Effectiveness of Evidence-Based Asthma Interventions

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abstract

BACKGROUND AND OBJECTIVES: Researchers often struggle with the gap between efficacy and effectiveness in clinical research. To bridge this gap, the Community Healthcare for Asthma Management and Prevention of Symptoms (CHAMPS) study adapted an efficacious, randomized controlled trial that resulted in evidence-based asthma interventions in community health centers.

METHODS: Children (aged 5–12 years; $N = 590$) with moderate to severe asthma were enrolled from 3 intervention and 3 geographically/capacity-matched control sites in high-risk, low-income communities located in Arizona, Michigan, and Puerto Rico. The asthma intervention was tailored to the participant's allergen sensitivity and exposure, and it comprised 4 visits over the course of 1 year. Study visits were documented and monitored prospectively via electronic data capture. Asthma symptoms and health care utilization were evaluated at baseline, and at 6 and 12 months.

RESULTS: A total of 314 intervention children and 276 control children were enrolled in the study. Allergen sensitivity testing (96%) and home environmental assessments (89%) were performed on the majority of intervention children. Overall study activity completion (eg, intervention visits, clinical assessments) was 70%. Overall and individual site participant symptom days in the previous 4 weeks were significantly reduced compared with control findings (control, change of −2.28; intervention, change of −3.27; difference, −0.99; $P < .001$), and this result was consistent with changes found in the rigorous evidence-based interventions.

CONCLUSIONS: Evidence-based interventions can be successfully adapted into primary care settings that serve impoverished, high-risk populations, reducing the morbidity of asthma in these high-need populations.

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Dr Kennedy served as co-investigator on the project; contributed to the planning and design of the study, including the manual of operations, data collection instruments, and training materials; conducted on-site and remote training; conducted site visits; collaborated on analyses; and led all phases of the authorship of the manuscript. Mr Bailey served as project coordinator on the project; contributed to the planning and design of the study, including the manual of operations, data collection instruments, and training materials; conducted on-site and remote training; conducted site visits; collaborated on analyses; and collaborated on all phases of the authorship the manuscript. Ms Jaffee served as lead statistician on the project; contributed to the design of the statistical analysis plan and data collection instruments; assisted with data collection and data quality assurance; led all statistical analyses on the project; and drafted sections and collaborated on the manuscript. Dr Markus served as the principal investigator on the project; contributed to the planning and design of the study, including the manual of operations, data collection instruments, and training materials; conducted site visits; and collaborated on analyses and the manuscript. Ms Gerstein served as project coordinator on the project; contributed to the

WHAT'S KNOWN ON THIS SUBJECT: The efficacy of asthma counseling and environmental remediation interventions has been established in carefully controlled clinical trials in pediatric populations, but it is unclear if these results can be replicated in the "real-world" community health center setting.

WHAT THIS STUDY ADDS: Successful adaptation of efficacious evidence-based asthma interventions is needed to bridge the gap between research settings and primary care services. Effective translation extends beyond the initial research population to improve asthma outcomes for high-risk patients in clinical care settings.

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Asthma remains one of the most common chronic diseases among children and is prevalent among lower income, minority, urban populations, in which 1 of every 10 children has been diagnosed with asthma.[1] In the 1990s, the National Institute of Allergy and Infectious Diseases formed an inner-city asthma consortium of investigators to explore the causes of asthma and design interventions to reduce asthma morbidity in this vulnerable population. These large-scale epidemiologic studies identified a variety of risk factors related to asthma morbidity, including difficulties accessing care, challenges managing the health care setting and insurance, lack of continuity of care and an asthma treatment plan, allergen sensitivities, inadequate understanding and avoidance of asthma triggers, and psychological disruption in the family setting.[2–4] Two sequential randomized controlled trial (RCT) interventions were developed by these researchers: National Cooperative Inner-City Asthma Study (NCICAS) and Inner City Asthma Study (ICAS). Given the diversity of factors affecting each particular child and family, the NCICAS intervention was designed to assess each child's specific risks and then apply intervention modules to address each child's unique risk pattern. Asthma counselors (ACs) identified risks by using the Child Asthma Risk Assessment Tool (CARAT).[5] In response to the high frequency and variety of environmental risks, a second RCT intervention (ie, ICAS) was designed with "environmental counselors" using an environmental risk assessment tool (ERAT) to facilitate the identification and remediation of the unique environmental exposures and sensitivities of each family.[6,7]

Both of these evidence-based interventions (EBIs) were found to be highly efficacious in the rigorous RCT setting, which was conducted under the supervision of an asthma specialist who performed the baseline assessment but lacked the direct involvement of primary care providers. It remained to be seen if these EBIs would remain effective when translated into real-world settings, such as being integrated into ongoing primary care practices in community health centers (CHCs), which frequently serve high-risk populations. The path from these tightly controlled, efficacious RCTs to applied settings is often fraught with failure, especially when the real-world setting has limited intervention resources and personnel.[8] However, the comprehensive model for CHCs requires psychosocial and continuity of care services, such as those identified by CARAT. Because health centers serve >3.3 million children at high risk between the ages of 5 and 12 years, demonstration of the successful implementation of the Community Healthcare for Asthma Management and Prevention of Symptoms (CHAMPS) intervention in CHCs has important implications for future policy and payment decisions that can improve the care and outcomes of children with asthma.[9] The purpose of the CHAMPS project was to test the effectiveness of the combined National Institutes of Health/National Institute of Allergy and Infectious Diseases inner city asthma evidence-based AC and environmental interventions (referred to as EBI throughout) in the applied setting of CHCs.

METHODS

Study Design

CHAMPS was a mixed methods,[10] controlled study conducted at 3 intervention and 3 geographically/capacity-matched control CHC sites located in Arizona, Michigan, and Puerto Rico. Each CHC in the study participated in Medicaid and thus had the special denomination of Federally Qualified Health Center. Intervention sites were selected to have different levels of capacity to conduct the intervention (as assessed across key areas such as electronic health records, asthma counseling, skin testing, home visits, and spirometry) to provide a robust assessment of the program's effectiveness. In addition to the clinical outcomes discussed here, key barriers and facilitators to successful and sustained implementation, caretaker and physician changes in attitude and satisfaction, and cost/benefit analyses were studied and will be reported elsewhere. Extensive details about the study, including the manual of operations, can be found on AsthmaCommunityNetwork.org, an asthma stakeholders' networking platform sponsored by the US Environmental Protection Agency.[11] A brief summary of the methods is provided here.

Each clinic was to recruit 100 children, ages 5 to 12 years, with moderate to severe asthma, in accordance with clinical guidelines.[12] CHAMPS was approved by the George Washington University Institutional Review Board. Sites began enrollment in April 2012 and concluded all visits in December 2014.

Intervention Planning

Study investigators and intervention site clinicians collaborated to identify components from the EBI deemed feasible to implement and evaluate in CHCs,[11] creating a "minimum agreed upon intervention" (Fig 1). Adaptations and comparisons to the EBI are shown in Table 1. Intervention sites received 6 weekly recorded e-trainings on the intervention and data collection. Optional supplemental training from asthma experts was elected by 2 of the 3 sites for additional training on asthma counseling[13] and 1 site on spirometry.[14] Control sites were

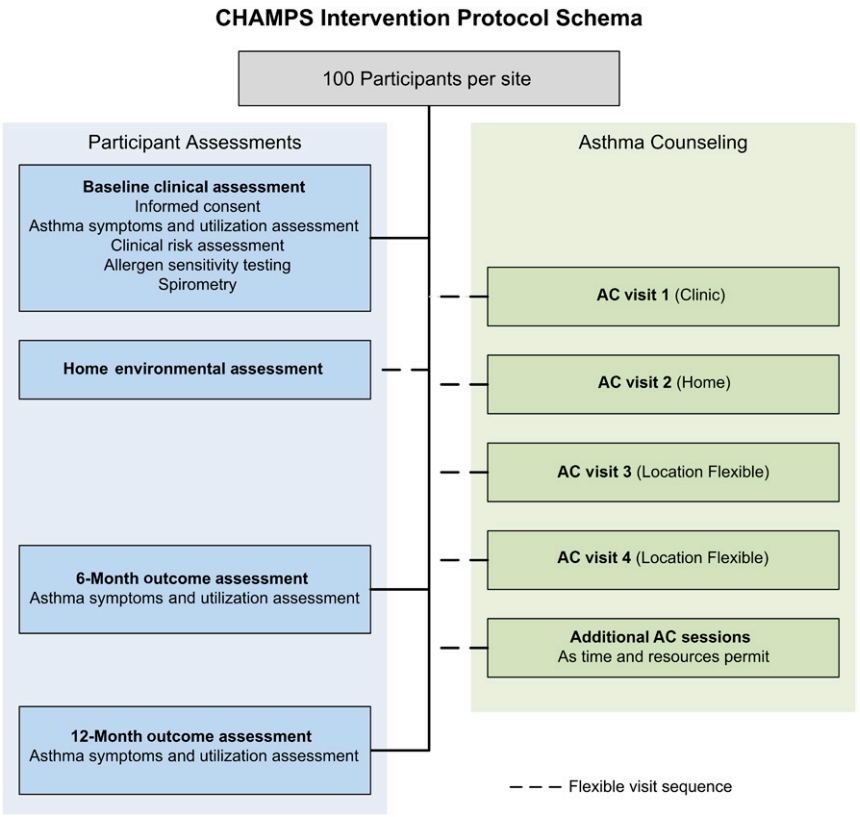

FIGURE 1

CHAMPS intervention protocol schema. The assessment and counseling activity structure for the CHAMPS project (ie, minimum agreed-upon intervention) is displayed. An initial baseline assessment was conducted to consent participants and collect data on the participant's asthma symptoms and health care utilization, environmental exposures, and allergies. A subsequent home assessment was conducted to identify potential environmental allergen and irritant exposures in the participant's home. Follow-up assessments were conducted at 6 and 12 months to collect asthma symptoms and health care utilization outcomes. Counseling sessions were scheduled with the families after the baseline visit, and followed a flexible schedule, per the needs of the participant and counselor. The initial counseling session was conducted in the clinic, with the second session conducted in the participant's home. Subsequent visits were ideally scheduled in the home but could occur in the clinic, a neutral location, or by telephone. A minimum of 4 counseling sessions were to be completed with each participant before the 12-month outcome assessment.

trained in recruitment and data collection.

Intervention Implementation

After parents of eligible participants provided informed consent for their child, participants completed a baseline clinic visit, providing demographic and socioeconomic data and completing a CARAT to evaluate the participant's asthma risks.[5,15] This baseline clinic visit could be conducted simultaneously with an AC visit (Fig 1).

Spirometry and sensitivity testing (prick skin test, 1 site; blood immunoglobulin E test, 2 sites) to a standard indoor allergen panel, as well as additional allergens of local interest, were conducted by the intervention sites.

After the baseline visit, CHC staff assessed each intervention participant's home environment for allergen exposures. This home assessment could be conducted simultaneously with an AC visit. Home assessment and allergen sensitivity data populated the ERAT.

ACs used the CARAT and ERAT output, along with the family's designated priorities, to create a patient-tailored, family-centered intervention.[6,13] ACs conducted at least 4 asthma counseling visits, with at least 1 held in the home. Each family was given an environmental kit similar to the EBI.[7] Participant asthma symptoms and health care utilization were collected by CHC staff (in person or over the telephone) 6 and 12 months after baseline.

Statistical Analysis

The primary outcome in CHAMPS was maximum symptom days (MSD) in the previous 4 weeks, which was the largest value among 3 asthma symptom variables: (1) the number of days with wheezing, tightness in the chest, or cough; (2) the number of nights with disturbed sleep as a result of asthma; and (3) the number of days the child had to slow down or discontinue play activities because of asthma.

A longitudinal general linear mixed model was performed to determine the effect of the intervention on MSD, in which MSD at both 6 and 12 months were modeled as the outcome. To examine the effect of the intervention on utilization, general linear mixed models with a binomial outcome were used for each category of utilization. All models were controlled for MSD/utilization at baseline, sex, race, and age at screening, and they were stratified according to study site (Arizona, Michigan, or Puerto Rico); the MSD model was also controlled for visit (6 or 12 months).

To compare intervention results between the CHAMPS MSD (which were reported over 4 weeks) versus the EBI MSD (which were reported over 2 weeks), CHAMPS MSD outcomes were first divided by 2. Separate linear models were then used for each study, with difference between MSD per 2 weeks at 12 months and baseline as the main outcome, and intervention site as the predictor of interest, while controlling for study site.

TABLE 1 Fidelity and Flexibility of the CHAMPS Intervention Compared With the EBI

Variable	NCICAS/ICAS	CHAMPS
Study design	RCT	Control sites
Location	Multiple large tertiary research sites	Multiple CHCs
N	NCICAS, 1033 ICAS, 937	590
Population	Inner-city census tracts with >20% poverty level Moderate to severe asthma	Low-income Moderate to severe asthma
Sensitivity assessment	Allergen skin test	Allergen skin test or IgE blood test
Exposure assessment	NCICAS/ICAS, self-report ICAS, visual inspection and dust sample collection by trained team	Self-report and visual inspection by AC or clinic staff
Intervention staff	NCICAS, master's level social worker asthma counselors ICAS, peer-level environmental counselors	Licensed practical nurses[a]
Intervention visits[b]	NCICAS, 2 group sessions, 6 AC visits, 6 telephone calls ICAS, 5–7 home visits during which an environmental kit was distributed and home remediation provided, 5–7 telephone calls	≥4 AC visits; of these, at least 1 occurred in the home where an environmental kit was distributed and demonstration of use provided; telephone calls were optional

IgE, immunoglobulin E.

[a] CHAMPS sites used clinic staff to fulfill the AC role. All held a licensed practical nurse degree. Three were certified asthma educators, and the remaining 3 completed asthma educator certification during the study.

[b] Intervention visits were tailored to the child's asthma risks, including allergen sensitivities and exposures.

Variables were considered statistically significant if the *P* value was < .05. Statistical analyses were performed by using SAS version 9.4 (SAS Institute, Inc, Cary, NC) and the R system for statistical computing version 3.2.2 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Demographic Characteristics

Children were primarily Hispanic, with >50% of the family income below $15 000 per year (Table 2). Children from the control sites seemed to have slightly higher asthma morbidity but were generally similar to the intervention participants; thus, baseline severity and several demographic characteristics were controlled for in the analyses. Control site participants were more likely to have prednisone prescribed (*P* < .01) and less likely to be taking controller medications (*P* = .01), missed more days of school due to asthma, and needed albuterol more often than the participants in the intervention sites (*P* < .01 for both). Asthma symptoms, such as wheeze and play and sleep disruptions, for control and intervention participants were similar; as a global symptom measure, however, we observed a trend toward greater MSD in the control population (*P* = .06). Table 3 presents these demographic and clinical characteristics for each intervention site. As a result of intentionally selecting diverse sites to provide greatest generalizability of our results, the sites differed on almost all of the collected measures. Of the intervention population, the Michigan children had the highest asthma morbidity. The Puerto Rico site had the lowest income and asthma symptoms; however, nearly 100% of children from this intervention site had been prescribed prednisone, which reflected how asthma was being treated episodically for symptoms without considering the chronic nature of the disease.

EBI Fidelity

Overall, the intervention sites were able to implement the agreed upon intervention. All of the sites averaged >4 AC sessions with the families, 96% of the children received sensitivity testing, and ∼89% of the homes were assessed for allergen exposures. The balance of AC visits over the course of the year was somewhat uneven in Michigan, with most of the asthma counseling sessions being conducted in the home in the first 6 months of the study (Table 4). When comparing the sites, Arizona and Michigan covered more intervention modules specific to the child's allergen sensitivities and exposures, whereas Puerto Rico spent more time on general asthma education intervention modules.

Clinical Outcomes: Asthma Symptoms

Figure 2 displays the decrease in MSD per 4 weeks, measured at baseline, 6 months, and 12 months. Both overall and individual study sites showed a significant difference in reduction of MSD, averaged between 6 and 12 months, between intervention and control (*P* < .01 for all).

When comparing CHAMPS versus the EBI, the CHAMPS intervention showed a similar and slightly larger difference, respectively, in MSD change (control, change of −2.28; intervention, change of −3.27; difference, −0.99; *P* < .001) between the intervention and control sites (Fig 3).

Clinical Outcomes: Utilization

Over the course of the study year, children at the intervention sites had significantly fewer instances of urgent visits compared with the control sites (53% intervention sites;

74% control sites; odds ratio, 0.4; $P < .01$) (Table 5). The difference in the percentage of participants with an urgent visit was particularly large for Arizona (35% difference between intervention and control; $P < .01$) and Puerto Rico (17% difference; $P < .01$) but much smaller in Michigan (5% difference; $P = .30$). Prednisone use among the intervention children was nearly one-half that of control children, with all the intervention sites exhibiting a significant difference between intervention and control sites (Arizona, $P < .01$; Michigan, $P = .05$; Puerto Rico, $P < .01$).

Hospitalizations over the course of 1 year were relatively rare, but a significant difference was observed between the intervention and control sites in Puerto Rico (9% intervention, 29% control), where the baseline event rate was rather high initially for both the intervention and control populations (Table 5). No significant difference was seen in Michigan or Arizona.

TABLE 2 Demographic and Clinical Characteristics for Intervention and Control Sites

Variable	Intervention Sites (n = 314)	Control Sites (n = 276)	P[a]
Male sex	61	55	.21
Age at screening, mean ± SD, y	7.8 ± 2.2	7.8 ± 2.2	.81
Race			<.01
Black	9	5	
Hispanic	83	74	
Other/mixed/white	8	21	
Caretaker married	42	56	<.01
Head of house completed high school	71	79	.03
Head of house employed	67	67	.99
Income < $15 000	52	57	.33
No. of people in the home	4.6 ± 1.5	4.3 ± 1.3	.01
Past 4 wk, mean ± SD, d			
Wheeze	8.7 ± 6.8	9.7 ± 7.8	.12
Slow play	4.7 ± 5.8	5.6 ± 6.6	.07
Woke during the night	4.7 ± 5.5	4.7 ± 5.5	.97
MSD	9.4 ± 7.3	10.6 ± 8.2	.06
Albuterol used (day or night)	8.2 ± 7.5	10.1 ± 9.0	<.01
School missed due to asthma	1.5 ± 2.5	2.4 ± 3.7	<.01
Past 12 mo (%) for asthma			
Overnight hospital stay	20	23	.42
Urgent visit[b]	91	95	.10
Prescribed prednisone[c]	80	90	<.01
Used prednisone for symptoms	38	37	.99
Prescribed a long-term controller agent	90	83	.01

Data are presented as % or mean ± SD.

[a] P values are from appropriate test for data: t test for normally distributed, continuous data, and either χ^2 or Fisher's exact tests for categorical data.

[b] Urgent visits include any unscheduled visit to a clinic, physician, or hospital emergency department.

[c] Prescribed prednisone at either an overnight hospital stay or urgent visit.

DISCUSSION

The CHAMPS study showed that clinical research interventions for a chronic disease can be successfully moved into practice. The EBIs were effectively translated into CHCs, demonstrated effectiveness at each site, and compared favorably with the efficacy shown in the rigorous RCT conducted in large tertiary care research settings.

Understanding why an efficacious study loses its effectiveness when translated to applied settings has been the subject of considerable discussion as efforts have increased to move from the "bench to the bedside."[16] Crossing the gap between the typical well-funded, tightly controlled efficacy trials and the applied clinical setting has even been called the "valley of death."[17]

Applying these EBIs to the CHC setting presents many challenges, given the limited resources and high demands placed on these clinics. One challenge was how to address site capacity and staff training. The NCICAS ACs had a master's degree in social work, received several days of centralized training, and were paid and fully resourced to research activities.[5] Likewise, the ICAS field research personnel who identified allergen exposures and the environmental interventionists who conducted remediation were fully paid and centrally trained.[7] CHAMPS took a minimal training approach to study a model for sustainable dissemination; the concept was to have the site decide how the CHC would staff the intervention and if staff would receive additional training beyond basic intervention and data collection components. Hence, the onus was on the site to request the services needed to provide and sustain the intervention.

Another challenge was to address the strict eligibility criteria and enrollment processes required of an RCT. This approach is not feasible in a CHC, where the priority is to serve the community. Although CHAMPS had eligibility criteria for moderate to severe asthma, sites were permitted to recruit patients who were visiting the clinic because their symptoms were uncontrolled and if the physician believed the patient would benefit from the intervention, which meant the CHAMPS population may have been incomparable to the EBI. However, in assessing the data, we observed that participants met national guidelines for moderate to severe asthma,[12] demonstrating that CHCs are able to identify those who symptoms are severe and may benefit from an asthma home intervention.[7]

TABLE 3 Demographic and Clinical Characteristics According to Intervention Site at Baseline

Variable	Arizona (n = 120)	Michigan (n = 88)	Puerto Rico (n = 106)	P[a]
Male sex	67	59	56	.22
Age at screening, mean ± SD, y	8.0 ± 2.2	7.6 ± 2.2	7.7 ± 2.1	.39
Race				<.01
Black	2	31	0	
Hispanic	93	49	100	
Other/mixed/white	5	20	0	
Caretaker married	55	31	38	<.01
Head of house completed high school	66	74	75	.22
Head of house employed	87	63	48	<.01
Income < $15 000	37	40	78	<.01
No. people in home	5.1 ± 1.7	4.6 ± 1.4	4.0 ± 1.1	<.01
Past 4 wk, mean ± SD, d				
Wheeze	8.3 ± 6.9	10.8 ± 8.2	7.5 ± 4.8	<.01
Slow play	5.9 ± 6.3	6.2 ± 7.0	2.1 ± 1.9	<.01
Woke during the night	4.1 ± 5.1	6.8 ± 7.4	3.6 ± 3.5	<.01
MSD	9.1 ± 7.6	12.2 ± 8.4	7.5 ± 4.8	<.01
Albuterol used (day or night)	9.4 ± 8.9	8.5 ± 7.8	6.6 ± 4.9	.02
School missed due to asthma	2.1 ± 2.8	2.0 ± 2.3	0.5 ± 1.7	<.01
Past 12 mo (%) for asthma				
Overnight hospital stay	12	11	36	<.01
Urgent visit[b]	98	75	97	<.01
Prescribed prednisone[c]	80	59	98	<.01
Used prednisone for symptoms	2	25	89	<.01
Prescribed a long-term controller	100	96	75	<.01
Allergen sensitivity	N = 115 (of 120)	N = 86 (of 88)	N = 101 (of 106)	
Dust mite	35	37	69	<.01
Cockroach	23	17	16	.41
Rodent	22	15	7	.01
Cat	28	29	3	<.01
Dog	18	30	4	<.01
Mold	37	35	2	<.01
Positive to any indoor allergen	71	59	73	.09
Environmental exposures				
Water damage	65	75	84	<.01
Cockroach	31	14	78	<.01
Rodent	16	25	61	<.01
Pet	55	32	73	<.01
Environmental tobacco smoke	39	31	39	.39
Incense/candles	4	10	28	<.01
Housing type				<.01
Detached home	58	59	24	
Duplex	7	13	23	
Low-rise	16	21	18	
High-rise/rowhouse/other	0	4	34	
Mobile home	19	3	1	

Data are presented as % or mean ± SD.

[a] P values are from appropriate test for data: t test for normally distributed, continuous data, and either χ^2 or Fisher's exact tests for categorical data.

[b] Urgent visits include any unscheduled visit to a clinic, physician, or hospital emergency department.

[c] Prescribed prednisone at either an overnight hospital stay or urgent visit.

The population in CHAMPS differed geographically and demographically from the EBIs and among the CHAMPS sites themselves. Socioeconomic status was consistently low across the sites, but race, housing conditions, and exposures all varied according to site and from the EBIs. Exposures and housing conditions in Michigan were more typical of the EBI, whereas Arizona had a substantial number of dilapidated mobile homes, and Puerto Rico had conditions unique to island living (eg, open-air handmade homes, water damage from rain coming in through screenless louvered windows). Despite these differences, all 3 intervention sites were able to implement the minimum agreed upon intervention components and significantly reduce MSD. This finding supports the notion that it is the tailoring of the intervention, not only to the participant but to the site, that made CHAMPS effective. This tailoring provided the flexibility needed for adaptation, while remaining faithful to the fidelity of the intervention.

TABLE 4 Completion of Study Assessments and Asthma Counseling Components

Study Activities Completion[a]	Arizona (n = 120)	Michigan (n = 88)	Puerto Rico (n = 106)	Overall (N = 314)
Symptom assessments	88	81	99	90
Sensitivity testing	96	98	95	96
Home assessment	88	77	99	89
Asthma counseling	87	68	73	77
Overall study completion[b]	77	61	70	70
AC visits	N = 112	N = 74	N = 105	N = 291[c]
Sessions before 6 mo	3.0 ± 1.2	4.7 ± 2.5	2.6 ± 1.4	3.3 ± 1.9
Sessions between 6 and 12 mo	1.3 ± 1.3	0.5 ± 1.3	1.6 ± 1.5	1.2 ± 1.4
Total AC sessions	4.3 ± 1.0	5.2 ± 2.3	4.2 ± 1.9	4.5 ± 1.8
Percentage of untailored modules completed[d]	91	97	37	73
Percentage of tailored modules completed when assigned[e]	86	97	29	66

Data are presented as % or mean ± SD.

[a] Completion of study activities is determined by using the following criteria: 3 total symptom assessments, blood draw for immunoglobulin E or a skin prick test administered, 1 home assessment, and a minimum of 4 asthma counseling sessions in-home, in-clinic, neutral location, or telephone call.

[b] Overall study completion represents completion of all the aforementioned study activities.

[c] N = 291 represents the number of participants who completed their 12-month symptom assessment.

[d] Untailored module completion is the percentage of participants completing all 3 untailored modules. All participants who saw an AC were assigned the untailored modules.

[e] Tailored module completion is the percentage of participants completing all tailored modules they were assigned (of the 4) based on sensitivity and exposure. The number of participants assigned at least 1 tailored module is as follows: Arizona, n = 61; Michigan, n = 21; Puerto Rico, n = 49; and overall, N = 131.

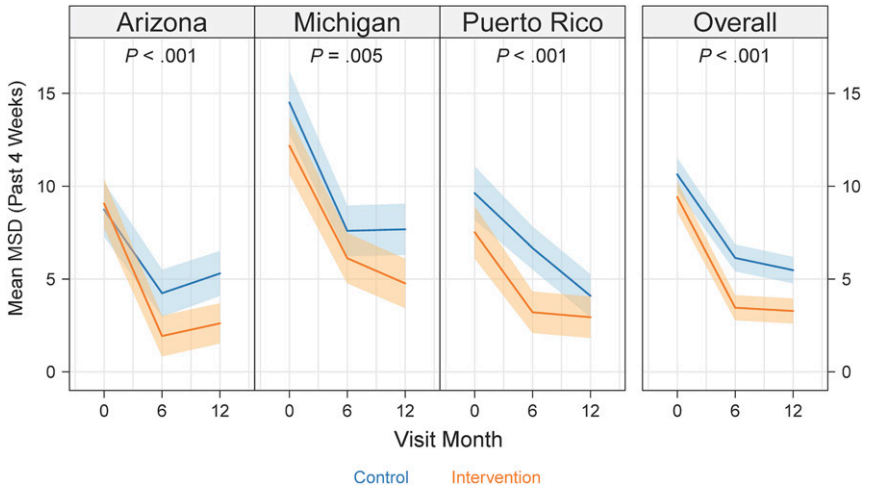

FIGURE 2
Asthma symptoms over the 1-year intervention period. The least-squares means and 95% confidence intervals for MSD in the intervention (orange) and control (blue) sites in Arizona, Michigan, Puerto Rico, and overall at baseline, month 6, and month 12 are displayed. Means are output from a longitudinal linear mixed model adjusted for sex, age at screening, race, study visit, season of clinic visit, and baseline MSD, and they are stratified according to study site.

For example, by tailoring the environmental kit to the needs of Puerto Rico's island population, participants at this site were able to receive screening on windows for those sensitive and exposed to cockroaches. The sequencing and timing of the intervention visits for CHAMPS also had some flexibility compared with the EBI. In the EBI, the visits had a strict sequence, which allowed the asthma interventionist to have all of the exposure and sensitivity data to effectively tailor the intervention before the first intervention visit. In CHAMPS, the visit order was flexible, which meant the first and sometimes second intervention visits occurred before both the sensitivity and exposure data were available. These initial CHAMPS visits were used to cover nonpatient-tailored intervention modules (ie, safe sleeping zone; asthma medications, delivery, adherence).[6] In this manner, the intervention remained faithful to the content of the intervention visits, while having flexibility in the timing to gather sensitivity and exposure data on the participant.

The Arizona and Michigan sites completed more modules tailored to the participant's allergen sensitivity and exposure than the Puerto Rico site. This outcome may have reflected a need to spend more time on general asthma education topics with the CHAMPS Puerto Rico population. The AC at this site relayed that several sessions were needed on general asthma education, which agrees with the fidelity to the intervention of not moving on to another module until success is observed with the initial module. In this way, the family is empowered and not overwhelmed. The need for more general asthma education may indicate that this population had a different base level knowledge of asthma compared with the other CHAMPS sites. Hence, this population may have further benefited from additional intervention visits or group asthma education sessions that cover general asthma education topics, as was provided in the EBI but not in CHAMPS. Also, this finding illustrates that the fidelity to the time line of a

protocol (ie, 1-year) and fidelity to the aims of the protocol (ie, deliver at family's pace) can be in conflict. However, when the needs of the patients are met with well-trained and engaged staff at the practice sites, these apparent conflicts can be resolved.

It is interesting to note the degree to which the asthma symptoms of the control participants dropped after study enrollment. This scenario has been observed repeatedly in asthma intervention studies.[5,7] We hypothesize that children in these studies are initially enrolled during periods when their asthma symptoms are greatest, and this initial high level of symptoms naturally regresses over time. Another possible reason for the decrease in symptoms observed in the control group is that families of these children, and the children themselves, know they are enrolled in a study and are being repeatedly asked about their symptoms. This process causes the family and child to become more attentive to their symptoms and undoubtedly more likely to notice symptom onset and take greater care in their asthma management. The key comparison for assessing intervention effectiveness is assessing whether the symptoms

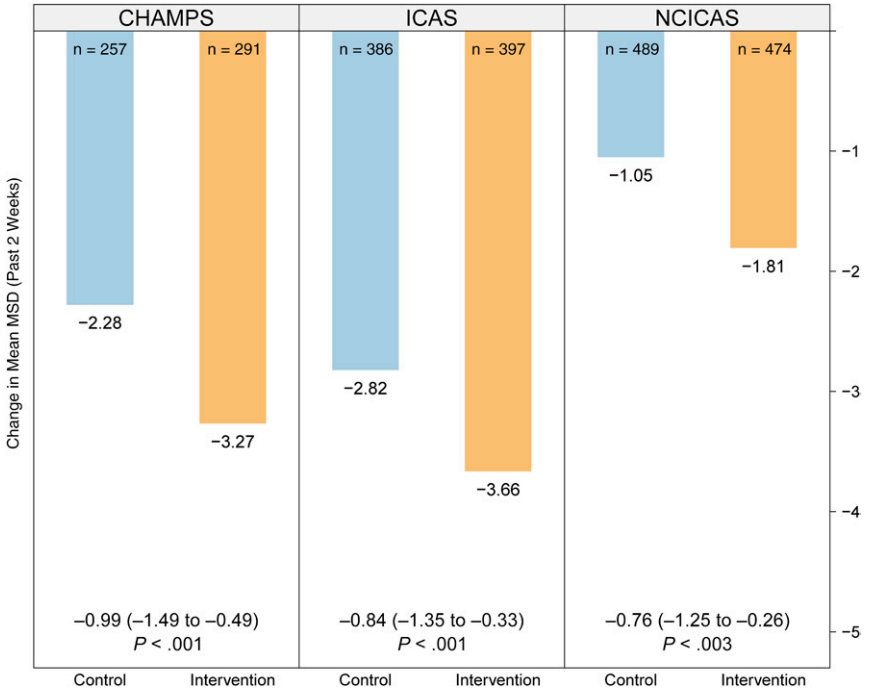

FIGURE 3
Comparison of the CHAMPS intervention with the EBI. The changes in MSD (per 2 weeks) from 12 months and baseline in the intervention (orange) and control (blue) sites for CHAMPS, ICAS, and NCICAS studies are displayed. Means and *P* values are output from a general linear model adjusted for study site.

decrease more rapidly and prominently for the intervention group, and we can see that they do. Moreover, the levels of the control and intervention participant symptoms exhibited sustained separation as the intervention year continued. The Puerto Rico site, along with Arizona, saw a significant drop not only in symptoms but also in health care utilization. A significant drop in health care utilization was not observed in Michigan. This outcome may be due to population characteristics, the lack of additional intervention training from an AC

TABLE 5 Prevalence of Health Care Utilization and Prednisone Use During the CHAMPS Study

Variable	Arizona (*n* = 186)	Michigan (*n* = 138)	Puerto Rico (*n* = 203)	Overall (*N* = 527)
Urgent visits[a]				
Intervention sites	39	52	69	53
Control sites	74	57	86	74
Odds ratio[b] (95% CI)	0.2 (0.1–0.5)	0.6 (0.3–1.5)	0.4 (0.2–0.7)	0.4 (0.2–0.6)
P	<.01	.30	<.01	<.01
Prednisone use				
Intervention sites	22	28	46	32
Control sites	46	49	85	62
Odds ratio[b] (95% CI)	0.4 (0.2–0.7)	0.4 (0.2–1.00)	0.1 (0.1–0.3)	0.2 (0.2–0.4)
P	<.01	.05	<.01	<.01
Overnight hospital stay				
Intervention sites	2	3	9	5
Control sites	3	6	29	14
Odds ratio[b] (95% CI)	0.8 (0.1–6.4)	0.6 (0.1–4.9)	0.2 (0.1–0.5)	0.4 (0.2–1.0)
P	.87	.64	<.01	.06

Values in the table represent percentage of participants with any emergency department/physician visit, hospitalization, or prednisone use during the 12 months of study participation.
[a] Urgent visits include any unscheduled visit to a clinic, doctor, or hospital emergency department.
[b] Odds ratios are from models stratified according to site and adjusted for sex, race, age at screening, and baseline utilization and can be interpreted as the following: if the odds ratio is 0.2, the odds for having a utilization is 4 times lower in the intervention group compared with the control group.

expert, and a strategy to involve 2 separate institutions to implement the AC and home visit interventions at this site.

Previous studies have shown that EBIs can be implemented beyond the RCT setting. The Inner City Asthma Intervention (ICAI), a Centers for Disease Control and Prevention–funded multisite project, was conducted to assess the implementation of NCICAS in a variety of real-world settings.[18,19] Although ICAI sites were able to deliver the intervention to 1355 families, they reported challenges translating the original research design. In particular, they acknowledged the need for greater flexibility in program adoption to accommodate differences in site dynamics and circumstances.[18,20] These lessons from ICAI were followed in the design and implementation of the Head-off Environmental Asthma in Louisiana (HEAL) project, a study funded by the National Institute of Environmental Health and the Merck Childhood Asthma Network, which was conducted in New Orleans after Hurricane Katrina. HEAL made adjustments to the EBIs to accommodate the many challenges in the post-disaster health care landscape. For example, rather than require that ACs have a master's degree in social work, HEAL employed ACs who held master's level education in diverse backgrounds.[13] HEAL also reduced the minimal number of intervention sessions (from ≥5 in person in the EBI to ≥2 in HEAL)[21] to reduce the demand placed on families, who were dealing with multiple conflicting priorities. Pre–post measures in HEAL demonstrated a significant reduction in symptom days (45% reduction; $P < .001$).[22] CHAMPS incorporated lessons from both ICAI and HEAL by implementing a design that accommodated site differences while also maintaining a comparable intervention and data collection method across the sites for evaluating outcomes. However, ICAI did not collect standardized participant outcomes across sites, and neither HEAL nor ICAI used a control group method, which made it problematic to make direct comparisons to the current CHAMPS results.

A limitation of CHAMPS is that individual participants were not randomized to an intervention, but control sites were instead identified according to the intervention site. Because we studied both the outcomes of individual patients as well as the capacity for organizations to implement a set of interventions, the organizations were a unit of analysis. Our study of the organizational and contextual influences would have been hindered if we had randomized the subjects of the study according to site. Control and intervention sites were matched according to demographic characteristics, geography, and capacity to minimize potential bias by site.

CONCLUSIONS

The family-centered, patient-tailored CHAMPS intervention was successfully adapted into diverse CHC settings. By addressing the needs of the participants and target populations while improving the delivery of asthma care, these tailored interventions led to reduced MSD and unnecessary health care utilization, and they bridged the gap between clinical trials and primary care for children at high risk in community-based settings.

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ABBREVIATIONS

AC: asthma counselor
CARAT: Child Asthma Risk Assessment Tool
CHAMPS: Community Healthcare for Asthma Management and Prevention of Symptoms
CHC: community health center
EBI: evidence-based intervention
ERAT: environmental risk assessment tool
HEAL: Head-off Environmental Asthma in Louisiana
ICAI: Inner City Asthma Intervention
ICAS: Inner City Asthma Study
MSD: maximum symptom days
NCICAS: National Cooperative Inner-City Asthma Study
RCT: randomized controlled trial

planning and design of the study, including the manual of operations, data collection instruments, and training materials; conducted site visits; and collaborated on analyses and the manuscript. Dr Stevens served as co-investigator on the project; contributed to the planning and design of the study, including the manual of operations, data collection instruments, and training materials; and collaborated on analyses and the manuscript. Ms Lesch served as associate director on the project; contributed to the planning and design of the study, including the manual of operations, data collection instruments, and training materials; and collaborated on analyses and the manuscript. Dr Malveaux served as executive director on the project; contributed to the planning and design of the study, including the manual of operations, data collection instruments, and training materials; and collaborated on analyses and the manuscript. Dr Mitchell served as

co-investigator on the project; contributed to the planning and design of the study, including the manual of operations, data collection instruments, and training materials; collaborated on analyses; and provided leadership, guidance, and authoring support on all phases of manuscript development.

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