for

10% dropout, but we recruited only 59 participants within the time limits of our funding period.

The SCORAD index and other continuous variables were compared between the groups using an unpaired *t* test. Anxiety scores were compared using the Mann–Whitney rank sum test. Mean differences were calculated with 95% confidence intervals (CIs). Data were analyzed using SPSS Statistics version 17.0J (SPSS Inc., Chicago, IL), with $p < 0.05$ considered statistically significant. Analyses for outcomes were conducted using the intention-to-treat approach with last observation carried forward imputation.

RESULTS

Fifty-nine patients were enrolled in this study: 29 in the PEP group and 30 in the control group. All patients participated with their mothers. The groups were well matched at baseline (Table 2). Three patients withdrew from the study after its initiation, and thus their full outcomes were not available for inclusion (Fig. 1). None of the patients required a change in topical corticosteroids or frequency of daily skin care, treatment with systemic corticosteroids, or an addition or increase in the dose of antihistamines during the trial. No side effects from the use of topical corticosteroids were observed.

The data of scores and changes at each time point are shown in Table 3. The change in SCORAD in the PEP group as a primary outcome was significantly better than that of controls at 6 months. Objective SCORAD in the PEP group improved significantly more at 6 months than in the control group. There was significantly greater improvement in the pruritus score at 3 months and the sleeplessness score at 3 and 6 months in the PEP group than in controls. The DFI

TABLE 2. Baseline Characteristics of Patients

Characteristic	Parental education program (<i>n</i> = 29)	Control (<i>n</i> = 30)
Age, mean $\pm$ SD (range)	2.2 $\pm$ 1.6 (0.5–5.7)	2.6 $\pm$ 1.4 (0.8–5.1)
Sex, <i>n</i> (%)		
Male	19 (65.5)	22 (73.3)
Female	10 (34.5)	8 (2.7)
SCORAD, mean $\pm$ SD	40.2 $\pm$ 14.2	42.0 $\pm$ 13.6
Objective SCORAD, mean $\pm$ SD	30.0 $\pm$ 12.8	30.8 $\pm$ 11.2
Symptom score, mean $\pm$ SD		
Pruritus	5.5 $\pm$ 2.5	6.5 $\pm$ 2.1
Sleeplessness	4.6 $\pm$ 2.5	4.7 $\pm$ 2.6
DFI score, mean $\pm$ SD	8.1 $\pm$ 6.7	7.1 $\pm$ 5.4

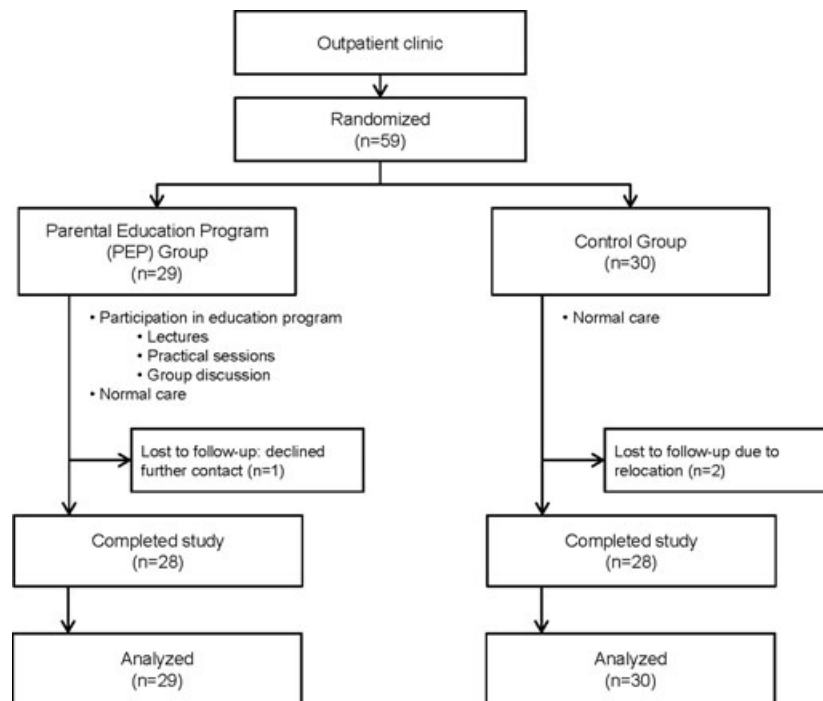


Figure 1. Study components and randomization flow chart.

improved in favor of the PEP group, but this difference was not significant between the groups.

The amount of topical corticosteroid usage was lower during the second 3 months than in the first 3 months in both groups (Table 4). The total amount used was less in the PEP group, but there was no significant difference between the groups. The amount of topical corticosteroid use did not correlate with the change in SCORAD or DFI score for each period (data not shown).

With respect to anxiety about corticosteroid usage, more than 70% of parents in both groups felt at least a little anxious (score 3) about corticosteroids at the beginning of the study. The anxiety scores in the PEP group were significantly better than in controls at 3 ($p = 0.02$) and 6 ($p = 0.02$) months. At 6 months, one in the PEP group and two in the control group remained very anxious (score 5). The anxiety in each group was not significantly associated with the level of corticosteroid use.

DISCUSSION

Main Findings

This RCT demonstrated the beneficial long-term effects on eczema severity in childhood AD of a 2-day PEP. The improvement in the SCORAD and objective SCORAD in the PEP group was significantly larger

at 6 months than in controls. Improvements were also seen in sleeplessness scores and corticosteroid anxiety scores.

Parents in the PEP group were educated about the benefits of proper skin care, empowering them and improving their quality of care, as has been reported in previous studies (4,8,16–18). In line with other studies (6,19), this program involved group discussion in addition to lectures. We believe that our program had elements that enhanced self-confidence and reduced anxiety, leading to better treatment outcomes (20).

Because the therapeutic efficacy of topical corticosteroids depends not only on potency, but also on the application method (21), we believe that the PEP group showed greater improvement because parents were educated in didactic and practical sessions. Moore et al (9) showed that nurse-led eczema workshops including treatment demonstrations resulted in greater improvement in eczema severity than a dermatologist-led clinic group, which was associated with a greater use of wet dressings, but patients in that trial were bathed more frequently. In our trial, there were no differences between groups with respect to bathing, and wet dressings were not used. Our previous study revealed that parents who were taught how to apply corticosteroids based on the fingertip unit applied greater amounts during the acute phase than those unaware of this measure (12). Therefore we focused on the practical sessions

TABLE 3. Scores and Changes of Eczema Severity, Symptom and QoL at 3 and 6 months

	PEP	Control	Mean difference in Δscore*	95% CI*	p*†
SCORAD (0–103)					
Baseline	40.2 ± 14.2	42.0 ± 13.6			
3 months	18.4 ± 9.9	27.8 ± 8.5			
Δ3M	22.0 ± 13.3	14.2 ± 14.7	6.8	–0.7–14.3	0.075
6 months	15.4 ± 7.6	27.8 ± 10.8			
Δ6M	24.1 ± 14.9	13.6 ± 14.6	10.0	2.3–17.7	0.012
Objective SCORAD (0–83)					
Baseline	30.0 ± 12.8	30.8 ± 11.2			
3 months	15.0 ± 7.8	18.9 ± 6.6			
Δ3M	14.8 ± 12.3	11.9 ± 12.6	2.3	–4.2–8.9	0.477
6 months	12.5 ± 4.9	21.0 ± 8.6			
Δ6M	16.8 ± 12.4	9.2 ± 12.0	7.1	0.8–13.5	0.028
Symptom score (0–10)					
Pruritus					
Baseline	5.5 ± 2.5	6.5 ± 2.1			
3 months	1.9 ± 1.8	5.0 ± 1.7			
Δ3M	4.0 ± 2.3	1.6 ± 2.5	2.2	0.9–3.4	0.001
6 months	1.6 ± 2.0	3.8 ± 2.2			
Δ6M	4.0 ± 2.6	2.8 ± 2.4	1.3	0.0–2.6	0.056
Sleeplessness					
Baseline	4.6 ± 2.5	4.7 ± 2.6			
3 months	1.5 ± 1.9	4.0 ± 2.0			
Δ3M	3.2 ± 2.4	0.7 ± 3.0	2.3	0.9–3.7	0.002
6 months	1.3 ± 2.2	3.0 ± 2.5			
Δ6M	3.4 ± 2.4	1.5 ± 3.4	1.6	0.0–3.1	0.048
DFI (0–30)					
Baseline	8.1 ± 6.7	7.1 ± 5.4			
3 months	4.7 ± 4.6	5.4 ± 4.8			
Δ3M	3.1 ± 5.1	1.7 ± 5.5	1.4	–1.3–4.2	0.294
6 months	3.9 ± 3.7	5.1 ± 4.8			
Δ6M	4.0 ± 5.5	1.8 ± 4.8	2.1	–0.5–4.8	0.111

PEP, parental education program; SCORAD, scoring atopic dermatitis; DFI, Dermatitis Family Impact Questionnaire; Δ3M, change from baseline to 3 months; Δ6M, change from baseline to 6 months. Values are expressed as mean ± SD.

*Intention-to-treat approach.

†Assessed by an unpaired *t*-test.

TABLE 4. Amount (Grams) of Topical Corticosteroid Used

	Parental education program	Control	95% CI	p*
0–3 mos	94.4 ± 63.6	99.8 ± 79.8	–43.8–33.0	0.78
3–6 mos	37.1 ± 31.6	57.0 ± 45.5	–40.6–0.94	0.06
Total	131.6 ± 84.0	156.8 ± 112.4	–78.0–27.6	0.34

Parental education program and control values are given as mean ± SD.

*Assessed using unpaired Student *t*-test.

of skin care during the program. Patients in the PEP group had lower SCORAD scores than the control group at 6 months, suggesting that their eczema was better controlled over a considerable period of time.

Many patients and parents of children with AD are worried about corticosteroid use (22), and in many cases this is not revealed to physicians. In our trial, corticosteroid anxiety scores in the PEP group were

lower at 3 and 6 months than in control group. It has been reported that parents were able to eliminate their anxieties about AD after discussions (23,24). Therefore it was possible that parents who underwent our education program used corticosteroids more appropriately, resulting in efficacious treatment and an overall reduction in the total amount of corticosteroids required. Nevertheless, several parents in both groups remained anxious about corticosteroid use at 6 months. Further psychoeducational intervention may be warranted in these cases.

Strength and Limitation

We evaluated the effect of PEP using objective scores and other validated scores. By using digital photographs, we could conceal group allocation and time of assessment from the objective scorer.

We stopped recruiting participants before achieving our target recruitment. Nevertheless, significant and clinically meaningful differences between the

groups were observed because we had overestimated the standard deviation of our main outcomes when powering the study.

Using a model of inpatient care to deliver this 2-day education package may not translate well to other health care settings. Nevertheless, this program had the advantage of allowing participants to engage in the education program without distraction, and people living a considerable distance away from the hospital could take part. It is likely that a similar education program delivered without the need for an overnight stay would be equally effective.

CONCLUSION

This study showed that a 2-day educational program resulted in a decrease in AD severity that was evident for 6 months. Because we did not follow these patients for longer than 6 months, longer-term studies may be warranted to assess the possible need for continuing parental education.

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REFERENCES

1. Chamlin SL, Frieden IJ, Williams ML et al. Effects of atopic dermatitis on young American children and their families. *Pediatrics* 2004;114:607–611.
2. Krakowski AC, Eichenfield LF, Dohil MA et al. Management of atopic dermatitis in the pediatric population. *Pediatrics* 2008;122:812–824.
3. Bodenheimer T, Lorig K, Holman H et al. Patient self-management of chronic disease in primary care. *JAMA* 2002;288:2469–2475.
4. Broberg A, Kalimo K, Lindblad B et al. Parental education in the treatment of childhood atopic eczema. *Acta Derm Venereol* 1990;70:495–499.
5. Cork MJ, Britton J, Butler L et al. Comparison of parent knowledge, therapy utilization and severity of atopic eczema before and after explanation and demonstration of topical therapies by a specialist dermatology nurse. *Br J Dermatol* 2003;149:582–589.
6. Grillo M, Gassner L, Marshman G et al. Pediatric atopic eczema: the impact of an educational intervention. *Pediatr Dermatol* 2006;23:428–436.
7. Ersser SJ, Latter S, Sibley A et al. Psychological and educational interventions for atopic eczema in children. *Cochrane Database Syst Rev* 2007;Issue 3:CD004054.
8. Schuttelaar ML, Vermeulen KM, Drukker N et al. A randomized controlled trial in children with eczema: nurse practitioner vs. dermatologist. *Br J Dermatol* 2010;162:162–170.
9. Moore EJ, Williams A, Manias E et al. Eczema workshops reduce severity of childhood atopic eczema. *Australas J Dermatol* 2009;50:100–106.
10. Eichenfield LF, Hanifin JM, Luger TA et al. Consensus conference on pediatric atopic dermatitis. *J Am Acad Dermatol* 2003;49:1088–1095.
11. Emerson RM, Williams HC, Allen BR. What is the cost of atopic dermatitis in preschool children? *Br J Dermatol* 2001;144:514–522.
12. Futamura M, Ito K, Otsuji K et al. Effects of “Skin Care School”, a parental education program on childhood atopic dermatitis conducted during short hospitalization stays. *Alerugi* 2009;58:1610–1618.
13. Saeki H, Furue M, Furukawa F et al. Guidelines for management of atopic dermatitis. *J Dermatol* 2009;36:563–577.
14. Severity scoring of atopic dermatitis the SCORAD index. Consensus report of the European task force on atopic dermatitis. *Dermatology* 1993;186:23–31.
15. Lawson V, Lewis-Jones MS, Finlay AY et al. The family impact of childhood atopic dermatitis: the dermatitis family impact questionnaire. *Br J Dermatol* 1998;138:107–113.
16. Kupfer J, Gieler U, Diepgen TL et al. Structured education program improves the coping with atopic dermatitis in children and their parents—a multicenter, randomized controlled trial. *J Psychosom Res* 2010;68:353–358.
17. Niebel G, Kallweit C, Lange I et al. Direct versus video-aided parent education in atopic eczema in childhood as a supplement to specialty physician treatment a controlled pilot study. *Hautarzt* 2000;51:401–411.
18. Staab D, Diepgen TL, Fartasch M et al. Age related, structured educational programmes for the management of atopic dermatitis in children and adolescents: multicentre, randomised controlled trial. *BMJ* 2006;332:933–938.
19. Shaw M, Morrell DS, Goldsmith LA. A study of targeted enhanced patient care for pediatric atopic dermatitis (STEP PAD). *Pediatr Dermatol* 2008;25:19–24.
20. Bandura A, Adams NE, Beyer J. Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev* 1977;84:191–215.
21. Lapsley P, Lapsley PM, Lapsley DK et al. The double benefits of educational programmes for patients with eczema. *BMJ* 2006;332:936.
22. Charman CR, Morris AD, Williams HC. Topical corticosteroid phobia in patients with atopic eczema. *Br J Dermatol* 2000;142:931–936.
23. Ricci G, Bendandi B, Aiuzzi R et al. Three years of Italian experience of an educational program for parents of young children affected by atopic dermatitis: improving knowledge produces lower anxiety levels in parents of children with atopic dermatitis. *Pediatr Dermatol* 2009;26:1–5.
24. Staab D, von Rueden U, Kehrt R et al. Evaluation of a parental training program for the management of childhood atopic dermatitis. *Pediatr Allergy Immunol* 2002;13:84–90.