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Methods and issues in conducting a community-based environmental randomized trial ☆

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Abstract

The environment is suspected to play an important role in the prevalence and severity of asthma in inner-city children. This paper describes the implementation and baseline data of an inner-city community-based participatory research clinical trial designed to test the effectiveness of a pollutant and allergen control strategy on children's asthma morbidity. Participants were 100 elementary-school-aged children with asthma, graduates of a school-based asthma education program in East Baltimore. The intervention for half of the randomly assigned families consisted of environmental control education, allergen-proof encasements, pest extermination, and a HEPA air cleaner at the beginning of the study. Controls received the same at the end of the study. Participants visited a clinic for questionnaires, allergy skin testing, spirometry, and blood sample at baseline and 12 months. Home environments, NO_2, O_3, airborne particulates, and allergens were evaluated at baseline and at 6 and 12 months. Asthma morbidity and adherence was assessed quarterly. Collaboration with the community proved very beneficial in creating a study design and procedures acceptable to an inner-city community.

Keywords: Asthma; Environmental intervention; Exposure assessment; Community-based research

1. Introduction

Recent NIH guidelines for the clinical treatment of asthma include reduction of environmental exposures as one of the four basic principles of therapy (NHLBI, 1997). Although many studies support this recommendation, there are few clinical trials evaluating environmental exposure reduction in inner-city populations (Carter et al., 2001; Evans et al., 1999; Shapiro et al., 1999). Since environmental and social issues in the inner-city differ significantly from those in the general population, such studies are needed to develop effective, culturally appropriate exposure mitigation strategies for inner-city asthmatics.

It is widely agreed that controlled clinical trials provide the most efficient means of rigorously evaluating therapies. However, proper clinical trials are challenging to conduct in inner-city communities. The principles of proper clinical trials are well described and include (1) using effective treatments, distinguishable from one another, acceptable to and administered equally to patients; (2) having outcomes that are objective, predetermined, and measured independent of the intervention; (3) randomly assigning participants to receive active and control treatments; and (4) masking

☆This research was conducted in accordance with national and institutional guidelines for the protection of human subjects. The Johns Hopkins University School of Medicine's IRB, The Joint Committee of Clinical Investigations, approved the study. All parents or caregivers signed the JCCI-approved consent and all children signed the approved assent prior to participating in the study. No animals were used in this research.

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the identity of treatments (Meinert, 1986). Inner-city communities are often suspicious of many aspects of proper clinical trial design, including the abstract issues of randomization, masking, and use of study protocols. They may feel that they are "guinea pigs" for treatments that might put them at risk while offering little benefit. Moreover, inner-city families may have problems arranging required visits and may not always have a stable address or telephone, making scheduling and follow-up difficult. As a result they may be less compliant with complicated, taxing regimens or may not report side effects.

Recently environmental studies have recognized the importance of partnering with the affected community. Community-based participatory research (CPBR), as described by Israel et al. (1998), refers to a "collaborative approach to research that equitably involves... community members, organizational representatives, and researchers in all aspects of the research process." It recognizes that research should meet the needs of the community, be sensitive to its culture and beliefs, and provide important health information. From the researcher's viewpoint, it should produce community-relevant information, take advantage of community resources, knowledge, and abilities, and be founded on the problems and needs of the community. It emphasizes the importance of the exchange of information and knowledge, providing benefits to all that may extend beyond the research project.

This paper describes an environmental intervention trial that embraces principles of both community-based research and appropriate controlled clinical trial design. It has been successfully launched and the preliminary results are available.

2. Materials and methods

2.1. Study overview

This was a 1-yr, randomized, parallel-group, controlled clinical trial designed to test the effectiveness of a multifaceted environmental control intervention strategy intended to reduce home exposure to pollutants and allergens on children's asthma morbidity. Participants were recruited from graduates of a school-based asthma education program conducted at six elementary schools in East Baltimore. Families were assigned randomly to either intervention or control groups. The intervention consisted of environmental control support provided by a home teacher, allergen-proof mattress and pillow covers, cockroach and mouse extermination, and a room HEPA air cleaner. Before randomization, each volunteer signed an informed consent and completed a questionnaire, had a home environmental evaluation to measure allergens, NO_2, O_3, and airborne particulate matter, and visited a clinic to complete questionnaires, undergo allergy skin testing and spirometry, and provide a blood sample for serum cotinine testing. Asthma morbidity and adherence to recommendations was assessed quarterly by telephone interview and a final clinic visit with questionnaires, spirometry, and a blood sample. Home environments were assessed at 6 and 12 months. Families in the Control Group eventually received the same materials as the Intervention Group, but only at the end of the study. The study procedures are summarized in Fig. 1.

2.2. Community advisory board

Early in the design stages of the research program, members of the community were recruited to join a Community Advisory Board (CAB). Members included two school principals, a pastor, a nun assigned by her order to work in the community, two community association presidents, a parent of a child with asthma, health personnel who had worked in the community, and a clinical social worker. The CAB met in a neighborhood school and members were given honoraria for their time spent at the meetings.

The study investigators and the CAB jointly developed important principles of the protocol including construction of the control group, recruitment strategy, and data collection. The community members felt that each participant should be treated the same and receive immediate benefit from participation. The control group became the "Treat Later" group. The benefit of the asthma education program was extended to all children with asthma in participating schools and all families received environmental education at the beginning of the study. The study catchment area was a compromise between the need for a nearby ambient air quality monitoring station and respect for existing political boundaries in East Baltimore. The CAB defined appropriate school partners and community organizations for presentations of the study.

During the course of working together, the CAB, study investigators, and study community staff encountered differing viewpoints and opinions regarding protocol details. In a series of retreats, these issues were formally addressed and a statement of core values was created. These guiding principles that everyone committed to honor were, in brief: (1) cultural competence and inclusiveness: investigators and community members recognize, accept, and celebrate their differences and value and include different community perspectives; (2) first do no harm: studies should be drafted so that they are safe and ethical; (3) honesty: conversations between the community and investigators should be frank and honest; (4) confidentiality: private information should be kept confidential; (5) productive use of

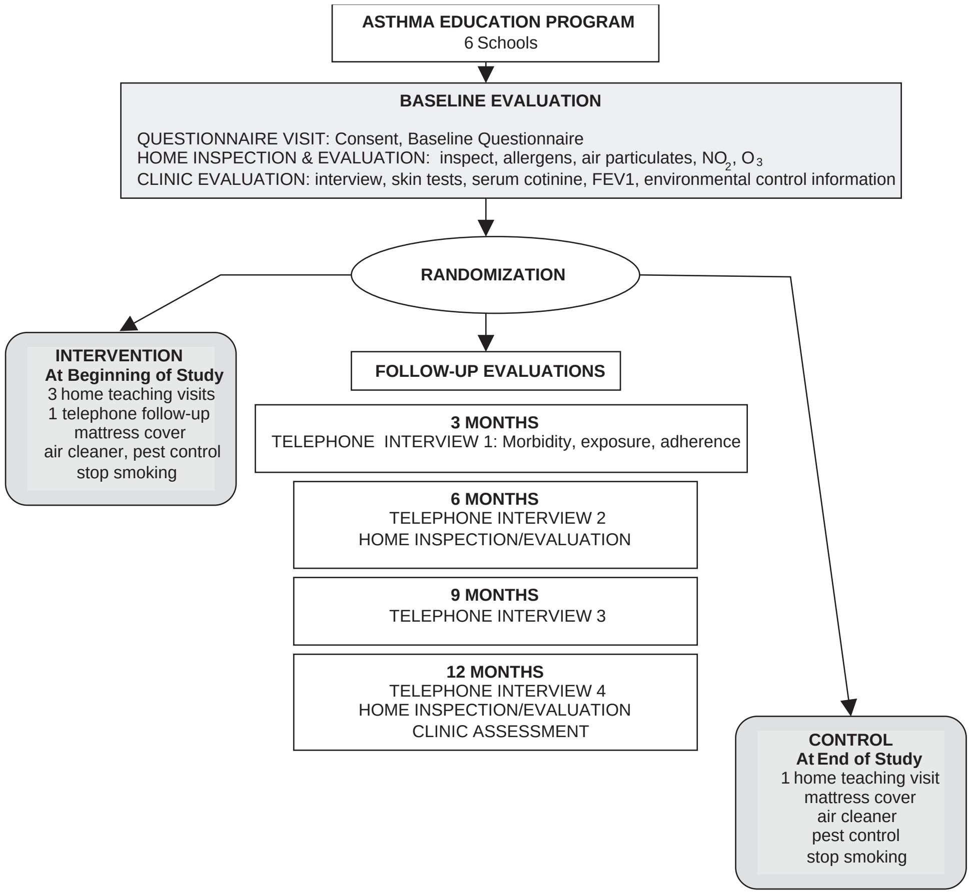

Fig. 1. Clinical trial of environmental interventions—study procedures.

resources: efficiency in time, effort, and money is important to investigators and community members; (6) effective communication: communications between investigators and community will be open and continuing and participants have a right to know study findings; (7) commitment to advocacy: investigators and community should use their information and energy to advocate for community improvement; (8) education/co-learning/sustainability: community and investigators should learn and share with one another; (9) sound science: any community intervention or research planning must be compatible with sound scientific principles. Establishing core values clarified the basis for the collaboration and formed the heart of future discussions.

As part of the co-learning experience, the CAB held three staff development forums to present the community from a cultural, historical, and social, as well as environmental approach. There were two lectures and a several-hour bus tour of the catchment area.

With the encouragement of the CAB, to promote acceptance and the establishment of an open, honest two-way relationship between participants and the study, the entire community staff was African–American and either lived or had lived in the community or had previous work experience in research or education in the community.

The CAB supported presentations to all agencies whose approval was necessary before beginning the study, the institutional review boards of the Johns Hopkins School of Medicine, the Baltimore City Health Department, the Baltimore City Department of Education, the Clinical Research Unit at Johns Hopkins Hospital, and the principals of participating elementary schools.

Beyond the specific conduct of this study, the CAB brought environmental health issues such as children's exposure to bioaerosols from trash in alleyways, neighborhood exposure to mobile source emissions on heavily trafficked urban arterials, and pollution related to building demolition to the investigators' attention. The investigators were sometimes able to help, for example, measuring pollutants from the demolition by implosion of high-rise buildings and distributing action guidelines based on these results in the community for the next demolition (Beck et al., 2003; Srinivasan et al., 2002).

2.3. Protocol

2.3.1. Recruitment

At the suggestion of the CAB, the functions of the asthma education program teachers and the clinical trial recruiting staff were separated so that families would feel free to enroll their children in the asthma education program without feeling obligated to join a research project. The asthma teachers were hired to deliver the school-based program, educate families, and be advocates for the child and family. Although the asthma teachers spoke to families about the study, the primary recruitment was not their function.

2.3.2. School-based education

At the beginning of each school semester, the asthma teachers sent a letter on school stationery, signed by the school principal and the study principal investigator, stating that an asthma education program would be offered and that an optional research program was connected. Families were asked to notify the school if their child had asthma and they were interested in participating in the program. Before enrollment, the asthma teachers contacted families to confirm their willingness to participate.

The school-based asthma education program, the A+ Club, was developed at Georgetown University (Schneider et al., 1997). It was taught from a manual that was given to the children and consisted of six 45-min lessons to teach children to recognize triggers for their asthma and early symptoms of an asthma attack, understand methods to stop the attack, cooperate with the correct use of medicines, and speak up to parents and other adults to seek help and support.

After the children graduated from the asthma education program, the teachers visited their homes to review with their caretakers or parents the lessons learned in the asthma curriculum and to give them the "A+ Parent Manual" and an Asthma Action Plan to take to their children's physicians. Following this the families were given materials describing the study, and, if they were willing to talk further about being in the study, the teachers gave their names and contact information to the study recruiter.

2.3.3. Home recruitment

The recruiter arranged an introductory home visit to present the study and its requirements in detail and to review eligibility criteria with the family. The recruiter used a manual with pictures and diagrams of each study step and specific information about procedures of concern to potential participants such as allergy skin testing, venipuncture, the air monitoring equipment, and intervention details. Depending on the family interest, informed consent was obtained during the visit or a second visit was scheduled to allow the family time to think over participation in the study.

Through close interaction with the community, staff members sometimes were made aware of families interested in participating but whose children had not been through the school-based asthma education program. As a result, an alternate method of recruitment was developed. Before being referred to the study recruiter, these families received a "Shortened Asthma Education Program" consisting of 2 h-long home visits from the asthma teachers, one visit with the parent and one with the child.

2.3.4. Entry criteria

To be eligible for the study, families met the following criteria: (1) child was aged 6–12; (2) child had doctor-diagnosed, current asthma symptoms or medication use at least once in the previous 3 months; (3) child had no other chronic illnesses; (4) the home had electricity and was within the catchment area. Only one child per household was included in the study.

2.3.5. Baseline assessments

Home administered questionnaire. At either the first or second home visit to participating families, the study recruiter administered the baseline questionnaire. This questionnaire covered demographics, child's medical history and recent asthma problems, caregiver social support and emotions, child's exercise and nutrition, and child's history of indoor environmental exposures during pregnancy, infancy, preschool age, school age, and present.

Home evaluation and exposure assessment. An indoor home assessment was scheduled within 2 weeks of completing the baseline questionnaire. In summary, this assessment consisted of a visual inspection of the entire home, a cockroach census, and 3 days of environmental monitoring. A trained technician completed an inspection form detailing the home's structure, heating, air conditioning and ventilation system, and condition including surface moisture measurements. The cockroach census was conducted by placing three sticky traps in the kitchen over the 3-day monitoring period.

The environmental assessment included both allergens and air pollutants. Dust samples were collected in a fabric sleeve fitted into the nozzle of a hand held vacuum. Samples were collected from the child's bedroom, the family or television room, and the kitchen. The bedroom sample was collected by vacuuming a 1-m^2 area near and underneath the bed for 2 min combined with a 2-min sample from the mattress and bedding. In the television/living room samples were collected for 2 min each from any upholstered furniture and from a 1 m^2 area next to the furniture. In the kitchen, the entire floor was vacuumed for 4 min with particular attention to the base of the counters and the interior of under-sink cabinets. After each room sampling, the fabric collector was removed from the vacuum, sealed in a plastic bag, and returned to the lab, where the samples were sieved (Platts Mills et al., 1992). An aqueous extract of 100 mg of sieved dust (sieve size 300 μm) specimen was prepared in 2 mL of borate-buffered saline. The extracts were stored at −30°C until they were assayed for Der p 1, Der f 1, Fel d 1, Bla g 1, and Mus m 1 using sandwich ELISA (Indoor Biotechnologies, Charlottesville, VA) (Chapman et al., 1987, 1988; Ohman et al., 1994; Pollart et al., 1991). Results were expressed as micrograms per gram of settled dust when appropriate standard were available or as units per gram in the case of Bla g 1.

Air pollution sampling was conducted over a 72-h period in the bedroom of the asthmatic child. PM_{10} (particulate matter with aerodynamic size less than 10 μm) and $PM_{2.5}$ (particulate matter with aerodynamic size less than 2.5 μm) airborne particle samples were collected using 37-mm impactors. Samples were collected using battery-operated pumps plugged into house electrical service to assure 72 h of operation. Ozone and nitrogen dioxide were sampled using passive monitoring badges. All sampling heads and passive badges were attached to the outside of a sampling frame that was placed in a convenient place in the child's bedroom. PM gravimetric analysis was conducted using a Metler T5 microbalance. Ozone samples were analyzed using ion chromatography and nitrogen dioxide samples were analyzed spectrophotometrically.

Clinic evaluation. Soon after the baseline home evaluation, the child visited the Johns Hopkins Hospital Outpatient Pediatric Clinical Research Unit. Transportation to the clinic via taxicab was arranged and paid for if the family desired it. To assess the impact of the child's asthma and allergies on his or her daily life, the child was asked the Juniper Pediatric Asthma Quality of Life and Pediatric Rhinoconjunctivitis Quality of Life Questionnaires (Juniper et al., 1996, 1998). Each child was allergy skin-tested using the skin-prick method (Multi-Test II, Lincoln Diagnostics, Decatur, IL) with 14 aeroallergens: American and German cockroach, dust mite mix, cat, dog, mouse, rat, ragweed, grass mix, oak tree, *Penicillium*, *Alternaria*, *Helminthosporium*, and *Aspergillus* (Hollister-Stier Laboratories, Spokane, WA and Greer Laboratories, Lenoir, NC). Wheal reactions at least 50% of the histamine response were considered positive. The child also performed spirometry before and after inhaled albuterol and provided a 10-mL blood sample for serum cotinine testing (American Health Foundation, Valhalla, NY). At the conclusion of the visit, the caregiver was given a letter in a sealed envelope informing him or her of family's study group assignment. Randomization assignment was based on a computer-generated schedule.

2.3.6. *Intervention*

Fifty families were each randomized to the intervention and control groups. Intervention families received 3-h-long home teaching visits and a telephone follow-up call over a 5-month period. These visits included a parent interview about the child's asthma symptoms and current environmental control behaviors (cleaning habits, smoking in the home, pests, sources of combustion) and a visual inspection of the home. Families were taught about asthma, the role of allergens and irritants in asthma, and methods for reducing exposure to indoor allergens and air pollutants. Appropriate reduction behaviors were modeled. Colorful visual aids and materials written at or below a fifth grade reading level (Flesch–Kincaid) augmented the verbal education. Children were encouraged to participate.

Each family was given a HEPA (Holmes Products Inc., Milford, MA) air filter for the child's bedroom and asked to keep the air cleaner on continuously. The on/off switch was locked in the "on" medium position on intervention family filters, making it necessary to unplug it to turn it off. To detect when the air cleaner was on and off, a data-logging electric field sensing detector was used. The home teacher also supplied allergen-proof mattress and pillow encasements (Allercare, Mission Allergy, Hawleyville, CT) and food storage containers.

When necessary, free professional exterminations (American Pest Management, Takoma Park, MD) using integrated pest management techniques were arranged. Extermination for cockroaches included the placement of MAXFORCE FC gel baits, fipronil 0.01%, throughout the kitchen and bathroom and in selected areas of other rooms if there was evidence of infestation. Contrac Blox, Bromadiolone 0.005%, were placed in the kitchen, usually behind the stove, to exterminate for mice. The rodent bait was placed in a tamper-resistant station (Bell Protecta RTU) to prevent access by children or pets. Obvious mouse entry points were closed with copper mesh and families were instructed on appropriate methods to prevent reinfestation. When recommended by the exterminator or when the cockroach sticky trap count was greater than 10, an additional application of gel bait was made a week later. If the family reported continuing infestation at 6 months, a second round of exterminations was arranged.

Prior to the home visits, the home teacher was provided with the results of the child's skin testing, the home inspection questionnaires and checklists, allergen levels from the home dust samples, and indoor air quality including O_3, $PM_{2.5}$, PM_{10}, and NO_2 levels. This child- and home-specific information was used to develop personal action plans for teaching allergen and indoor air pollutant control.

During the first home visit, families were provided with their home's air pollutant levels and taught about the sources of indoor air pollutants and ways to reduce it. All families were given information on the importance of avoiding exposure to secondhand smoke for their children with asthma. Families with current smoking in the home were also offered information on free and low-cost smoking cessation programs in the area and asked to smoke outside the home. No Smoking signs were given to all families who allowed smoking in their homes to remind family members and visitors not to smoke in the house.

During the second visit families were taught about indoor allergen and irritant control. Using a personalized, written action plan, specific to the child's allergies and exposure, educators worked with families to decide which changes could be implemented and to establish goals and family responsibility for each change. Families were given a calendar with monthly tips on allergen control along with stickers to help establish newly learned behaviors geared at lowering allergen exposure.

To keep in touch with the families, assess their children's asthma, use of the air purifier, and current smoking in the home, and confirm extermination, the home teacher conducted a follow-up phone call. This provided an opportunity to remind families to keep the air purifiers on, not to smoke in the home, and to keep up with the indoor allergen and air pollution control recommendations.

Five months after enrollment the final home visit was done. Its purpose was to reteach pertinent allergen and air pollutant information, reinforce the adoption of recommended behavioral changes, and encourage maintenance of the allergen and air pollutant control recommendations.

At the end of the study, the control group received the same supplies, pest extermination, and written information as the intervention group. The home teachers visited their homes once to provide the supplies and teach the families about indoor environmental controls to reduce allergens and pollutants.

2.3.7. *Follow-up evaluations*

A telephone interviewer called the child's primary caregiver quarterly to complete questionnaires detailing home environmental exposure (cigarette smoking, cockroach infestation, and rodent infestation), asthma-related symptoms, quality of life, heath care utilization, and adherence to environmental control recommendations. Follow-up home evaluations, identical to baseline, were conducted at 6 and 12 months postrandomization. The clinic visit was repeated at the conclusion of the study. All follow-up contacts were conducted by staff unaware of the participants' study assignment.

2.3.8. *Community worker safety*

Safety of study personnel who worked out in the field was always a consideration. To address these concerns, all field workers were provided with cell phones and were instructed to notify supervisors daily with their general plans for home visits. Additional training with a Baltimore City Police detective was required for the staff working in the community. The police officer provided information about the community, signs of problems to watch for, and ways to keep safe. In addition, if study personnel felt a home was unsafe, they were not asked to return there.

2.3.9. *Incentives*

The caregiver was given the results of the child's skin test and a folder of information about asthma and indoor allergen control techniques. He or she was compensated with $20 in cash for every completed encounter. The children were given t-shirts emblazoned with the study logo and small toys or school supplies at each visit. All family members attending clinic visits were given snacks.

2.3.10. *Analysis*

The major treatment variable for the study was the home environmental control intervention (treatment vs. control). Outcome variables for study included 12-month intervention changes in target dust allergen levels, airborne particulate matter, and environmental tobacco smoke (ETS), as determined by serum cotinine concentration. Secondary outcome measures of interest were Juniper Quality of Life Test scores, asthma symptoms, number of emergency room visits, and hospitalizations.

Our main objective was to compare differences in continuous response from baseline to 6 months and from baseline to 12 months (a measure of sustained adherence to environmental control recommendations) across the two groups. Trends in allergen and pollutant levels from baseline to 12 months in the two groups were compared.

The sample size of 50 patients per group was based on the assumption that we would have 80% power to detect a 38% reduction in house dust mite allergens (Marks et al., 1995) and a 50% reduction in airborne particle counts (Reisman et al., 1990). Based on the same assumption, this clinical trial was powered at a 74% level to detect a clinically significant difference (0.42) in the Juniper Quality of Life score (Juniper et al., 1994).

3. Results

3.1. *Recruiting*

Letters informing families of the asthma education program were sent home to approximately 3000 families. Out of an estimated 450 children with asthma in these schools, 387 children completed the asthma

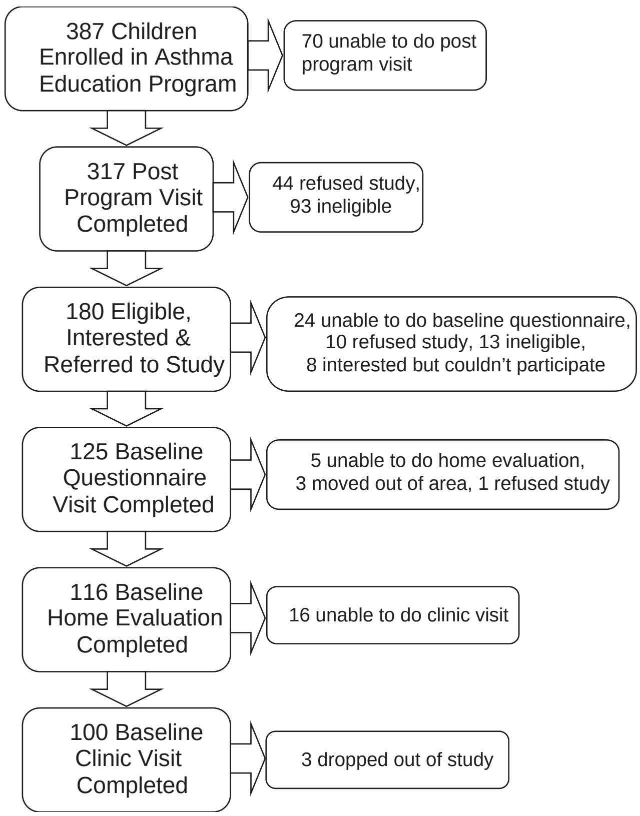

Fig. 2. Recruitment flow.

education program. The school administration and staffs were enthusiastic about the program. The families of 317 children were visited at the conclusion of the education program. One hundred eighty were interested in the study, had an eligible child, and were referred to the study recruiter. The most common reason for not referring a family to the recruiter was ineligibility.

Baseline home visits were conducted and informed consent obtained from 69% of families referred to the recruiter. Home evaluations were conducted on 116 homes. One hundred children and their caregivers (26% of those completing the asthma education program and 56% of those who agreed to talk to the recruiter about the study) completed the clinic visit and were randomized into the study. We were unsuccessful in getting 16 children who had completed the other baseline evaluations into the hospital for a clinic visit. Unless there were extenuating circumstances, when a family missed three scheduled clinic visits, we decided not to pursue them further. In some instances we made deliberate decisions to refer families for help with their housing problems rather than recruit them to the study. Our recruitment activities are detailed in Fig. 2.

3.2. *Child's baseline characteristics*

The children's baseline characteristics are reported in Table 1. The mean age was 8.4, 99% were African–American, and there were slightly more girls than boys in the study. Twenty-one percent of the children were born at least 3 weeks prior to their due dates and 18%

Table 1
Summary of child characteristics

Child	
Age, mean years and (range)	8.4 (6–12)
Female	54%
African–American	99%
Birth and early childhood	
Median birth weight (kg)	2.98 (0.54–4.31)
Premature births	21%
On ventilator at birth	18%
Mother smoke during pregnancy	37%
Ever breastfed	18%
Mean hours per week child spends outdoors	
Summer	35 (8–84)
Winter	10 (0–56)
Children who play indoors more often due to fear of violence	57%
Utilization and asthma symptoms	
Days wheeze, cough, chest tightness past 2 weeks	
0	46%
⩾1	54%
Days nighttime wake up past 2 weeks	
0	61%
⩾1	39%
ED, doctor or clinic visits for asthma attack past 3 months	
None	66%
1	14%
2–6	20%
Asthma medication use in previous 2 weeks	
Controllers (daily preventative asthma medication)	30%
Quick relievers (β_2-agonists)	54%
FEV1	
Mean % predicted	97% (22–159%)
Positive skin test	
American cockroach	24%
German cockroach	36%
Cat	21%
Dog	6%
Rat	9%
House dust mite	23%
Mold (*Alternaria, Helminthosporium, Aspergillus, Penicillium*)	29%
Pollen (grass, ragweed, or eastern oak)	25%
Mouse	47%
Quality of life	
Mean pediatric asthma quality of life score[a]	3.83 (1.48–7)
Mean pediatric rhinoconjunctivitis quality of life score[b]	4.34 (1.7–7)

[a] Response range is 1–7 with 1 meaning great negative impact, 7 no impact.
[b] Response range is 1–7 with 1 meaning no impact, 7 meaning great negative impact.

were placed on a ventilator at birth. The median birth weight was 2.98 kg. Thirty-seven percent of mothers smoked during pregnancy and 18% breast-fed.

Fifty-seven percent of parents said their children play indoors more often because of their fear of violence. At the same time, they also describe the children spending 35 h per week (5 h per day) outside during the summer and 10 h per week in the winter.

Fifty-four percent had daytime asthma symptoms and 39% had nighttime symptoms one or more days in the 2 weeks previous to the interview. Thirty-four percent had healthcare visits for asthma attacks in the previous 3 months. At the clinic visit FEV_1 was normal in most children. Sixty-eight percent had one or more positive skin tests, with the most common positive tests being cockroach, pollen, house dust mite, and mold. On a scale ranging from 1 to 7, with 1 indicating that asthma had a great negative impact on the child's QOL and 7 no impact at all, the mean asthma QOL was 3.83.

3.3. Caregiver characteristics

As shown in Table 2, 89% of caretakers were single women, either mothers or grandmothers, or other single women. Forty-eight percent of the mothers had not completed high school and 73% of the families lived below the US Department of Health & Human Services 2000 poverty guidelines (US HHH, 2000). Using the CES-D scale, 74% of the caregivers reported depression (Radloff, 1977).

Table 2
Family and home characteristics

Caretaker in child's home	
Mother only	75%
Other single female (grandmother, guardian, aunt)	14%
Mother and father	8%
Other	3%
Mother's highest level of education	
Less than high school	48%
High school	42%
One or two years college/tech/voc	10%
Annual household income	
< $10,000	37%
$10,000–14,999	15%
$15,000–19,999	21%
$20,000+	22%
No Data	5%
Social	
Median number children living in the home	3 (1–8)
Median length of time living at current residence	3 yr (1 mo–33 yr)
Caregiver depression	
not depressed	26%
mild to moderate depression	30%
severely depressed	44%

3.4. Home environment

As shown in Table 3, 91% of the homes were row houses, generally in some state of disrepair, with 24% having a leaky roof, 69% with broken plaster, and 66% with cracks or holes in walls and doors. In the kitchens, on inspection, 22% had moisture or leaks, 31% had living cockroaches, 38% had evidence of mice, and 70% had food exposed on the countertops. Thirty percent of children's bedrooms had food or food debris, 8% had cockroaches, and 7% had mice. Sixty-seven percent of children were exposed to tobacco smoke in their homes.

Table 3
Home environmental inspection

Type of home	
Detached	4%
Row house/townhouse	91%
Apartment	5%
General condition of dwelling	
Leaks in roof	24%
Broken plaster	69%
Peeling paint	53%
Peeling wallpaper	14%
Cracks or holes in wall and doors	66%
Pets in household	
Cat	26%
Dog	20%
Current smoking in home	
Children who have current smoking in the home	67%
Median number cigarettes smoked per day in the home	10 (2–120)
Kitchen	
Dishes in sink	69%
Moisture or leaks	22%
Food on countertops	70%
Living cockroaches	31%
Mouse droppings	38%
Child's bedroom	
Leaks in bedroom	18%
Food or food remains	30%
Mess on the floor	61%
Living cockroaches	8%
Mouse droppings	7%
Floor covering type	
wall to wall carpet	44%
linoleum/tile	30%
hardwood	26%
Changes made in home because child has asthma	
Removed pets	17%
Stopped or reduced smoking	40%
Changed pillows	14%
Changed floor covering	7%
Installed air cleaner	2%

3.5. Follow-up

Currently 50 families have successfully completed the study, with 47 remaining in active follow-up. Three families dropped out. Many of the participants had changes in their living arrangements and contact information during the course of the study; 23 families moved at least once, one as many as three times, and 49 changed their telephone numbers. Despite this, follow-up has been successful; an average of 91% of all follow-up visits so far have been completed.

Disaster, including house fire, home condemnation, parent death, parent incarceration, home break-in and theft of study equipment, and pedestrian car accident, struck seven families during their participation in the study. In many cases we were able, with the help of a social worker, to work with the families to solve these problems.

4. Discussion

This paper describes the methodology and conduct of a CBPR randomized clinical trial of environmental interventions in asthmatic children. We have succeeded in designing a scientifically valid clinical trial with the help of community collaborators and have successfully recruited 100 families.

Some in the community felt that we would not be able to find families to participate in the study envisioned. CAB members and the community staff felt that researchers had a history of doing studies in their community, then leaving without giving back individual benefit or information helpful to the community. Researchers were skeptical that a community-based clinical trial could be conducted. Some were concerned that the purpose and goals of the study would become diffuse and that scientific validity would be lost if planning involved open discussion and incorporation of all community concerns. Additionally, there were concerns that conducting a complex clinical trial requiring structured outcome collection and adherence to study regimens in a community of families that frequently moved and changed telephone numbers might not be possible.

In practice none of these concerns prevented the successful conduct of this study. At the beginning, the CAB and researchers did spend a great deal of time engaged in diffuse talking, but in the course of our discussions of protocols, questionnaires, and various aspects of the study, we became aware that we needed to formally identify the values that neither side would compromise. While the effort to do this was great, our core values made the framework for all our discussions clear and, in the end, saved time and will be the basis for continuing cooperation. We were able to adhere to our original purpose and create a scientifically valid protocol.

Once the protocol was agreed upon, we found many benefits of the community collaboration. We had a more realistic idea of the community geographic boundaries and political and social structures. Having school principals, community association presidents, and members of the clergy advising and helping us understand the political and social structure of the community was an invaluable resource. Offering a community service project based in the community schools, one of the formal community structures, was an excellent place to begin to become part of the community. It gave us validity in the community and helped us in developing relationships with families. The CAB helped us create the kind of study that would be acceptable to the community, develop successful recruiting and retention strategies, and write meaningful, understandable results reports for participants and for the community. The CAB members had rewards as well. They felt that their questions and advice had helped the researchers in developing and presenting materials in a way that clearly explained the research and the parameters of good science and that ultimately improved communication of findings.

The community staff participated in CAB and staff meetings and was empowered to represent the community. They attended community meetings, participated in community health fairs, and helped families with social problems outside the scope of the study. Their roles in the study extended beyond their research duties and into the community. This provided them with a larger purpose, making them more enthusiastic and invested in the study. Also, because they were so intensely involved in the community, their research jobs were easier.

We were pleased that we were able to enroll a high percentage of eligible families and, despite a high rate of changes in living arrangements, had such a high retention rate. We believe this was due primarily to the trust created by the overall project and the people working for the project. The CAB guided us to the development of a successful project. We first provided a service and then offered the research part as an option. Great care was taken not to pressure families in any way to join the study. As the study unfolded, we learned a great deal about ways to keep families engaged. When we encountered follow-up problems, possible courses of action were discussed with field staff and strategies developed. To make it easier for the participants to make use of their reimbursement money, all payments to participants were in cash. Sometimes we sent one of our staff members in the cab to personally pick up participants for a clinic visit. Though we asked all participating families to notify us when they moved or changed their telephone number, we knew it would not always happen so, at the beginning of the study, we asked parents to supply several names, addresses, and telephone numbers of people who would always know how to reach them. In several instances, even this was not enough to locate a family so our home visitors went out to the home, talked to neighbors and got names of family or friends to pursue. Because the field staff lived in the community or had previous work experience in the community, kept a constant presence in the community, and were known and trusted, neighbors were willing to provide information about our missing participants. Additionally, because we were involved with the schools, we were able to contact the child's school to obtain new information. Ultimately we believe it was the strength of the personal relationships with the study staff that kept participants engaged in the study.

This project that was involved in the schools and community and focused on the home yielded unexpected but gratifying results. We were able to identify social problems and find ways to help a great number of families, both in and not in the study and we were able to perform environmental studies of concern to the community.

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