

Group Education on Asthma for Children and Caregivers: a Randomized, Controlled Trial Addressing Effects on Morbidity and Quality of Life

A Cano-Garcinuño,¹ C Díaz-Vázquez,² I Carvajal-Urueña,³ M Praena-Crespo,⁴ A Gatti-Viñoly,⁵ I García-Guerra⁶

¹Centro de Salud de Villamuriel de Cerrato, Palencia, Spain

²Centro de Salud de Moreda, Asturias, Spain

³Centro de Salud de Las Vegas, Asturias, Spain

⁴Centro de Salud La Candelaria, Seville, Spain

⁵Dirección Departamental de Salud de Canelones, Uruguay

⁶Hospital General de Holguín, Cuba

■ Abstract

Objective: To establish the efficacy in terms of morbidity and quality of life of a group education program on asthma aimed at children and caregivers.

Methods: An open, randomized, controlled trial was undertaken in 13 primary health care centers in Spain, Cuba, and Uruguay and involved 245 children with active asthma aged 9 to 13 years and their caregivers. The intervention consisted of 3 educational sessions lasting 45 to 60 minutes each and was performed with 3 intervention groups: children alone, caregivers alone, and both children and caregivers. The outcome measures were difference between intervention and control groups in the rate of asthma attacks and hospital admission, as well as the quality of life of children and caregivers in the 6 months following the intervention.

Results: The rate of asthma attacks per patient-year decreased when the intervention was given only to children (mean difference, -1.61; 95% confidence interval [CI], -2.87 to -0.34) or to both children and caregivers (-1.60; 95%CI, -2.88 to -0.31). Hospital admissions per patient-year decreased in the intervention groups children alone (-0.28; 95%CI, -0.51 to -0.05) and both children and caregivers (-0.25; 95%CI, -0.49 to -0.02). Education provided to caregivers alone was not associated with any changes in morbidity. No differences were observed in terms of quality of life between controls and any of the intervention groups.

Conclusions: Group education on asthma reduces morbidity but does not improve quality of life. The benefits are apparent when education is aimed at children but no additional benefit is obtained if the intervention is also aimed at their caregivers. Finally, group education for adult caregivers alone is not effective.

Key words: Asthma. Children. Caregiver. Quality of life. Patient education. Clinical trial. Multicenter study. Questionnaires.

■ Resumen

Objetivo: Determinar la eficacia, en términos de morbilidad y calidad de vida, de un programa de educación grupal en asma dirigido a niños y cuidadores.

Métodos: Ensayo clínico aleatorio, controlado y abierto, realizado en 13 centros de atención primaria de España, Cuba y Uruguay, incluyendo a 245 niños de 9 a 13 años con asma activo, y a sus cuidadores. La intervención consistió en tres sesiones educativas de 45-60 minutos cada una, y se formaron tres grupos de intervención: niños sólo, cuidadores sólo, y niños y cuidadores. Las medidas de resultado fueron la diferencia respecto a un grupo control en incidencia de crisis y hospitalizaciones, y en la calidad de vida de niños y cuidadores en los seis meses siguientes a la intervención.

Resultados: La tasa de crisis por paciente-año disminuyó cuando la intervención se dirigió sólo a los niños (diferencia media: -1.61, 95% IC: -2.87 a -0.34) o tanto a niños como a cuidadores (-1.60, 95% IC: -2.88 a -0.31). Las hospitalizaciones por paciente-año disminuyeron

en el grupo de intervención solo en niños -0.28 , 95%IC: -0.51 a -0.05) y en el de intervención en niños y cuidadores (-0.25 , 95% IC: -0.49 a -0.02). La educación sólo a cuidadores no se asoció con cambios en la morbilidad. No se observaron diferencias en calidad de vida entre los controles y ninguno de los grupos de intervención.

Conclusiones: La educación grupal en asma reduce la morbilidad, pero no mejora la calidad de vida. Los beneficios aparecen cuando esta educación se dirige a los niños, y no aumentan cuando se añade la intervención sobre los cuidadores. Finalmente, la intervención sólo sobre cuidadores no es efectiva.

Palabras clave: Asma. Niños. Cuidadores. Calidad de vida. Educación del paciente. Ensayo clínico. Estudio multicéntrico. Cuestionarios.

Introduction

Bronchial asthma is the most prevalent chronic disease in childhood and adolescence and has the greatest impact on the quality of life of patients and their relatives [1,2]. The Global Strategy for Asthma Management and Prevention states that the integral management of this disease should attempt to control the symptoms, maintain normal lung function, and prevent future complications [3]. Another important objective in the treatment of chronic diseases is to maintain a good quality of life in patients and their caregivers [4]. Health-related quality of life is classically defined as “the functional effects of a disease and of its ensuing therapy on a patient as perceived by the patient himself” [5], and it is one of the results that should be considered in clinical trials on asthma [6].

Education is an essential cornerstone in the management of asthma. A systematic review has shown that education in children improves lung function and decreases visits to the emergency department, increases self-efficacy, and reduces school absenteeism [7]. Various asthma education programs have been used for children, including individual or group education given by physicians, nurses, or teachers and applied at school, specialized clinics, or general clinics. Group education takes advantage of pair interaction to facilitate the transfer of knowledge, skills, and attitudes. While it is assumed that the results of individual education and group education are equivalent, no direct comparisons have been undertaken. In practice, patients included in asthma management programs generally receive individual education, while group education is less frequently used and is always provided to complement individual education.

Some studies have analyzed the efficacy of group education for asthmatic children applied in primary care clinics and assessed outcomes such as the number of unscheduled medical visits, number of visits to the emergency department, frequency of hospital admissions, and pulmonary function [8-10]. However, the effect of group education on quality of life has only been studied in the school environment [11-14]. There is no information about the effects on quality of life of group education programs applied in primary care. Once primary care pediatricians have been trained, they can provide effective disease management for children with asthma, including diagnosis, prescription, education, monitoring, and continuity of care [15].

In this study, we evaluated the efficacy of a group education program applied in a primary care setting for children with

asthma and their caregivers in terms of patient morbidity and quality of life of patients and their caregivers.

Methods

Objective

To establish the efficacy of group education on asthma aimed at schoolchildren with asthma and/or their caregivers in terms of morbidity and quality of life.

Design

International, controlled, randomized, open clinical trial in a primary care setting, with a factorial design carried out between January 2002 and June 2004. The interventions tested were group education in children with asthma and their adult caregivers. The study was approved by the clinical trials ethics committees from Asturias, Spain, Programa Regional de Asma Infantil, Uruguay, and Hospital Pediátrico Tarará, Cuba.

Participants

Children aged between 9 and 13 years with active asthma (symptoms of asthma or treatment for asthma in the previous 12 months), followed in 13 participating primary care centers (8 in Spain, 3 in Uruguay, and 2 in Cuba). The exclusion criteria were as follows: group education on asthma in the past 2 years (individual education was accepted) or completion at any previous time of a quality-of-life questionnaire.

Interventions

The intervention was performed in primary care centers by pediatricians and pediatric nurses who were experienced in the education of asthmatic children. The style, content, materials, and methods used in the intervention were the same at all the centers and were discussed and agreed among the investigators through a restricted-access website and a discussion forum. Patients and their caregivers received education in separate groups, each including 6 to 10 participants. The educational program was given in 3 sessions lasting 45 to 60 minutes each, provided at 2-week intervals.

The first session dealt with “What asthma is and the factors involved (causes and triggers),” the second dealt with

"Basic treatment and use of inhalers," and the third with "Asthma attacks and their management at home. Sports and children with asthma." In all sessions, emphasis was placed on control of the disease by the patient and issues related to self-management of asthma. All of the issues were introduced in a 2-way dialogue setting, using language appropriate for children or their caregivers. Written material, handouts with charts, inhaled placebos for practicing, peak expiratory flow meters, and a 3-dimensional model of the normal, inflamed, and obstructed bronchus were provided.

Outcomes

The primary endpoints of the study were morbidity due to asthma during the first 6 months after the intervention (number of asthma attacks and number of hospital admissions) and quality of life (1 month and 6 months after the intervention). As a secondary endpoint, the knowledge of asthma by patients and caregivers was assessed 1 month and 6 months after the intervention.

Study Development

At the baseline visit, the caregivers signed an informed consent form. Epidemiological and asthma-related morbidity data were collected. A survey of knowledge of asthma and a quality-of-life questionnaire were administered to patients and caregivers. After the 3 educational sessions, the participants were called together for 2 evaluations, the first 15 to 30 days after the last educational session and the second 5 to 6 months later. In the first evaluation, the quality-of-life questionnaires and the knowledge survey were repeated. In the second, the questionnaire and survey were repeated and additional data on asthma morbidity in the 6 previous months were also collected.

Instruments

Information on asthma morbidity in the previous 6 months was obtained through asking the parents and reviewing the patient's medical records. An asthma attack was defined as worsening of the asthma symptoms leading to a nonscheduled medical visit or a visit to an emergency room. The number of hospital admissions for asthma, antiinflammatory drugs used, and other data were also recorded to classify asthma based on Global Initiative for Asthma (GINA) criteria [3]. Quality of life was evaluated with the Paediatric Asthma Quality of Life Questionnaire (PAQLQ) [16] and Paediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ) [17], using the versions with standardized activities that have been translated and validated in Spanish [18-20]. Those questionnaires score asthma-related quality of life between 1 (worst quality of life) and 7 (best quality of life), globally and in 3 specific dimensions: symptoms (only in patients), activity limitation, and emotional function. A questionnaire was provided on knowledge of asthma in patients and their caregivers. The questionnaire contained 10 statements for which the participants answered true or false, assessing knowledge of asthma, sport, smoking, triggering factors, use

of drugs, myths, and beliefs. Each correct answer was scored as 1 point, meaning that the results could range from 0 points (lowest knowledge) to 10 points (highest knowledge). Other clinical and epidemiological data were obtained through direct interview with caregivers and from medical records: years since the onset of asthma, history of asthma in the same household, educational level of the primary caregiver, number of people living in the home, parents' profession, and whether patients had received individual education on asthma (to include all of the following issues: what asthma is, triggering factors and prevention, management, use of inhaled treatments, and approach to dealing with asthma attack).

Although the 3 countries involved in the study share the same language, there are nuances in terms of dialect. Since the quality-of-life questionnaires have not been validated in either Cuba or Uruguay, a pilot study was performed in those countries to evaluate the understanding of both the questionnaire on knowledge and of the Spanish version of the quality-of-life questionnaire. This pilot study was conducted in 10 families (not participating in the study) per country. As a result, 4 words were changed in the questionnaire on knowledge but no changes were made in the quality-of-life questionnaires.

Sample Size

According to Juniper et al [16], the minimum clinically significant difference in the total score for quality of life in the PAQLQ is 0.5 points, with an SD between subjects of 0.75 points. Based on those figures, we calculated a minimum of 46 children in each group to detect such a difference, with a power of 0.90 and an α (bilateral) risk of 0.05.

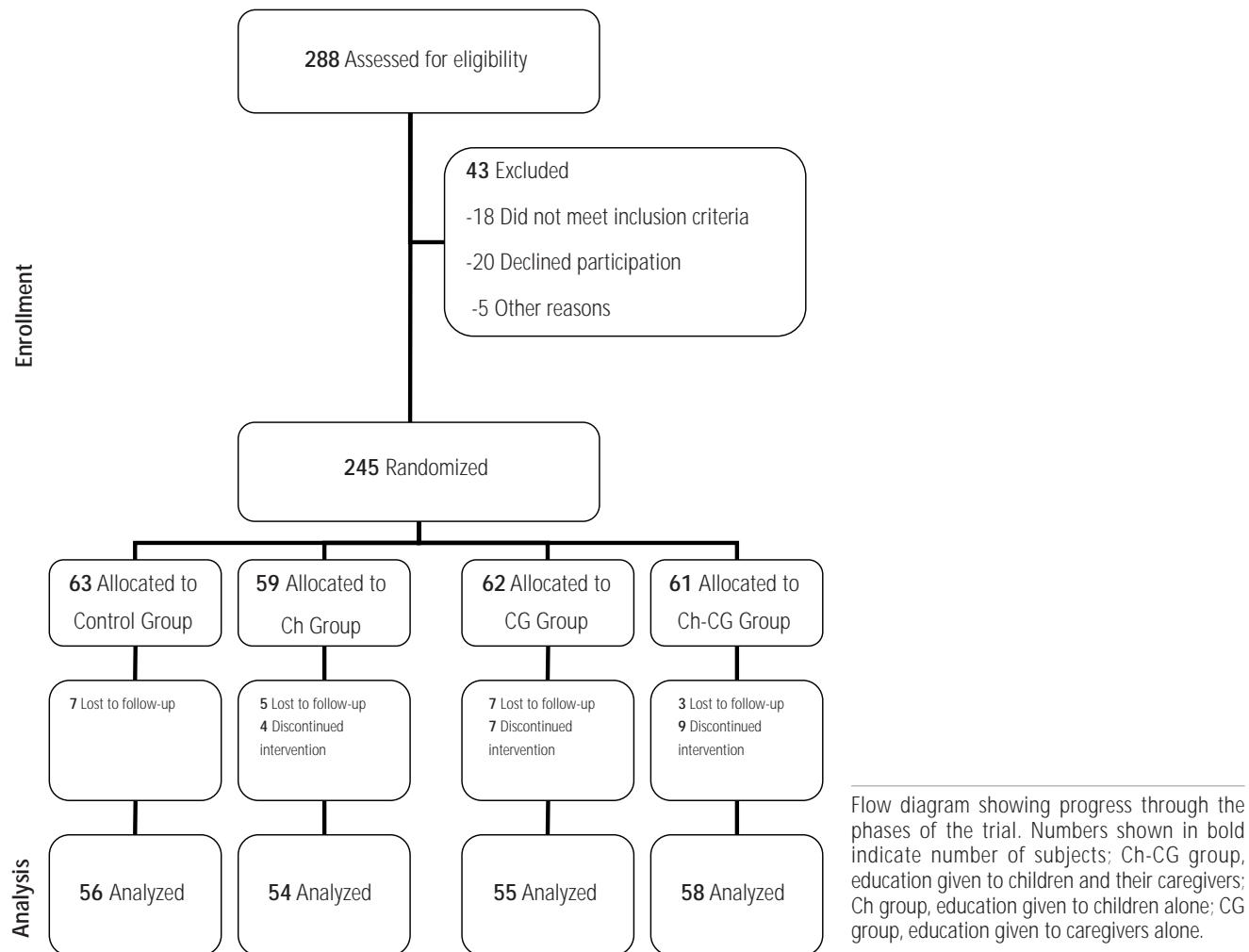
Selection and Randomization

Each center prepared a census of patients who met the inclusion criteria, stratified in 5 age groups: 9, 10, 11, 12, and 13 years. The allocation was made at each center. From an opaque box, papers with the names of the patients were taken at random and assigned consecutively to each of the 4 study groups according to a previously established order: controls, group education to children and their caregivers (Ch-CG group), group education to children alone (Ch group), and group education to caregivers alone (CG group).

Statistical Methods

The principle of analysis by intention to treat was followed. The number of asthma attacks and hospital admissions in the previous 6 months and after the intervention were transformed into annual rates. Changes occurring during follow-up in terms of morbidity, quality of life, and knowledge of asthma were analyzed within each group by paired *t* tests. The results are expressed as means and 95% confidence interval (CI).

Between-group differences were analyzed through multiple regression models, using the controls as the reference group. The models were adjusted by age, sex, country, educational level of the main caregiver (primary, secondary, or university), years from the onset of asthma, and severity of asthma according to the 4 levels of GINA classification. The results



are expressed as adjusted mean difference compared with the control group and 95% CI. The statistical analysis was carried out with the statistical package SPSS 11.0.

A change of 0.5 points or higher in the PAQLQ [16] and PACQLQ [17] scores was considered to be clinically significant, and the number of patients needed to treat (NNT) to obtain a clinical improvement was calculated according to the method proposed by Guyatt et al [21].

Results

Two hundred and eighty-eight children were evaluated for eligibility in the study, 245 of whom were included and distributed among the 4 groups. The figure shows the progress of patients through the trial and the causes of exclusion, and Table 1 shows the baseline patient characteristics. There were no differences among the groups in terms of baseline clinical and demographic variables.

Attendance at the educational sessions was greater in the children than in the caregivers: 85.8%, 11.7%, and 2.5% of the children attended a total of 3, 2, and 1 of the scheduled sessions,

respectively, while the equivalent rates for the caregivers were 80.5%, 12.2%, and 4.9%, respectively, and 2.4% of the caregivers did not attend any of the sessions. Twenty-two children (8.9%) were lost to follow-up: 7 (11.1%) in the control group and 5 (8.5%), 7 (11.3%), and 3 (4.9%) in the Ch, CG, and Ch-CG groups, respectively. Those patients were excluded from the analysis. All of the others were analyzed within the group that they had initially been assigned to, even if compliance with the intervention was absent or only partial.

Morbidity

The incidence of asthma attack was the same before and after the intervention in the control group, but in the other 3 groups it decreased significantly, falling by 67.9%, 47.5%, and 63.6% in the Ch, CG, and Ch-CG groups, respectively (Table 2). In the adjusted model, after the intervention there were fewer asthma attacks in the Ch and Ch-CG groups than in the control group (Table 3). The rates of hospital admission for asthma decreased after the intervention in the Ch group. In the Ch-CG group, there was a reduction of the same magnitude that was not statistically significant (Table 2). In the adjusted model, hospital admissions

Table 1. Baseline Demographic and Clinical Data*

	Total	Control	Intervention in Children Alone	Intervention in Caregivers Alone	Intervention in Children and Caregivers
No.	245	63	59	62	61
Country					
Spain	63.3%	63.5%	62.7%	62.9%	63.9%
Cuba	14.7%	15.9%	13.6%	14.5%	14.8%
Uruguay	22.0%	20.6%	23.7%	22.6%	21.3%
Age, y	11.0 ± 1.4	11.1 ± 1.5	11.0 ± 1.4	10.9 ± 1.4	11.0 ± 1.4
Men	64.9%	55.6%	71.0%	73.8%	59.3%
Duration of asthma, y	6.5 ± 3.0	6.3 ± 3.0	6.5 ± 3.2	6.5 ± 3.1	6.7 ± 2.7
Primary caregiver					
Mother	88.2%	87.3%	89.8%	88.7%	86.9%
Father	7.3%	6.3%	6.8%	4.8%	11.5%
Other	4.5%	6.4%	3.4%	6.4%	1.6%
Educational level of primary caregiver					
Primary	47.3%	51.6%	49.2%	44.3%	44.3%
Secondary	38.3%	32.3%	39.0%	42.6%	39.3%
University	14.4%	16.1%	11.9%	13.1%	16.4%
Occupation of primary caregiver					
Homemaker	38.0%	43.5%	30.5%	38.7%	39.3%
Employed	58.2%	51.6%	67.8%	56.5%	57.4%
Other	3.8%	4.8%	1.7%	4.8%	3.2%
People at home, n	4.1 ± 1.1	4.2 ± 1.3	4.3 ± 1.0	3.9 ± 0.9	4.1 ± 0.9
Severity of asthma					
Mild intermittent	35.2%	45.2%	32.2%	32.3%	31.1%
Mild persistent	36.5%	33.9%	40.7%	40.3%	31.1%
Moderate	23.8%	16.1%	22.0%	25.8%	31.1%
Severe	4.5%	4.8%	5.1%	1.6%	6.6%
Antiinflammatory treatment in the past 6 months	62.3%	56.5%	62.7%	61.3%	68.9%
Received individual education on asthma	85.3%	86.9%	84.7%	87.1%	85.2%

*Data are shown as means ± SD or percentages

were less frequent after the intervention in the Ch and Ch-CG groups than in the control group (Table 3).

Quality of Life in Children

The mean ± SD PAQLQ score before the intervention was 5.87 ± 1.12 . The mean scores by dimensions were as follows: symptoms, 5.73 ± 1.28 ; activity limitation, 5.75 ± 1.20 ; and emotional function, 6.14 ± 1.08 . No statistically significant differences were observed among the 4 groups (Table 4).

In all the groups, the PAQLQ score increased 1 month after the intervention and remained above the initial values 6 months later (Table 4). This improvement was observed in the total PAQLQ score and in each of its 3 dimensions.

Six months after the intervention, 34.9% of the children in the control group had increased their total PAQLQ score by at least 0.5 points (minimum clinically significant difference). The corresponding values for the Ch, CG, and Ch-CG groups were 44.1%, 41.9%, and 42.6%, respectively. The NNT for a clinically significant improvement in the total PAQLQ at 6

Table 2. Within-Group Changes in Morbidity and Knowledge During Follow-Up*

	Control	Intervention in Children Alone	Intervention in Caregivers Alone	Intervention in Children and Caregivers
No.	56	54	55	58
Asthma attacks per y				
Baseline	2.83 ± 6.62	2.24 ± 3.02	2.23 ± 2.61	2.61 ± 3.43
Follow-up	2.31 ± 7.40	0.72 ± 1.58	1.17 ± 1.74	0.95 ± 1.63
Difference	-0.52 (-1.11 to 0.08)	-1.52 (-2.07 to -0.97)‡	-1.07 (-1.78 to -0.36)‡	-1.66 (-2.39 to -0.94)‡
Hospital admissions per y				
Baseline	0.14 ± 0.74	0.24 ± 0.76	0.20 ± 0.80	0.31 ± 0.90
Follow-up	0.28 ± 1.32	0.00 ± 0.00	0.07 ± 0.36	0.07 ± 0.37
Difference	0.14 (-0.03 to 0.30)	-0.24 (-0.44 to -0.04) †	-0.13 (-0.32 to 0.05)	-0.24 (-0.49 to 0.02)
Children's knowledge				
Baseline	8.04 ± 1.41	8.04 ± 1.36	8.35 ± 1.53	8.17 ± 1.21
1 month	8.24 ± 1.65	9.12 ± 1.25	8.52 ± 1.41	8.93 ± 1.33
6 months	8.32 ± 1.45	8.94 ± 1.27	8.81 ± 1.27	9.00 ± 1.30
Difference 0–1 month	0.20 (-0.20 to 0.60)	1.08 (0.69 to 1.47)‡	0.17 (-0.18 to 0.52)	0.76 (0.39 to 1.13)‡
Difference 0–6 months	0.28 (-0.08 to 0.64)	0.90 (0.52 to 1.28)‡	0.46 (0.06 to 0.86)†	0.83 (0.50 to 1.17)‡
Caregivers' knowledge				
Baseline	8.11 ± 1.37	8.10 ± 1.16	7.98 ± 1.13	8.00 ± 1.03
1 month	9.05 ± 0.94	9.11 ± 1.02	9.15 ± 1.17	9.22 ± 0.93
6 months	9.14 ± 0.95	9.11 ± 0.99	9.22 ± 1.15	9.36 ± 1.03
Difference 0–1 month	0.93 (0.58 to 1.29)‡	1.00 (0.65 to 1.35)‡	1.17 (0.84 to 1.51)‡	1.22 (0.93 to 1.51)‡
Difference 0–6 months	1.02 (0.70 to 1.34)‡	1.00 (0.69 to 1.31)‡	1.24 (0.86 to 1.62)‡	1.36 (1.04 to 1.68)‡

*Data are shown as means ± SD or the mean difference (95% confidence interval) of the within-group changes. † $P < .05$; ‡ $P < .01$.

months was 9.0 (Ch group), 12.0 (CG group), and 13.5 (Ch-CG group).

There were no differences between the intervention and the control groups in either the total PAQLQ score or its 3 specific dimensions at any point during follow-up (Table 3).

Quality of Life in Caregivers

The mean PACQLQ score before the intervention was 5.83 ± 1.20 . The mean PACQLQ scores by dimensions were 5.92 ± 1.30 for activity limitation and 5.73 ± 1.21 for emotional function. There were no significant differences among the 4 groups (Table 4).

The total PACQLQ score and the specific score on the emotional function dimension had improved significantly in the 3 intervention groups 1 month after the intervention, and at 6 months those scores had also improved in the control group (Table 4). The activity limitation dimension only improved in the Ch and Ch-CG groups at 1 months and 6 months (Table 4).

Six months after the intervention, 31.4% of the caregivers in the control group had increased their total PACQLQ score by at least 0.5 points (minimum clinically significant difference). The corresponding figures for the Ch, CG, and Ch-CG groups were 43.6%, 36.0%, and 48.2%, respectively. The NNT for a clinically significant improvement in the total PACQLQ at 6 months was 7.7 in the Ch group, 24.6 in the CG group, and 4.3 in the Ch-CG group.

There were no differences between the intervention and the control groups in either the total PACQLQ or in its 2 specific dimensions at any point in follow-up (Table 3).

Knowledge in Children

The mean score for knowledge of asthma in children before the intervention was 8.13 ± 1.38 , with no significant differences among the 4 groups (Table 2).

The children's knowledge of asthma in the control group did not change during the follow-up period. In the Ch and Ch-CG groups, knowledge of asthma had improved at 1 month after the intervention. At 6 months, the children's knowledge had also improved in the CG group (Table 2).

The children in the Ch and Ch-CG groups obtained higher ratings than the control group at 1 month and 6 months. At 6 months, the children's knowledge in the CG group was greater than in the control group (Table 3).

Knowledge in Caregivers

The mean score for knowledge of asthma in the caregivers before the intervention was 8.03 ± 1.17 . There were no significant differences among the 4 groups, and in all of the groups the caregivers' knowledge had improved at 1 month and 6 months after the intervention (Table 2). No group obtained better results than in the control group (Table 3).

Table 3. Between-Group Adjusted Differences*

	Intervention in Children Alone	Intervention in Caregivers Alone	Intervention in Children and Caregivers
Asthma attacks per y	-1.61 (-2.87 to -0.34)†	-0.88 (-2.15 to 0.40)	-1.60 (-2.88 to -0.31)†
Hospital admissions per y	-0.28 (-0.51 to -0.05)†	-0.17 (-0.40 to 0.07)	-0.25 (-0.49 to -0.02)†
Total PAQLQ score			
1 month	0.09 (-0.22 to 0.40)	0.10 (-0.21 to 0.41)	0.10 (-0.21 to 0.41)
6 months	0.21 (-0.12 to 0.54)	0.00 (-0.33 to 0.34)	0.11 (-0.22 to 0.44)
PAQLQ symptoms dimension			
1 month	0.11 (-0.22 to 0.45)	0.04 (-0.29 to 0.37)	0.05 (-0.28 to 0.38)
6 months	0.22 (-0.15 to 0.59)	-0.00 (-0.38 to 0.37)	0.12 (-0.25 to 0.49)
PAQLQ activities dimension			
1 month	0.15 (-0.21 to 0.50)	0.16 (-0.20 to 0.52)	0.12 (-0.23 to 0.48)
6 months	0.28 (-0.08 to 0.63)	0.07 (-0.29 to 0.43)	0.08 (-0.28 to 0.44)
PAQLQ emotional dimension			
1 month	-0.06 (-0.39 to 0.28)	0.25 (-0.10 to 0.59)	0.13 (-0.21 to 0.47)
6 months	0.12 (-0.18 to 0.41)	-0.08 (-0.38 to 0.22)	0.12 (-0.18 to 0.42)
Total PACQLQ scores			
1 month	-0.03 (-0.37 to 0.31)	0.20 (-0.14 to 0.54)	0.12 (-0.21 to 0.46)
6 months	-0.14 (-0.48 to 0.21)	0.07 (-0.29 to 0.43)	0.31 (-0.04 to 0.67)
PACQLQ-activities dimension			
1 month	-0.05 (-0.43 to 0.32)	0.16 (-0.22 to 0.54)	0.11 (-0.26 to 0.49)
6 months	-0.12 (-0.50 to 0.25)	0.04 (-0.34 to 0.42)	0.35 (-0.03 to 0.72)
PACQLQ emotional dimension			
1 month	-0.06 (-0.39 to 0.28)	0.25 (-0.10 to 0.59)	0.13 (-0.21 to 0.47)
6 months	-0.15 (-0.50 to 0.21)	0.10 (-0.27 to 0.46)	0.28 (-0.08 to 0.65)
Children's knowledge			
1 month	0.73 (0.20 to 1.26)‡	0.28 (-0.26 to 0.81)	0.66 (0.13 to 1.19)†
6 months	0.61 (0.09 to 1.13)†	0.62 (0.09 to 1.15)†	0.74 (0.22 to 1.26)‡
Caregivers' knowledge			
1 month	0.09 (-0.27 to 0.44)	0.10 (-0.26 to 0.45)	0.24 (-0.11 to 0.59)
6 months	-0.08 (-0.46 to 0.29)	0.03 (-0.35 to 0.41)	0.16 (-0.22 to 0.53)

*Data are shown as the mean difference (95% confidence interval), adjusted for age, sex, country, educational level of the main caregiver, and duration and severity of asthma. The control group was used as the reference group.

PAQLQ indicates Paediatric Asthma Quality of Life Questionnaire; PACQLQ, Paediatric Asthma Caregiver's Quality of Life Questionnaire. † $P < .05$;

‡ $P < .01$.

Discussion

The results of our study show that group education aimed at children with asthma improves morbidity and knowledge of the disease but not quality of life, and that group intervention in the caregivers does not provide any improvement in the issues studied. Although we were not able to demonstrate quality-of-life changes, there was a marked improvement in morbidity as a result of group education in children and the frequency of asthma attacks decreased by approximately 1.6 attacks per patient-year compared with the control group (adjusted results).

At present, education is considered to be one of the bases of the management of asthma in adult and pediatric patients [3]. In a systematic review of clinical trials published until 1998, Wolf et al [7] found that education of children with asthma aimed at self-management improves pulmonary function and self-efficacy and reduces the days of school absence and restricted activities, the number of nights with asthma, and the number of visits to the emergency department, but has no clear effect on asthma attacks or hospital admissions. That review included 18 studies of group or combination interventions and the efficacy of those interventions was found to be similar to individual education, although no study compared them directly. Since most of our patients had received a complete

Table 4. Within-Group Quality-of-Life Changes During Follow-up (PAQLQ and PACOLQ questionnaires)*

	Control	Intervention in Children Alone	Intervention in Caregivers Alone	Intervention in Children and Caregivers
No.	56	54	55	58
Children (total)				
Baseline	5.91 ± 1.12	5.76 ± 1.19	5.81 ± 1.21	5.90 ± 1.05
1 month	6.09 ± 1.09	6.23 ± 1.06	6.23 ± 1.01	6.24 ± 0.94
6 months	6.29 ± 0.89	6.40 ± 0.86	6.27 ± 1.11	6.34 ± 0.89
Difference 0-1 month	0.19 (0.02 to 0.36)†	0.48 (0.28 to 0.66)‡	0.42 (0.19 to 0.65)‡	0.34 (0.18 to 0.50)‡
Difference 0-6 months	0.38 (0.16 to 0.60)‡	0.64 (0.41 to 0.88)‡	0.47 (0.25 to 0.68)‡	0.43 (0.19 to 0.68)‡
Children (symptoms)				
Baseline	5.85 ± 1.21	5.62 ± 1.44	5.65 ± 1.37	5.80 ± 1.15
1 month	6.06 ± 1.11	6.22 ± 1.10	6.11 ± 1.07	6.14 ± 0.95
6 months	6.23 ± 0.92	6.33 ± 0.93	6.19 ± 1.17	6.25 ± 0.97
Difference 0-1 month	0.21 (0.01 to 0.41)‡	0.60 (0.33 to 0.87)‡	0.46 (0.16 to 0.75)‡	0.34 (0.13 to 0.56)‡
Difference 0-6 months	0.38 (0.09 to 0.66)‡	0.71 (0.37 to 1.04)‡	0.54 (0.27 to 0.81)‡	0.45 (0.15 to 0.76)‡
Children (activities)				
Baseline	5.75 ± 1.19	5.62 ± 1.27	5.76 ± 1.25	5.71 ± 1.18
1 month	5.96 ± 1.20	6.14 ± 1.11	6.16 ± 1.07	6.14 ± 1.03
6 months	6.16 ± 1.06	6.39 ± 0.91	6.27 ± 1.14	6.21 ± 1.02
Difference 0-1 month	0.21 (0.00 to 0.41)†	0.52 (0.28 to 0.77)‡	0.40 (0.15 to 0.65)‡	0.42 (0.22 to 0.63)‡
Difference 0-6 months	0.41 (0.17 to 0.66)‡	0.77 (0.50 to 1.04)‡	0.51 (0.29 to 0.74)‡	0.50 (0.21 to 0.79)‡
Children (emotional)				
Baseline	6.13 ± 1.05	6.12 ± 1.11	6.02 ± 1.15	6.19 ± 1.07
1 month	6.28 ± 1.07	6.36 ± 1.07	6.41 ± 0.99	6.45 ± 0.96
6 months	6.44 ± 0.85	6.53 ± 0.83	6.39 ± 1.13	6.57 ± 0.82
Difference 0-1 month	0.15 (-0.02 to 0.31)	0.25 (0.10 to 0.39)‡	0.39 (0.19 to 0.59)‡	0.26 (0.06 to 0.45)‡
Difference 0-6 months	0.31 (0.13 to 0.49)‡	0.41 (0.24 to 0.59)‡	0.36 (0.15 to 0.58)‡	0.38 (0.17 to 0.59)‡
Caregivers (total)				
Baseline	5.84 ± 1.28	5.69 ± 1.21	5.87 ± 1.08	5.83 ± 1.28
1 month	6.07 ± 1.22	6.04 ± 1.20	6.18 ± 0.82	6.19 ± 0.85
6 months	6.19 ± 1.06	6.01 ± 1.14	6.22 ± 0.92	6.44 ± 0.84
Difference 0-1 month	0.23 (-0.04 to 0.51)	0.35 (0.12 to 0.57)‡	0.31 (0.04 to 0.57)†	0.36 (0.15 to 0.57)‡
Difference 0-6 months	0.35 (0.05 to 0.65)†	0.32 (0.10 to 0.54)‡	0.35 (0.02 to 0.67)†	0.60 (0.28 to 0.93)‡
Caregivers (activities)				
Baseline	5.90 ± 1.36	5.74 ± 1.49	5.98 ± 1.09	5.95 ± 1.34
1 month	6.15 ± 1.29	6.10 ± 1.26	6.20 ± 0.87	6.23 ± 0.96
6 months	6.21 ± 1.11	6.10 ± 1.15	6.28 ± 0.98	6.50 ± 0.84
Difference 0-1 month	0.25 (-0.06 to 0.57)	0.37 (0.08 to 0.65)†	0.22 (-0.09 to 0.53)	0.28 (0.05 to 0.52)†
Difference 0-6 months	0.31 (-0.02 to 0.65)	0.36 (0.03 to 0.70)†	0.30 (-0.06 to 0.65)	0.56 (0.22 to 0.90)‡
Caregivers (emotional)				
Baseline	5.79 ± 1.23	5.53 ± 1.22	5.76 ± 1.19	5.74 ± 1.27
1 month	5.99 ± 1.27	5.93 ± 1.21	6.17 ± 0.84	6.13 ± 0.83
6 months	6.13 ± 1.07	5.95 ± 1.23	6.21 ± 0.93	6.38 ± 0.88
Difference 0-1 month	0.20 (-0.04 to 0.44)	0.40 (0.17 to 0.63)‡	0.41 (0.15 to 0.67)‡	0.39 (0.16 to 0.61)‡
Difference 0-6 months	0.34 (0.08 to 0.61)†	0.42 (0.19 to 0.66)‡	0.44 (0.14 to 0.75)‡	0.64 (0.33 to 0.96)‡

*Data are shown as means ± SD or the mean difference (95% confidence interval) of the within-group changes. PAQLQ indicates Paediatric Asthma Quality of Life Questionnaire; PACOLQ, Paediatric Asthma Caregiver's Quality of Life Questionnaire. † $P < .05$; ‡ $P < .01$.

individual education, our study addressed whether group education provides additional benefit over individual education alone. Individual education is the most common educational intervention in primary care settings, where it is part of the integrated care program for asthma treatment.

In the review by Wolf et al [7], no group intervention study analyzed the impact on quality of life. Although subsequent studies did analyze this variable, the results were inconsistent. While some found certain improvement in PAQLQ score [11-13], others did not [14]. All of those studies were performed in schools, with educational sessions directed by nurses, teachers, or students. This is the main difference from our study, which was carried out within a primary care setting, with an educational intervention provided by pediatricians and nurses with direct healthcare responsibilities.

The quality of life of the caregivers of children with asthma improves with provision of antiinflammatory treatment in the children [22], but the influence of education has been little studied. In a study by Dolinar et al [23], the quality of life of caregivers did not improve as a result of individual home education. In our study, we found no improvement in caregiver quality of life as a result of any group education modality. Thus, quality of life of the caregivers appears to be determined by the severity of asthma [24] and factors such as the caregiver affect [25].

The disagreement between quality of life and other measures for controlling asthma is a recognized phenomenon that depends on the severity of the disease [26]. Quality-of-life scales appear to measure issues that differ from those influencing pulmonary function, symptoms, need for rescue bronchodilators, or airway inflammation markers [27,28]. Some factors may have influenced the disagreement between the results for quality of life and morbidity in our study. Firstly, morbidity and quality of life followed a different natural course. The quality-of-life scores improved in patients and their caregivers in all groups, including the controls, although the change of 0.5 points considered clinically significant was generally not reached. However, there was no improvement in morbidity in the control group, for which the same rates of asthma attack and hospital admission were observed. Secondly, mild asthma attacks probably do not cause a significant impairment in quality of life. Although we did not measure the severity of the attacks, most of them were probably mild. Hospital admissions can have a greater effect on quality of life, but they were scarce. Finally, our patients had an initially high quality of life, with a higher overall score than the one reached after intervention in other educational group studies [11,13]. Cicutto et al [12] found an improvement in quality of life associated with a reduction in the number of asthma attacks that was much lower than the one obtained by us; however, in that study the PAQLQ score obtained after the intervention was lower than our initial score. In a scale with an upper limit, such as the PAQLQ, significant increases are unlikely to occur when the initial values are high. Finally, it is obvious that measurements of quality of life and morbidity address different factors, and from our results it is clear that quality of life is more difficult to modify.

An improvement in morbidity compared to controls was only found when group education was aimed at children,

and that effect did not change by adding provision of group education to caregivers. Our patients were older children and it is therefore possible that they were mainly responsible for their own care. Educating their caregivers appears to provide few advantages, but educating the patients, together with other children of their age, offers the added benefits of social group interaction.

Individual education is provided to patients together with their caregivers, and in that face-to-face situation, caregivers play the main role, leaving the child in the background. Therefore, individual education acts mainly on caregivers and their subsequent participation in group education activities adds no further benefits. In children, group education where they are in a situation together with their peers can be more effective in improving their responsibility towards the disease. The secondary results of our study support this hypothesis. Group education to caregivers does not improve their knowledge of asthma as compared to controls, while group education to children does increase their knowledge of the disease.

Our results are applicable to patients in the age range studied (9–13 years) with persistent asthma (mild or moderate) who require maintenance treatment and are regularly managed by pediatric primary care and receive individual education on asthma. The source of the patients from primary care prevents the bias introduced by hospital-based selection. Furthermore, this is an international study in which countries with markedly different economic and social conditions have participated, thereby increasing the applicability of the results.

This study has certain potential limitations: a) The follow-up period of only 6 months did not allow us to establish the duration of the effect of group education. Over time, some of the knowledge provided by education is lost [29], meaning that educational actions should be repeated. b) The initially high quality of life of our patients may have masked the effect of the intervention, and it is likely that quality of life improves when group education is applied to patients with a worse initial condition. c) The heterogeneity of the population studied is likely to have caused some reduction in the effect of group education on all outcomes tested, while increasing the external validity of the results. d) We used a questionnaire on knowledge that has not been subject to a formal validation procedure, and therefore, could yield inaccurate or biased measures of the knowledge of asthma. e) Compliance was lower in caregivers, and that may have reduced the effect of their education in the analysis by intention to treat. f) Some changes in morbidity and quality of life during follow-up may have been due to the seasonal nature of asthma, and this may even have been exaggerated by the international nature of the study; however, that cannot have affected the differences between groups, because each center compiled the data from all participants at the same time. g) The values of SD for quality of life were higher than those initially estimated for the determination of the sample size, so our analysis had only a 64% power to detect a difference of 0.5 for quality-of-life score as significant (minimum clinically significant difference). However, the mean differences found in quality of life compared with the control group were well below 0.5 (Table 3). h) We transformed the rates of asthma attack and hospital admission into annual means, although the follow-up

was only conducted for 6 months. However, the measurement error that this may have caused did not affect the differences between groups (equal results without transformation, data not shown), and the results are easier to understand when expressed as annual rates.

In conclusion, group education provided in a primary care setting for children with asthma is associated with lower asthma morbidity, while education provided to their adult caregivers does not provide any additional benefit. Future studies should compare the efficacy of adding a group education program versus increased medication in selected patients with persistent morbidity despite provision of treatment and individual education.

Acknowledgments

We thank the children and their parents for their enthusiastic participation in this study. We also thank the pediatricians and pediatric nurses who enrolled the patients and performed the group education in each center:

In Spain: Javier Blanco-González (center coordinator), Begoña Domínguez-Aurrecoechea (center coordinator), Carmen Fernández-Carazo (center coordinator), Agueda García-Merino (center coordinator), Antonio Jiménez-Cortés (center coordinator), Juan José Morell-Bernabé (center coordinator), Jesús Rodríguez-García, Angel José Carbajo-Ferreira, María Dolores Chica-Mora, Carmen Díez-Fernández, María Expósito-Sáez, María Dolores Gómez-Albarrán, Lidia González-Guerra, Manuel Romero-García, Josefina Sánchez-Gómez. In Uruguay: Elena Isabel García-Martínez (center coordinator), Gretel María Morena-Borrell (center coordinator), Adelia María Lemos-Cavagnin (center coordinator), Beatriz Lemes-Correia, Marcos Carambula-Volpi, Lourdes Salvo. In Cuba: Tania Raymond-Villena (center coordinator), Elianny Estévez de la Torre, Angelina Fumero-Madam, Adelquis Guerrero-Betancourt, Mirna Rodríguez-Pérez, Daysi Sánchez-Picouto.

References

- Masoli M, Fabian D, Holt S, Beasley R. The Global Burden of Asthma: executive summary of the GINA Dissemination Committee Report. *Allergy*. 2004;59:469-78
- Tamburini G, von Ehrenstein OS, Bertollini R. Children's health and environment: A review of evidence. A joint report from the European Environment Agency and the WHO Regional Office for Europe. EIP Report nº 29, 2002
- Global Strategy for Asthma Management and Prevention (Updated 2005). NIH Publication No 02-3659
- Juniper EH. How important is quality of life in pediatric asthma? *Pediatr Pulmonol*. 1997;Suppl 15:17-21
- Schipper H, Clinch J, Powell V. Definitions and conceptual issues. In: Spilker B, editor. *Quality of life assessment in clinical trials*. New York: Raven Press; 1990. p. 11-24
- Silverman M. Choosing the right outcomes. *Allergy*. 1999;54:35-41
- Wolf FM, Guevara JP, Grum CM, Clark NM, Cates CJ. Educational interventions for asthma in children. *Cochrane Database Syst Rev*. 2003; (1): CD000326
- Shields MC, Griffin KW, McNabb WL. The effect of a patient education program on emergency room use for inner-city children with asthma. *Am J Public Health*. 1990;80:36-8
- Weingarten MA, Goldberg J, Teperberg Y. A pilot study of the multidisciplinary management of childhood asthma in a family practice. *J Asthma*. 1985;22:261-5
- Lewis CE, Rachelefsky G, Lewis MA, De la Sota MA, Kaplan M. A randomized trial of A.C.T. (Asthma Care Training) for Kids. *Pediatrics*. 1984;74:478-86
- Shah S, Peat JK, Mazurski EJ, Wang H, Sindhusake D, Bruce C, Henry RL, Gibson PG. Effect of peer led programme for asthma education in adolescents: cluster randomised controlled trial. *BMJ*. 2001;322:583-5.
- Cicutto L, Murphy S, Coutts D, O'Rourke J, Lang G, Chapman C, Coates P. Breaking the access barrier: Evaluating an Asthma Center's efforts to provide education to children with asthma in schools. *Chest*. 2005;128:1928-35
- Henry RL, Gibson PG, Vimpani GV, Francis JL, Hazell J. Randomized controlled trial of a teacher-led asthma education program. *Pediatr Pulmonol*. 2004;38:434-42
- Patterson EE, Brennan MP, Linskey KM, Webb DC, Shields MD, Patterson CC. A cluster randomised intervention trial of asthma clubs to improve quality of life in primary school children: The School Care and Asthma Management Project (SCAMP). *Arch Dis Child*. 2005;90:786-91
- Evans D, Mellins R, Lobach K, Ramos-Bonoan C, Wiesemann S, Klein I, Donahue C, Burke D, Levison M, Levin B, Zimmerman B, Clark N. Improving care for minority children with asthma: professional education in public health clinics. *Pediatrics*. 1997;99:157-64
- Juniper EF, Guyatt GH, Feeny DH, Ferrie PJ, Griffith LE, Townsend M. Measuring quality of life in children with asthma. *Quality of Life Research*. 1996;5:35-46
- Juniper EF, Guyatt GH, Feeny DH, Ferrie PJ, Griffith LE, Townsend M. Measuring quality of life in the parents of children with asthma. *Quality of Life Research*. 1996;5:27-34
- Tauler E, Vilagut G, Grau G, Gonzalez A, Sanchez E, Figueras G, Vall O, Ferrer M, Alonso J. The Spanish version of the paediatric asthma quality of life questionnaire (PAQOL): metric characteristics and equivalence with the original version. *Qual Life Res*. 2001;10(1):81-91
- Alonso Lebrero E. Utilization and clinical validation of the Spanish version of the Pediatric Asthma Quality of Life Questionnaire (PAQOL) and the Diary for Caregivers of Asthmatic Children (DCA). VALAIR study [in Spanish]. *Allergol Immunopathol (Madr)*. 2000;28:175-83
- Badia X, García-Hernández G, Cobos N, López-David C, Nocea G, Roset M. Validity of the Spanish version of the Pediatric Quality of Life Questionnaire for evaluating quality of life in asthmatic children [in Spanish]. *Med Clin (Barc)*. 2001;16:565-72
- Guyatt GH, Juniper EF, Walter SD, Griffith LE, Goldstein RS. Interpreting treatment effects in randomised trials. *BMJ*. 1998; 316:690-3
- Murphy KR, Fitzpatrick S, Cruz-Rivera M, Miller CJ, Parasuraman B. Effects of budesonide inhalation suspension compared with cromolyn sodium nebulizer solution on health status and caregiver quality of life in childhood asthma. *Pediatrics*. 2003; 112(3):e212-9

23. Dolinar RM, Kumar V, Coutu-Wakulczyk G, Rowe BH. Pilot study of a home-based asthma health education program. *Patient Educ Couns.* 2000;40:93-102
24. Halterman JS, Yoos HL, Conn KM, Callahan PM, Montes G, Neely TL, Szilagyi PG. The impact of childhood asthma on parental quality of life. *J Asthma.* 2004;41:645-53
25. Price MR, Bratton DL, Klinnert MD. Caregiver negative affect is a primary determinant of caregiver report of pediatric asthma quality of life. *Ann Allergy Asthma Immunol.* 2002;89:572-77
26. Moy ML, Israel E, Weiss ST, Juniper EF, Dubé L, Drazen JM. Clinical predictors of health-related quality of life depend on asthma severity. *Am J Respir Crit Care Med.* 2001;163:924-29
27. Juniper EF, Wisniewski ME, Cox FM, Emmett AH, Nielsen KE, O'Byrne PM. Relationship between quality of life and clinical status in asthma: a factor analysis. *Eur Respir J.* 2004;23:287-91
28. Ehrs PO, Sundblad BM, Larsson K. Quality of life and inflammatory markers in mild asthma. *Chest.* 2006;129:624-31
29. Shames RS, Sharek P, Mayer M, Robinson TN, Hoyte EG, Gonzalez-Hensley F, Bergman DA, Umetsu DT. Effectiveness of a multicomponent self-management program in at-risk, school-aged children with asthma. *Ann Allergy Asthma Immunol.* 2004;92:611-8.

■ *Manuscript received November 15, 2006; accepted for publication January 18, 2007*

■ **Alfredo Cano**

Campo de Gomara 39
CP 47008 Valladolid, Spain
E-mail: acanog@compalencia.org