Short-term Impact of a Randomized Multifaceted Intervention for Wheezing Infants in Low-Income Families

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Objective: To present an interim analysis of the effect of a home-based intervention with low-income caregivers of wheezing infants at risk for childhood asthma on mediating variables.

Method: Infants aged 9 to 24 months with 3 or more physician-documented wheezing episodes were randomly assigned to environmental support intervention (ES) (n=90) or control (n=91) groups. Nurse home visitors intervened for 1 year to decrease allergen and environmental tobacco smoke exposure and improve symptom perception and management. Assessments at baseline and 12 months included allergens in house dust, infant urinary cotinine levels, caregivers’ symptom reports, quality of life, illness management, and quality of caregiving. Medical records were coded for hospitalizations, emergency department visits, and corticosteroid bursts.

Results: Within the ES group, cockroach allergen levels were significantly reduced and there was a trend toward reduction in dog dander levels. Among infants with detectable urinary cotinine, levels were significantly reduced in the ES group. Caregiver psychological resources modified the impact, and low-resource ES caregivers were the most strongly affected. Asthma knowledge and provider collaboration improved significantly in the ES group. Neither reports of infant symptoms nor emergency department visits or hospitalizations showed positive intervention effects. Number of corticosteroid bursts for infants was significantly higher for the ES group.

Conclusions: The Childhood Asthma Prevention Study intervention was effective in reducing several environmental exposures and improving illness management. However, even with an intensive home-based intervention, we failed to reduce respiratory symptoms or medical use in the ES group relative to the control group, illustrating the difficulty of changing the course of early asthma development among low-income infants.
that affect onset, severity, and morbidity, such as exposure to environmental allergens and tobacco smoke and the psychosocial and medical aspects of caregiving that influence the course of early asthma.

The Childhood Asthma Prevention Study (CAPS) was the first secondary prevention study conducted with a more broadly defined high-risk group of children that intervened with psychosocial as well as environmental factors. Randomly controlled, CAPS focuses on low-income children younger than 2 years with multiple episodes of wheezing, for whom the initial phases of asthma may have occurred. For these children, morbidity attributable to wheezing illness had reached high levels prior to 2 years of age.

The primary objective of this report was to evaluate the effect of the year-long intervention on targeted variables, including ETS and cockroach, cat, and dog allergens and maternal caregiving, including asthma management and emotional caregiving. Although the outcome evaluation for CAPS was planned to occur when the children reached age 4 years, a secondary objective was to evaluate the intervention effects on wheezing-related morbidity as measured by maternal report of symptoms and quality of life and medical record review of corticosteroid bursts, emergency department visits, and hospitalizations.

**METHODS**

Children were eligible for the study if they were between 9 and 24 months of age, had medical record documentation of at least 3 separate episodes where wheezing was observed, and were from low-income (Medicaid-eligible) families. Infants were excluded if they had less than 34 weeks' gestation, a postnatal oxygen requirement greater than 48 hours, or complicating medical conditions. Subject families were recruited from pediatric departments of local hospitals and clinics in the metropolitan Denver, Colo, area, screened for eligibility, and enrolled and randomized (Figure 1). Outcome data were available for 150 children (85% of those randomized). Families lost to follow-up and dropouts were not different from those followed up on any demographic or baseline measure. No differences in baseline characteristics were found across treatment groups except for child sex; more girls were randomly assigned to the intervention group.

At enrollment, caregivers signed consent forms approved by the institutional review boards of participating institutions. Subsequent in-home interviews, conducted with the infants' primary caregivers, obtained baseline medical, environmental, and behavioral background information, and house dust and infant urine samples were collected. Study materials were administered in either English or Spanish, according to the institutional review boards of participating institutions. Subsequent in-home interviews, conducted with the infants' primary caregivers, obtained baseline medical, environmental, and behavioral background information, and house dust and infant urine samples were collected. Study materials were administered in either English or Spanish, according to language status. After concealed randomization, the ES intervention was initiated. During a single clinic visit for medical testing 1 to 6 months after enrollment, infants were skin tested for allergies and had blood drawn. Twelve months after enrollment, caregivers were interviewed at home, and house dust and infant urine samples were collected. Interviewers were blind to treatment group status. The children's medical records since birth were obtained at baseline and again at follow-up.

Demographic and medical background variables were obtained through standardized interview and medical record review. Total serum IgE levels were determined for 144 infants ever, foreign-born Hispanic individuals were demographically unique and had significantly different illness histories and lifestyle patterns, and risk factors for asthma occurred at significantly lower levels for the foreign-born, monolingual Spanish-speaking group. We expected that foreign-born status would modify the impact of the intervention as well as influence the children's long-term respiratory outcome.

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by fluoroenzyme immunoassay. Allergy skin-prick testing for common indoor inhalant allergens and food allergens was conducted by Quintest (Bayer, Spokane, Wash) for 161 infants (procedural details available).23

INTERVENTION

Caregivers from both groups received an educational videotape at the baseline interview that described their children’s risk for developing asthma, factors that increased risk, and actions that could be taken. All subjects received feedback letters regarding allergen and cotinine levels following the baseline assessment.

Home visitors were nurses with bachelor of science in nursing degrees and experience in community outreach. Intervention goals included decreasing allergens in the home, reducing ETS exposure, and improving quality of maternal caregiving and illness management. At each home visit, nurses used interview and biological data to guide caregivers in setting behavioral goals to work on before the next visit. The intent was to provide 18 home visits across 12 months. The median number of visits per family, including telephone calls, was 15, with visits lasting an average of 53 minutes (SD = 13). Nurses spent 15% of the visit time on allergen and ETS reduction, 37% on health promotion, 14% on parent-child interaction, and 30% on caregiver psychological health.

ETS and Allergen Reduction

For ETS reduction, nurses used caregivers’ reports of smoking in the home and infant urinary cotinine levels to identify ETS sources and to problem solve to reduce the child’s exposure. Caregivers were encouraged to avoid smoking and not to allow others to smoke in the child’s presence or living area, and smokers who were ready received smoking cessation counseling. Reduction of allergen levels was addressed by using the allergen levels and reported exposure within and outside the home as guides for goal setting. For homes with cockroach allergen levels greater than 2 U/g, caregivers were taught to remove food sources and were provided with cleaning materials and traps. Since public housing–project administrators conducted regular projectwide extermination, families living in those units were helped to gain information about extermination dates and to clean before and after extermination. For homes with cat dander levels greater than 1000 ng/g and/or dog dander levels greater than 10000 ng/g, families were counseled to remove the pet and clean thoroughly. If unwilling, they were advised to confine the pet and to restrict it from the child’s sleeping area. Caregivers without vacuum cleaners were provided them.

Health Promotion and Parent-Child Interaction

To intervene with the caregivers’ illness-related caregiving, the nurses used a second videotape that addressed all aspects of respiratory illness management, including assessment of respiratory illness symptoms, communication with the medical care professional, action plans, types of medications, and effective administration strategies. In addition, nurses addressed well-child care and safety and quality of parent-child interaction, including caregivers’ emotional responsivity and behavior management.

Caregiver Mental Health

The nurse visitors continually assessed caregivers’ mental health, including mood disorders, relationship difficulties, problems in living, and parenting problems, and they intervened using problem solving, support, and referrals as needed.

TARGETED VARIABLES

Environmental Exposure

House dust samples were collected at baseline (n = 175) and at 12 months (n = 140). A research assistant vacuumed the family living area, the bedroom carpet beside and underneath the bed, the upper surface of the bed, and kitchen floor areas adjoining the cupboard. The combined dust was sieved (> 200 mg per household) and was sent for analysis to The Johns Hopkins University Dermatology, Allergy, and Clinical Immunology Reference Laboratory, Baltimore, Md, for determination of major allergen content, including cockroach (Bl a 1), dust mite (Der f 1 and Der p 1), cat dander (Fel d 1), and dog dander (Can f 1) allergens.26-28 No families had measurable dust mite allergens in the home, given Denver’s semiarid, high-altitude climate.

To measure ETS exposure, infant urine samples were obtained at baseline (n = 168) and at 12 months (n = 130) and subjected to radioimmunoassay analysis of cotinine, a specific metabolite of nicotine (American Health Foundation Laboratories, Valhalla, NY). Levels are reported as nanograms of cotinine per gram of creatinine.29

Caregiving Variables

At baseline and 12 months later, caregivers were administered the semistructured Family Asthma Management System Scale30 adapted to assess caregivers’ illness management practices with wheezing infants. Two subscales, knowledge and collaborative relationship with medical care provider, were appropriate for assessing change among caregivers of children with and without respiratory problems 12 months later. Scores ranged from 1 to 9 for each subscale, with higher scores reflecting more knowledge or more effective caregiver–provider relationships. Interrater reliability among raters, blind to experimental condition, ranged from 0.82-0.96 (knowledge) and 0.79-0.96 (collaborative relationship).

The Home Observation for Measurement of the Environment Inventory (0-3 years)31,32,33,34,35,36 an assessment of parent-child interaction at home, was administered at baseline and 12 months later while the child was present and awake. Summary scores ranged from 12 to 45, with higher scores indicating a better-quality emotional and intellectual environment. Interrater reliability for the Home Observation for Measurement of the Environment Inventory was 93.2%.

MODIFIER VARIABLES

Families classified themselves according to racial, ethnic, and language groupings. Among Hispanic families, monolingual Spanish-speaking caregivers were born in Mexico. Since risks among foreign-born families differed from US-born white, African American, and Hispanic families,24 families were classified as US-born vs foreign-born.

Caregivers’ psychological resources37 were measured at baseline and a low/high variable was created based on the average z scores of their (1) mental health,33 (2) cognitive functioning,34,35 and (3) sense of mastery.36 Baseline illness severity was classified according to caregiver report of medication use, with as-needed bronchodilators indicating low severity (ES, 61%; C, 54%) and scheduled bronchodilators and/or anti-inflammatory medication indicating high severity (ES, 37%; C, 46%).
**OUTCOME VARIABLES**

At baseline and at 12 months, caregivers were asked to rate their infants’ respiratory symptoms for the past 6 months using a 5-point scale: (1) daily, (2) weekly, (3) monthly, (4) less than monthly, or (5) never. The symptoms were (1) wheezing, coughing, or tightness in the chest, (2) nights awakened by breathing problems, (3) slowed or stopped play owing to breathing problems, and (4) breathing problems on awakening. They responded yes/no to the fifth question: Has child had breathing problems, (3) slowed or stopped play owing to breathing problems, (4) nights awakened by breathing problems, or tightness in the chest, (2) wheezing, coughing, or breathing problems so severe that he/she couldn’t vocalize? Mean scores ranged from 0 to 4, with higher scores reflecting greater frequency and severity of symptoms.

Caregivers responded to the Pediatric Asthma Caregiver’s Quality of Life scale, which consists of 13 items about the effect of the child’s asthma on the parent. For this study, “asthma” items were reworded “when your child experienced cough, wheeze, or breathlessness” or “breathing problems,” so that the scale was applicable for infants with wheezing illness. Mean scores ranged from 1 to 7, with higher scores reflecting better quality of life.

Data regarding number of hospitalizations for wheezing illness, emergency department visits, and corticosteroid bursts were obtained from medical records and coded using a standard system. Interrater reliability, assessed for 25% of the records, ranged from 0.88 to 0.97 (95% confidence interval, 0.62-0.99).

**DATA ANALYSES**

Data are presented as mean±SD for continuous data and percentage of the whole for dichotomous data. If demographic and baseline variables were normally distributed, the 2-sample t test was applied to compare the environmental support and control groups; otherwise, the χ² test or the Wilcoxon rank sum test was used.

For the intent-to-treat evaluation of the primary and secondary questions, multiple regression models were used appropriate to the data-distribution profile for response variables. A multiple logistic-lognormal-normal model for data with clumping at zero was applied to child cotinine levels. Cockroach, cat, and dog allergen levels were dichotomized using the following standard cutoffs, 2 U/g, 1000 ng/g, and 10000 ng/g, respectively, and effects were evaluated via a multiple logistic regression model. Intervention impacts on caregiving, maternal report of outcomes, and medical record outcomes were evaluated with either multiple normal regression or multiple Poisson regression. For ease of interpretation, raw values are presented in the tables. For medical record outcomes, baseline response measures were adjusted for child’s age at study entry. The final model for each response variable included foreign-born status and psychological resources as covariates as well as group status, sex, and the corresponding baseline responses. A 2-sided P value <.05 was considered statistically significant.

**RESULTS**

Table 1 shows that the CAPS families were largely minority and extremely impoverished and that most of the infants were at risk for atopy. Cockroach allergen (bla g 1) levels higher than the standard cutoff were present at baseline in 21 homes (12%) and were not different across the 2 groups (Table 2). Cat dander (fel d 1) levels were higher than the cutoff in 54 homes (31%) and dog dander levels, (can f 1) in 34 homes (19%). Cigarette smokers were present at baseline in the homes of 64% of children (ES, 54 [61%; C, 59 [66%]; P=.0493), including
At baseline, infant urinary cotinine levels were detectable in 94 families (56%). Baseline caregiving variables are also presented in Table 2; the collaborative relationship score for the control group was significantly higher at baseline.

**CHANGES IN TARGETED VARIABLES**

For cockroach allergen levels, logistic modeling (Table 3) demonstrated a significant group effect with fewer homes having cockroach dander of 2 U/g or higher in the ES group (P<.03) by year’s end. There was no sig-
significant difference between study groups for changes in cat dander levels. For dog dander levels, logistic modeling showed nonsignificant trends toward greater reduction in the ES group compared with the C group by year's end ($P = .07$).

The logistic part of a logistic-lognormal-normal model showed no differences in numbers of families with infants with detectable cotinine levels at year's end (Table 3). The lognormal part of the logistic-lognormal-normal model with detectable cotinine levels (ES = 42 [66%]; C = 37 [56%]) was significantly lower in the ES group than the C group at the end of the year ($P = .02$), and the reduction was greatest among low–psychological resource families ($P = .01$) (Figure 2A) (ES = 29.2; C = 63.4; $P = .03$) but not among high–psychological resource families ($ES = 43.9; C = 45.3; P = .93$).

Although caregivers in the ES and C groups had comparable scores on the Family Asthma Management System Scale knowledge subscale at baseline, 12 months later the families in the ES group had significantly greater asthma knowledge scores ($P < .04$; effect size of 0.32). The ES caregivers' collaboration with medical provider scores were rated significantly lower at baseline than those for the C group; at outcome, these ratings were significantly higher for the ES group ($P < .04$; effect size of 0.34). There was no significant effect of intervention for the Home Observation for Measurement of the Environment Inventory scores or any significant interaction with the modifier variables.

OUTCOME VARIABLES

Caregivers' reports of functional severity of illness did not change differentially by group during the year, nor were there significant interactions with modifiers. Changes in caregiver ratings of illness-related quality of life were modified by foreign-born status ($P < .03$). Foreign-born caregivers in the C group reported at year's end significantly poorer quality of life than foreign-born caregivers in the ES group, but this difference was not seen in US-born caregivers ($P < .04$) (Figure 2B) (ES foreign-born = 6.69; C foreign-born = 6.10; $P = .04$; ES US-born = 6.41; C US-born = 6.41; $P = .98$).

There was no significant difference between treatment groups in occurrence of emergency department visits or hospitalizations throughout the year, nor were interactions with modifiers significant. Number of corticosteroid bursts during the year was significantly higher for the infants in the ES group than in the C group ($P < .01$).

The primary objective of this report was to evaluate the impact of the intervention phase of CAPS on variables targeted for intervention. In this sample of low-income infants at risk for asthma, we demonstrated that a multifaceted, nurse home visitor intervention successfully affected several environmental and caregiver variables within the ES group. As hypothesized, the intervention had greater impact on ETS exposure among caregivers with low psychological resources. Despite these effects on some aspects of the children's environment, there was no evidence that the intervention decreased the children's respiratory symptoms by year's end. Infants from the ES group had more corticosteroid bursts during the year, although they did not have fewer emergency department visits or hospitalizations.

The study sample of infants at risk for asthma was recruited based on having had 3 or more episodes of wheezing documented by a medical care professional. Unlike infant cohorts with wheezing illness followed up by several investigators, this sample was not selected on the basis of having been hospitalized for bronchiolitis but rather on the basis of having repeated wheezing symp-
toms in or out of the hospital, which were for the most part unrelated to respiratory syncytial virus. Because this was a “secondary” intervention with infants with a history of wheezing, where the goal was to halt the progression of the disease, the intervention differed from primary prevention studies that have attempted to prevent the occurrence of wheezing episodes in the first or second year of life. In contrast, we focused on reducing environmental exposures that may contribute to persistent symptoms among infants who have already wheezed, most of whom were atopic or were at familial risk for atop. The intense home-based intervention was designed to also address the psychosocial context of these severely impoverished families, for whom economic and psychosocial difficulties impede compliance with recommendations aimed at primary or secondary prevention.

Reducing environmental allergens in the homes of these low-income families was a central intervention aim. We previously reported for this sample that cockroach allergen in the home, independently of respiratory syncytial virus, was associated with hospitalizations prior to study entry. Although others have found cockroach infestation to be difficult to affect, we showed a significant reduction in affected families in the ES group. Our success was likely because low-income dwellings in this community tend to be relatively small and freestanding, reducing reinestation from adjoining structures. There was a nonsignificant trend toward reduction of dog dander levels in the ES group. We were unsuccessful in reducing the number of families with high cat dander levels in their homes.

Reduction of ETS was targeted because of evidence that cigarette smoke is an important contributor to infant wheezing. Although both ES and C families received feedback regarding cotinine levels in their children, only families in the ES group received problem-solving aid from home-visiting nurses regarding reducing ETS. All families showed reduced cigarette smoke exposure, but the reduction from baseline was significantly greater among ES families, especially where caregivers had fewer psychological resources, reflecting poorer mental health, cognitive skills, and sense of mastery. That the greatest reductions occurred among the low-psychological resource women in the ES group is consistent with data from the Olds et al home visitation study, which found reductions in smoking among mothers with fewer psychological resources.

Beside reducing environmental exposures, a central aim of the intervention was to improve caregivers’ awareness of their infants’ breathing problems and to impress on them the importance of bringing those problems to the attention of medical care professionals and following recommendations. The ES group showed significant improvements on the knowledge and the collaborative relationship subscales relative to the C group. While increased knowledge does not necessarily indicate improved illness management, a working knowledge of relevant symptoms and effective medications for infant breathing problems are critical components of caring for wheezing infants. The collaborative relationship subscale uses parent report to assess the parent-physician partnership in treating infant wheezing illness. Baseline assessments showed that the C group began with significantly better scores on the collaborative relationship subscale, while at the end of the intervention the ES group had improved to a significantly higher level than the control group. Given the goals of this study, the significant improvement in the ES group on the collaborative relationship subscale is an important achievement, suggesting increased access to medical care and improved quality in the care received.

Despite some modest changes in environmental exposures and caregiver variables, there was no evidence for greater reductions of wheezing in the ES group. There were also no differences between groups in medical care use across the course of the treatment year. Children in the ES group received significantly more corticosteroid bursts during the year. The meaning of this difference is unclear, since there was no significant difference between the groups on symptom levels at year’s end, nor were increased oral corticosteroids associated with differential emergency department visits.

The design of the study may have impeded significant improvements in the ES group compared with the C group. Both groups received attention, information about prevention of childhood asthma, and objective feedback about the children’s allergen and ETS exposure. Provision of a low-level intervention to the C group was considered necessary for ethical reasons and to address the practical challenges of engaging low-income parents of ill infants in long-term research. Also, the nature of the sample made change difficult, since caregivers were not only limited in knowledge and skills, but they were constantly beset by personal problems and life crises that impeded their compliance with recommendations. Regardless of the barriers, the modest environmental changes and the failure to affect clinical outcomes raises questions about the usefulness of this intensive intervention in decreasing wheezing symptoms among young children from impoverished families and suggests that it may be premature to adopt this broad intervention with a population that has so many socioeconomic and psychosocial challenges. Further analyses of these data may be instructive in determining characteristics of families that were positively affected, what facets of the intervention are feasible, and how to modify the intervention to enhance effectiveness. Analyses can also address how the children’s clinical status is associated with outcome at age 4 years, when objective measures of lung function are planned to evaluate the effects of the intervention on child asthma status.

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