**Title**
Results from a Community-Based Trial testing a Community Health Worker Asthma Intervention in Puerto Rican Youth in Chicago

**Authors**
Molly A Martin,[1] MD, MAPP
Giselle S. Mosnaim,[2] MD, MS
Daniel Olson, BA[3]
Susan Swider,[4] PhD
Kelly Karavolos,[2] MS
Steven Rothschild,[2] MD

1.University of Illinois at Chicago, Department of Pediatrics. 840 S Wood St, Chicago, IL, 60612.
2. Rush University Medical Center, Department of Preventive Medicine. 1700 W Van Buren, Suite 470, Chicago, IL, 60612.
3. Rush University Medical Center, Rush Medical College. 600 S. Paulina Street, Suite 202, Chicago, IL, 60612.
4. Rush University Medical Center, College of Nursing. 600 S. Paulina Street, Suite 1080, Chicago, IL, 60612.

**Corresponding Author**
Molly A Martin, MD, MAPP
University of Illinois at Chicago
Department of Pediatrics
840 South Wood Street, M/C 856
Chicago, IL 60612
Email: mollyma@uic.edu
Phone: 312-996-2363

**Running Head**
Asthma Intervention in Puerto Rican Youth

**Key Words**
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**Abstract**

Objective: Puerto Rican children suffer disproportionately from asthma. Project CURA tested the efficacy of a community health worker (CHW) intervention to improve use of inhaled corticosteroids (ICS) and reduce home asthma triggers in Puerto Rican youth in Chicago. Methods: The study employed a behavioral randomized controlled trial design with a community-based participatory research approach. Medications and technique were visually assessed; adherence was determined using dose counters. Home triggers were assessed via self-report, visual inspection, and salivary cotinine. All participants received education on core asthma topics and self-management skills. Participants in the CHW arm were offered home education by the CHW in four visits over four months. The attention control arm received four newsletters covering the same topics. Results: While most of the participants had uncontrolled persistent asthma, < 50% had ICS at baseline. In the CHW arms, 67% of participants received the full 4-visit intervention. In the Elementary School Cohort (n=51), the CHW arm had lower odds of having an ICS (OR=0.2; p=0.02) at 12-months; no differences were seen in other outcomes between arms at any time point. The only significant treatment arm difference in the High School Cohort (n=50) was in inhaler technique where the CHW arm performed 18.0% more steps correct at 5-months ($p < 0.01$) and 14.2% more steps correct at 12-months ($p < 0.01$). Conclusions: While this CHW intervention did not increase the number of participants with ICS or reduce home asthma triggers, important lessons were learned that inform future investigations of the real-life effectiveness of CHW asthma interventions.

## Introduction

Asthma exacerbations can be readily prevented and controlled with proper inhaled corticosteroid medication usage and the reduction of environmental triggers [1,2]. Yet despite our increased ability to control asthma, disparities in asthma outcomes documented over ten years ago still persist in the US [3-5]. Reasons for these disparities are difficult to disentangle, and include differential trigger exposure, access to healthcare, behaviors, and genetic factors [6-11]. Of all US racial/ethnic groups, Puerto Rican children experience the highest asthma prevalence, morbidity, and mortality rates [3-4,12] and yet intervention research in this population is sparse. Effective interventions designed to improve asthma self-management behaviors are urgently needed for this high risk population.

Chicago is home to the third largest Puerto Rican population in the mainland US [13] and has reported asthma rates higher than the national averages. A population-based survey from 2002-2004 documented an asthma prevalence in Puerto Rican children in Chicago of 21%, with another 13% reporting asthma symptoms but not a physician diagnosis [14-15]. As a response, *La Comunidad Unida Retando el Asma* (The Community United to Challenge Asthma, referred to as Project CURA) was created in 2009. Project CURA was a behavioral randomized controlled trial to test the efficacy of a community health worker (CHW) intervention to improve asthma outcomes in Puerto Rican children and adolescents in Chicago. The CHW intervention was chosen because of its success in the reduction of triggers and improvement of asthma control in other populations [16-18]. Several modifications were made from previous studies using a process of adaptation described by the Merck Childhood Asthma Network where contextual factors are balanced with intervention fidelity to achieve a "best fit" for the target community [19]. Due to sustainability concerns, CHWs provided education on environmental remediation

but no cleaning or remediation equipment (such as vacuums or allergy covers). CHWs also focused on assisting participants to obtain medications and optimal medication delivery technique. We hypothesized the CHW arm would improve adherence to inhaled corticosteroid medications (ICS) and decrease asthma triggers in the home compared to an attention control arm. Two cohorts were created – one of children in kindergarten through 8th grade (Elementary School Cohort, abbreviated as ESC), and another of adolescents in high school (High School Cohort, abbreviated as HSC). In this paper, we present the results of the trial as well as a discussion of the challenges of intervention implementation in this high-risk population.

## Methods

### Study Design

A community-based participatory research approach was incorporated from the study's inception. Partners included a local health coalition (The Greater Humboldt Park Community of Wellness, http://ghpcommunityofwellness.org/), a social service organization (the Puerto Rican Cultural Center, (www.prcc-chgo.org), a parent-led service organization (Women Living with Hope), and an Evangelical Christian church (New Life Covenant Church). Community partners participated in all aspects of the study through their representatives on the study steering committee. Caregivers of children with asthma, local health providers, and representatives from local organizations and churches served on the community advisory board [20].

A behavioral randomized controlled trial design was used. An attention-control group (Mailings arm) received a written version of the asthma content on the same schedule as the intervention group (CHW arm). Outcomes were assessed by research assistants blinded to study arm at pre-randomization, 5-months (immediately after intervention completion), and 12-months post-randomization to determine sustainability. Participants were randomized by the data

management team using a standard computerized four-block randomization scheme. Written informed consent from caregivers and child assent were obtained in the home by the research assistant in the preferred language. The study was approved by the Rush University Medical Center Institutional Review Board.

While this study was intended to be exploratory, sample size estimates were determined a priori for both primary outcomes. For adherence to ICS, we expected baseline adherence to be between 10-50% [5,16,21]. With 20 subjects in each group, we would be able to detect an effect size of 0.736 with 80% power at alpha=0.05. Assuming a standard deviation of 29%,[21] this translated to an improvement of 20 percentage points or more in the intervention group compared to the control group. For home triggers, power was based on the work of Krieger et al.[16]. Using a behavior summary score similar to ours, their team published a 0.9 reduction in trigger behavior summary score with a one-time CHW home visit for children 4-12 years old with asthma[16]. Intervention group participants in Project CURA were going to receive a larger "dose" (4 home visits) and the control group would receive no CHW intervention, which allowed us to conservatively estimate a between groups difference in mean trigger score of at least 1 (standard deviation of 1.28)[22]. With 20 subjects in each of two arms, the study would have 84% power to detect a difference of 1 point, on average, between the two groups on the trigger behavior summary score (alpha of 0.05). We expected a drop-out rate of no more than 20% over the course of the study. Therefore, we recruited 25 subjects per group.

Inclusion Criteria

Participants were recruited through community partner, school-based, and community clinic outreach efforts. Inclusion criteria included: 1) self-described Puerto Rican heritage, 2) child between the ages of 5-18, 3) child lives in same household as caregiver at least 5 days out

of the week, and 4) child has persistent asthma and/or uncontrolled asthma. Persistent asthma was determined by self-report of having been prescribed an ICS in the last year OR any of the following: In the past 4 weeks, had asthma symptoms (cough, wheezing, shortness of breath, chest tightness) > 2 days/week, nighttime symptoms ≥ 3-4 times/week, short acting $\beta_2$-agonist use for symptom control >2 days/week, some interference with normal activity; or ≥ 2 exacerbations requiring oral systemic corticosteroids in the past year [23]. A score ≥ 1 on the Asthma Therapy Assessment Questionnaire (ATAQ) was used at screening to determine uncontrolled asthma [24]. Only one child per family could be enrolled.

Outcomes

Detailed descriptions of the outcomes instruments are presented elsewhere [20,25]. To ensure no differential ascertainment, bilingual Puerto Rican research assistants blind to study arm collected data in the home. All questions were asked verbally, with the exception of the depression screening instrument which was administered via paper. Instruments without validated Spanish translations were professionally translated into Spanish. All instruments were then pilot tested with Puerto Rican Spanish- and English-speaking volunteers.

Primary intervention goals were to increase adherence to ICS and decrease home asthma triggers. Adherence to ICS was defined as the objectively measured number of doses of ICS taken compared to ICS recommended doses. The research assistants asked to see all of the children's asthma medications. For children with an ICS, adherence was then determined. For ICS in a metered dose inhaler, a medication dose counter was placed on the inhaler to document the number of times the inhaler was actuated daily (Doser CT, MediTrack, Inc., South Easton, MA). If the dose counter could not be fitted to the inhaler, the number of actuations remaining in the ICS canister's integrated dose counter was recorded. The research assistant returned 21 days

later to remove the medication adherence dose counter or record the number of actuations remaining in the ICS canister. Sometimes medication monitor data exceeded expected doses. Most families did not have prescription labels indicating the prescribed dosage. Therefore, standard doses were assumed and adherence was truncated at 100% of the standard dose [26]. Children were asked to demonstrate their medication technique using their own medication or a demonstration inhaler [27-28].

Home asthma trigger data were obtained by self-report, a visual home assessment, and objective measurement. The self-report questions were drawn from the instrument used in the Seattle-King Healthy Homes Project that asked about behaviors related to allergens such as dust mites, pets, roaches and rodents [16]. Questions about exposures to irritants such as cigarette smoke and chemicals such as cleaning products were added. The visual home assessment included examination (both visual and olfactory) of the child's bedroom, main living area, kitchen, bathroom, and heating source [17,29]. Saliva was taken from children and tested for cotinine with an ELISA using a high sensitivity quantitative immunoassay (Salimetrics, Inc, State College, PA), calibrator range 0.8-200 ng/mL, sensitivity 0.05 ng/mL. Salivary cotinine levels ranging from 1-7 ng/ml were coded as passive smoking and $\geq$8 ng/ml as active smoking [30-32]. Potential triggers were reported individually and as a 13-item home summary score of negative trigger behaviors (referred to as the Behavior Summary Score). A positive report of a trigger from any one of the three data sources resulted in a single score of 1 for each behavior and behaviors were then summed to create the Behavior Summary Score; higher scores indicated more trigger-promoting behaviors.

Based on the Expert Panel Report 3 guidelines, questions regarding symptoms, medication usage, and missed activities were used to determine asthma control over the past four

weeks [23]. Asthma control over the prior 12 months was assessed using the asthma functional severity scale [6,33]. Caregivers and HSC participants were screened for depression symptoms using the PHQ-9 [34-36]. The Perceived Stress Scale [37-39] was used to capture stress in caregivers, while the Life Events Checklist was used in children [40].

Participants were offered travel assistance to come to the research office for skin allergy testing using the Multi-test® II device (Lincoln Diagnostics, Inc. Decatur, IL). Allergens included dust mite mix (*Dermatophygoides farinae* and *Dermatophygoides pteronyssinus*), cockroach mix (German and American), mold mix (*Alternaria, Cladosporium, Penicillium, Aspergillus*), cat, dog, and mouse. A positive test was defined as a wheal diameter $\geq$ 3 mm than the negative control.

Intervention

Both arms covered general asthma facts, controller and quick-relief medications, inhalers and spacers, symptom recognition, asthma triggers, and access to care as recommended in the Expert Panel Report 3 Guidelines [23]. Families were given written information on places they could receive medical care, insurance, housing assistance, and home remediation services. Families were not given supplies such as vacuums or cleaning materials and their physicians were not directly contacted regarding the study because the goal was to empower families to seek out and use existing resources. Self-management skills were also addressed, including environmental rearrangement, problem solving, enlisting social support, and self-monitoring [41-42] For example, when discussing asthma symptoms, participants were encouraged to track their symptoms on a piece of paper for a week (self-monitoring). Participants were encouraged to move medications somewhere that would help them remember to take them (environmental rearrangement). Participants in the CHW arm were offered four CHW visits over four months in

the home. Four visits were chosen based on the experience of others [18,43-35]. CHWs used lung models and demonstration  metered dose inhalers to lead discussions with families, emphasizing exploratory learning. At the end of each visit, families filled out a behavior change plan on which they wrote one small change they wanted to make in the upcoming month.  The plan required them to specify the time and manner in which they were going to implement the change, to brainstorm challenges and strategies, and to assess their confidence.  Participants in the Mailings arm received four single-page bilingual color newsletters that covered the same core asthma topics and self-management skills.

CHWs were recruited through community advertisements.  Two initial trainings were conducted; one was 12 hours, the other 15 hours.  Trainings were led by a certified asthma educator and covered asthma pathophysiology, symptoms, triggers and environmental control, management and medications, home visitation, and integrated pest management.  Of the 13 people who completed the training, four were invited to a second 12-hour training led by the principal investigator which reviewed asthma medications, self-management skills, behavior change plans, and the research protocol.  CHW competency was evaluated using standardized role plays and medication technique demonstration [42]. The two CHWs hired then shadowed more experienced CHWs from a different asthma program for a minimum of 2 visits before beginning intervention delivery.

Intervention fidelity was maintained in two ways.  CHWs met with the principal investigator every 2-4 weeks to discuss active participants and conduct continuing education. CHWs filled out detailed encounter forms after each home visit documenting time, people engaged with, and topics covered.

Analysis

The analysis was stratified by cohort. Basic summary statistics (means, medians, frequencies) were calculated for demographics, covariates, and primary outcomes at baseline. Differences between the treatment arms at baseline were assessed via t-tests, Wilcoxon tests, Pearson chi-square tests or Fisher's exact test where appropriate. Changes from baseline within treatment arms were assessed via paired t-tests, sign tests, Wilcoxon sign-ranks tests or McNemar's test for matched pairs, as appropriate. Changes from baseline at five and twelve months between treatment arms in primary outcomes, as well as moderation of change from baseline by covariates, were assessed by either logistic regression or linear regression. All statistical analyses were conducted in SAS (SAS Institute Inc., Cary, North Carolina), version 9.2.

## Results

Fifty-one participants were recruited into the ESC and 50 in the HSC (Figure 1). Retention was high in both cohorts: the ESC had 96% retention at both follow-up visits, while the HSC had 96% retention at 5-months and 88% at 12-months. In the CHW arm, 34 out of 51 participants received the full four-visit intervention: 16 (62%) in the ESC and 18 (72%) in the HSC. One participant refused all CHW visits. Several months into the study, fidelity measures led to the discovery that one CHW had falsified visit reports. Contact had not been attempted with 9 participants (7 in ESC and 2 in HSC) in the CHW arm during the intervention period. When discovered and verified with participants, the CHW's employment was terminated and those participants were coded as receiving no CHW visits.

### Elementary School Cohort (ESC)

*Demographics and Asthma Characteristics:* As seen in Table 1, half of caregivers had an education level of more than high school and home ownership was low. Depressive symptoms

were common for caregivers (27% in CHW arm, 24% in Mailings arm). Enrollment was limited to children with persistent and/or uncontrolled asthma at baseline; the majority of participants met criteria for uncontrolled over the past four weeks (Table 2). At baseline, 42% in CHW arm and 48% in Mailings arm had an ICS with adherence numbers lower than the standard recommended 4 doses/day [median (interquartile range): CHW arm = 0.70 (0.14, 1.4), Mailings arm = 1.5 (0.9, 1.9), p=0.11]. Smoking in the home was uncommon; 88% of children in the CHW arm and 92% in Mailings arm had no tobacco exposure as assessed via cotinine levels.

*Medications:* No differences were seen between treatment arms at any time point with the exception of having an ICS at 12-months (see Figure 2). The CHW arm had lower odds of having an ICS (OR = 0.2; 95% CI 0.0, 0.8; p=0.02). Although not significant between arms, the CHW arm showed a median improvement in medication technique of 18.8% (p=0.01) at 5-months and 25% (p=0.01) at 12-months.

*Triggers and Control:* No between arm differences were seen for Behavior Summary Score (see Table 3), cotinine, or asthma control. Within both arms, the proportion of participants reporting controlled asthma increased from baseline at 5-months (20% to 56% in the CHW arm, p=0.05; 25% to 63% in the Mailings arm, p=0.02) and 12-months (20% to 60.0% in the CHW arm, p<0.01; 25% to 70.8% in the Mailings arm, p<0.01).

*Psychosocial Modifiers:* The only significant psychosocial modifier of treatment effect in the ESC was caregiver depressive symptoms at 12-months on asthma control. Every point increase in baseline caregiver depressive symptoms was associated with a lower odds of controlled asthma (OR 0.9; 95% CI = 0.8, 1.0; p=0.02). Including caregiver depressive symptoms into the model did not change the non-significant effect of treatment arm.

<u>High School Cohort (HSC)</u>

*Demographics and Asthma Characteristics:* Depressive symptoms were more common in this cohort with 40% of caregivers in the CHW and Mailings arms with symptoms of depression, in addition to 28% of adolescents in the CHW arm and 40% in the Mailings arm. Only 8% of the CHW arm and 16% of the Mailings arm had an ICS. While adherence numbers in both cohorts fell into our predicted range, the overall low numbers of participants with ICS (especially in the HSC) made us realize the more important outcome for this population was obtaining an ICS since this is a necessary pre-requisite for adherence. Tobacco smoke exposure was slightly more common in the HSC: 24% in CHW arm and 32% in the Mailings arm via cotinine levels.

*Medications:* While no differences were seen between treatment arms at any time point for having an ICS or quick-relief medication, medication technique differed at both time points. At 5-months, the CHW arm performed 18.0% (95% CI = 8.0, 28.1; $p < 0.01$) more steps correct than the Mailings arm. At 12-months, the CHW arm performed 14.2% (95% CI = 4.4, 24.1; $p < 0.01$) more steps correct than the Mailings arm. Although having an ICS was not different between arms, the CHW arm at 5-months compared to baseline had an increase in participants reporting having an ICS (8.7% to 34.8%, p=0.03). At 12-months in the Mailings arm, an increase in participants with an ICS was documented (13.6% to 45.5%, p=0.04).

*Triggers and Control:* Although no differences were seen between treatment arms at any time point for Behavior Summary Score (Table 3), the Mailings arm had an increase in the proportion of participants with cotinine exposure at 5-months (33.3% to 62.5%, p=0.02). At 12-months, cotinine exposure also increased in the Mailings arm (31.8% to 59.1%, p = 0.03), but not in the CHW arm, resulting in a borderline difference between arms (OR 0.2; 95% CI 0.0, 1.1; p=0.07). No differences were seen between treatment arms at any time point for achieving asthma control.

*Psychosocial Modifiers:* Bivariate analyses suggested teen depressive symptoms were associated with having an ICS and cotinine exposure but in full models, teen depressive symptoms were not significantly associated with having an ICS at 5- or 12-months. Interpretation of full models of cotinine exposure moderated by teen depression was not reliable due to poor fit.

Per Protocol Analyses

A secondary analysis was conducted including only those who received CHW intervention. In the ESC at both time points, the difference between arms for having an asthma controller became non-significant. (At 5-months, OR = 0.4; 95% CI = 0.1, 2.0; p = 0.29. At 12-months, OR = 0.2; 95% CI = 0.1, 1.2; p = 0.08.) In the HSC, the difference between arms on medication technique remained significant at both time points.

**Discussion**

Project CURA was intended to translate the CHW asthma intervention model initially demonstrated by Krieger et al. [16] into a high-risk Puerto Rican community in Chicago. In contrast to most pediatric asthma CHW studies, Project CURA did not give families cleaning supplies or equipment, it tested the intervention in a population with the highest reported asthma prevalence and morbidity, and it then objectively measured adherence and trigger outcomes. The study shifted its primary aim of ICS adherence to the precursor step of obtaining an ICS because the majority of participants did not have an ICS to adhere to. In the ESC, no differences were seen in outcomes between arms at any time point with one exception: the CHW arm had lower odds of having an ICS at 12-months but this difference was not significant in secondary analyses excluding those who did not receive intervention. The only significant treatment arm difference in the HSC was in inhaler technique. Therefore, while the pediatric asthma CHW intervention

has demonstrated efficacy by others, [46] our results suggest the modified intervention was not adequate to improve the medication or trigger environment for these high-risk families.

Most CHW trials to date have not reported outcomes related to medication use or they useself-report data [16], making the ability of the CHW intervention to improve ICS adherence unproven. . Because self-reported data are often biased toward the desired outcome [47], we suspect our objective measurement in Project CURA resulted in our documentation of lower medication rates than expected in the homes. More than four CHW visits are needed to make changes in the medication environment. The CHW had to first convince families they needed the medicine, and then encourage families to make appointments with their providers. Future interventions also need to connect CHWs with providers and provide additional provider education. Project CURA took a "ground-up" approach and educated patients how to effectively seek and obtain quality care, with the goal that patients could carry these skills with them. CHW home visit documentation shows almost all participants received education on indications and insurance coverage for medications, and communication with providers. However the CHW reported several instances when participants went to their providers as instructed by the CHW but were told they did not need ICS. This could reflect an issue with how we measured uncontrolled issue but also signals a potential provider barrier.

One area where the CHW intervention did show change was in inhaler device technique. Device technique is a critically important area of asthma management that is often overlooked. Improper technique can significantly limit delivery of medication [21,48]. Improvements were clearly seen in the HSC with sustained improvement after intervention cessation, and similar non-significant trends were seen in the ESC.

The other primary aim for this intervention was to reduce home triggers. Home triggers were reduced equally in both ESC arms, and not at all in the HSC. This is contrary to the results of other CHW studies which showed improvements in home triggers with CHW interventions [16-18,46,49-50]. These other studies provided families with equipment such as HEPA vacuums, mattress covers, and cleaning supplies. Project CURA's conceptual model based on social cognitive theory aimed instead to empower families to seek out their own resources which may explain some of the differences between our outcomes and those of others. The biggest challenge to home trigger reduction was the housing conditions. With a mean home age of 93 years, the homes needed significant remediation to reduce triggers. Families did not have the financial resources or ownership rights to make these changes. CHWs connected families with tenants' rights organizations but moving was frequently the best option which requires time and money. Similar challenges have been reported by others [16].

The study was underpowered to assess asthma control and measurements of asthma control did not show change which is not surprising since the behaviors influencing control did not change adequately. Our results are consistent with other studies showing a general trend of asthma control improvement in younger children over time, and poorer overall control in adolescence [51-52].

CURA demonstrated the urgency of mental health challenges in the care of children with asthma and their families in this high-risk population. Caregivers and adolescents had high rates of depressive symptoms. Future asthma interventions should consider a formal approach to mental health within asthma programs.

Strengths of the trial include recruitment and retention of a high- risk cohort and a rigorous design which objectively observed medications, adherence, and home triggers in the

home environment. This provides an important window into the real lives of patients which is not typically available to clinicians. Limitations are that the sample size was small and contains only Puerto Ricans which does not allow for comparisons beyond this ethnic group. Medication measurement was prone to observation bias because placing counters on the medicines potentially provided additional motivation for participants to take their medicines, although our results suggest this was not the case. The primary outcome of medication adherence was changed to the precursor step of obtaining an ICS which challenges the adequacy of the original sample size calculations. The attention-control arm received a weak intervention which could potentially have attenuated some of the results. Asthma control was based on self-report and control varied by arm at baseline in the HSC. Healthcare utilization was very low. Finally, intervention was not received by some participants due to a problem with one of the CHWs. CHWs connect well with participants because of their similar life experiences but those same experiences often pose challenges for fulfilling the obligations of professional employment. This problem is not unique to our study—CHW programs need to provide strong, comprehensive support for CHWs while also closely monitoring intervention fidelity. Audio recording or observations of visits are one way to achieve this, along with careful review of documentation and close communication.

**Conclusion**

This pilot trial of a CHW asthma intervention in Puerto Rican youth provides important information for future asthma self-management interventions. Project CURA took a pragmatic approach to objectively measure what could be accomplished using families' existing resources. Although medication technique improved, the CHW intervention did not increase medication usage or reduce home asthma triggers. We attribute this to a lack of connection with providers,

insufficient dose of the CHW intervention, limited participant resources, and mental health challenges among participants. Table 4 highlights these issues and provides suggestions for future interventions. Project CURA also provides a clear example of the need for careful support and monitoring of CHWs in the field in a way that allows them to remain community-centered but maximizes intervention fidelity. Further investigation of the CHW model is needed to better determine its real-life efficacy and practical expectations for integrating CHWs into the healthcare delivery system.

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**Declaration of interest**

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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**Table 1: Project CURA Participant Characteristics at Baseline**

| | Elementary School Cohort | | | High School Cohort | | |
|---|---|---|---|---|---|---|
| | CHW Arm N=26 | MAIL Arm N=25 | P Value | CHW Arm N=25 | MAIL Arm N=25 | P Value |
| ***Child*** | | | | | | |
| Age in years, , median (Q1,Q3) | 9 (7,11) | 9 (8,12) | 0.54[b] | 15 (15,17) | 16 (15,17) | 0.54[b] |
| Female, N (%) | 7 (27) | 13 (52) | 0.07 | 15 (60) | 14 (56) | 0.77 |
| Ethnicity, N (%) | | | 0.73[a] | | | 0.40[a] |
| Puerto Rican | 20 (77) | 18 (72) | | 17 (68) | 20 (83) | |
| Other Latino/Hispanic | 3 (12) | 5 (20) | | 7 (28) | 4 (17) | |
| Other ethnicity | 3 (12) | 2 (8) | | 0 | 0 | |
| Place of birth, N (%) | | | 1.00[a] | | | - |
| Puerto Rico | 3 (12) | 2 (8) | | 0 | 0 | |
| Mainland US | 23 (88) | 23 (92) | | 25 (100) | 25 (100) | |
| Grade in school, median (Q1,Q3) | 4 (1,6) | 4 (3,6) | 0.54[b] | 10 (9,11) | 10 (9,12) | 0.66[b] |
| Type of insurance, N (%) | | | 0.11 | | | 0.047 |
| Public | 20 (77) | 14 (56) | | 22 (88) | 16 (64) | |
| Private | 6 (23) | 11 (44) | | 3 (12) | 9 (36) | |
| Body Mass Index (BMI),[c] N (%) | | | 0.46[a] | | | 0.77[a] |
| Underweight | 1 (4) | 0 | | 1 (4) | 1 (4) | |
| Normal | 6 (23) | 5 (20) | | 10 (40) | 7 (28) | |
| Overweight | 3 (12) | 7 (28) | | 1 (4) | 3 (12) | |
| Obese | 8 (31) | 7 (28) | | 6 (24) | 5 (20) | |
| Depression symptoms,[d] N (%) | *not assessed* | | | | | 0.31 |
| Normal/mild | | | | 17 (68) | 13 (52) | |
| Moderate/severe | | | | 7 (28) | 10 (40) | |
| Negative life events in last 12 months,[e] median (Q1,Q3) | 3.5 (1,5) | 4 (1.5,4) | 0.78[b] | 3 (2,5) | 4 (1,6) | 0.79[b] |
| ***Caregiver*** | | | | | | |
| Age in years, median (Q1,Q3) | 37.5 (32,42) | 39 (25,41) | 0.55[b] | 39 (36,44) | 40 (36,47) | 0.64[b] |
| Female, N (%) | 25 (96) | 23 (92) | 0.61 | 24 (96) | 22 (88) | 0.61 |
| Education level, N (%) | | | 0.18 | | | 0.39 |
| Less than high school | 8 (31) | 3 (12) | | 9 (36) | 5 (20) | |
| High school grad/GED | 5 (19) | 9 (36) | | 7 (28) | 7 (28) | |
| Greater than high school | 13 (50) | 13 (52) | | 9 (36) | 13 (52) | |
| Place of birth, N (%) | | | 1.00[a] | | | 0.23 |
| Puerto Rico | 7 (27) | 7 (28) | | 6 (24) | 10(40) | |
| Mainland US | 17 (65) | 16 (64) | | 19 (76) | 15 (60) | |
| Other | 2 (8) | 2 (8) | | 0 | 0 | |
| Years living in mainland US, median (Q1,Q3) [f] | 30 (8,40) | 34 (20,40) | 0.63[b] | 33 (23,37) | 29 (25,40) | 0.67[b] |
| Married/living with partner, N (%) | 16 (62) | 13 (52) | 0.49 | 13 (52) | 13 (52) | 1.00 |
| Home ownership, N (%) | | | 0.39 | | | 0.73 |
| Own home | 4 (15) | 6 (24) | | 4 (16) | 5 (20) | |
| Rent | 22 (85) | 18 (72) | | 21 (84) | 19 (76) | |
| Living with friends/family | 0 | 1 (4) | | 0 | 1 (4) | |
| Depression symptoms,[d] N (%) | | | 0.81 | | | 1.00 |
| Normal/mild | 19 (73) | 19 (76) | | 15 (60) | 15 (60) | |
| Moderate/severe | 7 (27) | 6 (24) | | 10 (40) | 10 (40) | |

P-values reported for continuous variables are for t-tests and for categorical variables Pearson's Chi-Square test unless otherwise noted.

[a] Fisher's exact test

[b] Wilcoxon two sample test

[c] Children were measured by research assistants either in the home or research office. CDC age/sex growth charts were used. Underweight is BMI < 5%, normal is a BMI 5% to 85%, overweight is BMI greater than or equal to 85% but less than 95%, and obese is BMI 95% or greater. Elementary School Cohort: N=37 (CHW N=18, Mail N=19). High School Cohort: N=34 (CHW N=18, Mail N=16).

[d] A score of 10 or higher on the PHQ-9 indicates moderate to severe depressive symptoms. [33-35]

[e] Life Events Checklist in children [39]

[f] Elementary School Cohort: N=18 (CHW N=9, Mail N=9). High School Cohort: N=16 (CHW N=6, Mail N=10).

**Table 2: Project CURA Asthma Characteristics at Baseline**

| | Elementary School Cohort | | | High School Cohort | | |
|---|---|---|---|---|---|---|
| | CHW Arm N=26 | MAIL Arm N=25 | P Value | CHW Arm N=25 | MAIL Arm N=25 | P Value |
| 12 month severity score, N (%) | | | 0.33[a] | | | 0.59[a] |
| Low | 3 (12) | 5 (20) | | 4 (16) | 3 (12) | |
| Mild | 9 (35) | 6 (24) | | 7 (28) | 5 (20) | |
| Moderate | 7 (27) | 11 (44) | | 10 (40) | 15 (60) | |
| Severe | 7 (27) | 3 (12) | | 4 (16) | 2 (8) | |
| Control over past 4 weeks,[c] N (%) | | | | | | |
| Daytime symp >2 times/wk | 9 (35) | 6 (24) | 0.41 | 10 (40) | 8 (32) | 0.56 |
| Nighttime symp >once/mo | 18 (69) | 18 (72) | 0.83 | 12 (48) | 10 (40) | 0.57 |
| Use quick-relief med >3times/wk | 10 (39) | 7 (29) | 0.49 | 7 (28) | 8 (32) | 0.76 |
| Misses activities $\geq$ once/wk | 9 (35) | 6 (24) | 0.41 | 4 (16) | 3 (13) | 1.00 |
| Uncontrolled over past 4 weeks,[c] N (%) | 21 (81) | 19 (76) | 0.68 | 18 (72) | 12 (48) | 0.08 |
| Over the past 12 months | | | | | | |
| Any hospitalizations, N (%) | 2 (8) | 3 (12) | 0.67[a] | 1 (4) | 1 (4) | 1.00[a] |
| Any ED visits, N (%) | 16 (62) | 12 (48) | 0.33 | 5 (20) | 6 (24) | 0.73 |
| Any prednisone use, N (%) | 18 (69) | 12 (48) | 0.12 | 6 (24) | 7 (28) | 0.74 |
| Days missed school, median (Q1,Q3) | 4 (2,10) | 4 (0,9) | 0.36[b] | 2 (0,10) | 5 (0,12) | 0.51[b] |
| Has inhaled corticosteroid, N (%) | 11 (42) | 12 (48) | 0.68 | 2 (8) | 4 (16) | 0.67[a] |
| Has albuterol, N (%) | 20 (77) | 20 (80) | 0.79 | 20 (80) | 21 (84) | 1.00[a] |
| Has spacer, N (%) | 8 (31) | 6 (24) | 0.70[a] | 1 (4) | 2 (8) | 0.55[a] |
| Inhaler Technique - % of steps correct,[d] median (Q1,Q3) | 50 (38,63) | 63 (50,75) | 0.06[b] | 63(50,75) | 63(50,75) | 0.56[b] |
| Doses per day of inhaled corticosteroid, median (Q1,Q3)[e] | 0.7 (0.14,1.4) | 1.5 (0.9,1.9) | 0.11[b] | 1.8 (1.1, 2.4) | 0.4 (0.1,0.8) | 0.30[b] |
| Self-reported smoker lives in home, N (%) | 5 (19) | 6 (24) | 0.63 | 13 (52) | 9 (36) | 0.25 |
| Cotinine levels[f] | | | 1.00[a] | | | 0.10[a] |
| No smoke exposure | 23 (88) | 23 (92) | | 18 (72) | 17 (68) | |
| ETS, N (%) | 3 (12) | 2 (8) | | 5 (20) | 2 (8) | |
| High ETS/smoker, N (%) | 0 | 0 | | 1 (4) | 6 (24) | |
| Trigger behavior summary score, median (Q1,Q3) | 6 (5,7) | 6 (5,7) | 0.69[b] | 7 (6,7) | 6 (5,7) | 0.44[b] |

[a] Fisher's exact test

[b] Wilcoxon two sample test

[c] Asthma control over the last four weeks was determined using control questions from the Expert Panel Report 3 guidelines regarding daytime symptoms, nighttime symptoms, quick-relief medication usage, and missed activities. An answer in the "not well controlled" range of any of these four questions resulted in an overall score of not controlled [21,23].

[d] Reported only data for inhaler without spacer due to small numbers with spacers, masks, and discus inhalers. Elementary School Cohort: CHW arm N=21, Mail arm N=17. High School Cohort: CHW arm N=22, Mail arm N=24.

[e] Combined data from adherence monitors and medication counters. Elementary School Cohort: CHW arm N=11, Mail arm N=11. High School Cohort: CHW arm N=2, Mail arm N=4.

[f]Environmental tobacco smoke (ETS) if cotinine level 1-8ng/ml; High ETS/smoker if cotinine >8ng/ml [32]. N=25 in CHW arm of High School Cohort.

**Table 3: Home Asthma Triggers and Behavior Summary Score (Sum of Negative Triggers)**

| **ELEMENTARY SCHOOL COHORT: Number positive for trigger/behavior and *number positive if skin test positive*** | **Baseline** | | **5-Months** | | **12-Months** | |
|---|---|---|---|---|---|---|
| | **CHW Arm N=26** | **MAIL Arm N=25** | **CHW Arm N=25** | **MAIL Arm N=24** | **CHW Arm N=25** | **MAIL Arm N=24** |
| Dust in the bedroom | 0 | 0 | 0 | 0 | 0 | 0 |
| *Skin test positive for dust** | - | - | - | - | - | - |
| Dust in the overall home | 0 | 1 | 0 | 0 | 0 | 0 |
| *Skin test positive for dust** | - | *0* | - | - | - | - |
| No air cleaner | 24 | 25 | 23 | 24 | 23 | 23 |
| No allergen covers | 22 | 21 | 14 | 19 | 19 | 21 |
| *Skin test positive for dust** | *3* | *3* | *1* | *4* | *2* | *4* |
| Pets in the bedroom | 9 | 7 | 8 | 8 | 8 | 8 |
| *Skin test positive for dog** | *1* | *1* | *0* | *1* | *0* | *1* |
| *Skin test positive for cat** | *2* | *3* | *1* | *3* | *1* | *3* |
| Pets in the overall home | 12 | 12 | 12 | 10 | 8 | 10 |
| *Skin test positive for dog** | *1* | *1* | *1* | *1* | *0* | *1* |
| *Skin test positive for cat** | *2* | *3* | *2* | *3* | *1* | *3* |
| Roaches | 9 | 8 | 5 | 5 | 3 | 6 |
| *Skin test positive for roach** | *2* | *1* | *2* | *0* | *1* | *1* |
| Rodents | 4 | 5 | 2 | 4 | 2 | 4 |
| *Skin test positive for mouse** | *0* | *3* | *refused* | *2* | *0* | *2* |
| Cracks/holes | 7 | 7 | 3 | 3 | 7 | 3 |
| *Skin test positive for roach** | *0* | *0* | *refused* | *0* | *3* | *0* |
| *Skin test positive for mouse** | *0* | *1* | *refused* | *0* | *2* | *1* |
| Strong cleaning smells | 24 | 25 | 22 | 23 | 22 | 22 |
| Smoke exposure | 8 | 10 | 9 | 11 | 11 | 12 |
| Fragrance | 18 | 18 | 17 | 16 | 21 | 15 |
| Mold | 12 | 12 | 10 | 5 | 10 | 6 |
| *Skin test positive for mold** | *2* | *3* | *1* | *1* | *0* | *1* |
| Behavior Summary Score, mean (SD) | 5.8 (1.9) | 6.0 (1.8) | 5 (1.4) | 5.4 (1.9) | 5.5 (1.6) | 5.5 (1.5) |

*Skin test data missing on 27 participants. Positive skin tests by allergen (N=24): Dust N=11; Dog N=5; Cat N=9; Roach N=6; Mouse N=14; Mold N=7.

| **HIGH SCHOOL COHORT: Number positive for trigger/behavior and *number positive if skin test positive*** | **Baseline** | | **5-Months** | | **12-Months** | |
|---|---|---|---|---|---|---|
| | **CHW Arm N=25** | **MAIL Arm N=25** | **CHW Arm N=23** | **MAIL Arm N=24** | **CHW Arm N=22** | **MAIL Arm N=22** |
| Dust in the bedroom | 1 | 0 | 0 | 0 | 0 | 1 |
| *Skin test positive for dust** | *0* | - | - | - | - | *refused* |
| Dust in the overall home | 0 | 0 | 0 | 0 | 1 | 1 |
| *Skin test positive for dust** | - | - | - | - | *0* | *refused* |
| No air cleaner | 25 | 24 | 22 | 24 | 21 | 21 |
| No allergen covers | 21 | 22 | 18 | 22 | 19 | 19 |
| *Skin test positive for dust** | *6* | *4* | *4* | *4* | *6* | *4* |
| Pets in the bedroom | 11 | 10 | 10 | 10 | 10 | 10 |
| *Skin test positive for dog** | *0* | *2* | *0* | *2* | *1* | *3* |
| *Skin test positive for cat** | *2* | *0* | *4* | *0* | *3* | *1* |

| | | | | | | |
|---|---|---|---|---|---|---|
| Pets in the overall home | 16 | 17 | 11 | 15 | 12 | 18 |
| *Skin test positive for dog** | *2* | *2* | *0* | *3* | *1* | *4* |
| *Skin test positive for cat** | *4* | *0* | *4* | *1* | *4* | *2* |
| Roaches | 8 | 6 | 7 | 4 | 4 | 4 |
| *Skin test positive for roach** | *2* | *0* | *0* | *0* | *0* | *0* |
| Rodents | 6 | 4 | 6 | 4 | 6 | 4 |
| *Skin test positive for mouse** | *3* | *1* | *3* | *2* | *4* | *1* |
| Cracks/holes | 7 | 4 | 4 | 5 | 7 | 4 |
| *Skin test positive for roach** | *1* | *0* | *1* | *0* | *1* | *0* |
| *Skin test positive for mouse** | *4* | *1* | *3* | *1* | *3* | *1* |
| Strong cleaning smells | 24 | 23 | 22 | 24 | 20 | 18 |
| Smoke exposure | 15 | 14 | 13 | 17 | 11 | 16 |
| Fragrance | 17 | 17 | 14 | 17 | 20 | 18 |
| Mold | 8 | 10 | 6 | 5 | 11 | 10 |
| *Skin test positive for mold** | *1* | *2* | *0* | *2* | *1* | *1* |
| Behavior Summary Score, mean (SD) | 6.4 (1.4) | 6.2 (1.4) | 5.7 (1.9) | 6.1 (1.5) | 6.5 (1.7) | 6.7 (1.7) |

*Skin test data missing on 32 participants. Positive skin tests by allergen (N=18): Dust N=10; Dog N=6; Cat N=6; Roach N=4; Mouse N=11; Mold N=4.

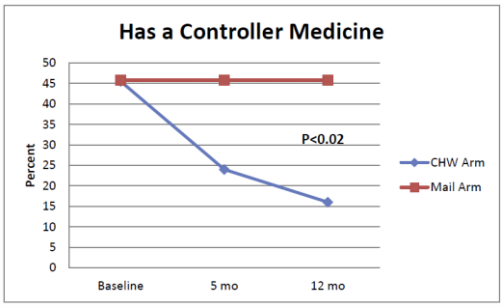
**TABLE 4: Lessons Learned from Project CURA CHW Asthma Trial**

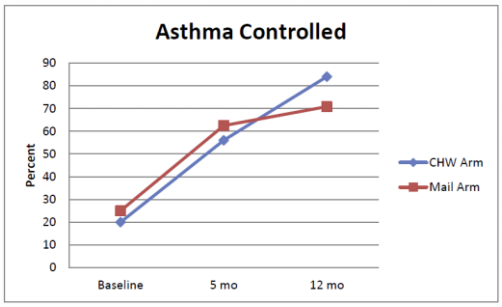
| Strengths | Limitations | Implications for Future Studies |
|---|---|---|
| • Exceptional recruitment and retention of a high-risk population<br>• Strong partnerships for research with community clinics and organizations<br>• Excellent intervention adoption (only one participant refused CHW) | • Lack of connection between CHWs and medical providers<br>*Participants reported difficulty communicating needs to providers and receiving prescriptions despite CHW coaching.*<br>• Inadequate "dose" of intervention<br>*Four visits over four months were not sufficient for families to make change.*<br>• Home remediation difficult due to resource limitations and age of homes<br>*The mean age of homes was 93 years.*<br>• Poor mental health was a significant barrier to implementing change<br>*CHWs struggled with limited resources to help families with depression, stress, and violence.*<br>• CHW intervention delivery compromised<br>*Written visit documentation and frequent supervisor meetings not adequate.* | • Formally connect CHWs and medical providers, while allowing CHWs to keep their community focus<br>• Increase number of visits and intervention duration<br>• Partner with medical centers that provide social services for housing improvement<br>• Provide cleaning and home remediation supplies<br>• Partner with medical centers that have strong mental health services<br>• Careful monitoring of CHW activities in the field |

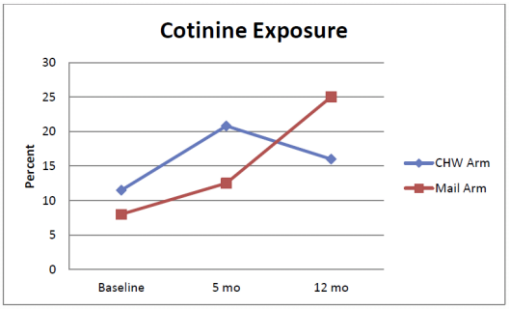
**Figure 1: Consort Diagram**

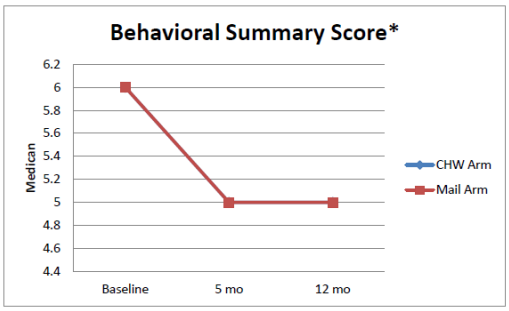
## Figure 2: Primary Medication and Trigger Outcomes at 5 and 12 Months

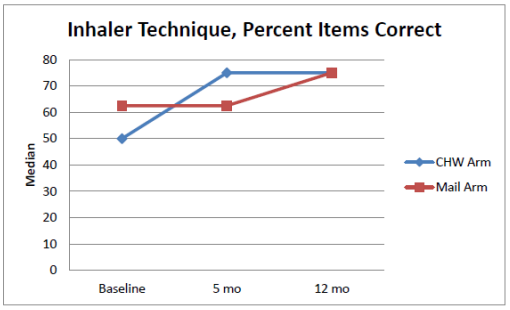
Elementary School Cohort



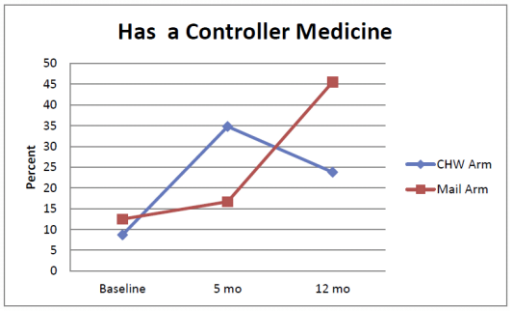



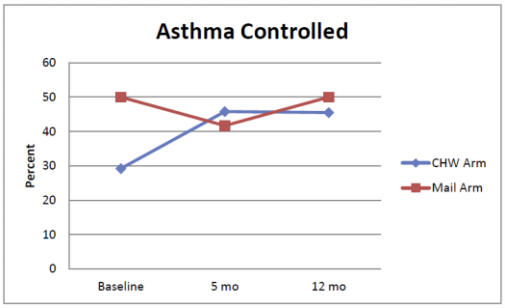



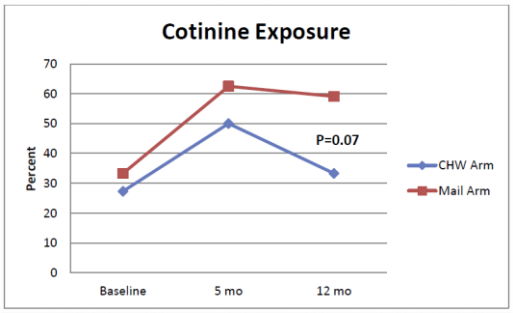



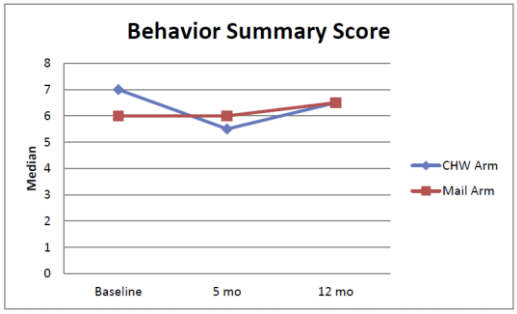



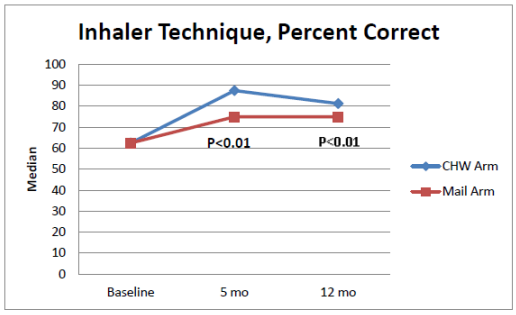

High School Cohort



Models are controlled for baseline value of outcome measure.  P-values reflect treatment effect and are displayed when significant at the 5- or 12-month assessment respectively.
*CHW Arm and Mail arm superimposed.