

ORIGINAL ARTICLES

Observational Study to Evaluate the Impact of an Educational/Informative Intervention in the Emotional Status (Anxiety) of Patients With Atopic Dermatitis (Cuida-DeL)

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Abstract. *Introduction.* One of the first therapeutic measures in atopic dermatitis should be the educational and informative approach about prophylactic aspects and evolution of the disease. This type of proceedings has been shown to be beneficial for the anxious type of emotional status in patients with atopic dermatitis. We evaluated the impact of an educational/informative intervention in the emotional status (anxiety) of patients with atopic dermatitis in Spain.

Material and methods. Investigators were randomized into two study groups: the control group (CG) that followed current clinical practice and the intervention group (IG) that handed patients, in each visit, a booklet of information about different prophylactic aspects and care of atopic dermatitis. The duration of the study was 6 months with quarterly visits. All included patients had a diagnosis of atopic dermatitis. Anxiety was evaluated with the STAI anxiety questionnaire and clinical data regarding dermatological aspects (IGA, pruritus scale, location of the lesions) were also recorded.

Results. A total of 1,247 patients were recruited thanks to the collaboration of 158 investigators. Patients were distributed as follows: 683 (54.7%) in the CG and 564 (45.2%) in the IG. Both groups were homogeneous with respect to basal characteristics, and were constituted by 54% of women with a mean age of 19 years. Eighty-six percent of atopic dermatitis lesions were preferentially located in extremities. Patients of both study groups showed improvement in their emotional status (trait and state anxiety) throughout the study with significant decreases in the STAI scores compared to basal ones. Regarding improvement in the questionnaire scores, no significant differences were observed between groups except in children aged 9 to 15 years, in the pediatric version of the STAI trait where the percentage of score decrease at 6 months adjusted to the basal score was 5.5 (19.0) for the CG and 10.6 (18.9) for the IG, ($p < 0.05$). A higher percentage of patients finished the study in the IG compared to the CG (83.1% vs. 76.1% $p < 0.005$).

Discussion and conclusions. Although patients in the IG showed greater compliance with the follow-up of the study, the informative intervention about prophylactic aspects of atopic dermatitis designed in this study does not appear to have had an impact in improving the emotional status of adult patients.

Key words: atopic dermatitis, educational intervention, informative intervention, emotional status, clinical study.

ESTUDIO OBSERVACIONAL PARA EVALUAR LA REPERCUSIÓN DE UNA INTERVENCIÓN EDUCATIVA-INFORMATIVA EN EL ESTADO EMOCIONAL (ANSIEDAD) DE LOS PACIENTES CON DERMATITIS ATÓPICA (CUIDA-DEL)

Resumen. *Introducción.* Una de las primeras actuaciones terapéuticas en dermatitis atópica (DA) debe ser el abordaje educacional e informativo sobre los aspectos preventivos y de evolución de la enfermedad. Actuaciones de este tipo han demostrado ser beneficiosas en el estado emocional de tipo ansioso de los pacientes

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con DA. Se evaluó la repercusión de una intervención educativa-informativa en el estado emocional (ansiedad) de pacientes afectados de DA en España.

Material y métodos. Se aleatorizaron a los investigadores en dos grupos de estudio: control (GC), que siguió práctica clínica habitual y grupo intervención (GI) que entregó, en cada visita, un boletín informativo sobre diferentes aspectos preventivos y de cuidados de la DA a los pacientes. La duración del estudio fue de 6 meses con visitas trimestrales. Todos los pacientes incluidos tenían diagnóstico de DA. La ansiedad se valoró con los cuestionarios de ansiedad *State Trait Anxiety Inventory* (STAI) y se recogieron datos clínicos de evolución dermatológicos: IGA, escala de prurito y localización de la DA.

Resultados. Se reclutaron 1.247 pacientes gracias a la colaboración de 158 investigadores. Los grupos de pacientes se distribuyeron: 683 (54,7 %) en el GC y 564 (45,2 %) en el GI. Ambos grupos fueron homogéneos basalmente, constituidos por un 54 % de mujeres, con una edad media de 19 años. El 86 % de la DA estuvo localizada preferentemente en extremidades. Los pacientes de ambos grupos del estudio mejoraron en su estado emocional (ansiedad rasgo y estado) a lo largo del mismo con descensos significativos en las puntuaciones del STAI respecto a la basal. No se apreciaron diferencias significativas entre los grupos en la mejoría del cuestionario, excepto en niños de 9 a 15 años, en la versión infantil del STAI rasgo, donde el porcentaje de descenso, de la puntuación a los 6 meses corregida por la puntuación basal, fue para el GC de 5,5 (19,0) y para el GI de 10,6 (18,9) ($p < 0,05$). En el GI un mayor porcentaje de pacientes finalizaron el estudio comparado con el GC (83,1 % frente a 76,1 % $p < 0,005$).

Discusión y conclusiones. A pesar de que en el GI se consiguió una adherencia mayor de los pacientes en el seguimiento del estudio, la intervención informativa sobre hábitos de prevención de DA diseñada en este estudio no parece haber tenido una repercusión significativa en la mejoría del estado emocional de los pacientes adultos.

Palabras clave: dermatitis atópica, intervención educativa, intervención informativa, estado emocional, estudio clínico.

Introduction

Atopic dermatitis is a skin condition that occurs in patients with a complex, genetically determined syndrome known as atopy, which includes the tendency to develop eczema and other skin lesions, bronchial asthma, and allergic rhinoconjunctivitis. Its prevalence is estimated to be between 5% and 20% in developed countries. A recent study conducted in Madrid, Spain, among schoolchildren aged between 3 and 16 years over the period of a year reported a prevalence of 9.95%.¹ Fifty percent of patients with atopic dermatitis develop lesions within a year of birth and 80%-90% develop them by the age of 5. The primary cutaneous manifestations are dry skin and eczema, accompanied by pruritus. The majority of patients develop a mild (84%) or moderate (14%) form of the disease.² Treatment is based on controlling the factors that trigger and perpetuate the dermatitis, restoring the epidermal barrier through correct moisturizing, and reducing the cutaneous inflammation.

The cause of atopic dermatitis is still unknown. In addition to the complex immunological reactions that constitute the underlying etiopathogenic mechanisms, there is a considerable psychological component, which is exacerbated by the chronic nature of the disease.³ Psychosomatic factors

have long been suspected to have an impact on atopic dermatitis⁴ and several studies have found an association between the disease and anxiety states.⁵⁻⁷ Atopic dermatitis has a considerable social and familial impact as it can cause stress not just in young patients but in their parents as well.⁸ Uncertainties regarding disease course become particularly pronounced when young children are involved, resulting in increased anxiety levels.⁹ Caring for young patients with moderate to severe atopic dermatitis, for example, has been seen to have a greater impact on the family than caring for children with type I diabetes mellitus.¹⁰ Impaired quality of life, measured using the Children's Dermatology Life Quality Index, has also been reported in over 60% of pediatric patients with moderate to severe disease.¹¹ Evidence of impaired quality of life included pain and itching and difficulty dressing and sleeping.¹¹

Providing patients with information about disease course and preventive measures has proven to be beneficial in terms of reducing anxiety levels in patients with atopic dermatitis.⁶ Ehlers et al,⁶ for example, in a comprehensive study of preventive dermatological and psychological approaches in patients with atopic dermatitis, found that an intervention based on providing patients with information about the disease, the influence of varying factors, and basic skin care,

led to a considerable reduction in anxiety levels, measured by the State Trait Anxiety Inventory (STAI). This intervention strategy had the same effect on anxiety levels as an intervention program based on disease information and education and a cognitive-behavioral program. Other studies have shown that interventions designed to help patients with atopic dermatitis to modify their behavior or habits can be more beneficial than the use of certain drug therapies such as corticosteroid therapy.¹² Staughton, in his contribution to the consensus meeting on atopic dermatitis held in Rome, Italy in 1999, indicated that behavior-modification strategies should be simple and based on actions such as self-observation and the recording of symptoms such as itching, dryness, and redness.

Knowing that we were likely to find an association between the emotional state of patients with atopic dermatitis and disease course, we wished to test the hypothesis that an intervention based on educating and informing patients about clinical and preventive aspects of the disease could improve their emotional state.

Objectives

Based on the above hypothesis, the following objectives were set:

1. Primary objective: to study the impact of an education-information intervention on the emotional state (anxiety levels) of patients with atopic dermatitis.
2. Secondary objectives: *a*) to study the association between clinical features of atopic dermatitis and the emotional state of patients during the baseline visit; *b*) to compare the emotional state of parents of children with atopic dermatitis in a control group and an intervention group; and *c*) to compare disease progression over a follow-up period of 6 months in the 2 groups based on number of outbreaks, itch intensity, and overall disease severity measured using the Investigator's Global Assessment (IGA) scale, and to explore the association between disease progression and the emotional state of the patients and their parents at the end of the study.

Materials and Methods

Study Design

We conducted a prospective, parallel-group, multicenter study in which investigators were assigned randomly to either a control group or an intervention group.

1. Control group. The patients in this group were managed in accordance with the investigator's standard clinical practices.

2. Intervention group. The patients in this group were also managed in accordance with the investigator's standard clinical practices but in addition they were provided with purpose-designed educational material and information.

The intervention material included:

1. An information leaflet given to each patient by the investigator at each 3-month visit during the monitoring period. This leaflet contained information about important everyday patient-oriented aspects of atopic dermatitis.
2. A diary for recording itch and redness intensity with instructions on usage; symptom intensity was recorded using a visual analog scale ranging from 0 to 10.
3. A calendar card showing the dates of future visits within the study program.

Study Conduct

Three visits were held during the study period. These included a baseline visit and 2 follow-up visits (at 3 months and 6 months). Relevant clinical data (disease severity [IGA], itch intensity, and location of lesions) were recorded and the patients' emotional states were evaluated on the basis of STAI scores. The STAI for children was administered where appropriate and both the state and trait anxiety scales (STAI-S and STAI-T, respectively) were evaluated.¹³ To study the association between clinical features of atopic dermatitis and the emotional state of patients at baseline and throughout the study, we analyzed state rather than trait anxiety levels. All statistical calculations were carried out using the PASS statistical package, version 2002. (NCSS/PASS; Number Cruncher Statistical Systems, Kaysville, Utah, USA).

Results

A total of 1247 patients were recruited with the collaboration of 158 participating investigators. The patients were distributed as follows: 683 (54.7%) in the control group and 564 (45.2%) in the intervention group. The mean (SD) age of the patients was 19.7 (15.3) years in the control group and 19.1 (16.3) years in the intervention group. There were no statistical differences between the groups in terms of the proportion of men and women or the educational level.

The percentage of patients with concomitant skin disease was 26.8% in the control group and 26.6% in the intervention group, and the most common concomitant disease was viral skin infection (affecting 11% of the control group and 12.1% of the intervention group).

Table 1. Clinical History of Atopic Dermatitis by Study Group

	Control Group						Intervention Group						p
	M	SD	Med	Min	Max	No.	M	SD	Med	Min	Max	No.	
Age of first episode of atopic dermatitis, y	9.5	12.2	4.1	0	68	664	8.0	10.8	3.0	0	80	546	.105
Outbreaks in past 8 months, No.	3.0	2.6	2.0	0	20	555	2.6	3.0	2.0	0	50	488	.006 ^a
Duration of last outbreak, d	25.5	29.2	15.0	1	365	579	30.6	48.5	15.0	1	730	496	.373

Abbreviations: m indicates mean; max, maximum; med, median; min, minimum.

^aStatistically significant differences between the 2 groups ($P < .05$).

There were no statistically significant differences between the groups for either the age at which the first episode of atopic dermatitis occurred or the duration of the most recent outbreak. There was a statistically significant difference, however, for the number of outbreaks that had occurred in the preceding 6 months. The mean (SD) was higher in the control group (3.0 [2.6]) than in the intervention group (2.6 [3.0], $P < .05$) (Table 1). The most affected areas of the body were the hands and feet in both groups (over 85% of patients in each group). The difference in itch intensity between the 2 groups was also statistically significant, with the intervention group scoring higher than the control group for severity of baseline signs and symptoms (1.8 [0.8] vs 1.7 [0.8], $P < .05$) (Table 2).

On analyzing the association between the clinical features of atopic dermatitis and a history of stressful situations or psychological disorders by study group, we found a statistically significant difference for itch severity between patients who had a history of stress or psychological disease and those who did not. The decrease in anxiety levels (state and trait) over the course of the study was statistically significant for patients aged between 9 and 15 years in both groups ($P < .05$), although the differences between the 2 groups were not statistically significant ($P > .05$) (Figure 1). A greater percentage of patients completed the study in the intervention group than in the control group (83.1% vs 76.1%, $P < .005$). A significant decrease in anxiety levels (state and trait) was observed in patients aged over 15 years in both groups ($P < .05$). Statistically significant differences were found between the groups for anxiety levels at baseline ($P < .05$) but not at 6 months. This implies that the intervention group experienced a greater decrease in anxiety levels as their baseline scores were higher (Figure 2).

With respect to the impact of our intervention on the emotional state of parents of patients younger than 9 years, we observed a significant decrease in both state and trait anxiety levels over the course of the study in both groups ($P < .05$). The differences between groups, however, were not statistically significant ($P > .05$). (Figure 3).

We found an association between the patients' emotional state at baseline (measured on the STAI-S scale) and 3 clinical features of atopic dermatitis: presence of the symptom

Table 2. Baseline Signs and Symptoms of Atopic Dermatitis by Study Group

Signs and Symptoms of Atopic Dermatitis	Control Group	Intervention Group
No. of outbreaks		
Mean	3.0 ^a	2.6 ^a
SD	2.6	3.0
No.	555	488
Investigator's Global Assessment		
Mean	2.6	2.6
SD	0.9	0.9
No.	675	560
Itch scale		
Mean	1.7	1.8 ^a
SD	0.8	0.8
No.	667	554

^aStatistically significant differences between the 2 groups ($P < .05$).

“change in skin temperature,” IGA rating, and itch intensity score (linear regression analysis, $P < .05$).

The IGA score was the only clinical variable that was associated with the patients' emotional state throughout the study ($P < .001$) (Table 3).

On analyzing disease progression over the 6 months, we observed a considerable reduction in the 3 factors analyzed (number of outbreaks, itch intensity, and overall disease severity) in both groups ($P < .05$). Statistically significant differences between the 2 groups were found for number of outbreaks at baseline, IGA score at 3 months, and itch intensity score at baseline and 3 months ($P < .05$).

Discussion

Although the entity now known as atopic dermatitis was first described by Robert Willan as far back as 1808, the concept of “atopic” was not introduced until 1923, when the term “atopy” was proposed by Coca and Cooke to group together different clinical skin, lung, and nasal

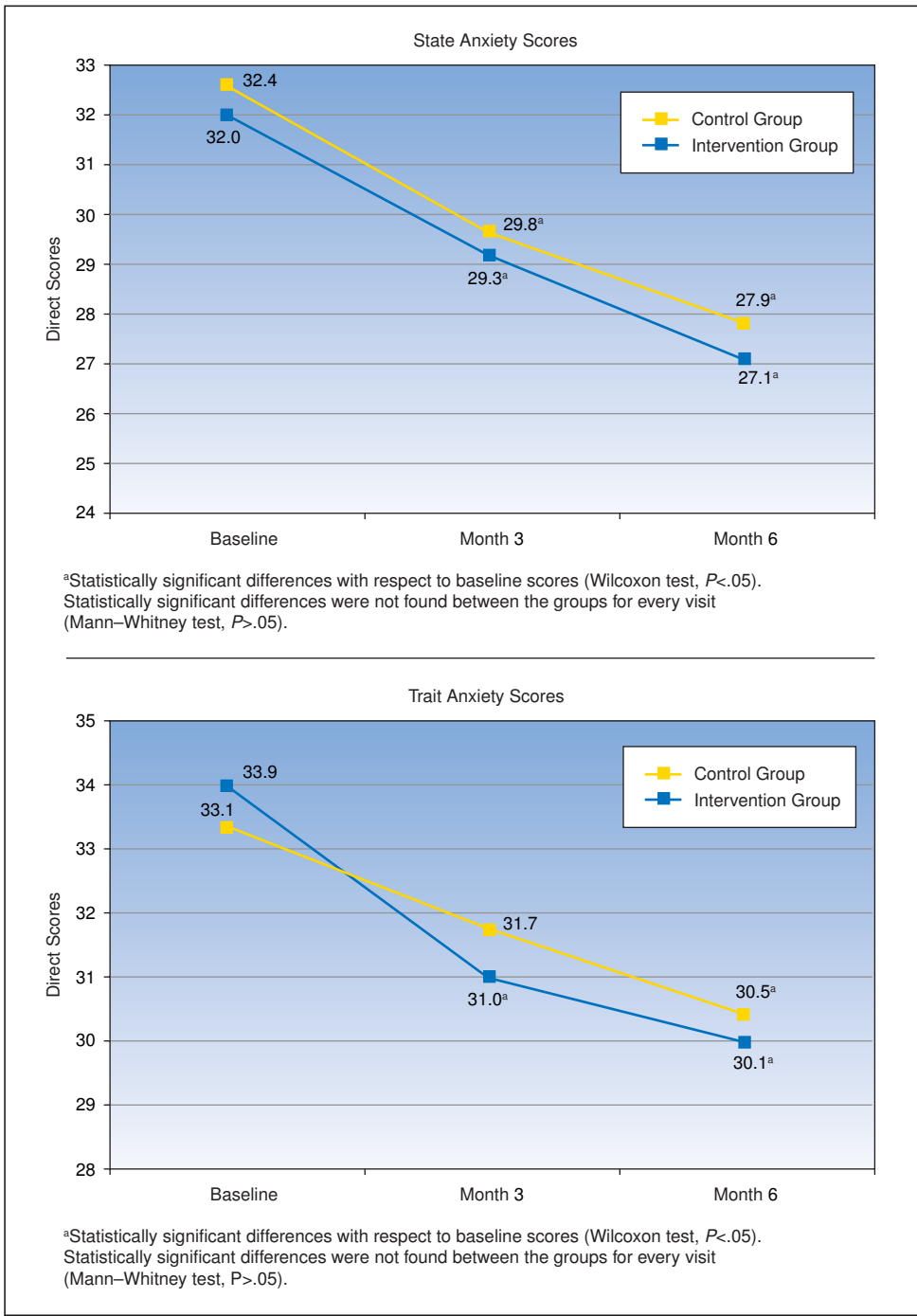


Figure 1. Progression of anxiety (state and trait) in children by study group

hypersensitivity manifestations (including atopic dermatitis). It was not until many years later, however, that the psychological component of atopic dermatitis—which is capable of triggering and perpetuating symptoms—received the attention it deserved. Its impact on quality of life is so great that in one study it was seen to be greater than that of diabetes in children.¹⁴ Anxiety exerts a 2-way effect: when present, it has a negative effect by exacerbating the hypersensitivity reaction, and when absent, it leads to an

improvement of symptoms. Likewise, clinical deterioration increases anxiety while clinical improvement enhances patients' emotional well-being. Anxiety also has an impact on parents of patients under 9 years old, and psychological intervention has been shown to improve the quality of life of these patients.¹⁵

Psychological support, for example, can take the form of an education#-information intervention based on providing patients with information about clinical and

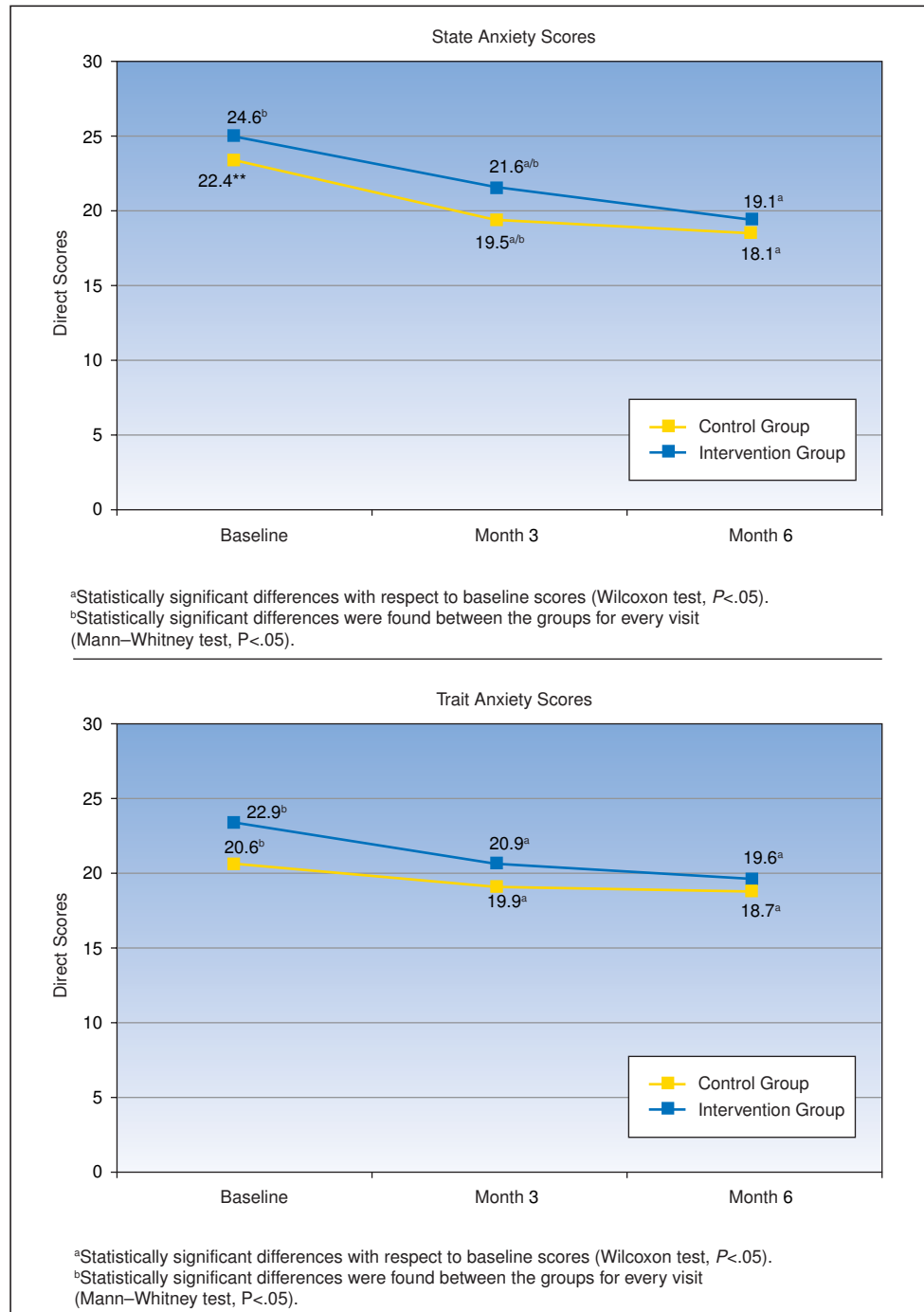


Figura 2. Progression of anxiety (state and trait) in adults by Study group.

preventive aspects of atopic dermatitis in an effort to improve their emotional well-being. One such intervention study, for example, found a greater decrease in anxiety levels (measured by the STAI-T) after a year in patients who had participated in the education and information program than in those who had not (decrease of 3.1 points in the intervention group compared to a decrease of 0.1 points in the control group).¹² This study is used as a reference when measuring the effect of education and information on the

results of the trait anxiety test. Although the ultimate aim of our study was similar to that of the above study, both our design (graphic and written rather than face to face intervention) and observation period (6 months rather than a year) were different. We should also remember that trait anxiety is the most stable of the 2 types of anxiety studied and that because state anxiety is associated with temporary conditions or situations, it should be more sensitive to the effects of intervention. In view of this, and given the nature

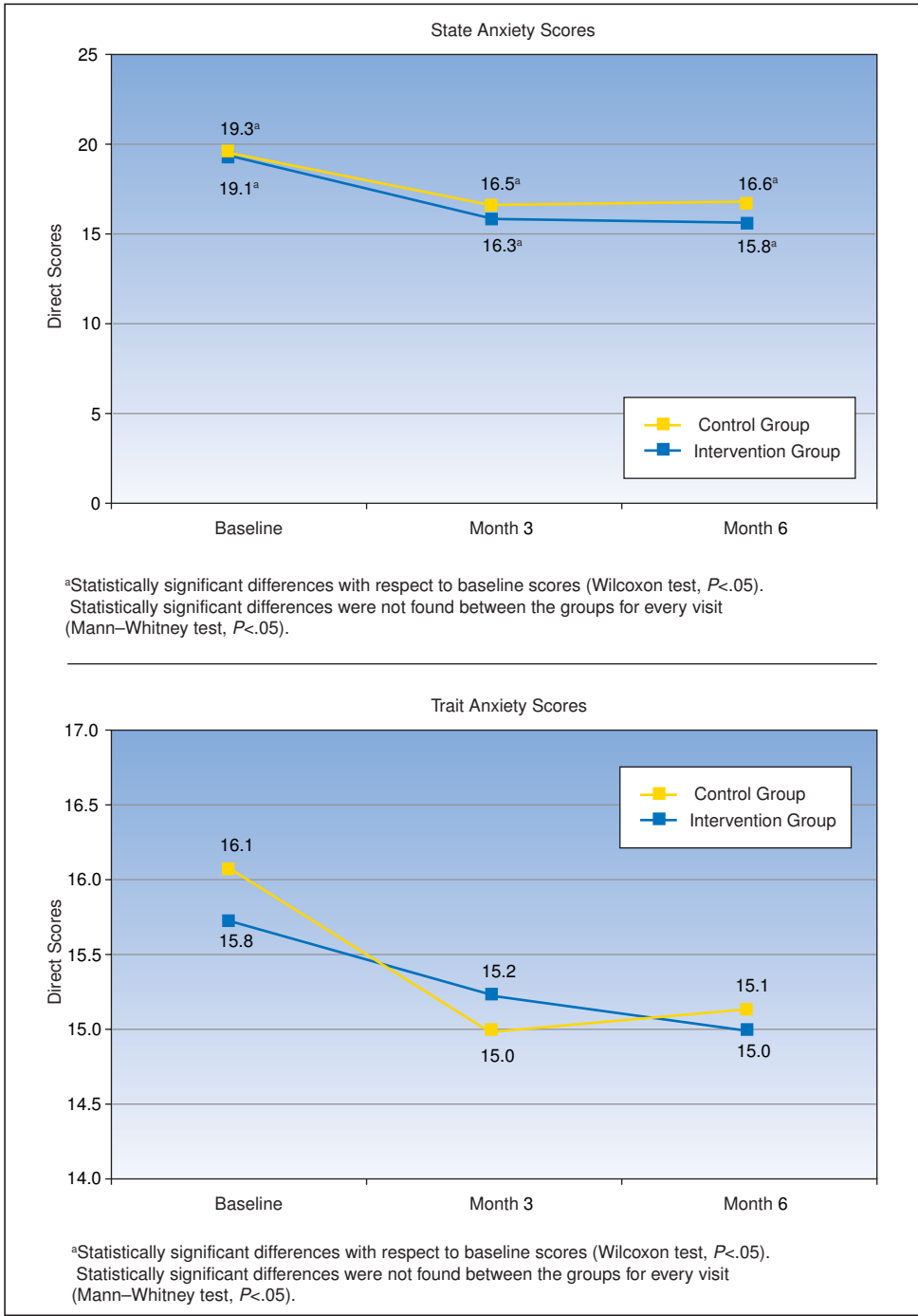


Figure 3. Progression of anxiety (state and trait) in parents of children under 9 years with atopic dermatitis by study group

of our intended intervention, we established a minimum detection level of 2 points for the STAI-T score at 6 months. We worked on the assumption that we would obtain a mean STAI-T score of 48.3 (10.1) for the control group and 46.3 (10.1) (2 points less) for the intervention group. We took the highest SD value recorded for both groups in the reference study, and, assuming greater variability, took a more conservative approach with the results. On the basis

of the above assumptions, we needed a sample of 1194 patients (597 per group) for a statistical power of 90% and a significance level (α) of 5%, assuming a 10% loss.

The clinical evaluation (IGA) conducted at the beginning of the study revealed mild to moderate disease and pruritus in both groups. Approximately 28% of the patients in both groups reported having experienced a stressful situation that had modified their emotional state.

The difference in the percentage of patients who had left school early between the 2 groups was statistically significant (23.9% in the control group compared to 16.9% in the intervention group).

With respect to the main aim of the study, we found no statistically significant differences between the groups in terms of emotional state (anxiety) measured by the STAI.

We did, however, find statistically significant differences between the 2 groups for adult patients (older than 15 years) when we analyzed the decrease in anxiety levels from baseline to month 3 (for direct scores but not for corrected scores). Patients in the intervention group had significantly higher levels of state and trait anxiety than those in the control group at baseline but these differences were not noticeable by the end of the study.

In general, we observed considerable decreases from baseline in STAI scores for both children and adults throughout the study, with both the intervention group and the control group showing improvement (probably because the patients knew that they were receiving emotional support from the specific tests they completed at each visit).

We did not find any statistically significant differences between the control and intervention group for other age groups (created in accordance with the criteria followed when administering the STAI: parents answered the questionnaire when the patient was under 9 years old, patients aged between 9 and 15 answered the STAI for children, and patients over the age of 15 years answered the STAI for adults). We did, however, find statistically significant differences within these groups for improvement from baseline to month 6.

Our study has certain limitations. Although the investigators were randomly assigned to either an intervention group or a control group, it appears that selection bias may have occurred when forming these groups. This would explain the differences between the baseline levels of anxiety in the adult patients, that is, the investigators may have tended to assign patients who were more worried about their disease to the intervention group rather than the control group.

Another possible limitation is the type of education intervention chosen. The informative/educational messages delivered by the 3 purpose-designed leaflets were probably not powerful enough to create a detectable difference between the 2 groups in terms of the main test variable (anxiety). The intervention strategy used by Ehlers et al⁶—in which patients were educated and informed by nurses in a face-to-face situation—yielded positive results in terms of improved emotional state measured by the STAI. Thus, the ability to modify habits related to health and prevention hinges on the design of the intervention variable. In the present study, the effect of our strategy was probably diluted by the fact that we are living in an information era with ready access to knowledge. This would explain why patients

Table 3. Association Between Clinical Features of Atopic Dermatitis and Improvement in Patients' Emotional State Over the Course of the Study

Variables	Odds Ratio ^a	95% CI		P
		Low	High	
Progression According to Investigator's Global Assessment				< .001
Improvement	1	–	–	–
No change	0.49	0.33	0.73	<.001
Deterioration	0.32	0.18	0.57	<.001

^aAn odds ratio of <1 indicates an association with a decrease in the percentage of patients that showed improvement

in both groups judged themselves to be well informed about atopic dermatitis.

The improvement in the emotional state of patients with atopic dermatitis is significantly associated with clinical improvement measured by IGA. Our study, however, did not analyze drug use, a variable which probably exerted an effect on clinical and therefore emotional improvement.

Conclusions

The intervention we designed—which was based on providing patients with information about how to prevent atopic dermatitis—does not appear to have had a significant impact on the improvement of the patients' emotional state.

There was, however, a noticeable clinical improvement over the course of the study—both in terms of IGA rating and itch intensity—that was accompanied by an improvement in the patients' emotional state. The lack of data regarding drug treatment prevented us from analyzing the possible role of drugs in the clinical improvement observed.

It seems clear, however, that emotional improvement only occurs when there is clinical improvement, regardless of whether or not patients have taken part in an education program.

Two symptoms that had a significant influence on the emotional state of the patients were a sensation of increased skin temperature and itching.

Patients in the intervention group rated their knowledge of atopic dermatitis more highly than those in control group. Although the difference was only slight, it was statistically significant.

Adherence to the program was greater in the intervention group than in the control group.

Conflicts of Interest

This study was sponsored by Novartis Farmacéutica.

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