Contemporary Clinical Trials 79 (2019) 55–65

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Design and baseline characteristics of a low-income urban cohort of children with asthma: The Asthma Action at Erie Trial

Giselle S. Mosnaim*, Sally M. Weinstein, Oksana Pugach, Genesis Rosales, Angkana Roy, Surrey Walton, Molly A. Martin

NorthShore University HealthSystem, University of Illinois at Chicago, United States

ARTICLE INFO

Keywords:
Asthma
Health outcomes
Community health workers
Disparities
Adherence
Pediatrics

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 occured 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 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 effectivness design that integrates interventionists and intervention delivery into a clinical setting. Categorizing asthma control in community settings for research purposes presents unique challenges.

Clinical trial registration: University of Illinois at Chicago Protocol Record R01HL123797, Asthma Action at Erie TrialClinicalTrials.gov Identifier: NCT02481986 "ClinicalTrials.gov Registration" *register@clinicaltrials.gov*

1. 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; $p < .001$) and Puerto Rican children 5.41 (CI 3.23–9.04; $p < .001$) 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

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

* Corresponding author at: Research Institute, 1001 University Place, Evanston, IL 60201, United States.
E-mail address: gmosnaim@northshore.org (G.S. Mosnaim).

https://doi.org/10.1016/j.cct.2019.02.006
Received 29 August 2018; Received in revised form 24 January 2019; Accepted 13 February 2019
Available online 14 February 2019

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 different 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. 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 Fig. 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 post-intervention 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 < 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 7 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.

3. Interventions

3.1. CHWs

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 2 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

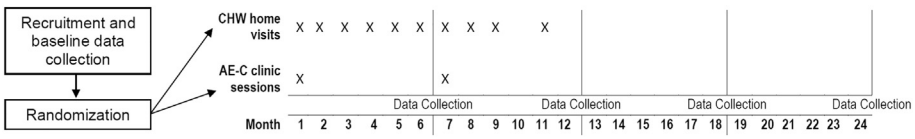

Fig. 1. Asthma action at Erie Trial design.

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.

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.

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 h 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.

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.

3.2. Certified asthma educator (AE-C)

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.

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.

3.3. 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

Table 1
Asthma action at Erie outcomes measures

Domain	Questions	# of items	0 mo base line	6 mo	12 mo	18 mo (phone)	24 mo
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 control questionnaire [21–24,27,28]	6					
	Oral steroids	1					
	Asthma functional severity scale [35]	6					
Asthma	Caregiver self-report [36]	5					
Medicines	Child self-report [36]	3					
	Observed medicines [36]	2					
	Observed technique [36]	11/12/10					
	Adherence [36]	5					
Triggers	Home assessment (self-report and observed) [16,37]	167					
	Salivary cotinine [37,38]	1					
Health Services	Urgent care visits	1					
Utilization	Emergency dept. visits	1					
	Hospitalizations	1					
	Missed school	1					
	Missed work	1					
Demographics	Height/weight	2					
	Demographics	27					
Psychosocial	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					
	Social support (PROMIS Emotional, Informational, Instrumental) [49,50]	24					
	Family functioning (CHAOS) [48,51]	15					
Implementation	Intervention tracking	19					

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)

* Primary outcome

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 7 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 post-traumatic symptomatology experienced over the past 7 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 [19]. 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.

3.4. Recruitment, randomization, and retention

3.4.1. Recruitment

All participants were recruited from Erie Family Health Center. Recruitment of 223 child/caregiver dyads occurred from March 2016–August 2017. Fig. 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.

3.4.2. 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.

3.4.3. 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.

3.5. Human subjects

3.5.1. 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.

3.5.2. 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.

3.6. Analyses

3.6.1. 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 $\alpha = 0.05$.

3.6.1.1. 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 $p < .05$, 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

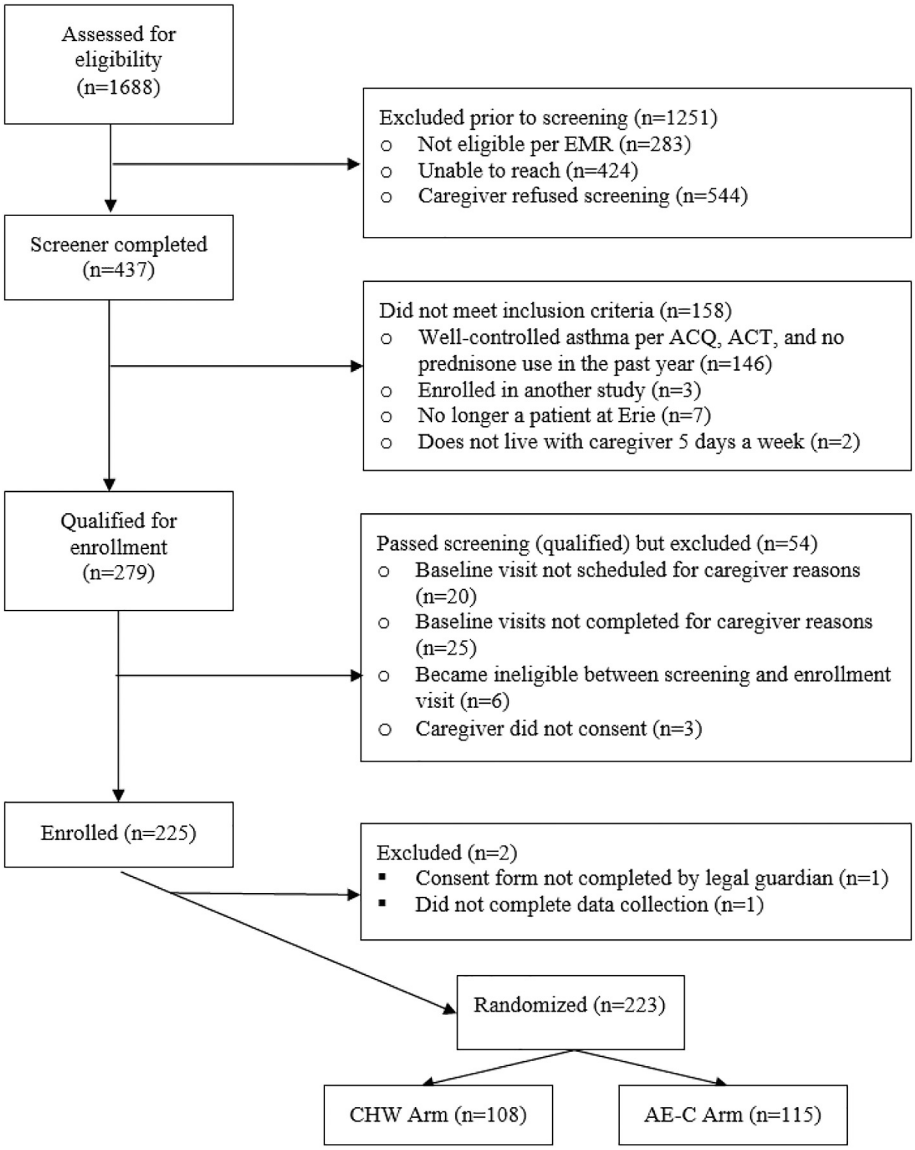

Fig. 2. Asthma action at Erie consort diagram.

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.

3.6.2. 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

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]		
< 20 k	46 (20.9)	
20 k–59 k	91 (41.4)	
> 60 k	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)	
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.

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.

4. Results

4.1. 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).

4.2. 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).

4.3. 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 ($p = .26$), 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 ($p = .04$). 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 ($p = .20$); the Kappa dropped to 0.26, but the sample size for this age group was small ($n = 47$). Fig. 2 shows the correlation between the ACQ and cACT/ACT.

4.4. 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

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[e],			
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[f]			
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] $N = 217$ in Total, N = 106 in CHW arm, $N = 111$ in AE-C arm.
[f] $N = 221$ in Total, N = 107 in CHW arm, $N = 114$ in AE-C arm.

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.

4.5. 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.

5. 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)

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, > 4 doses/day adjudicated to 4.
[e] Verified 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.

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 Spanish, 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 sevend 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 that 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

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)

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.

Contributors' statement page

Dr. Mosnaim assisted with conceptualization, design, and implementation of the study, drafted the initial manuscript, and reviewed and revised the manuscript.

Dr. Weinstein assisted with conceptualization, design, and implementation of the study, and critically reviewed and revised the manuscript.

Dr. Roy assisted with conceptualization, design, and implementation of the study, and critically reviewed and revised the manuscript.

Dr. Walton assisted with conceptualization, design, and implementation of the study, and critically reviewed and revised the manuscript.

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.

Funding source

This study was funded by the National Heart, Lung, and Blood Institute grant # 1R01HL123797 (PI Molly Martin).

Financial disclosure

Drs. Weinstein, Pugach, Roy, Walton and Martin and Ms. Rosales have indicated they have no financial relationships relevant to this article to disclose. Dr. Mosnaim receives research grant support from GlaxoSmithKline and Propeller Health; owns stock options in Electrocore; and serves as a consultant and/or member of a scientific advisory board for Electrocore, GlaxoSmithKline, Teva, Novartis, Astra Zeneca, Boehringer Ingelheim and Propeller Health.

Conflict of interest

All authors have indicated they have no potential conflicts of interest to disclose.

Acknowledgments

We would like to thank the staff who collected these data: Gizelle Alvarez, Daisy Cintron, Jazmin Morales, and Genesis Rosales. We thank Karen Reyes for her administrative assistance in formatting the manuscript for publication. We also want to recognize the Asthma Action at Erie Steering Committee who are not authors: Michael Berbaum, Ana Cesan, Hannah Chi, Andrea Fragoso, Denise Guerrero, Melissa Hernandez, and Steven Rothschild. The Chicago Asthma Consortium Asthma Community Advisory Board provides oversight for the study. We would like to thank everyone at Erie Family Health Center. This includes medical directors, providers and staff at the West Town Health Center, Evanston/Skokie Health Center, Erie Helping Hands Health Center, Erie Humboldt Park Health Center, Erie Westside Health Center at Laura S. Ward Elementary School, and Erie Johnson School-Based Health Center. Finally, we would like to thank all the families who made this research possible.

References

[1] C.A. Keet, et al., Neighborhood poverty, urban residence, race/ethnicity, and asthma: rethinking the inner-city asthma epidemic, J. Allergy Clin. Immunol. 135 (3) (2015) 655–662.
[2] CDC, National Health Interview Survey (NHIS), (2016), p. 2016.
[3] T.K.R. Nurmagambetov, P. Garbe, *The economic burgen of asthma in the United States* 2008-2013, Ann. Am. Thorac. Soc. 3 (15) (2018) 348–356.
[4] H.S. Zahran, et al., Vital signs: asthma in children - United States, 2001-2016, MMWR Morb. Mortal. Wkly Rep. 67 (5) (2018) 149–155.
[6] US Environmental Protection Agency, Coordinated Federal Action Plan to Reduce Racial and Ethnic Asthma Disparities, Available from: *https://www.epa.gov/sites/production/files/2014-08/documents/federal_asthma_disparities_action_plan.pdf*.
[7] K.B. Weiss, et al., The burden of asthma in the Chicago community fifteen years after the availability of national asthma guidelines: the design and initial results from the CHIRAH study, Contemp. Clin. Trials. 30 (3) (2009) 246–255.
[8] J.B. Nath, R.Y. Hsia, Children's emergency department use for asthma, 2001-2010, Acad. Pediatr. 15 (2) (2015) 225–230.
[9] Global Initiative for Asthma, Global Strategy for Asthma Management and Prevention, 2018 [cited 2018 June 20,]; Available from, 2018. *www.ginasthma.org*.

[10] National Heart, L., and Blood Institute, Expert Panel Report 3: Guidelines for Diagnosis and Management of Asthma. National Asthma Education and Prevention Program, [cited 2018 August 6]; Available from, 2007. *https://www.nhlbi.nih.gov/files/docs/guidelines/asthgdln.pdf*.
[11] G. Mosnaim, et al., The impact of peer support and mp3 messaging on adherence to inhaled corticosteroids in minority adolescents with asthma: a randomized, controlled trial, J Allergy Clin Immunol Pract 1 (5) (2013) 485–493.
[12] J.A. Krishnan, et al., Adherence to inhaled corticosteroids: an ancillary study of the childhood asthma management program clinical trial, J. Allergy Clin. Immunol. 129 (1) (2012) 112–118.
[13] E.L. McQuaid, et al., Medication adherence in pediatric asthma: reasoning, responsibility, and behavior, J. Pediatr. Psychol. 28 (5) (2003) 323–333.
[14] G. Canino, E.L. McQuaid, C.S. Rand, Addressing asthma health disparities: a multilevel challenge, J. Allergy Clin. Immunol. 123 (6) (2009) 1209–1217 (quiz 1218-9).
[15] J. Krieger, et al., A randomized controlled trial of asthma self-management support comparing clinic-based nurses and in-home community health workers: the Seattle-King County healthy homes II project, Arch. Pediatr. Adolesc. Med. 163 (2) (2009) 141–149.
[16] J.W. Krieger, et al., The Seattle-King County healthy homes project: a randomized, controlled trial of a community health worker intervention to decrease exposure to indoor asthma triggers, Am. J. Public Health 95 (4) (2005) 652–659.
[17] W.J. Morgan, et al., Results of a home-based environmental intervention among urban children with asthma, N. Engl. J. Med. 351 (11) (2004) 1068–1080.
[18] P.A. Eggleston, et al., Home environmental intervention in inner-city asthma: a randomized controlled clinical trial, Ann. Allergy Asthma Immunol. 95 (6) (2005) 518–524.
[19] E.A. Parker, et al., Evaluation of community action against asthma: a community health worker intervention to improve children's asthma-related health by reducing household environmental triggers for asthma, Health Educ. Behav. 35 (3) (2008) 376–395.
[20] M. Viswanathan, et al., Community-based participatory research: assessing the evidence, Evid. Rep. Technol. Assess (Summ) 99 (2004) 1–8.
[21] E.F. Juniper, et al., Asthma control questionnaire in children: validation, measurement properties, interpretation, Eur. Respir. J. 36 (1416) (2010) 1410–1416.
[22] E.F. Juniper, et al., Measurement properties and interpretation of three shortened versions of the asthma control questionnaire, Respir. Med. 99 (5) (2005) 553–558.
[23] J.M. Nguyen, et al., Validation and psychometric properties of the Asthma Control Questionnaire among children, J. Allergy Clin. Immunol. 133 (1) (2014) 91–97 (e1–6).
[24] M.M. Cloutier, et al., Asthma outcomes: composite scores of asthma control, J. Allergy Clin. Immunol. 129 (3 Suppl) (2012) S24–S33.
[25] M. Schatz, et al., Asthma control test: reliability, validity, and responsiveness in patients not previously followed by asthma specialists, J. Allergy Clin. Immunol. 117 (3) (2006) 549–556.
[26] A.H. Liu, et al., Development and cross-sectional validation of the childhood asthma control test, J. Allergy Clin. Immunol. 119 (4) (2007) 817–825.
[27] S. Voorend-van Bergen, et al., Asthma control questionnaires in the management of asthma in children: a review, Pediatr. Pulmonol. 50 (2) (2015) 202–208.
[28] C. Picado, et al., Validation of the Spanish version of the asthma control questionnaire, Clin. Ther. 30 (10) (2008) 1918–1931.
[29] J.M. Vega, et al., Validation of the Spanish version of the asthma control test (ACT), J. Asthma 44 (10) (2007) 867–872.
[30] C.E. Rodriguez-Martinez, et al., Validation of the Spanish version of the childhood asthma control test (cACT) in a population of Hispanic children, J Asthma 51 (8) (2014) 855–862.
[31] P. Freire, Pedagogy of the Oppressed, Herder and Herder, New York, 1970 (186 p).
[32] N. Wiggins, Popular education for health promotion and community empowerment: a review of the literature, Health Promot. Int. 27 (3) (2012) 356–371.
[33] W.R. Miller, S. Rollnick, Motivational Interviewing : Preparing People for Change, 2nd ed., Guilford Press, New York, 2002, p. xx (428 p).
[34] R.S. Zeiger, et al., Evaluation of the National Heart, Lung, and Blood Institute guidelines impairment domain for classifying asthma control and predicting asthma exacerbations, Ann. Allergy Asthma Immunol. 108 (2) (2012) 81–87.
[35] M.J. Rosier, et al., Measurement of functional severity of asthma in children, Am. J. Respir. Crit. Care Med. 149 (6) (1994) 1434–1441.
[36] M.A. Martin, et al., Recruitment, asthma characteristics, and medication behaviors in Midwestern Puerto Rican youth: data from project CURA, Ann. Allergy Asthma Immunol. 109 (2) (2012) 121–127.
[37] M.A. Martin, et al., Home asthma triggers: barriers to asthma control in Chicago Puerto Rican children, J. Health Care Poor Underserved 24 (2) (2013) 813–827.
[38] R. Kumar, et al., A community-based study of tobacco smoke exposure among inner-city children with asthma in Chicago, J. Allergy Clin. Immunol. 122 (4) (2008) 754–759 (e1).
[39] K. Kroenke, R. Spitzer, The PHQ-9: a new depression diagnostic and severity measure, Psychiatr. Ann. 32 (9) (2002) 509–515.
[40] M. Kovacs, I. Multi-Health Systems, Children's depression inventory (CDI) : Technical Manual update, North Tonawanda, Multi-Health Systems, Inc., N.Y, 2003.
[41] S.L. Warttig, et al., New, normative, English-sample data for the short form perceived stress scale (PSS-4), J. Health Psychol. 18 (12) (2013) 1617–1628.
[42] M.T. Ramirez, R.L. Hernandez, Factor structure of the perceived stress scale (PSS) in a sample from Mexico, Span. J. Psychol. 10 (1) (2007) 199–206.
[43] S. Cohen, G. Williamson, S. Spacapam, S. Oskamp, Perceived stress in a probability sample of the U.S.: The Social Psychology of Health, in: S. Spacapan, S. Oskamp (Eds.), Claremont Symposium on Applied Social Psychology. Newbury Park, CA: Sage, Sage Publications, Newbury Park, Calif, 1988.
[44] J.N. Miles, G.N. Marshall, T.L. Schell, Spanish and English versions of the PTSD checklist-civilian version (PCL-C): testing for differential item functioning, J. Trauma. Stress. 21 (4) (2008) 369–376.
[45] G.N. Marshall, Posttraumatic stress disorder symptom checklist: factor structure and English-Spanish measurement invariance, J. Trauma. Stress. 17 (3) (2004) 223–230.
[46] A.J. Lang, M.B. Stein, An abbreviated PTSD checklist for use as a screening instrument in primary care, Behav. Res. Ther. 43 (5) (2005) 585–594.
[47] M.F. Ziegler, et al., Posttraumatic stress responses in children: awareness and practice among a sample of pediatric emergency care providers, Pediatrics 115 (5) (2005) 1261–1267.
[48] A.P. Matheny, et al., Bringing order out of chaos: psychometric characteristics of the confusion, hubbub, and order scale, J. Appl. Dev. Psychol. 16 (3) (1995) 429–444.
[49] P.A. Pilkonis, et al., Item banks for measuring emotional distress from the patient-reported outcomes measurement information system (PROMIS(R)): depression, anxiety, and anger, Assessment 18 (3) (2011) 263–283.
[50] E.A. Hahn, et al., New English and Spanish social health measures will facilitate evaluating health determinants, Health Psychol. 33 (5) (2014) 490–499.
[51] L.M. Haack, et al., Advancing our knowledge of ADHD in Latino children: psychometric and cultural properties of Spanish-versions of parental/family functioning measures, J. Abnorm. Child Psychol. 39 (1) (2011) 33–43.
[52] M. Schatz, et al., The minimally important difference of the Asthma Control Test, J. Allergy Clin. Immunol. 124 (4) (2009) 719–723 (e1).
[53] S. Voorend-van Bergen, et al., Monitoring childhood asthma: web-based diaries and the asthma control test, J. Allergy Clin. Immunol. 133 (6) (2014) 1599–1605 (e2).
[54] S. Cohen, T. Kamarck, R. Mermelstein, A global measure of perceived stress, J. Health Soc. Behav. 24 (4) (1983) 385–396.
[55] A.K. Allgaier, et al., Is the Children's depression inventory short version a valid screening tool in pediatric care? A comparison to its full-length version, J. Psychosom. Res. 73 (5) (2012) 369–374.
[56] D.E. Irwin, et al., Development of six PROMIS pediatrics proxy-report item banks, Health Qual. Life Outcomes 10 (2012) 22.
[57] R. Greenwald, A. Rubin, Assessment of posttraumatic symptoms in children: development and preliminary validation of parent and child scales, Res. Soc. Work. Pract. 9 (1) (1999) 61–75.
[58] R. Greenwald, et al., *Psychometrics of the CROPS & PROPS in multiple cultures/translations*. in *annual meeting of the International Society for Traumatic Stress Studies, Baltimore, MD*, (2002).