A randomized clinical trial to reduce asthma morbidity among inner-city children: Results of the National Cooperative Inner-City Asthma Study

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Objective: To evaluate a family-focused asthma intervention designed for inner-city children 5 to 11 years old with moderate to severe asthma.

Study design: Randomized, multisite, controlled trial to minimize symptom days (wheeze, loss of sleep, reduction in play activity) measured by a 2-week recall assessed at 2-month intervals over a 2-year follow-up period. The intervention was tailored to each family's individual asthma risk profile assessed at baseline.

Results: Averaged over the first 12 months, participants in the intervention group (n = 515) reported 3.51 symptom days in the 2 weeks before each follow-up interview compared with 4.06 symptom days for the control group (n = 518), a difference of 0.55 (95% CI, 0.18 to 0.92, $P = .004$). The reduction among children with severe asthma was approximately 3 times greater (1.54 d/2 wk). More children in the control group (18.9%) were hospitalized during the intervention compared with children in the intervention group (14.8%), a decrease of 4.19% (CI, –8.75 to 0.36, $P = .071$). These improvements were maintained in the intervention group during the second year of follow-up, during which they did not have access to the asthma counselor.

Conclusions: We demonstrated that an individually tailored, multifaceted intervention carried out by Masters-level social workers trained in asthma management can reduce asthma symptoms among children in the inner city.

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In a review of 19 asthma self-management programs, Wigal et al[1] found that although the burden of asthma is especially great in urban areas with high levels of poverty and large minority populations,[2-5] few interventions have been designed or evaluated specifically for these settings.[6-10] Among these, the impact has varied. A supervised nurse case manager directly involved in the delivery of medical care was shown to decrease acute health care use.[6] An evaluation of Open Airways, an asthma education and self-management program, reported a decrease in emergency department use and hospitalization only among children with the most severe asthma.[7] An education program for hospitalized children with asthma resulted in a subsequent decrease in ED use among the most severe group.[8] Evans et al[9] intervened directly with inner-city health clinics and showed positive changes on measures of access, continuity, and quality of care, whereas an urban health maintenance organization-based program failed to reduce ED use.[10]

AC	Asthma counselor
ARAT	Asthma Risk Assessment Tool
ED	Emergency department
NCICAS	National Cooperative Inner-City Asthma Study

Many of these interventions have design or impact characteristics that limit their applicability in an inner-city setting. For example, the use of an asth-

ma specialist working with a nurse case manager is likely to be too expensive for most inner-city clinics. Several interventions benefit only the most severe asthmatics, and interventions that reduce health care use, while economically important, are not always associated with a corresponding reduction in asthma symptoms or severity.[11]

The National Cooperative Inner-City Asthma Study intervention was a comprehensive, individualized, multifactor intervention based on the NCICAS phase I broad-based epidemiology study.[12-14] This intervention was designed to reduce asthma symptoms to improve the quality of life for inner-city children with asthma. We report on the effectiveness of the NCICAS phase II intervention.

METHODS

Population

The intervention targeted English- or Spanish-speaking 5- to 11-year-olds with physician-diagnosed asthma living in inner-city census tracts where at least 20% of the population was below federal poverty guidelines at 8 Asthma Study Units (Appendix A). Techniques developed in phase I were used to maximize participant retention.[15]

The child had to fulfill at least one of the following severity criteria during the 6 months before recruitment: (1) use of ≥2 asthma medicines, (2) ≥1 asthma hospitalizations, and (3) ≥1 unscheduled visits for asthma. Alternatively, during the 2 weeks before recruitment, the child had to have (4) respiratory symptoms for more than 2 days or sleep disruption from these symptoms for more than 2 nights.

Screening and Recruitment

Lists of eligible children were generated from 3 sources: (1) participants in NCICAS phase I, (2) children with asthma identified in the ED, and (3) children with asthma identified in primary care clinics.

Baseline

All study participants completed a comprehensive 2-hour baseline assessment. Information was collected regarding the child's health, hospitalizations, and unscheduled medical visits in the past 2 months, asthma symptoms in the past 2 weeks, characteristics of the home environment, and medical care. Psychologic status was measured for the caretaker by the Brief Symptom Inventory[16,17] and for the child by the Child Behavior Checklist.[18] All children were skin-tested for cockroach, dust mite, cat, dog, rat, and mold. A positive test result was defined as a wheal diameter 2 mm or more larger than control.

Randomization

After completing the baseline assessment, children were randomized. Randomization was stratified by Asthma Study Unit and the 3 recruitment sources with randomized blocks of 6 or 8 children.

Intervention

The intervention was delivered by Masters-level social workers, called asthma counselors, who were familiar with the problems of inner-city families. The ACs were centrally trained at the project coordinating center over a 3-month period in 3 separate 2½-day training sessions and attended local asthma clinics for at least 2 weeks. Each AC assisted approximately 60 families.

The AC did not work directly with the participants' physicians. Instead, they worked with the child's caretaker to encourage improved communication between the family and physician. The primary care physician was sent a blank asthma care plan, a spacer, a peak flow meter, and National Heart Lung and Blood Institute asthma treatment guidelines. Of the 515 intervention families, 276 (53.6%) were able to obtain their plan. Another 230 (44.7%) worked with the AC to construct a plan based on oral instructions from their physician. Arrangements were made to assign a primary care physician for participants in both the intervention and control groups without one.[19]

Caretakers, identified by self-report at recruitment, were invited to attend 2 adult group asthma education sessions and 1 individual meeting with their AC during the 2 months after baseline assessments. Based on the *A+ Asthma* program,[20] group sessions covered asthma triggers, environmental controls, asthma physiology, strategies for problem solving, and communicating with their child's physician. Two group sessions for children were conducted during the next 2-month period. If a group session was missed, topics were covered later at individual sessions.

The AC provided the caretakers with referrals to appropriate community resources for smoking cessation and psychologic and social issues. Feedback regarding the use of metered dose inhalers was given to all children prescribed those devices (Appendix B).

Environmental Intervention

All families were given pillow and mattress covers and were encouraged to minimize exposure to environmental tobacco smoke and pets. For children with a positive cockroach skin test result, the families were instructed on ways to reduce food sources, and 2 visits for the professional application of the insecticide abamectin (Avert) were conducted.

Tailoring the Intervention

After the group sessions, at a minimum the AC and caretakers met in person every 2 months and spoke on the telephone on the alternate months. The number and length of contacts and the nature of discussions were based on the family's baseline asthma risk profile, assessed by the Asthma Risk Assessment Tool and other problems or issues that developed. The ARAT was derived from the baseline assessment. It included exposure to allergens, allergen sensitivity, smoking, access to care, adherence, and measures of adult and child mental health.

Table I. Comparison of the baseline characteristics of the intervention and control groups

	Intervention (n = 515)	Control (n = 518)
% Male	62.1	65.8
Mean age ± SD (y)	7.7 ± 1.9	7.6 ± 1.8
Race/ethnicity		
Black (%)	75.9	73.1
Hispanic (%)	17.1	17.4
Other (%)	7	9.5
Recruitment source		
Phase I (%)	43.9	44.6
New ED (%)	40.4	39.4
New clinic (%)	15.7	16.0
Had primary care physician (%)	84.7	79.3
Income <$15,000/y (%)	68.9	66.0
Mean number of asthma medications	2.6 ± 1.4	2.7 ± 1.5
At least 1 positive allergen skin test result (%)	84.0	87.1
Caretaker smokes (%)	43	41.5
BSI (above clinical cut-off) (%)	42.5	45.1
CBCL (T score for total problems)	54.6 ± 11.5	54.7 ± 11.6
Maximum symptom days per 2 weeks	5.1 ± 4.5	5.1 ± 4.6
At least 1 hospitalization in previous 2 months (%)	5.1	3.9

None of the above are statistically significant.
BSI, Brief Symptom Inventory; *CBCL*, Child Behavior Checklist.

Outcome Measures

After the initial group sessions, participants were called every 2 months for 2 years by an independent survey research group that was not aware of the participants' randomization status. The first year of follow-up occurred while the AC was in contact with the family. The primary outcome measure was the self-reported maximum number of symptom days (wheeze, loss of sleep, or reduction in play activity caused by asthma) measured by a 2-week recall. The sample size of approximately 500 participants per group provided a power of 90% to detect a difference of 25% in the mean number of symptom days between groups.

A secondary outcome, hospitalizations, and unscheduled visits were assessed by 2-month recall at each contact. The sample size of approximately 500 participants per group permitted a power of 80% to detect a 25% difference in hospitalizations or unscheduled visits.

Statistical Analyses

Baseline and outcome data were compared with either analysis of variance or the Mantel-Haenszel chi-square test controlling for ASU and recruitment source. Consistent with the intention-to-treat analyses, all randomized subjects were included in the analysis.

RESULTS

Of 2847 children with asthma screened, 1196 were eligible. Baseline interviews were completed for 1033 (86.4%) participants, who were then randomized into the intervention (n = 515) or control group (n = 518). Based on screening criteria, the 163 (13.6%) who were not enrolled were not different from the study participants in terms of age, sex, use, and symptoms. However, enrolled participants had a higher number of asthma medications (1.57 vs 1.41, $P > .01$). Follow-up interview response rates were very high, ranging from 95% at 2 months to 93% at the 12-month follow-up interview. Four or more of the 6 follow-up telephone assessments in year 1 were completed by 93.4% of participants, and 81.5% completed all 6. During the second year of follow-up, response rates remained high, with a range of 88% to 86%. Of the 12 possible follow-up telephone calls, 92.2% of families in the intervention group and 95.2% of families in the control group completed at least 6 calls, and 65.6% and 69.3% of families in the intervention and control groups, respectively, completed all 12 calls. The comparison of baseline characteristics between the intervention and control groups revealed no important differences (Table I).

Maximum symptom days, the primary outcome measure, was calculated as the mean number of symptom days over a 2-week period averaged over the 6 follow-up measurements for each of the 2 years of follow-up. The data are presented separately by follow-up year. The intervention and control groups had the same number of maximum symptom days at enrollment. Averaged over the first 12-month assessment period, the intervention group reported 3.51 symptom days in the 2 weeks before follow-up interviews compared with 4.06 symptom days for the control group ($P = .004$, Table II). A trend toward fewer symptom days in the intervention group was first noted at the 4-month follow-up. During the summer months of July and August, when asthma symptoms are typically low, the difference between the groups disappeared (Fig 1). The divergence between the control and intervention groups was noted again in the fall with the return of asthma symptoms in both groups.

Assessment of hospitalization rates, a secondary outcome, revealed that 14.8% of the children in the intervention group versus 18.9% of the children in the control group were hospitalized during the year follow-up period. This difference approached

significance at $P < .071$. No difference was seen between unscheduled acute care visits for asthma between groups (Table II).

A number of subgroup analyses were undertaken. A comparison between phase II participants who had also been phase I participants and the "new" phase II participants indicated that participation in phase I did not increase the efficacy of the intervention. When the participants were stratified by baseline severity measures (symptoms, unscheduled visits, or hospitalizations), the intervention had the greatest effect in the most severe groups, a reduction of maximum symptom days that was 4 to 5 times greater than the milder groups (Table III).

Fig 2 reveals that the difference observed during the AC intervention period in year 1 was maintained through year 2. Children in the intervention group had an average of 2.64 days of symptoms across the 2-week follow-up measures, whereas children in the control group had 3.16 ($P = .007$, Table II). Again, in year 2 the difference between the intervention and control groups in terms of number of hospitalizations approached significance, with 10.2% of the intervention group and 13.8% of the control group having at least 1 hospitalization in year 2 ($P = .078$). During the year 2 follow-up, unscheduled visits to EDs and physician offices began to show a decline, with an average of 1.89 unscheduled visits in the intervention group and 2.24 in the control group ($P = .075$, Table II).

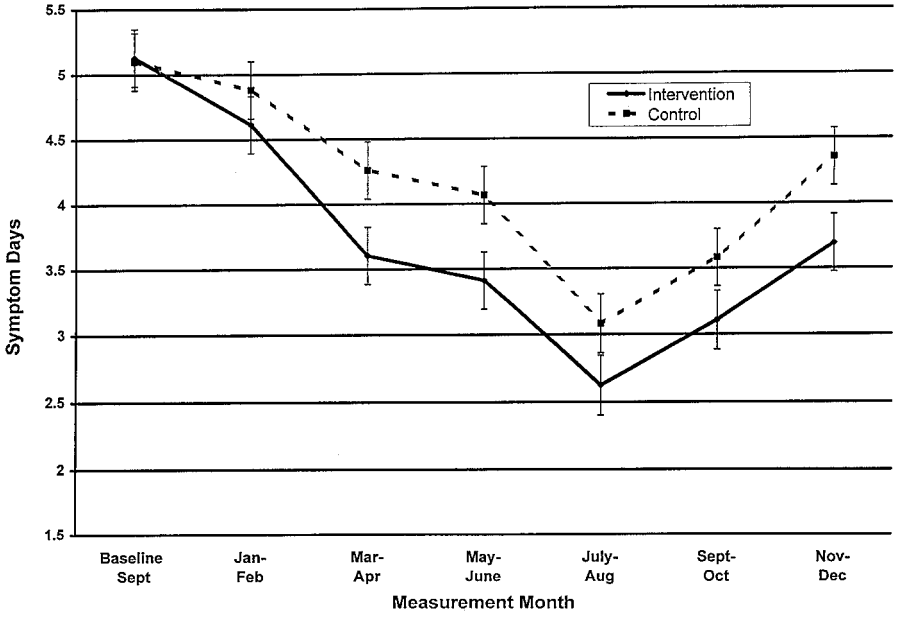

Fig 1. Maximum symptom days by month of follow-up: year 1.

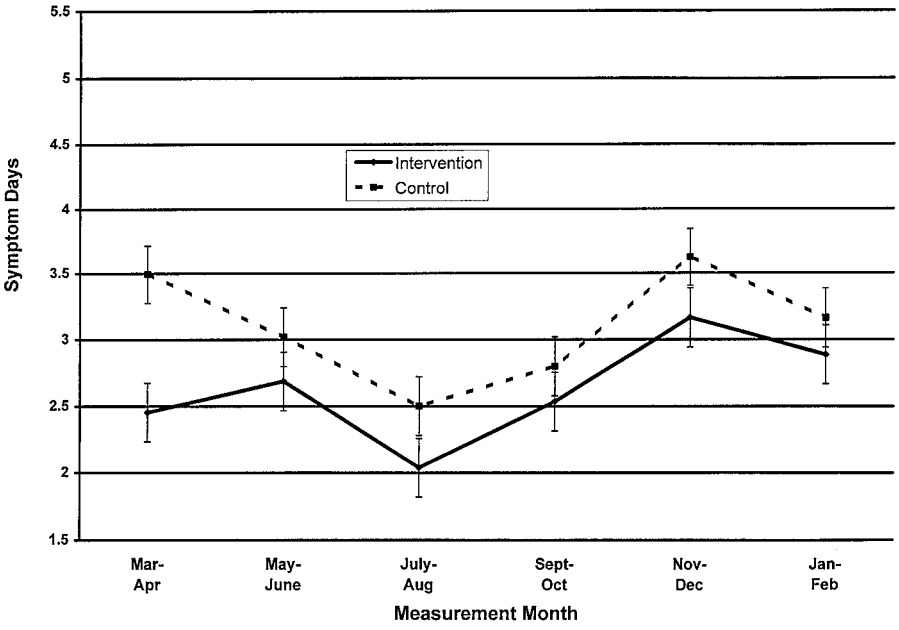

Fig 2. Maximum symptom days by month of follow-up: year 2.

DISCUSSION

The NCICAS intervention is unique. NCICAS did not attempt to have an asthma specialist (allergist or pulmonologist) take over the child's medical care or provide a nurse case manager who was a liaison to such a specialist.[6] It is clear that children with asthma who receive care from asthma specialists tend to have better control of their asthma because of their increased access to the proper medication, devices, and training on how to use them.[21,22] Although this approach has been shown to work, it is unlikely to be implemented because of the high costs involved in providing specialty care to all those with asthma. The NCICAS intervention took a different approach to empower the family to increase their asthma self-management and to improve their interaction with the primary care physician to improve the quality of care. The observed reduction in symptoms occurred without extensive changes to the pre-existing medical services to these families. Morbidity reduction was first seen in lowered symptoms and later appeared to generalize to a reduced use of health care services.

Table II. Symptoms and use over first and second year of follow-up

Follow-up	Intervention (n = 515)	Control (n = 518)	Difference	95% CI	*P* value
Year 1					
Maximum symptom days*	3.51	4.06	–0.55	–0.92, –0.18	.004
1 or more hospitalizations in the past year (%)	14.80	18.90	–4.19	–8.75, 0.36	.071
Unscheduled visits per year	2.64	2.85	–0.21	–0.62, 0.20	.32
Year 2					
Maximum symptom days*	2.64	3.16	–0.51	–0.89, –0.13	.007
1 or more hospitalizations in the past year (%)	10.20	13.80	–3.72	–7.86, 0.41	.078
Unscheduled visits per year	1.89	2.24	–0.35	–0.72, 0.03	.075

*Numbers represent mean of maximum symptom days for 2 weeks averaged across the 12-month follow-up period.

Table III. Maximum symptom days by baseline severity

	Intervention		Control			
Severity measures at baseline	No.	Mean	No.	Mean	Difference (95% CI)	
Symptom days in previous 2 weeks*						
Mild (0 - 7 days)	392	2.96*	397	3.24	–0.29	(–0.67, 0.10)
Severe (8 - 14 days)	114	5.39	115	6.93	–1.54	(–2.25, –0.83)
Hospitalizations in previous 2 months						
None	481	3.52	492	4.02	–0.51	(–0.89, –0.13)
1 or more	26	3.14	20	5.18	–2.03	(–3.98, –0.08)
Unscheduled visits in previous 2 months						
0-1	470	3.41	471	3.88	–0.47	(–0.85, –0.09)
2 or more	37	4.13	41	6.25	–2.12	(–3.54, –0.70)

*Numbers represent mean of maximum symptom days for 2 weeks averaged across the 12-month follow-up period.

It was especially notable that the intervention effect continued at the same strength during the second year of the program, when the AC intervention was no longer available to the family.

The NCICAS intervention reduced by more than half a day the number of days over a 2-week period that a child had asthma symptoms. The magnitude of this effect is apparent when it is extrapolated over the course of 1 year, eliminating more than half a month of symptoms for all children in this study and more than 1½ months of symptoms for children with the most severe asthma. Although the effect was stronger in the most severe groups, it was not limited only to these groups as has been seen in other studies.[7,8] A reduction of 1.5 to more than 2 days per 2-week period was observed among the severe group, whether defined by previous symptoms or health service use. It is important to notice that the decrease in symptoms was accompanied by a trend toward decreased use because of asthma. Although the number of children who were hospitalized for asthma showed a decline approaching significance in both years of measurement, unscheduled visits did not begin to decline until the second year.

An important feature of the NCICAS program was the use of the ARAT to tailor the intervention for each family. The ARAT identified the important asthma risk factors for each family and allowed the AC to focus on them. Kotses et al[23] also emphasized the individualization of asthma self-management to better engage the family in the program and minimize the amount of irrelevant teaching. In an evaluation of their tailored program, the individualized self-management participants demonstrated a decrease in the frequency of asthma attacks, whereas the group self-management participants did not.[24]

Simply increasing knowledge of asthma is not sufficient to alter morbidity. Attempts to decrease asthma morbidity by increasing asthma knowledge have been generally unsuccessful.[25] Data

from NCICAS phase I found that families living in these inner cities had a high level of asthma knowledge and were very motivated to care for their children with asthma.[12] However, these same caretakers were not good problem solvers regarding asthma. The NCICAS intervention focused on both problem solving and asthma education, so that participants had an improved understanding of their child's disease and the skills to properly use their medications, avoid triggers, and communicate with their physician regarding their medical needs.

Inner-city children and their parents live in highly challenging, difficult environments. These families often face economic uncertainty and live in homes or apartments with poor ventilation and high allergen levels.[12-14] Children in these settings frequently have multiple caretakers for their asthma and little continuity of health care. In this environment it is not surprising that health care concerns can be overwhelmed by more pressing, immediate problems. Traditional educational interventions such as those mentioned previously may not be adequate to reduce asthma morbidity when so many other factors are disrupting everyday life. As part of the NCICAS protocol, the AC was allowed the flexibility to determine the number of contacts with the family based on the family's unique needs. These needs frequently were not asthma-related but were problems inherent with living in an inner-city environment. Addressing these problems helps to reduce distractions in the family's life, providing them with the ability to focus more clearly on the child's asthma concerns.

The effects of poverty are not specific to asthma but are manifest in higher rates of virtually all diseases. Among the many effects of poverty are less access to quality health services and greater family disruption.[26,27] To be realistic our program had to be designed to help the families cope successfully with this adverse environment. The asthma counselor is a very flexible model potentially adaptable to a wide variety of settings. The intervention made use of existing community resources such as referrals to existing smoking cessation programs, because limited resources made it impossible to create programs specifically for the intervention. The NCICAS intervention offers an effective program, applicable to the inner-city environment, which is both efficient and transportable to a wide variety of settings.

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APPENDIX A

The National Cooperative Inner-City Asthma Study, phase II, was a collaboration of the following institutions and investigators. Principal investigators are indicated by asterisks.

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APPENDIX B

The NCICAS Intervention, "A Guide for Helping Children with Asthma" is available from:

Division of Allergy. Immunology and Transplantation

National Institute of Allergy and Infectious Diseases, NIH

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