

Reducing asthma health disparities in poor Puerto Rican children: The effectiveness of a culturally tailored family intervention

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Background: Island and mainland Puerto Rican children have the highest rates of asthma and asthma morbidity of any ethnic group in the United States.

Objective: We evaluated the effectiveness of a culturally adapted family asthma management intervention called CALMA (an acronym of the Spanish for “Take Control, Empower Yourself and Achieve Management of Asthma”) in reducing asthma morbidity in poor Puerto Rican children with asthma.

Methods: Low-income children with persistent asthma were selected from a national health plan insurance claims database by using a computerized algorithm. After baseline, families were randomly assigned to either the intervention or a control group.

Results: No significant differences between control and intervention group were found for the primary outcome of symptom-free days. However, children in the CALMA intervention group had 6.5% more symptom-free nights, were 3 times more likely to have their asthma under control, and were less likely to visit the emergency department and be hospitalized as compared to the control group. Caregivers receiving CALMA were significantly less likely to feel helpless, frustrated, or upset because of their child’s asthma and more likely to feel confident to manage their child’s asthma.

Conclusion: A home-based asthma intervention program tailored to the cultural needs of low income Puerto Rican families is a promising intervention for reducing asthma morbidity. (*J Allergy Clin Immunol* 2008;121:665-70.)

Key words: Family asthma management intervention, controlled clinical trial, Puerto Rican, children

Abbreviations used

ED: Emergency department

IDR: Incidence density ratio

Asthma is the most common chronic childhood illness, and minority groups are disproportionately affected by asthma.¹ Mainland and island Puerto Rican children have the highest rates of asthma of any ethnic group and are more likely to die because of their asthma compared with other children.²⁻⁷ Numerous factors have been implicated in explaining the higher rates of asthma and morbidity among minority children, yet the factors accounting for this disparity are poorly understood. Poor adherence and inadequate overall asthma management by disadvantaged minority families have been linked to elevated asthma morbidity, service utilization, poor quality of life, and even asthma deaths in children.⁸⁻⁹ Because poor asthma management is one of the contributing factors to this excess morbidity, family management and educational interventions are needed to reduce the observed disparity in health and health care.

Treatment recommendations for asthma can be complex, including multiple medications, symptom monitoring, and environmental control precautions. Educational and behavioral interventions designed to help families develop the skills necessary to manage their child’s asthma have been shown to improve family asthma management practices and reduce children’s asthma morbidity (see reviews^{10,11}).

Although family asthma management interventions have been tested in samples that include mainland Latinos,¹²⁻¹⁴ separate analyses for the effectiveness of the intervention in Latino populations have not been provided, and none have been tested for island Puerto Rican families and children. The cultural adaptation and testing of a family-based intervention can provide important information about how to establish successful interventions in communities with different customs and cultures.¹⁵ In this article, we present the results of a randomized controlled clinical trial study to test the effectiveness of a culturally adapted family-based intervention called CALMA developed for reducing asthma morbidity in poor Puerto Rican children (age 5-12 years) with persistent asthma. To our knowledge, this is the first family-based asthma intervention focused on reducing health care disparities among minority low income Puerto Rican children.

METHODS

Participant selection and screening

Children were enrolled from 2 health regions under the government of Puerto Rico Health Insurance Administration Agency Plan and received

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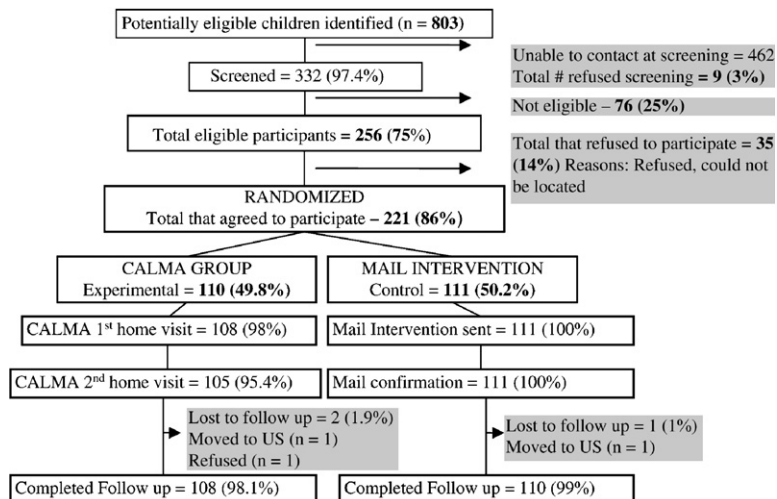


FIG 1. Recruitment of participants to the study.

asthma-related services during fiscal year 2004 to 2005. The agency requires that the family be at most 100% above the poverty level to be eligible (the poverty level is \$400). To determine eligibility, the agency considers the number of household members and their total monthly income and adds \$190 for each additional member.

Families identified using the claims data set were asked to complete a screener questionnaire. The children and their families were selected to participate in the study by using a computerized claims data algorithm based on the Health Plan Employer Data and Information Set criteria for classifying children with persistent asthma.¹⁶ The criteria required that the child had at least 1 claim with diagnostic code for asthma or reactive airway disease (International Classification of Diseases, Ninth Revision, diagnostic code 493.xx) and over a 1-year period had either been hospitalized or had at least 2 emergency department (ED) visits or 3 to 5 ambulatory visits caused by asthma or used asthma medications from 2 of the following therapeutic categories: anticholinergics, cromolyn, sympathomimetics, steroid inhalants, methylxanthines, leukotriene inhibitors, or corticosteroids.

Eligibility criteria for selection after screening were (1) families with a child between the ages of 5 and 12 years; and (2) poor asthma control, as defined by any of the following in the last 4 weeks: (a) use of any asthma medication more than once a week, (b) experiencing asthma symptoms such as wheezing, tightness of chest, problems coughing, or waking up at night because of asthma either daily or continuously, (c) using the emergency department 2 or more times during the last 4 weeks, and (d) using oral steroids or having been hospitalized in the last year. Exclusion criteria were (1) currently participating in another asthma study, (2) being the sibling of a selected child, and (3) no appropriate address for follow-up in the claims data. At the time of screening, the caregiver was defined as the adult legally responsible for the child and was the only person authorized to complete the screening procedure. Children were screened from April 1 to June 30, 2006, the baseline interview was conducted from April 17 to June 28, 2006, and the follow-up was conducted from August 17, 2006, to October 27, 2006.

Recruitment and randomization

Of the 803 children 5 to 12 years of age who met the Health Plan Employer Data and Information Set claims criteria, 341 (42.5%) had updated contact information (Fig 1). Of these, 332 (97.4%) consented to be screened, and 256 (75%) met eligibility criteria for participation in the study. Of the eligible children, 221 (86%) were enrolled in the study and completed baseline information. Children were randomized into the CALMA (N = 110) or control group (N = 111) by using a computerized algorithm based on a mixed block randomization scheme. Groups of subjects of different sizes (blocks) were assigned either to the experimental or control group according to a previously specified proportion within each block.

Description of intervention and control conditions

The main goal of CALMA is to improve asthma outcomes by educating families about asthma self-management. Asthma counselors are trained to deliver 8 asthma education modules based on an evidenced-based educational program developed elsewhere¹⁷ and modified by investigators at John Hopkins University and our team of researchers. These 8 modules were delivered over the course of 2 home visits with telephone contacts for ongoing follow-up and reinforcement of recommended plans and home assignments. The interval mean time between the first and second intervention was 18.4 days. No further intervention was administered between the second intervention and follow-up evaluation. The modules were intended to achieve the following goals: help the patients/family (1) understand the nature (chronicity) of asthma, (2) identify and overcome barriers to care and to appropriate medication use, (3) better understand and use the types of medications, (4) appropriately use the health care system and keep follow-up appointments, (5) enhance use of action plans, (6) improve identification of asthma triggers and environmental avoidance techniques, (7) encourage identification of onset of symptoms and early management, (8) assume an active role in the communication with the provider, (9) identify the stressors that may affect the psychological well being of the parent and learn when and where to look for psychological and family therapy help, and (10) provide a culturally competent environment in which the family feels understood and free to share cultural beliefs and practices. All families were given a manual to keep as a reference for the material taught in the 2 sessions. The intervention was culturally adapted using a collaborative participatory research approach that involved all affected partners in the research process.¹⁸ We collaborated with several community partners—health educators and mothers of children with asthma—in adapting the evidence-based intervention to the needs of the community. Cultural adaptations included the inclusion of common practices and myths that Puerto Rican parents have about asthma, proper use of home remedies, culturally congruent pictures, and common asthma triggers in the island, such as Sahara dust and eruptions from Caribbean volcanoes. New educational material was developed related to coping with marital and family stress resulting from the consequences of the child's asthma, increasing parental empowerment to deal with the Puerto Rican health system, and educating parents how to teach their child and others how to manage asthma.

The control group received 5 flyers of educational materials that contained information about the following topics: a description of control and rescue medications, when to use them and their benefits, information about what asthma is, common allergens and triggers and how to prevent episodes, how to take care of asthma equipment, and common foods that may be allergenic.

Preserving fidelity of intervention

Fidelity of the intervention was maintained by standardizing the intervention using a portfolio the asthma counselor carried to the homes, and by strict

training and certification of intervention counselors. In addition to the weekly monitoring of asthma counselors by field supervisors and audio taping of all interviews and interventions, asthma counselors were required to complete checklists of all educational components given during a session. These sheets as well as a review of 20% of audio tapes were used to assure the intervention was delivered as intended. Quality measures were based on established criteria for the areas of content fidelity; functioning of technical equipment; rapport; interaction with family; tailoring the intervention to the family's needs; and clarity, sequencing, and pacing during delivery. Recertification of asthma counselors was required if the audio tape and/or checklists revealed poor fidelity to the standardized intervention.

Study measures

All study participants (N = 221) completed a comprehensive 1-hour in-home baseline interview and a similar postinterview 4 months after randomization. All measures were adapted for use among Spanish-speaking populations by using multistage, state-of-the-art methods for cross-cultural adaptation.¹⁹

Primary asthma outcome. Symptom-free days are an index of asthma morbidity estimated by subtracting the numbers of days or nights with asthma symptoms in the past month and in the past 2 weeks as reported by caregivers during the follow-up interviews. Previous studies have shown that improvements of 2 to 3 symptom-free days are clinically meaningful.²⁰

Child secondary asthma outcomes. Asthma control was assessed with the Childhood Asthma Control Test²¹ developed to assess asthma control in children 4 to 11 years of age. The Childhood Asthma Control Test is reliable (classifying 72% of cases) and accurate in its assessment. A score of ≤ 19 points indicates that a patient's asthma may not be controlled. Child functional limitations were measured with 3 items that assessed how often sports and other activities were affected in the last 12 months by asthma symptoms. ED visits and number of hospitalizations were measured with items that assessed the number of ED visits or hospitalizations in the last 30 days. Medication use was determined in the last 12 months through retrospective daily self-report of various asthma medications (eg, inhaled and systemic steroids, β -agonists, and so forth). Parents were asked to bring the medications used by their child to the interviewer.

Caregiver's Outcome Measures. Caregiver's quality of life was measured with the Juniper Pediatric Asthma Care Quality of Life Questionnaire.²² Two subscales assess caregivers' concern about how much their work and household activities are affected by the child's asthma as well as the caregiver's emotional functioning. The internal consistency of the Juniper Pediatric Asthma Care Quality of Life Questionnaire in this sample is adequate ($\alpha = 0.75$). Asthma knowledge was assessed with the Caregiver Asthma Knowledge Scale²³ ($\alpha = 0.54$), which measures caregivers' awareness of asthma triggers and treatment. Family empowerment was assessed with the health service system subscale ($\alpha = .87$) of the Family Empowerment Scale²⁴ designed to assess whether the caregiver feels empowered to procure the services the child needs, such as knowing what to do if the services are deficient. Self-efficacy²⁵ measures how confident the caregiver feels about preventing their child's asthma episodes (prevention subscale ($\alpha = 0.75$)) and about managing her children's asthma (management subscale ($\alpha = .81$)).

Statistical analysis

Baseline differences between the intervention and control group were tested for statistical significance by means of the χ^2 test of association for categorical variables and by means of independent groups *t* tests for continuous and count variables. Analysis of follow-up data was conducted by means of regression analysis. The posttest score on the outcome variables was regressed on the pretest score and a dummy variable representing treatment group membership. The statistical significance of the dummy variable represents the effectiveness of treatment. Treatment effects were therefore defined as differences in the posttest scores between the treatment groups after adjusting for their pretest scores. The regression model used depended on the type of outcome variable being analyzed. For continuous outcomes, linear regression was used; for dichotomous outcomes, logistic regression; for categorical outcomes, multinomial regression; and for count variables, negative binomial regression. We

present the regression coefficients representing the estimated effects of treatment, and 95% confidence limits. For linear regressions with continuous variables, the parameter estimate represents the mean difference between the CALMA and control group. For logistic regressions of dichotomous variables, the regression coefficient is exponentiated to obtain an adjusted odds ratio representing the effect of treatment on the odds of event occurrence. For count variables, the regression coefficient is also exponentiated to obtain an incidence density ratio (IDR), which represents the factor by which the expected rate of the count variable is expected to change as the result of treatment. The percentage change in the expected count because of treatment can be estimated by the following formula: $100 \times (\exp[b] - 1)$, where *b* represents the regression coefficient associated with treatment. We report 95% CIs for each outcome but do not control for multiplicity of estimation.

All analyses were based on the intention-to-treat principle. Respondents were analyzed in the group to which they were assigned, and we attempted to follow up with all respondents to the completion of the trial even if they had discontinued their participation in the trial or never participated in the CALMA. Results are presented uncorrected for multiple comparisons. We were unable to follow up with 3 subjects (1.3% of the sample), 1 from the control and 2 from the CALMA groups.

RESULTS

Participant baseline characteristics

Children in the control group were significantly older than in the CALMA group, and because of this, all comparative analyses controlled for child's age. There was no significant difference at baseline between the intervention and control group in any other demographic characteristic, child asthma outcomes, or caregiver characteristics (Table I). The sample was very poor, with 75% receiving social assistance. The vast majority averaged 4 visits to the ED annually and 1 hospitalization in the last 6 months. Only 26% had their asthma under control. More than half (63.8%) reported receiving both rescue medication (albuterol or anticholinergic or systemic corticosteroids) and controller medication (inhaled corticosteroids, leukotrienes, cromolyn, or β -agonists of long duration), whereas 28.9% of the children were using only rescue medication.

Child asthma morbidity outcomes

Table II shows the overall mean results of the intervention and control groups, the regression coefficients, and CIs for the primary and secondary asthma outcomes. No significant difference between the control and intervention group was observed for our primary asthma outcome of symptom-free days. Both groups experienced more symptom-free days at posttest. In addition, no differences were observed between the groups for the secondary outcomes of activity limitation and medication use. However, children in the CALMA group had significantly more symptom-free nights (6.5% increase; IDR = 1.065) compared with the control group. In addition, children in the CALMA group were 3 times more likely to have their asthma under control (regression coefficient = 3.35), 37% less likely to visit the ED (IDR = .627), and 68% less likely to be hospitalized (IDR = .324) compared with the control group.

Caregiver outcomes

Caregivers in the CALMA intervention were significantly less likely than caregivers in the control group to report feeling helpless, frustrated, or upset because of their child's asthma (RC = 2.41), and more likely to feel confident that they could manage their child's asthma (RC = 1.80), as evidenced by their

TABLE I. Baseline demographic and medical characteristics of CALMA and control groups (N = 221)*†‡

Variables	CALMA (N = 110)		Control (N = 111)		Total		P value
	No.	Percent/mean	No.	Percent/mean	No.	Percent/mean	
Child characteristics							
Age (y)	110	6.96	111	7.73	221	7.35	.01‡
Male	69	62.73	62	55.86	131	59.28	.30†
Primary asthma outcomes							
Symptom-free days (30 d)	109	23.36	110	22.97	219	23.16	.68‡
Symptom-free nights (30 d)	109	25.28	108	24.44	217	24.86	.36‡
Secondary child asthma outcomes							
Asthma control							
Under control >20	17	21.25	25	31.25	42	26.25	.15†
ED visits (6 mo)	109	4.21	108	3.79	217	4.00	.63‡
Hospitalization (6 mo)	110	1.39	106	1.11	216	1.25	.43‡
Asthma medication use							
Any rescue only	29	26.36	35	31.53	64	28.96	.40†
Any rescue and any control	74	67.27	67	60.36	141	63.80	.28†
Functional limitations							
Activities limitation (30 d)	103	4.03	108	3.89	211	3.96	.60‡
Secondary caregiver asthma outcomes							
Quality of life (total)							
Emotion	110	34.85	111	32.69	221	33.77	.06‡
Activity	110	17.05	111	15.95	221	16.50	.13‡
Asthma knowledge	110	11.24	111	11.60	221	11.42	.24‡
Self-efficacy (total)	103	40.30	105	40.77	208	40.54	.60‡
Prevention	103	20.19	105	20.86	208	20.53	.08‡
Management	103	20.10	105	19.90	208	20.00	.75‡
Family empowerment	110	43.22	111	43.33	221	43.28	.93‡
Family demographic characteristics							
Marital status							
Married or living with couple	67	65.05	71	65.14	138	65.09	.75†
Separated/divorced/widowed	23	22.33	21	19.27	44	20.75	
Never have been married	13	12.62	17	15.60	30	14.15	
Household annual income (\$)							
None	28	27.18	33	31.43	61	29.33	.54†
50-6999	48	46.60	41	39.05	89	42.79	
≥7000	27	26.21	31	29.52	58	27.88	
Receive social assistance	82	75.23	83	74.77	165	75.00	.94†
Household composition	110	4.07	110	4.23	220	4.15	.35‡
Father educational level							
Less than high school	44	43.56	34	34.00	78	38.81	.29†
High school/equivalent	39	38.61	41	41.00	80	39.80	
Some college/college degree	18	17.82	25	25.00	43	21.39	

*Entries in table are based on cases with complete data only; therefore, the sample size for each contrast varies slightly because of missing data.

† χ^2 .

‡t Test.

scores on the quality of life and self-efficacy scales (Table II). In addition, caregivers in the CALMA group were significantly more likely to report an increase in asthma knowledge compared with the control, although no difference between groups was observed in the caregiver's empowerment to manage the health care system.

DISCUSSION

This study demonstrated that the CALMA intervention, a home-based family management intervention culturally adapted for low-income Puerto Rican families, was significantly more effective in improving several asthma outcomes in children and their caregivers compared with a usual care control group. In families that received the CALMA intervention, the 6.5% increase in symptom-free nights was the equivalent of 1 day a month and was statistically significant; however, this increase may not be considered clinically significant. No significant

differences were observed between the intervention and control group in the primary outcome of symptom-free days. Nevertheless, large effects were observed for parent reports of better asthma control, ED visits, and hospitalizations. It is noteworthy that both study groups showed significant improvement in several asthma morbidity outcomes compared with baseline. Such improvements (common in asthma intervention studies) may reflect generalized intervention effects or regression to the mean and underscore the importance of randomized controlled study designs.²⁶

Research regarding the effectiveness of family educational programs has been equivocal, with many studies finding an increase in asthma knowledge and self-efficacy but no significant or small effects in reducing morbidity (see reviews^{10,11}). However, our results are consonant with several other randomized asthma intervention programs that have reported modest effects for decreased morbidity, increases in asthma knowledge, and

TABLE II. Effects of CALMA intervention on primary and secondary asthma outcomes*

	Baseline				Follow-up				Treatment effects	95% CI	No.
	CALMA (N = 110)		Control (N = 111)		CALMA (N = 108)		Control (N = 110)				
	No.	Percent/ mean	No.	Percent/ mean	No.	Percent/ mean	No.	Percent/ mean			
Primary asthma outcomes											
Symptom-free days (30 d)	109	23.36	110	22.97	108	25.45	109	23.34	1.07†	.98-1.18	215
Symptom-free nights (30 d)	109	25.28	108	24.44	108	27.81	109	25.73	1.06†	1.01-1.12	213
Secondary child asthma outcomes											
Asthma control											
Under control >20	17	21.25	25	31.25	31	45.59	22	28.21	3.35‡	1.45-7.73	114
ED visits (6 mo)	109	4.21	108	3.79	108	1.13	109	1.66	.63†	.41-.95	213
Hospitalization (6 mo)	110	1.39	106	1.11	108	.41	109	.95	.32†	.15-.72	212
Asthma medication use											
Any rescue only	29	26.36	35	31.53	33	30.56	30	27.27	1.39‡	.69-2.82	218
Any rescue and any control	74	67.27	67	60.36	70	64.81	71	64.55	.89‡	.46-1.71	218
Functional limitations											
Days absent from school (30 d)	110	3.58	109	3.63	108	1.62	109	2.93	.61†	.38-.98	216
Activities limitation (30 d)	103	4.03	108	3.89	93	3.13	100	3.63	-.46§	-.1.01-.09	184
Secondary caregiver asthma outcomes											
Quality of life (total)	110	51.90	111	48.65	108	58.04	109	53.66	3.15§	-.13-6.43	217
Emotion	110	34.85	111	32.69	108	38.54	109	35.54	2.26§	.07-4.45	217
Activity	110	17.05	111	15.95	108	19.49	109	18.12	.89§	-.49-2.26	217
Asthma knowledge	110	11.24	111	11.60	108	12.64	110	11.65	1.10§	.50-1.69	218
Self-efficacy (total)	103	40.30	105	40.77	108	43.40	109	41.08	2.42§	.96-3.88	204
Prevention	103	20.19	105	20.86	108	21.00	109	20.70	.58§	-.12-1.27	204
Management	103	20.10	105	19.90	108	22.41	109	20.39	1.80§	.84-2.77	204
Family empowerment	110	43.22	111	43.33	108	44.79	109	45.02	-.03§	-.1.94-1.88	217

*Entries on table are based on cases with complete data only; therefore, the sample size for each contrast varies slightly because of missing data.

†Negative binomial reg - IDR shown.

‡Logistic regression - odds ratio.

§Linear regression. Regression coefficient shown.

acquisition of asthma management skills.^{12,17,27} For example, Kelly et al²⁷ reported significant 1-year differences between participants in a family educational intervention compared to control in ED visits, hospitalizations, and both caregiver's and child's quality of life. Bonner et al¹² found that Latino and African American families who received a 3-month individualized intervention from an asthma counselor reported significantly less symptom persistence and activity limitations, more self-report medication adherence, and higher asthma knowledge and self-efficacy. The Inner City Asthma Study¹⁷ used a family intervention that served as the basis for CALMA and found a clinically significant decrease in symptom days and in hospitalizations in the intervention group over a 2-year period. However, this intervention included other interventions besides the family asthma intervention.

Similar to the CALMA intervention, these studies administered a family asthma intervention to individual caregivers versus groups, emphasized behavior change, and customized the intervention to the family's needs, all factors that have been associated with desired asthma outcomes.^{10,28} However, our intervention was unique inasmuch as it was tailored to the specific cultural needs of island Puerto Rican families and used a community-based participatory approach for developing the culturally specific content/modules of the intervention.

Despite the notable gains in asthma outcomes reported by caregivers receiving the CALMA intervention, there were important target outcomes and behaviors that did not change significantly during the 4-month follow-up period. There were no significant differences in our primary study outcome, symptom-free days, between the CALMA and control groups, although

significant differences were observed in symptom-free nights. It is possible that parents are more likely to recall symptom-free nights compared with days given that at night their sleep is interrupted. It is puzzling that a significant reduction in service utilization was observed in the CALMA group relative to the control group, but no change was observed in medication use or symptom-free days. There are a number of possible explanations for this inconsistency. Studies have found that parent reports of medication use and adherence are often inaccurate²⁹; therefore our failure to find an association between medication use and symptoms may reflect measurement error. An additional possibility is that parents learned other asthma management strategies (ie, environmental control, symptom monitoring, and so forth) or gained self-efficacy in managing asthma at home that resulted in reduced health care utilization.

Our study had a number of methodological strengths. We used a population-based sampling strategy and obtained high participation rates (86%), high follow-up rates (98%), and high rates of intervention delivery (95%). The study maintained rigorous attention to treatment fidelity, including audio taping of the intervention and performing quality assessment of the same to assure fidelity. However, in spite of these strengths, our design and methods had several limitations. All measures were based on caregiver's self-report without confirmation by objective measures, and treatment assignment was not double-masked. For this reason, caregivers in the CALMA intervention may have overestimated the effect of the intervention because of the participant's response bias toward success.¹² However, self-report of health care utilization has been found to be a reasonably valid

measure for short-term recall.³⁰ Although the current study evaluated an asthma intervention specifically tailored for low-income Puerto Rican families, the current study design does not allow us to determine whether the success of the intervention was attributable to this tailored cultural adaptation, nor can we determine whether the observed effects are generalizable to other low-income Latino populations. An additional limitation of the study is the short duration. For this reason, the long-term effects of the intervention remain unclear, as do the effects of seasonality. Future studies will be needed to assess the sustainability and costs of this program. Finally, because we present the study results uncorrected for multiple comparisons, some observed significant differences may be more likely to reflect chance associations.

Conclusion

Our study showed that a home-based asthma family management intervention program tailored to the needs of low-income Puerto Rican families and culturally adapted is a promising intervention for reducing asthma morbidity in children. The development of this intervention is of particular clinical importance in low-income minority groups of Puerto Rican children from the island and mainland because of their known high morbidity and asthma mortality. Future research is required to test the long-term effectiveness of this intervention.

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Clinical implications: Asthma management interventions tailored to the needs of a specific community can be an important tool for clinicians and policy makers for significantly reducing asthma morbidity in children.

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