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Design and Baseline Characteristics of a Low-income Urban Cohort of Children with Asthma: The Asthma Action at Erie Trial

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Abstract

Objective: To describe the methodology of a randomized controlled trial comparing the efficacy of integrated asthma community health workers (CHW) and a certified asthma educator (AE-C) to improve asthma outcomes in low-income minority children in Chicago.

Methods: Child/caregiver dyads were randomized to CHW home visits or education in the clinic from an AE-C. Intervention was delivered in the first year after enrollment. Data collection occurred at baseline, 6-, 12-, 18, and 24-months. The co-primary outcomes included asthma control using the Asthma Control Test/childhood Asthma Control Test (ACT/cACT) and activity limitation over the past 14 days.

Results: A total of 223 participants ages 5-16 years were randomized. The majority of children were in the 5-11 year old range (78.9%). Most caregivers (96.9%) and 44% of children were female. Approximately 85% of caregivers and children reported Hispanic ethnicity and 62.3% reported a household income of \$59,000. Over half (55.7%) had uncontrolled asthma as

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Contributors' Statement Page

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Dr. Pugach designed the data collection process, carried out the main study analyses and reviewed and revised the manuscript.

Ms. Rosales assisted with the design of the data collection process, collected data, carried out preliminary analyses, and reviewed and revised the manuscript.

Dr. Martin conceptualized and designed the study and the larger clinical trial from which this study is drawn, and reviewed and revised the manuscript.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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measured by ACT/cACT; 13.9% had a normal ACT/cACT score but were uncontrolled using the Asthma Control Questionnaire and 20.2% were controlled on both measures but had received oral steroids in the past year for asthma.

Conclusion: The Asthma Action at Erie Trial successfully recruited a largely Hispanic cohort of children with uncontrolled or high-risk asthma to study the differential effects of clinic-based AE-C and home-based CHW interventions. Strengths of the trial include its comparative effectiveness design that integrates interventionists and intervention delivery into a clinical setting. Categorizing asthma control in community settings for research purposes presents unique challenges.

Keywords

asthma; health outcomes; community health workers; disparities; adherence; pediatrics

1.0 Introduction

Asthma is one of the most prevalent chronic diseases in the pediatric population in the United States, as demonstrated by a current childhood asthma prevalence rate of 10.7%[1]. Overall, it affects 26.5 million people and imposes 81.9 billion dollars in health care costs each year[2, 3]. Minority children suffer a disproportionate burden of asthma prevalence and morbidity. In particular, Non-Hispanic black (17.1%) and Puerto Rican (19.8%) children endure a significantly higher prevalence of asthma than non-Hispanic white (9.6%) children[1, 4]. Odds ratios for asthma exacerbations and emergency department visits are also substantially higher in non-Hispanic black (4.07 (CI 3.03-5.46; $p < 0.001$) and Puerto Rican children 5.41 (CI 3.23-9.04; $p < 0.001$) compared to non-Hispanic white children[1]. These alarming inequities exist despite decades of research aimed at developing and implementing strategies to address pediatric asthma disparities.[6-8]

Effective behavioral interventions to control pediatric asthma are needed. While the Global Initiative for Asthma (GINA) and National Heart, Lung, and Blood Institute (NHLBI) National Asthma Education and Prevention Program Expert Panel Report 3 (NAEPP EPR-3) asthma guidelines cite the efficacy of treatment with daily preventive medications and environmental control measures,[9, 10] adherence to these medications and implementation of trigger avoidance remains dismally low.[11-19] Increased asthma knowledge often fails to translate into changes in behavior[13]. Effective interventions to improve cornerstone asthma self-management behaviors, including medication adherence and trigger avoidance, are critical to improving pediatric asthma outcomes. There is emerging literature focused on defining the role of community health workers (CHWs) to help control pediatric asthma. There is also strong evidence for the efficacy of CHW home visits for reductions in home triggers, asthma symptoms and urgent care use in children[14-19]. Further, the CHW model fits well into the current movement in healthcare to incorporate the delivery of more preventive care by non-physicians. However, significant barriers to CHW intervention implementation exist. One key issue is that most successful CHW asthma interventions tested to date have provided costly equipment and supplies to participants during the study period which increases program dissemination costs and limits sustainability[16]. The efficacy of a CHW home asthma intervention fully integrated into a clinical setting has not been established. Other recommended educational support services, such as certified asthma

educators (AE-C), also have not been rigorously tested. The Asthma Action at Erie Trial (NCT02481986) is a randomized controlled trial comparing the efficacy of integrated asthma CHWs and an AE-C to improve asthma outcomes in children in Chicago. The primary aim is to assess the efficacy of the integrated CHW home asthma intervention relative to the AE-C intervention at 12-months post-randomization as demonstrated by asthma control. We hypothesize that the CHW intervention arm will have significantly improved asthma control compared to the AE-C arm. This is assessed with two primary asthma control outcomes: activity limitation and achievement of minimal clinically important difference on validated asthma control test instruments. This manuscript describes the design and baseline sample of the trial as well as the challenges encountered in assessing asthma control in this community-based population of mainly low-income Hispanic children.

2.0 Methods

2.1 Design

The Asthma Action at Erie Trial employs a modified community-based participatory research (CBPR) approach. CBPR is characterized by a reciprocal transfer of expertise, shared decision-making power, and mutual ownership of research products and processes. [20] The trial community partner, Erie Family Health Centers (Erie), is a group of community health centers serving mainly low-income Hispanic and African-American families in the Chicago area. Erie leadership participated in the initial study design and grant writing process. They also hold co-investigator positions on the trial's Steering Committee and they directly employ and supervise the intervention staff. The trial is monitored by an asthma-focused community advisory board operated by the Chicago Asthma Consortium (www.chicagoasthma.org) which convenes twice a year to review the study design, progress, and outcomes.

Asthma Action at Erie is a two-arm behavioral randomized controlled trial. As shown in Figure 1, child/caregiver dyads were recruited and then randomized to one of two arms: (1) CHW home visits, or (2) education in the clinic from an AE-C. The intervention was delivered in the first year after enrollment. Data collection occurs at baseline and 6-months, and postintervention at 12-months, 18-months, and 24-months.

2.2 Population

Eligibility criteria included children ages 5 to 16 years who lived with the index caregiver at least 5 days out of the week, had a working telephone, and had uncontrolled asthma [10] defined as a score of 1.25 or higher on the Asthma Control Questionnaire [21-23] (ACQ) or a score of less than 20 on the Asthma Control Test/childhood Asthma Control Test (ACT/cACT) [24-27] or a report of at least one oral corticosteroid (OCS) burst for asthma in the past year. All child participants had to be an active patient in the Erie system. Screening was conducted with the caregiver only, usually via telephone. At enrollment, the child and caregiver answered questions together.

The ACQ consists of six questions (the seventh question regarding FEV1 measurement was not utilized), uses a Likert scale, and assesses asthma-related nighttime awakenings, early morning symptoms, activity limitation, shortness of breath, wheezing, and use of quick-relief medication.[21-23] The ACQ is available in multiple languages, including English and Spanish, for use in children 6-16 years of age.[28] The ACT consists of five questions and is administered to children 12 years and older.[24, 25] The cACT has a total of seven items with the child answering four and the parent answering three questions[26, 27]. Both use a Likert scale and assess nighttime awakenings and perceived asthma control.[24-27] Whereas the ACT also asks about activity limitation regarding work, school and home tasks, shortness of breath, and use of quick-relief medication,[24, 25] the cACT also measures wheezing, coughing, exercise limitation and daytime asthma symptoms.[26, 27] These instruments have been tested in multiple languages, including English and Spanish. [28-30] The ACQ and ACT/cACT are recommended by the NHLBI as validated instruments for use in pediatric asthma studies[24]. Important differences between the ACQ and cACT/ACT include the timeframe for symptom recall (i.e. ACQ asks for the past seven days, and the cACT/ACT asks for the past four weeks), assessment domains, and parent versus child self-report[21-27].

Families were excluded if caregivers were not fluent in English or Spanish, did not have permanent housing (e.g. lived in a shelter), did not have permanent custody of the child, and if the child had significant developmental delays or co-morbidities that would significantly limit their ability to participate in the study.

2.3 Interventions

2.3.1 CHWs

2.3.1.1 CHW training and hiring: Candidates for the CHW positions were recruited through Erie, community list-serves, and word of mouth. Preference was given to candidates who had been patients at Erie, were bilingual in English and Spanish, and if they had personal experience in their families with asthma. The 16-hour initial training was divided into two days on March 3-4, 2016. The purpose of this initial training was to build community capacity and skills around asthma, allow investigators to determine the best candidates for the position, and provide a pool of backup candidates for the future. The curriculum was developed by the principal investigator (MAM) and covered asthma basics (general epidemiology, physiology, symptoms, medications, devices, triggers, allergies, healthcare system navigation, and school navigation) and self-management (social support, problem-solving, self-monitoring, and environmental rearrangement). The training used Paulo Friere's critical pedagogy or popular education model in order to provide a curriculum for people of varying literacy levels, languages, and cultures.[31, 32] To facilitate learning, the training limited lectures and instead focused on brainstorming exercises, self-discovery related learning exercises, and role-playing.

Two CHWs were chosen for the trial and hired by Erie. Subsequent training was provided to these two CHWs on the trial protocol, Erie policies, home visitation strategies, and documentation. Medications and trigger remediation were reinforced through role-playing and practical exercises. CHWs completed the 16-hour Mental Health First Aid course

(<http://www.c4chicago.org/MHFA>). The trial's clinical psychologist (SW) provided a follow-up 2- hour training session in motivational interviewing techniques[33] and to discuss anticipated mental health challenges and how to obtain services for their participants. New CHWs shadowed experienced CHWs on other projects as well as Erie clinicians. Ongoing continuing education was provided through meetings with the principal investigator and the Erie site principal investigator every 2-4 weeks for the duration of the intervention phase. CHWs also attended local educational seminars and events.

2.3.1.2 CHW supervision: CHWs are not clinicians, and they often struggle with many of the same issues as their clients in terms of health problems, childcare, poor housing conditions, and poverty. This allows them to intimately understand the challenges their clients face and usually translates into strong bonds between them and their clients, but it sometimes transforms into a tremendous burden when clients struggle with serious issues. Further, the CHWs must deal with the stresses of home visitation (safety, cleanliness, hectic households, and poverty). In order for the study CHWs to successfully perform their job, they require adequate supervision and support. Supervision is best conducted using a team approach with a group of CHWs so as to facilitate self-discovery and group learning. In this trial, CHWs reported directly to the Erie AE-C for day-to-day supervision and support as needed. The Erie AE-C accompanies CHWs on a home visit every several months to monitor fidelity to the intervention protocol. Every 2-4 weeks, CHWs and the Erie AE-C also met with the principal investigator and site principal investigator for discussion of clinical issues, self-management skills support, and for continuing education. In addition, one of the UIC co-investigators (SW), a clinical psychologist, met with CHWs once a month to discuss mental health issues related to participants or the CHW job and to generate strategies for resolution.

2.3.1.3 CHW intervention protocol and content: Families were offered ten home visits over 12 months. At the CHW home visits, CHWs spent 1-2 hours with the family. CHWs educated them on the "core curriculum" which consisted of standard topics for asthma educators and are intended to reduce impairment (prevent chronic symptoms, reduce use of quick-relief medications, maintain healthy activity levels) and reduce risk (prevent exacerbations, minimize emergency care, prevent reduced lung growth, and minimize adverse therapy effects)[10]. The CHWs approached each visit with the intention to teach one or two of the core curriculum topics. However, each visit began with several minutes of social discussion for the purpose of relationship building. Behavior change plans from the previous visit, which are small goals leading to a specific change over a several-week period, were also reviewed and discussed. The main portion of the visit involved an education session around a core curriculum topic and when a CHW noted a barrier in the delivery of the education, she then incorporated a relevant self-management skill. After each visit, the CHWs filled out a report of the topics covered, behavior change plans, and potentially relevant issues.

2.3.1.4 Integrating CHWs in the Clinic: CHWs had access to all Erie clinics, computers, and staff. Once a participant was assigned to a CHW, the CHW reviewed the child's health record. Erie providers manage pediatric asthma using a detailed asthma smart form in the

electronic medical record (EMR). CHWs offered to meet with their participants' providers in order to understand their concerns and recommendations for the patients. If providers were not available to meet with the CHWs, CHWs proceeded with the standard home protocol. CHWs uploaded summaries of their participant encounters and communications with providers into the EMR. CHWs also communicated directly with the behavioral health staff and case managers at Erie on an as-needed basis for participants.

2.3.2 Certified Asthma Educator (AE-C)

2.3.2.1 AE-C hiring and training: The AE-C position required a bilingual (English and Spanish) person with community experience. Clinical experience and current AE-C certification were not required. The reason for this was that the majority of individuals with AE-C certification have a nursing or respiratory therapy degree and the concern of Erie and investigators was that clinical training might result in the AE-C being pulled into tasks other than asthma education. Erie hired a person with a college bachelor's degree and prior experience providing asthma education and tobacco cessation counseling at a local safety-net hospital. Once on the job, she completed a preparatory course (American Lung Association Asthma Educator Institute Course) and passed the AE-C certification exam (National Asthma Educator Certification Board Exam). Further, she attended the CHW trainings and also completed training with the research investigators to become familiar with her role in the intervention and the AE-C protocol.

2.3.2.2 AE-C intervention protocol and content: Participants in the AE-C arm were eligible for two in-clinic education sessions. The first session occurred in the month after randomization and the second session window began just after the sixth month. The AE-C had 60 days to try to meet with families during each session window. The AE-C received contact information and had access to the Erie clinical chart for participants randomized to her arm. The AE-C scheduled the participant's family to come in for an educational session in the clinic. At this visit, the AE-C assessed and provided education on asthma symptoms, control, triggers, medication technique, adherence, the presence of a written asthma plan, and addressed caregiver/child concerns. The AE-C called the family on the telephone 2-4 weeks later to discuss self-monitoring of symptoms and medication and answer any questions. This same protocol was repeated at the six-month education session.

2.4 Outcomes

Screening typically occurred via telephone, but almost all subsequent data are collected in the home (see Table 1). Data were collected in English, Spanish, or both depending on the preference of the family. Data were collected verbally, with prompt cards showing answer options, and then entered directly into Research Electronic Data Capture (REDCap). On the rare occasions when Wi-Fi or servers were not functioning, data were captured on paper forms and then entered into REDCap as soon as connectivity was restored.

The goal of the interventions, and the primary outcome of this study, is to improve child asthma control. This is captured by two co-primary outcomes, asthma control and activity limitation. Asthma control over the past four weeks was captured using the ACT/cACT. A minimal important difference (MID) of 3 for the ACT/cACT[24-27, 52, 53] will be used to

determine intervention efficacy. Because activity limitation has been shown to be a powerful component of asthma control[34] it was included as a co-primary outcome defined as the number of days out of the past 14 with activity limitation.

Short-term (past 7-days) asthma control was also assessed with the ACQ. Additional secondary outcomes include oral corticosteroid use, health services utilization (urgent care visits, emergency department visits and hospitalizations for asthma), and asthma symptoms over the past year (using the Asthma Functional Severity Scale) were also captured to inform long-term control.

Children and their caregivers were asked what medications they use and how often they are used. They were then asked to show the research assistants (RAs) all the medications and equipment they had. Medications were only recorded if they were actually seen by the RAs. Medication instructions were documented when available. Families were asked to demonstrate how the children take their primary inhaled medicines (left to the participants to determine which one this was). If no inhalers were present, children were given a demonstrator metered dose inhaler with a spacer by the RA to demonstrate their technique. RAs then recorded the steps done correctly and incorrectly during medication administration. For participants with inhaled corticosteroids, the number on the internal dose counter on this medication was recorded. Then an objective electronic medication monitor, the DoserCT (MediTrack Products, Easton, MA), was fitted to the inhaled corticosteroid. Two weeks later, the RA returned and again recorded the number on the internal medication counter and recorded the DoserCT adherence data. Self-reported, daily adherence data was also collected from caregivers and children over 11 years old. Prescriptions for ICS controller medications were verified against each participant's EMR to ensure accuracy in differentiating between children not needing a controller medication and those who did not have their medication present at the time of the home visit.

Home triggers were assessed through a series of questions and observations. Families were asked about the child's triggers and environmental exposures such as tobacco smoke, roaches, rats, and mice. RAs then walked through the home and documented triggers seen (e.g., mold, dust, roaches) and smelled (e.g., strong odors, tobacco smoke). Children were asked to provide a saliva sample for cotinine analysis to determine exposure to environmental tobacco smoke (ETS).

Children's height and weight were measured, and family demographics assessed. Families were also asked about numerous psychosocial characteristics. Caregiver depression symptoms were assessed using the reliable and valid Patient Health Questionnaire-9.[39] Caregiver post-traumatic stress disorder (PTSD) symptoms were determined using the Short Form of the PTSD checklist[46], a 6-item measure designed to screen for PTSD in primary care settings. Caregivers were also asked about perceived stress, including how unpredictable and overloaded they find their lives over the past month using the 4-item Perceived Stress Scale (PSS).[41-43, 54] Depression symptoms for children ages seven and above were assessed using the 12-item Children's Depression Inventory 2, short form (CDI2-S)[40], which has shown strong reliability and validity in the pediatric population. [55] For children less than seven years old, caregivers completed the Patient-Reported

Outcomes Measurement Information System (PROMIS) Depressive Symptoms Parent Proxy form, which has good psychometric properties for caregiver-report of depressive symptoms in children aged five to seven.[56] Child posttraumatic stress symptoms were assessed via the 28-item Child Report of Post-Traumatic Symptoms (CROPS, child-report for youth 7 years) and the 30-item Parent Report of Post-Traumatic Symptoms (PROPS, caregiver report for full sample).[57, 58] The CROPS and PROPS assess a wide range of posttraumatic symptomatology experienced over the past seven days, with high reliability and convergent validity. Because neither of these scales captures the specific traumatic event(s), an additional measure of asthma-specific trauma was added at the 24-month assessment. Caregiver emotional, instrumental, and informational social support were assessed using the PROMIS short-form social support instruments, which were developed and validated to measure social function in adults.[59] Family functioning was captured with the Chaos, Hubbub, and Order Scale (CHAOS),[48] which assesses the level of commotion, confusion, disorganization, and routine within the household (e.g., “We are usually able to stay on top of things”).

Throughout the length of the study, caregivers receive a monthly follow-up call when they have no primary data collection visit. During the call, RAs verify contact information and ask if the child has had any urgent care or emergency department (ED) visits, hospitalizations, or missed school days due to asthma in the past month. If caregivers endorse urgent care visits, ED visits, or hospitalizations, clinic and hospital records are obtained to verify the dates and reasons for the events. Events not related to asthma are re-coded. Lastly, caregivers are asked to report the number of work days missed to care for the child due to asthma.

Implementation is assessed by reports and tracking logs that capture the number, duration, location, and content of all intervention encounters.

2.5 Recruitment, Randomization, and Retention

2.5.1 Recruitment—All participants were recruited from Erie Family Health Center. Recruitment of 223 child/caregiver dyads occurred from March 2016-August 2017. Figure 2 illustrates the flow of participants from recruitment through final data collection.

Of note, although they did not initially meet inclusion criteria for uncontrolled asthma, 18 participants qualified after being screened twice, and one participant qualified after being screened three times. Participants were recruited via three pathways. In the first, the Erie electronic medical records were queried to identify all patients with a diagnosis of asthma and between five to 16 years old. Potentially eligible families were sent a letter stating they should call if they did not wish to be considered for the study. Families that did not respond within one week were called on the telephone by designated trained study staff to assess interest in the study. Potential participants that expressed interest in the study were formally screened by UIC RAs. In pathway two, Erie providers and staff were instructed to refer potential participants to call the study enrollment number, email the study enrollment team, talk to one of the study staff in-clinic, or allow the study staff to contact them. Finally, some participants contacted the study staff by dialing the number on flyers and signs posted at Erie.

2.5.2 Randomization—Randomization was conducted in a 1:1 ratio using randomly mixed permuted blocks of size four and six to ensure reasonably equal allocation while reducing predictability of the assignment sequence. Upon completion of the randomization assignment, the data management team generated a letter to the participant that informed him/her of their study status and also notified the Erie AE-C who assigned the patient to a CHW if randomized to that arm. Although double blinding in a behavioral controlled trial is impossible, blinding was maximized by the following four strategies: 1) incomplete disclosure of study goals for participants during consent, 2) blinding outcomes assessors; 3) incomplete disclosure of research hypotheses for non-investigators staff, and 4) training co-investigators and staff in the concept of equipoise. Intervention investigators and staff were un-blinded to treatment arm because they needed to work with the CHWs and monitor intervention fidelity and data accuracy. However, study staff and investigators did not have access to interim outcomes data.

2.5.3 Retention—Multiple contacts were obtained for each participant at enrollment and reviewed at each study encounter. Participants receive \$50 cash at each in-person data collection and \$25 at the 18-month telephone data collection. All participants receive a study completion certificate at the 24-month data collection.

2.6 Human Subjects

2.6.1 Informed Consent—The University of Illinois at Chicago, Rush University Medical Center and NorthShore University HealthSystem Institutional Review Boards and the Erie Research Committee all approved the study protocol. Children ages eight and above and caregivers provided signed assent and consent, respectively.

2.6.2 Data Safety Monitoring Board—A Data Safety Monitoring Board (DSMB) was created to provide oversight for the trial. The DSMB includes six members: a health psychologist, a behavioral intervention researcher and health psychologist, a biostatistician, a health center administrator, a community pediatrician, and a local health expert from the department of public health. The DSMB meets annually, and additionally as needed.

2.7 Analyses

2.7.1 Analysis Plan—Basic summary statistics will be calculated for outcome variables and covariates. Continuous variables will be assessed for normality using Q-Q plots and compared using two-sample t-tests. If distributions are sufficiently non-normal, then a suitable transformation or non-parametric test will be used. Categorical variables will be compared using chi-square tests. Significance tests will be two-sided at level $\alpha=0.05$.

2.7.1.1 Aims 1-4: The first aim is to assess the efficacy of the integrated CHW home asthma intervention relative to the AE-C intervention at 12-months post-randomization as demonstrated by asthma control. We hypothesize that the CHW intervention arm will have significantly improved asthma control compared to the AE-C arm. This is assessed with two primary outcomes. The mean total number of days with activity limitation over the previous 14-day period will be assessed at 12-months between the two treatment arms using the two-sample t-test or Mann-Whitney test. If the mean days with activity limitation in the

intervention arm is at least 30% lower than that of the AE-C arm and $p < 0.05$, we will conclude that the CHW intervention is more effective. The ACT/cACT will be analyzed using similar methods, and a minimal important difference (MID) of 3 for the ACT/cACT[24-27, 52, 53] will be used to determine intervention efficacy. Linear mixed models will then be employed to analyze primary outcomes at twelve months. To test the CHW intervention's efficacy on these outcomes, we will first conduct per protocol analyses limited to those patients who received the CHW intervention. We will correct potential selection bias by including covariates found to be differentially related to nonadherence. Additionally, to test the intervention's effectiveness in clinical practice, we will conduct intention-to-treat analyses that include outcomes for all patients randomized. Potentially confounding covariates will be considered for model inclusion.

Aim 2 assesses maintenance of intervention efficacy, as demonstrated by asthma control at 18 and 24 months after randomization. We hypothesize that changes in asthma control will be maintained after cessation of the intervention. The asthma control measures will be compared between the two treatment groups at 18- and 24-months post-randomization in the same way as done for aim 1. An indicator variable will be added to the models to allow distinction between the time during intervention periods.

Aim 3 compares the costs and cost-effectiveness of the two interventions. The analysis will be conducted from the societal perspective, including the costs borne by the program, individual participant and family, and the healthcare system. Efficacy will be measured as asthma control (ACT/cACT and activity limitation). Cost-effectiveness will be evaluated by combining the mean total cost per participant with the change in asthma control.

Aim 4 is to assess the efficacy of the CHW intervention relative to AE-C education, as demonstrated by asthma control, among those experiencing depression, stress, and/or PTSD. We hypothesize that among those living with depression, stress, and/or PTSD, the CHW intervention will be significantly more effective in achieving and maintaining asthma control than the AE-C education intervention. Interaction terms between treatment indicators for depression, stress, and PTSD will be examined to test for heterogeneity of treatment effects.

2.7.2 Sample size and power—The sample size for the study was determined to allow assessment of the relative efficacy of the proposed interventions with respect to asthma control. While a strong clinical definition of asthma control has been in place for some time, there is no gold standard for assessing asthma control. We have conducted two calculations to ensure adequate power. Using preliminary data to generate an estimated standard deviation (SD) and baseline rate, we determined that 110 patients per arm with 15% attrition would assure 93 patients for analysis at the 12-month follow-up. With 80% power and 0.05 significance level for a two-sided test, this sample size allows us to detect 0.4 of an SD increase in mean ACT/cACT which is sufficient to capture the minimally important difference of the ACT/cACT.

We performed a separate power calculation using the number of days with activity limitation (over the past 14-days) as Zeiger et al.[34] found “activity limitation” to be a strong determinant of the composite asthma control score. In a multi-site inner-city (including

Chicago) randomized trial of a home CHW asthma intervention, Morgan et al. reported activity limitations over the previous 14-day period.[17] Based on their data, we hypothesize a mean of 3.9 “activity limitation” days at baseline in both groups (SE 0.22) and, in the AE-C comparison group, a mean at 12 months of 2.84 days (SE 0.10). We anticipate the proposed CHW intervention will be more potent than that tested by Morgan et al. because it involves a higher dose and more physician involvement since the CHWs were integrated into the clinical setting. Within the proposed CHW home intervention group, we anticipate a mean of two “activity limitation” days over a 14-day period at 12 months (SE 0.10), representing a 30% reduction from the AE-C comparison group (and 50% reduction from the baseline mean). Further, assuming an attrition rate of 15% and 80% power, the standard two-group t-test for comparing means (at 12 months) requires a sample size of 110 per group, for a total of 220 participants. Analyses to examine heterogeneity of treatment effects by age, race, or other groups have more limited power, but results will be considered suggestive for further research.

3.0 Results

3.1 Baseline Demographics

Table 2 presents the baseline characteristics of the 223 randomized participants. No differences were noted between arms on any baseline characteristics. The sample is remarkable for a predominantly low caregiver educational level (66.4% of sample with primary caregiver having achieved high school/GED or less), largely Hispanic (with 85.7% of caregivers and 85.2% of children reporting Hispanic ethnicity), low-income (62.3% with household income of \$59,000 or less), and a high child body mass index (BMI) (58.7% of children with BMI 85% or higher).

3.2 Baseline Psychosocial Characteristics

The sample demonstrates high rates of depression symptoms among the children (18% had depression scores of elevated or very elevated) and caregivers (14.8% were above the clinical cutoff for depression on the PHQ-9) and elevated rates of PTSD symptoms among caregivers (19.3% met screening criteria for PTSD) and trauma symptoms among children (51.3% in the range of clinical concern). Rates of child and caregiver depression symptoms and caregiver PTSD symptoms were higher in the CHW arm compared to the AE-C arm. All indices of social support fell within the normal range. The measure of family CHAOS had a mean of 3.2 (SD 2.8).

3.3 Baseline Asthma Characteristics

See Table 3 for a description of the sample’s baseline asthma characteristics. The sample demonstrated overall poor asthma control with 55.7% indicating uncontrolled asthma as measured by the cACT for participants ages 5-11 and the ACT for participants ages 12-16 years. High rates of oral corticosteroid bursts (60.4%), ED visits (38.3%), and hospitalizations (16.7%) for asthma in the past 12 months demonstrate a high-risk population with significant morbidity.

Children met inclusion criteria for uncontrolled asthma in the following ways. Some qualified only with one measure as follows: ACQ alone (31, 13.9%), ACT alone (3, 1.3%), cACT alone (9, 4.0%), and oral steroid burst alone (45, 20.2%). Others (135, 60.5%) met inclusion criteria in more than one way. The median length of time between screening and enrollment was 7.0 days (interquartile range 4 - 11, full sample range 1 – 167 days). Eighteen children did not meet inclusion criteria for uncontrolled asthma at the time of enrollment. This happened because they met criteria during screening but then reported fewer symptoms or steroid use at enrollment. The investigators, Erie, and community advisory board agreed to leave these participants in the trial because they had histories consistent with uncontrolled asthma and to remove them would damage the trial's reputation in the clinic and community.

In comparisons of ACQ to cACT/ACT, no difference in the categorization of uncontrolled asthma was found for the total sample ($p=0.26$), and the Kappa coefficient was 0.42. For children ages 5-11 that completed the cACT, a slight difference was noted in the categorization of uncontrolled asthma with more children uncontrolled with the ACQ but not the cACT ($p=0.04$). With cACT, a slight increase in the Kappa coefficient to 0.45 was observed. For children ages 12-16, no significant difference between categorization with the ACT and ACQ was noted ($p=0.20$); the Kappa dropped to 0.26, but the sample size for this age group was small ($n=47$). Figure 2 shows the correlation between the ACQ and cACT/ACT.

3.4 Baseline Asthma Medicines

Table 4 displays the sample's baseline asthma medications. Only 82.1% of children had a quick-relief medication, and 44% had an ICS controller medication observed in the home. When asked to demonstrate medication technique, children were only able to accurately complete, on average, 63.6% of the required steps even with about half (45.6%) of caregivers assisting. Additionally, only 9.5% of participants demonstrated entirely correct inhaled medication technique. Of the 12.2% of families that reported being prescribed a medicine for which they did not fill the prescription or use the medicine, the most common reasons cited included not needing it (29.6%), side effects (37%), and not being covered by their health insurance (18.5%). ICS could only be measured using an objective electronic dose counter in 39% of participants because ICS was not prescribed in 35.9%, ICS was prescribed but not observed in the home in 19.7% of cases, and ICS was available, but the caregiver refused measurement in 5.4% of cases. The mean number of doses recorded using the electronic dose counter (2.1/day) was similar to the number captured on the standard device medication counters (2.4/day). Children received an average of only 53.4% (SD 25.2) of prescribed doses of ICS.

3.5 Baseline Triggers

Table 5 reports on the sample's baseline asthma triggers. Most families (77.1%) lived in rental housing, 37.4% reported pets (31.4% had dogs, 4.5% had cats), 24.7% reported problems with roaches, and 97.3% had mold observed somewhere in their home.

4.0 Discussion

This manuscript described the design and baseline characteristics of the cohort of 223 children enrolled in the Asthma Action at Erie Trial which seeks to compare the effectiveness of a CHW intervention versus an AE-C intervention on asthma outcomes in a low-income predominantly Hispanic sample of children ages 5-16 years with uncontrolled asthma. Strengths of the trial include its unique design. The intervention staff is fully integrated into a clinical setting where they communicate with providers and regularly meet patients. The intervention staff provides education, care coordination, and social support but they do not provide asthma equipment such as vacuum cleaners or dust mite covers as these are not usually covered by insurance. Most of the successful asthma CHW interventions to date have included the provision of this type of equipment.[14-19] The interventionists instead work with families to identify solutions to their asthma needs that leverage existing resources. If either arm of the study demonstrates acceptable improvements in asthma outcomes, sustainability of the intervention without independent grant funding is feasible.

Another unique aspect of the trial is the comparative effectiveness design. While comparing the CHW intervention to usual care would have provided the most robust efficacy data, this design was not acceptable. In the clinical setting, service provision always takes precedence over research. To offer intervention to only some patients with uncontrolled asthma would have diminished enthusiasm by the providers and staff in the clinics which in turn would have influenced recruitment and potentially led to cross-over. The clinic wanted an AE-C which is considered best practice. In a focus group of Erie parents conducted before starting the intervention, the parents also expressed a preference for the AE-C intervention over the CHW intervention. Therefore, comparing CHWs to the AE-C offered an opportunity to provide desired services to all clinic sites and participants, although the intensity of the interventions is very different and should allow for adequate comparisons.

Furthermore, at the onset of the study design, particular importance was placed in the implementation of bilingual (English/Spanish) measures for data collection. Considering the sample would consist of minority child/caregiver dyads and trends indicate a decline in U.S.-born children speaking Spanish², the assumption was that we would regularly encounter households with Spanish-speaking caregivers and English-speaking children. As such, data capturing tools were programmed to show questionnaire items in both English and Spanish simultaneously. The result of this approach is seen in the differences in language used at screening and enrollment. At screening, 105 (47.1%) caregivers completed the screener in Spanish, two (0.9%) in English and Spanish, and 116 (52.0%) in English. At enrollment, however, 70 (31.4%) visits were completed in Spanish, 44 (19.7%) in English and Spanish, and 109 (48.9%) in English. The significant increase in the English and Spanish category at enrollment justifies the bilingual approach to data collection. Using this method allowed households consisting of mixed, monolingual individuals to participate in the study, caregivers to better understand sensitive questions in their preferred language, families to feel more included in the entire data visit, and increased rapport between RAs and families, which aids in retention.

Using the cACT, ACT and ACQ to identify patients with uncontrolled asthma in community settings for research purposes presents unique challenges. First, asthma is characterized by periods in which individuals have increased symptoms and flares, as well as quiescent periods. In this study, 18 participants were screened multiple times before meeting inclusion criteria for uncontrolled asthma. Because the cACT and ACT ask participants to report symptoms over the past four weeks,[24-26] and the ACQ over the past seven days,[21-23] some participants had uncontrolled asthma by one instrument but not the other. We also encountered gaps between the time of screening and enrollment where several participants' symptoms changed sufficiently to influence their control categorization. Our field staff also reported problems with the questions on activity limitation. Some caregivers responded that their children do not have any activity limitation simply because they do not allow them to participate in physical activities due to their asthma. If the clinician and/or research staff do not probe with follow up questions, this domain of asthma control may not capture a true lack of control. These issues highlight some of the variability that occurs when non-clinicians collect data in non-clinical settings. These instruments were developed and validated in clinical populations, and their application in community settings requires more consideration and testing.

Our baseline findings raise important information and questions for future work. The ACQ, ACT, and cACT have strong validations, and the ACT/cACT are used regularly in clinical settings, but their administration in homes by non-clinical staff is not common. In our study, overall reports of asthma control were lower than expected and the ACQ and ACT/cACT did not perform equally. They seem to capture slightly different asthma domains, and the cACT specifically reported less symptoms than the ACQ. We suspect this is because children under the age of 12 may be less aware of their symptoms than their parents. Another concern is that, given the wide age range of participants, children and families may respond differently to the intervention due to developmental differences. While this large range increases the generalizability of the study findings, it limits the control over the impact of the intervention. To address this concern, age differences will be explored in secondary analysis. Of note, the standard medication counters on inhaler devices recorded very similar rates of use to the electronic medication dose counters. While there is a demonstrated discrepancy between self-report, built-in dose counters and electronic medication monitors in drug trials and behavioral intervention studies that provide participants with free study medications,[11, 12] this suggests that future studies that do not provide study drugs could consider reliance on the standard medication counters for adherence data. Finally, some would argue that research should focus on children with repeat oral steroid use, emergency department visits, and hospitalizations due to asthma rather than our study sample. However, while fewer asthmatic children fall into this high-risk category, this study addresses the unmet needs of the large number of asthmatic children who have activity limitation, school absenteeism, and reduced quality of life due to uncontrolled asthma.

In conclusion, the Asthma Action at Erie Trial successfully recruited a largely Hispanic cohort of children with uncontrolled asthma to study the differential effects of clinic-based AE-C and home-based CHW interventions. The interventionists are integrated into the clinic system with strong fidelity monitoring. Outcomes are collected in homes and will determine the ability of the interventions to improve asthma control, healthcare utilization, and costs.

Special emphasis is placed on the collection of psychosocial measures for both caregivers and children to determine the mediating effects of psychosocial factors on intervention efficacy and outcomes. Trial outcomes will be revealed in the fall of 2019. These results will contribute to the understanding of how to best provide asthma education and support to high-risk children with asthma in healthcare systems serving low-income minority families.

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Abbreviations:

ACT	Asthma Control Test
cACT	childhood Asthma Control Test
ICS	inhaled corticosteroid
ACQ	Asthma Control Questionnaire
CHW	community health worker
GINA	Global Initiative for Asthma
NHLBI	National Heart, Lung, and Blood Institute
AE-C	certified asthma educator
NAEPP EPR-3	National Asthma Education and Prevention Program Expert Panel Report 3

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Figure 1:
Asthma Action at Erie Trial Design

Figure 2:
Asthma Action at Erie Consort Diagram

Table 1:**Asthma Action at Erie Outcomes Measures**

Domain	Questions	# of items	0mo Base line	6mo	12mo	18mo (phone)	24mo
Screening	Erie pre-screen Screen	25/27					
Two Co-Primary Outcomes for Asthma Control	* Childhood Asthma Control Test / Asthma Control Test[24-27, 29, 30]	7/5					
	* Activity limitation over 14 days[17, 34]	1					
Secondary Outcomes for Asthma Control Asthma Medicines	Asthma Control Questionnaire[21-24, 27, 28]	6					
	Oral steroids	1					
	Asthma functional severity scale[35]	6					
	Caregiver self-report[36]	5					
	Child self-report[36]	3					
	Observed medicines[36]	2					
	Observed technique[36]	11/12/10					
	Adherence[36]	5					
	Triggers						
Health Services Utilization	Home assessment (self-report and observed) [16, 37]	167					
	Salivary cotinine[37, 38]	1					
	Urgent care visits	1					
	Emergency dept visits	1					
	Hospitalizations	1					
	Missed school	1					
Demographics	Missed work	1					
	Demographics						
Psychosocial	Height/weight	2					
	Demographics	27					
	Caregiver depression (PHQ-9)[39]	9					
	Child depression (CDI2 Short Form or PROMIS Parent Proxy)[40]	6/13					
	Perceived Stress Scale 4-item[41 –43]	4					
	Caregiver trauma (Short Form of the PTSD Checklist – Civilian Version)[44–46]	6					
	Child trauma (PROPS/CROPS)[47, 48]	26					
	Asthma-Related Trauma Event Items	9					
Implementation	Social Support (PROMIS Emotional, Informational, Instrumental)[49, 50]	24					
	Family functioning (CHAOS)[48, 51]	15					
	Intervention tracking	19					

* Primary outcome

Patient Health Questionnaire-9 (PHQ-9); Children's Depression Inventory 2 Short Form (CDI2) for children age 7 and older; Patient-Reported Outcomes Measurement Information System (PROMIS) Parent Proxy Bank v1.1 – Depressive Symptoms for caregivers of children under age 7 or who cannot complete CDI2; Child Report of Post-traumatic Symptoms (CROPS) for children age 7 and older, Parent Report of Post-traumatic Symptoms (PROPS) for all caregivers; Confusion, Hubbub and Order Scale (CHAOS)

Table 2:**Baseline Demographics of Asthma Action at Erie Participants**

Baseline Data	Caregiver N=223	Child N=223
Female (%)	216 (96.9)	98 (44.0)
Age, mean (SD)	36.3 (7.1)	9.4 (3.0)
Child age category		
5-11 years old (%)		176 (78.9)
12-16 years old (%)		47 (21.1)
Caregiver is mother/father (%)	216 (96.9)	
Highest degree earned (%)		
Less than high school	64 (28.7)	
High school/GED	84 (37.7)	
Some college	54 (24.2)	
College graduate (baccalaureate) or more	21 (9.4)	
Race (%) ^a		
Black	34 (15.3)	39 (17.6)
White	68 (30.6)	63 (28.4)
Other	120 (54.1)	120 (54.1)
Hispanic (%)	191 (85.7)	190 (85.2)
Hispanic ethnicity (%) ^b		
Mexican	142 (74.4)	159 (83.7)
Puerto Rican	27 (14.1)	20 (10.5)
Other Hispanic	22 (11.5)	11 (5.8)
Place of birth (%)		
United States	102 (45.7)	215 (96.4)
Mexico	99 (44.4)	2 (0.9)
Puerto Rico	6 (2.7)	4 (1.8)
Other outside mainland United States	16 (7.2)	2 (0.9)
Household income in last year (%) ^c		
<20k	46 (20.9)	
20k-59k	91 (41.4)	
>60k	13 (5.9)	
Don't know	70 (31.8)	
Language of interview (%)		
English	109 (48.9)	
Spanish	70 (31.4)	
Mixed English and Spanish	44 (19.7)	
Relationship status (%) ^d		
Single	54 (24.4)	
Living with partner/spouse	144 (65.2)	

Baseline Data	Caregiver N=223	Child N=223
Separated/Divorced/Widowed	23 (10.4)	
Child BMI category		
Overweight (85-95%)	46 (20.6)	
Obese (95% or higher)	85 (38.1)	

^a: N=222;

^b: N=191 for caregiver and N=190 for child;

^c: N=220;

^d: N=221

Table 3:**Asthma Characteristics of Asthma Action at Erie Children**

Baseline Data	Total N=223	CHW Arm N=108	AE-C Arm N=115
Asthma Control Questionnaire, mean (SD)	1.5 (1.0)	1.6 (1.0)	1.5 (1.0)
Uncontrolled by ACQ (%)	132 (59.2)	68 (63.0)	64 (55.7)
Uncontrolled asthma by combined c/ACT ^a (%)	123 (55.7)	64 (60.4)	59 (51.3)
Asthma Control Test ^b , mean (SD)	16.3 (4.1)	15.0 (4.0)	17.5 (4.0)
Uncontrolled by ACT (%)	35 (74.5)	18 (85.7)	17 (65.4)
Childhood Asthma Control Test ^c , mean (SD)	18.8 (4.3)	18.6 (4.5)	19.0 (4.2)
Uncontrolled by cACT (%)	88 (50.6)	46 (54.1)	42 (47.2)
Asthma severity in past 12 months ^d , mean (SD)	10.1 (4.7)	10.3 (4.8)	10.0 (4.6)
Low, 0-4 (%)	23 (10.4)	11 (10.3)	12 (10.4)
Mild, 5-8 (%)	62 (27.9)	30 (28.0)	32 (27.8)
Moderate, 9-14 (%)	96 (43.2)	46 (43.0)	50 (43.5)
Severe, 15-24 (%)	41 (18.5)	20 (18.7)	21 (18.3)
Number of missed school days for asthma in past year of school ^f ,			
Mean (SD)	6.7 (7.4)	7.4 (7.9)	6.1 (6.9)
Median (range)	4.0 (0-40)	4.0 (0-40)	4.0 (0-30)
Number of missed caregiver work days for child's asthma in past 30 days ^g ,			
Mean (SD)	1.2 (3.5)	1.1 (3.3)	1.2 (3.7)
Median (range)	0.0 (0-30)	0.0 (0-30)	0.0 (0-30)
Number of days of activity limitation in past two weeks,			
Mean (SD)	3.6 (3.9)	3.7 (3.9)	3.4 (4.0)
Median (range)	2.0 (0-14)	2.8 (0-14)	2.0 (0-14)
Any unscheduled doctor visits for asthma in past 12 Months ^d (%)	137 (61.7)	67 (62.6)	70 (60.9)
Mean (SD)	3.0 (2.5)	3.1 (3.1)	2.9 (1.9)
Median (range)	2.0 (1-20)	2.0 (1-20)	2.0 (1-8)
Any emergency department visits for asthma in past 12 months ^d (%)	85 (38.3)	40 (37.4)	45 (39.1)
Mean (SD)	2.1 (1.5)	1.9 (1.4)	2.2 (1.5)
Median (range)	2.0 (1-7)	1.0 (1-7)	2.0 (1-7)
Any hospitalizations for asthma in past 12 months ^d (%)	37 (16.7)	10 (9.4)	27 (23.5)
Mean (SD)	1.5 (1.1)	2.1 (1.8)	1.2 (0.5)
Median (range)	1.0 (1-7)	2.0 (1-7)	1.0 (1-3)
Any oral corticosteroid for asthma in past 12 months ^d (%)	134 (60.4)	59 (55.1)	75 (65.2)
Mean (SD)	2.1 (1.6)	2.1 (1.8)	2.1 (1.4)
Median (range)	2.0 (1-12)	2.0 (1-12)	2.0 (1-8)

^a: N = 221 in Total, N = 106 in CHW arm;

^b: N = 47 in Total, N = 21 in CHW arm, N = 26 in AE-C arm;

c : N = 174 in Total, N = 85 in CHW arm, N = 89 in AE-C arm;

d : N = 222 in Total, N = 107 in CHW arm;

e : N = 207 in Total, N = 101 in CHW arm, N = 106 in AE-C arm;

f : N = 217 in Total, N = 106 in CHW arm, N = 111 in AE-C arm,

g : N = 221 in Total, N = 107 in CHW arm, N = 114 in AE-C arm

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Table 4:Asthma Medication in Asthma Action at Erie Children ($N = 223$)

Baseline Data	Caregiver Report	Child Report	Observed
Reliever medication (%)	187 (84.2) ^a	175 (78.5)	183 (82.1)
ICS controller medication (%)	119 (53.4)	94 (42.1)	99 (44.4)
Has a spacer (%)			161 (72.2)
Parents help with medicine (%)			
Always	113 (50.9) ^a	92 (41.8) ^b	
Most of the time	50 (22.5)	34 (15.5)	
Sometimes	34 (15.3)	57 (25.9)	
Rarely/Never	25 (11.3)	37 (16.8)	
In the past 6 months, doctor prescribed medicine you did not get or use (%)	27 (12.2)		
Reasons ($N = 27$):			
Medicine does not help	2 (7.4)		
Health insurance does not cover it	5 (18.5)		
Doctor is not prescribing it	1 (3.7)		
Does not need the medicine	8 (29.6)		
Medication secondary effects	10 (37.0)		
Taste	1 (3.7)		
Percent of correct medication technique, ^b mean (SD)			63.6 (22.2)
Inhaled controller medicine (%)			
Adherence measured			87 (39.0)
Not prescribed (verified by EMR)			80 (35.9)
Prescribed but not available			44 (19.7)
Available but caregiver refused			12 (5.4)
Inhaled controller mean doses per day (SD)			
Standard medication counter ^c			2.4 (1.1)
Electronic dose counter ^d			2.1 (1.0)
Inhaled controller percent adherence ^e			
Mean (SD)	74.7% (34.4)	71.9% (30.7)	53.4% (25.2)
Median (range)	88.5 (0 – 169.2)	76.9 (11.5 – 100.0)	50.0 (11.5 – 100.0)

^a $N = 222$ ^b $N = 220$ ^c $N = 79$. Doses per day = (end counter number – start counter number) / (days under observation minus 1).^d $N = 75$. Number of actuations per day on electronic dose counter, day 0 and 14 dropped, more than 4 doses/day adjudicated to 4.^eVerified against prescription. When prescription not available, most commonly used dose applied. $N = 83$ for caregiver report, $N = 16$ for child report, $N = 75$ for electronic dose counter measurement.

Table 5:**Asthma Trigger Environment in Asthma Action at Erie Children**

Baseline Data	N=223	Frequency
Age of home, mean (SD)	216	92.1 (25.9)
Ownership (%)	223	
Own		38 (17.0)
Rent/Section 8/public housing		172 (77.1)
Live with family/friends		13 (5.8)
Basement apartment (%)	223	24 (10.8)
Where child sleeps (%)	223	
Own bedroom		157 (70.4)
Caregiver's bedroom		58 (26.0)
Living room/family room		8 (3.6)
Smoker in the home (%)	223	67 (30.0)
Caregiver smokes (%)	223	31 (13.9)
Child exposure to secondhand smoke (%)	223	
At least once a day		22 (9.9)
2-6 days/week		4 (1.8)
Once a week		10 (4.5)
Once or several times a month		16 (7.2)
Less than once a month		35 (15.7)
Never		125 (56.1)
Don't know		11 (4.9)
Smoke observed in home (%)	218	14 (6.4)
Pets in home (%)	222	83 (37.4)
Dust observed anywhere in home (%)	219	48 (21.9)
Allergy covers on child's bed (%)	208	39 (18.8)
Roaches observed or self-reported in the home in past 3 months (%)	223	55 (24.7)
Rats/mice observed or self-reported in the home in past 3 months (%)	223	43 (19.3)
Mold seen anywhere in home (%)	219	213 (97.3)
Cracks/holes seen anywhere in home (%)	218	89 (40.8)
Strong smells observed anywhere in home (candles, air fresheners, cleaning or chemical smells, sewer) (%)	220	127 (57.7)
Gas burning furnace	223	201 (90.1)