

Therapeutic patient education in children with moderate to severe atopic dermatitis: A multicenter randomized controlled trial in China

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Abstract

Background: Therapeutic patient education is a continuous, systematic, patient-centered learning process to help patients and their families acquire and maintain the skills they need to manage their lives with a chronic disease. It has been proven effective in increasing treatment adherence and improving quality of life for patients with atopic dermatitis (AD) in Western countries. We introduce the first multicenter, randomized controlled clinical trial of therapeutic patient education in Chinese children with AD.

Objectives: To evaluate the effects of therapeutic patient education on the severity of AD, quality of life, and understanding and successful use of emollients in Chinese children with eczema.

Methods: We recruited 580 children, ages 2-14 years, with moderate to severe AD from six hospitals in China. Participants were randomized (1:1) to an intervention (n = 293) or control (n = 249) group. In addition to the severity of AD, data on quality of life and a questionnaire on family and patient knowledge of emollients were evaluated at the 6-month follow-up.

Results: On study completion, we found that the intervention group showed a significantly greater reduction in mean SCORing Atopic Dermatitis ($P < .001$) and Infant's Dermatology Life Quality Index ($P = .030$) scores than the control group. In addition, knowledge about the use of emollients improved significantly in the intervention group. There was no significant difference between groups in Children's Dermatology Life Quality Index scores.

Conclusions: The first randomized controlled trial of a therapeutic patient education program in China had positive long-term effects on decreasing eczema severity and improvement of quality of life in children 2-4 years of age with AD, as well as in promoting greater understanding of the use of emollients.

KEYWORDS

atopic dermatitis, eczema, quality of life

1 | INTRODUCTION

Atopic dermatitis (AD) is characterized by a chronic, relapsing course and pruritic eczematous lesions. Its pathogenesis is multifactorial, with variable genetic and environmental triggers playing a role. Current treatments are usually long term, and good response requires adherence to the regimen. AD also has a high economic burden associated with the use of health care resources, with costs comparable to asthma.¹ The symptoms of itching, scratching, and sleeplessness have a profound negative effect on patients' quality of life and psychological well-being and affect the whole family.² Furthermore, a lack of understanding of the disease process and management plan, corticosteroid phobia, lack of confidence in therapies, and a sense of helplessness lead to poor clinical outcomes and low adherence to AD treatment.³ Therefore educational programs for people with AD are important in controlling disease severity.

In 1998 a World Health Organization European Working Group defined "therapeutic patient education (TPE) as a process that would enable patients to acquire and maintain skills that optimize management of their lives with their disease." It was conceived as a continuous process integrated with health care.⁴ There are some data on the use of TPE in chronic dermatologic disorders such as psoriasis and AD that have lessened the severity of these diseases.⁵⁻¹² Hence we conducted the first multicenter randomized controlled trial using TPE in Chinese children with AD and their parents to see if this program would have a positive effect on AD severity, quality of life, and emollient knowledge.

2 | METHODS

2.1 | Participants and study design

The study was designed as a multicenter, open-label, randomized controlled parallel study. All participants were randomized in a 1:1 simple, nonstratified randomization scheme generated using randomization tables.

From May 2012 to August 2013, 580 children ages 2-14 years of age, with moderate to severe AD and their parents were recruited from six centers in China: five children's hospitals (Beijing, Chongqing, Shenzhen, Dalian, Harbin) and one general hospital (Shanghai). Each of the local ethics committees approved the study. The inclusion criteria required participants to fulfill the criteria of Hanifin and Rajka for AD and have moderate to severe disease (SCORing Atopic Dermatitis [SCORAD] score >20). Children who received systemic corticosteroids within 2 weeks before the trial or had other acute or chronic illnesses or psychiatric disorders were excluded. In total, 542 children were eligible to participate and were randomized to the intervention group ($n = 293$) or control group ($n = 249$). All participants' parents gave written informed consent.

Children were assessed at baseline and after 3 and 6 months. During the study, neither participants nor trainers could be blinded, because they were aware of the education or training received.

2.2 | Interventions

The intervention program consisted of four once-weekly group sessions (30-40 participants) in the six hospitals. In each session, intervention participants listened to a 2-h lecture comprising five parts: long-term treatment and management of AD, food allergy and AD, how to increase the family happiness index of patients using psychological interventions, skin care, and the use of emollients for AD. A multidisciplinary team of two pediatric dermatologists, a psychologist, and one advanced practice nurse in dermatology gave the lectures.

Immediately after the lectures, there was time for patients and parents to consult and discuss the concepts covered in the session with the instructors. The lectures were also video recorded and each family took home a video of the talks and related printed materials. Patients received therapy and diet recommendations based on their individual disease severity, with no restrictions in the study protocol.

2.3 | Outcome measures

2.3.1 | Disease severity

Disease severity was the primary outcome measure and was assessed using the SCORAD index. The groups did not differ significantly in total SCORAD or objective SCORAD scores at baseline.

2.3.2 | Quality of life

Quality of life was measured with the Children's Dermatology Life Quality Index (CDLQI) questionnaire¹³ (ages 5-16 years) and the Infants' Dermatitis Quality of Life Index (IDQOL) questionnaire¹⁴ (ages 2-4 years) at the three study visits.

2.3.3 | Questionnaire on knowledge of emollients

We designed a questionnaire for parents to assess their knowledge of the use of emollients in treating AD. The questionnaire consisted of nine questions covering three aspects of knowledge about emollients: understanding of use, functions, and ingredients of emollients. Parents were rated on a scale of 1 to 4 on their knowledge and understanding of emollient use.

2.4 | Statistical analysis

Assuming a 30% dropout rate, a sample size of 580 participants was chosen to ensure a sufficiently powered study. All statistical analyses were conducted using SAS version 9.1.3 (SAS Institute, Cary, NC, USA). Intra- and between-group comparisons were made using the Wilcoxon rank sum test or rank sum test for nonparametric data. Between-group comparisons of qualitative data were made using the chi-square test. All tests were two-sided and the alpha risk was set at 5% for the whole study.

3 | RESULTS

A total of 580 children were assessed for eligibility to take part in the study. Of these, 542 were randomized and analyzed: 293 in the TPE group and 249 in the control group. The severity of AD and all other outcome measures did not differ significantly between the intervention and control groups at baseline. Participants' demographic and clinical characteristics at inclusion are presented in Table 1.

3.1 | AD severity

The mean SCORAD scores were 45.1 ± 20.1 for the intervention group and 42.0 ± 18.2 for the control group at baseline. After 3 months, the mean SCORAD scores of the intervention group decreased by 24.4 ± 18.5 and of the control group by 19.0 ± 16.6 ($P < .001$; Table 2). The mean SCORAD scores also decreased between baseline and 6 months (intervention, 29.6 ± 21.4 ; control, 24.0 ± 20.6) ($P < .001$; Table 2).

3.2 | Quality of life of children with AD and their parents

At 6 months, improvement in quality of life for children 2-4 years of age was significantly greater in the intervention group, whose mean IDQOL fell from 10.3 ± 5.5 at baseline to 4.2 ± 3.5 , than in the

control group, whose mean IDQOL fell from 10.1 ± 5.2 at baseline to 5.1 ± 4.2 ($P = .030$; Table 2).

Although there was no statistically significant between-group difference in the CDLQI for children 5-14 years of age, the mean CDLQI in the intervention group (4.5 ± 6.0) was greater than in the control group (3.1 ± 5.4) after 6 months of follow-up ($P = .44$; Table 2).

3.3 | Knowledge of emollients of children with AD and their parents

Table 3 shows the changes in knowledge about emollients of the parents from baseline to the 6-month follow-up. At the beginning of the study, knowledge about emollients was similar in the intervention and control group parents in all nine subsets, whereas at the end of the study, improvement in the knowledge of emollients was significantly greater in the intervention group ($P < .001$).

4 | DISCUSSION

Results from the first Chinese, multicenter, long-term randomized controlled trial of a TPE program for the management of AD in children and adolescents showed that a TPE program combined with conventional AD therapy is statistically significantly more effective in decreasing the severity of the disease than conventional treatment alone. Significant benefits were seen over a 6-month period in the intervention group in terms of disease severity and quality of life.

TABLE 1 Participant demographic and clinical characteristics at inclusion

Characteristic	Intervention group	Control group	P-value
Sex, n			.99
Male	158	135	
Female	133	114	
Missing	2	0	
Age, years, mean $\pm$ SD	5.6 ± 2.9	5.6 ± 3.0	.76
Age at atopic dermatitis onset, months, mean $\pm$ SD	13.0 ± 22.3	14.4 ± 22.4	.18
Total SCORing Atopic Dermatitis score, mean $\pm$ SD	45.1 ± 20.1	42.0 ± 18.2	.11
Personal or family history of allergies, n			.62
Yes	115	103	
No	178	146	
Already treated at baseline, n	258	213	.39
Topical corticosteroids	258	213	.39
Topical antibiotics	46	26	.07
Oral antihistamine	110	79	.16
Emollients use	190	148	.20

SD, standard deviation.

TABLE 2 Eczema severity and quality of life scores and changes at 3 and 6 mo

Variables	Intervention group	Control group	Statistics ^a	P-value
SCORAD	(n = 293)	(n = 249)		
Baseline	45.11 ± 20.07	41.96 ± 18.25	-1.62	.11
3 mo	20.71 ± 15.37	22.94 ± 15.67	1.80	.07
$\Delta 3M$	24.40 ± 18.52	19.02 ± 16.62	3.62	<.001
6 mo	15.47 ± 13.58	17.93 ± 14.88	1.89	.06
$\Delta 6M$	29.64 ± 21.37	24.03 ± 20.65	3.39	<.001
IDLQI	(n = 178)	(n = 151)		
Baseline	10.33 ± 5.5	10.11 ± 5.22	0.10	.75
3 mo	5.53 ± 4.19	6.09 ± 3.92	2.60	.11
$\Delta 3M$	5.46 ± 5.52	4.48 ± 5.02	5.70	<.05
6 mo	4.23 ± 3.51	5.08 ± 4.25	2.00	.16
$\Delta 6M$	7.26 ± 5.97	5.76 ± 6.19	4.47	<.05
CDLQI	(n = 96)	(n = 83)		
Baseline	8.69 ± 5.92	8.19 ± 5.22	0.06	.81
3 mo	6.11 ± 4.37	6.22 ± 4.96	0.13	.72
$\Delta 3M$	2.87 ± 5.45	1.75 ± 5.08	2.16	.14
6 mo	4.71 ± 4.32	5.43 ± 4.36	1.38	.24
$\Delta 6M$	4.51 ± 5.96	3.14 ± 5.43	0.59	.44

^aRank sum test.

TABLE 3 Responses to emollient knowledge questionnaire at baseline and 6-month follow-up

Item	Baseline				6 mo			
	Intervention group (n = 235)	Control group (n = 195)	Chi-square	P-value	Intervention group (n = 235)	Control group (n = 195)	Chi-square	P-value
	n (%)				n (%)			
1.Do you use emollients for your child's skin care?			1.62	.65			20.80	<.001
Very frequently	31 (13.19)	27 (13.85)			110 (46.81)	65 (33.33)		
Frequently	73 (31.06)	54 (27.69)			102 (43.40)	80 (41.03)		
Occasionally	93 (39.57)	74 (37.95)			18 (7.66)	41 (21.03)		
Never	38 (16.17)	40 (20.51)			5 (2.13)	9 (4.62)		
2. Do you think an emollient can relieve skin dryness?			2.60	.46			23.05	<.001
Significantly	23 (9.79)	21 (10.77)			126 (53.62)	67 (34.36)		
Moderately	107 (45.53)	75 (38.46)			97 (41.28)	97 (49.74)		
Mildly	71 (30.21)	71 (36.41)			11 (4.68)	27 (13.85)		
None	34 (14.47)	28 (14.36)			1 (0.43)	4 (2.05)		
3. Do you think an emollient can improve skin pruritus?			1.89	.60			20.19	<.001
Significantly	12 (5.11)	11 (5.64)			104 (44.26)	57 (29.23)		
Moderately	82 (34.89)	57 (29.23)			98 (41.70)	81 (41.54)		
Mildly	92 (39.15)	87 (44.62)			30 (12.77)	45 (23.08)		
None	49 (20.85)	40 (20.51)			3 (1.28)	12 (6.15)		
4. How frequently do you think emollients should be used?			2.34	.51			25.84	<.001
Everyday	143 (60.85)	113 (57.95)			210 (89.36)	137 (70.26)		
Every 2-3 d	55 (23.40)	52 (26.67)			17 (7.23)	45 (23.08)		
1 time per week	22 (9.36)	13 (6.67)			5 (2.13)	7 (3.59)		
>1 time per week	15 (6.38)	17 (8.72)			3 (1.28)	6 (3.08)		
5. How long do you think an emollient should be used?			3.07	.38			46.26	<.001
1-3 mo	81 (34.47)	83 (42.56)			10 (4.26)	39 (20.00)		
About 6 mo	36 (15.32)	28 (14.36)			16 (6.81)	31 (15.90)		
About 1 y	19 (8.09)	13 (6.67)			9 (3.83)	15 (7.69)		
>1 y	99 (42.13)	71 (36.41)			200 (85.11)	110 (56.41)		
6. How helpful do you think an emollient is for your child's AD?			1.73	.63			28.68	<.001
Significantly	23 (9.79)	26 (13.33)			123 (52.34)	61 (31.28)		
Moderately	106 (45.11)	80 (41.03)			99 (42.13)	98 (50.26)		
Mildly	81 (34.47)	70 (35.90)			10 (4.26)	31 (15.90)		
None	25 (10.64)	19 (9.74)			3 (1.28)	5 (2.56)		
7. Do you think emollients specifically for AD are different from normal children's skin care cream?			0.38	.95			32.91	<.001
Significantly	67 (28.51)	54 (27.69)			150 (63.83)	72 (36.92)		
Moderately	103 (43.83)	88 (45.13)			58 (24.68)	75 (38.46)		
Mildly	41 (17.45)	36 (18.46)			18 (7.66)	37 (18.97)		
None	24 (10.21)	17 (8.72)			9 (3.83)	11 (5.64)		

(Continues)

TABLE 3 (Continued)

Item	Baseline				6 mo			
	Intervention group (n = 235)	Control group (n = 195)	Chi-square	P-value	Intervention group (n = 235)	Control group (n = 195)	Chi-square	P-value
	n (%)	n (%)						
8. How important are an emollient's ingredients in its effectiveness?			0.87	.83			38.10	<.001
Significantly	100 (42.55)	77 (39.49)			205 (87.23)	133 (68.21)		
Moderately	77 (32.77)	71 (36.41)			27 (11.49)	45 (23.08)		
Mildly	43 (18.30)	33 (16.92)			1 (0.43)	13 (6.67)		
None	15 (6.38)	14 (7.18)			2 (0.85)	4 (2.05)		
9. How important do you think it is for an emollient's ingredients to be non-allergenic?			0.17	.98			27.31	<.001
Significantly	145 (61.70)	117 (60.00)			205 (87.23)	133 (68.21)		
Moderately	61 (25.96)	53 (27.18)			27 (11.49)	45 (23.08)		
Mildly	19 (8.09)	17 (8.72)			1 (0.43)	13 (6.67)		
None	10 (4.26)	8 (4.10)			2 (0.85)	4 (2.05)		

AD, atopic dermatitis.

There was also a significant effect on knowledge about emollient use in children with AD and their parents.

These findings support previous studies showing that educational interventions that emphasize self-management skills rather than focusing only on adherence reduce severity and improve quality of life, patient knowledge, habits, and coping strategies. A few educational programs for adults with AD, including habit-reversal therapy, cognitive behavioral therapy, and psychological intervention, have proven to be useful adjuncts to dermatologic treatment of AD.¹⁵⁻¹⁷ Several studies have also demonstrated a therapeutic effect on dermatologic and psychological problems associated with childhood AD.^{18,19} Kupfer and colleagues⁸ showed that psychological variables including itching-scratching cognitions and the coping behavior of children responded well to an educational training program.

A novel feature of our study was the use of video-based educational tools that were taken home for further review by intervention participants. Video materials had many advantages, including ease of distribution, accessibility, and combined audio-visual appeal. Studies^{7,20} have suggested that video and print interventions promote recall of health-related information. In addition, materials that families can review may improve retention of knowledge. Armstrong and colleagues⁷ found that video interventions not only had better effects on promoting immediate and delayed retention of AD knowledge than written pamphlets alone, but also significantly decreased AD severity and improved clinical outcomes.

Our study also included an emollient knowledge questionnaire, which confirmed that the TPE program resulted in intervention subjects becoming more knowledgeable about the use of emollients in the treatment of AD than those receiving no education. A few studies have shown that daily use of moisturizers can prevent or delay the onset or flares of AD.²¹⁻²³ Sidbury and colleagues²⁴

recommended in the latest guidelines of care for the management of AD that moisturizers should be an integral part of the maintenance treatment plan, given their low risk and ability to improve skin hydration. One limitation of our study is that the validity and reliability of the questionnaire regarding emollients used in our study were not established. Few studies have used such questionnaires,²⁵ and none has been validated. Another limitation of our study is a lack of evaluation of the effect of TPE on psychological variables and the cost of illness in children with AD, which will require further study. The third limitation is that the investigators were not blinded during the study, which may have influenced the results.

In conclusion, the first randomized controlled trial of a multidisciplinary TPE program in China proved that it was significantly more effective at decreasing disease severity and increasing emollient knowledge in all children studied and improving quality of life in children 2-4 years of age than conventional treatment. Such intervention programs should be integrated into routine care of AD, as well as other chronic dermatoses such as psoriasis.

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