Original Investigation

# Community Health Worker Home Visits for Adults With Uncontrolled Asthma

## The HomeBASE Trial Randomized Clinical Trial

James Krieger, MD, MPH; Lin Song, PhD; Miriam Philby, MA

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**IMPORTANCE** Asthma is often poorly controlled. Home visitation by community health workers (CHWs) to improve control among adults has not been adequately evaluated.

**OBJECTIVE** To test the hypothesis that CHW home visits for adults with uncontrolled asthma improve outcomes relative to usual care.

**DESIGN, SETTING, AND PARTICIPANTS** Randomized parallel group study with 1-year follow-up, conducted 2008 through 2011 at homes of low-income adults aged 18 to 65 years with uncontrolled asthma living in King County, Washington.

**INTERVENTIONS** The CHWs provided a mean of 4.9 home visits during a 1-year period to assess asthma control, self-management, and home environment and to support asthma self-management practices.

**MAIN OUTCOMES AND MEASURES** Primary prespecified outcomes were symptom-free days (number of 24-hour periods in prior 2 weeks without asthma symptoms), asthma-related quality of life (Mini Asthma Quality of Life Questionnaire), and asthma-related unscheduled health care use.

**RESULTS** Of 463 individuals who completed eligibility screening, 443 were eligible, 366 participated (177 in intervention and 189 in control groups), and 333 completed the study (91%). The intervention group had significantly greater increases in mean symptom-free days per 2 weeks (2.02 [95% CI, 0.94-3.09]; $P < .001$) and quality of life (0.50 [95% CI, 0.28-0.71] points; $P < .001$) relative to the control group, adjusted for age, sex, race/ethnicity, and education level. The number needed to treat to increase symptom-free days by 2 days per 2 weeks was 7.4 and to improve quality of life by 0.5 points was 2.6. Mean urgent health care use episodes in the past 12 months decreased significantly and similarly in both groups, from a mean of 3.46 to 1.99 episodes in the intervention group (mean change, −1.47 [95% CI, −2.28 to −0.67]; $P < .001$) and from a mean of 3.30 to 1.96 episodes in the control group (mean change, −1.34 [95% CI, −2.00 to −0.72]; $P < .001$) ($P = .83$ comparing groups).

**CONCLUSIONS AND RELEVANCE** The provision of in-home asthma self-management support by CHWs to low-income adults with uncontrolled asthma improves asthma control and quality of life but not unscheduled health care use. Additional studies are needed to confirm these findings and determine the value of wider implementation of this approach.

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**Author Affiliations:** Chronic Disease and Injury Prevention Section, Public Health–Seattle and King County, Seattle, Washington (Krieger, Philby); School of Public Health, University of Washington, Seattle, Washington (Krieger); School of Medicine, University of Washington, Seattle, Washington (Krieger); Assessment, Policy Development, and Evaluation Unit, Public Health–Seattle and King County, Seattle, Washington (Song); now with Jail Health Services, Public Health–Seattle and King County, Seattle, Washington (Philby).

**Corresponding Author:** James Krieger, MD, MPH, Public Health–Seattle and King County, 401 5th Ave, Ste 900, Seattle, WA 98104 (james.krieger@kingcounty.gov).

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Asthma continues to increase in prevalence and now affects 24.6 million Americans, including 17.5 million adults.[1] Control of asthma is inadequate despite the availability of effective methods for managing it.[2,3]

Asthma self-management is a cornerstone of asthma control,[2,4-6] yet many people with asthma have not had the opportunity to learn self-management skills or do not practice them. Many report not being told how to respond to an asthma exacerbation or how to reduce trigger exposure and not receiving an asthma action plan.[1] Many people with asthma neither use controller medication nor follow advice on trigger reduction consistently.[3,7,8]

People with asthma can learn self-management skills in a variety of settings: clinics, community sites, and their homes. Home-based support facilitates participation and allows assessment of home conditions affecting asthma control. The effectiveness of home-based self-management support for improving asthma control among children is well established,[9,10] but the effectiveness of home visits for adults has not been well studied. In this article, we report on the Home-Based Asthma Support and Education trial (HomeBASE), which tested the hypothesis that community health workers (CHWs) providing in-home self-management support would reduce asthma morbidity among adults with uncontrolled asthma.

## Methods

The University of Washington institutional review board approved the study. Written informed consent was obtained from all participants.

### Trial Design

We used a randomized parallel-group controlled design to compare the intervention with usual care.

### Participants

Eligible participants had clinician-diagnosed asthma that was not well controlled or very poorly controlled and were aged 18 to 65 years, King County (Washington) residents, conversant in either English or Spanish, and lived in a household whose income was less than 250% of the 2007 federal poverty level. We based our definition of asthma control on national guidelines, slightly modified to account for the data that were available to us for assessing control.[2] We defined not well or very poorly controlled asthma as either any of the following in the past 2 weeks—symptoms more than 4 days, nighttime awakenings more than once, use of a short-acting β-agonist more than 4 days, or interference with normal activity due to asthma—or one 1 or more emergency department visits or hospitalizations for asthma in the past year.

We excluded potential participants who planned to move within the next year or lacked permanent housing, had a mental or physical disability making it impossible to participate in the protocols, had other serious chronic medical conditions that would limit functional status, were taking anti-inflammatory medications other than nonsteroidal anti-inflammatory drugs, had a greater than 15 pack-year smoking history or clinician diagnosis of chronic obstructive pulmonary disease, had completed an asthma education program within the past 3 years, or if their home appeared unsafe for visitation by CHWs. We recruited participants primarily from community, public health, and hospital-based clinics (82% of the 1467 potentially eligible participants), from other community agencies, from a Medicaid health plan, and through self-referrals. Clinics provided us with lists of patients aged 18 to 65 years with an asthma encounter during the previous 12 months. Patients with current asthma (≥2 clinic visits and prescription for asthma medication during this period); whose preferred language was English, Spanish, or unknown; and living in King County were invited to participate in a telephone interview to assess additional eligibility criteria.

Baseline home environmental data were obtained in participants' homes, and clinical data (questionnaire, spirometry, and allergy skin prick testing) were collected at the University of Washington Clinical Research Center, prior to randomization. Pulmonary function was assessed with an EasyOne diagnostic spirometer (ndd Medical Technologies) using American Thoracic Society protocols.[11] A pulmonologist provided pulmonary function testing training to study staff and reviewed random samples of tests quarterly. The Multi-Test II (Lincoln Diagnostics) was used to test for dust mite mix, regional mold mix, cat, dog, cockroach, and rodent antigens.[12,13] Project staff (other than the CHW who worked with the participant) collected exit data 1 year later in participants' homes (93% had exit data collected less than 13 months after baseline). Participants received $35 and $50 incentives for completing baseline and exit data collection, respectively. Data collection tools and protocols are available in the eAppendix in the Supplement.

### Interventions

We based our intervention on 2 health behavior models: social cognitive theory[14-16] and self-regulation.[17,18] A CHW provided education, support, and service coordination during home visits. The CHWs were full-time employees recruited from the communities that the project served and had high school or equivalent (General Educational Development) degrees. They were native Spanish speakers with strong connections to the community and personal experience with asthma. All CHWs received 80 hours of classroom training followed by biweekly training sessions. A health educator and nurse provided clinical support, and a manager provided supervision and operations oversight.

The CHW made an initial visit to assess the participant's knowledge of asthma, current status of asthma control, challenges with controlling asthma, self-management practices, and exposure to asthma triggers. The CHW used motivational interviewing methods[19-21] to work with participants to develop a tailored asthma management plan. The participant then was offered 4 planned follow-up visits 0.5, 1.5, 3.5, and 7 months later. In addition to planned visits, the CHWs provided as-needed support via telephone, e-mail, or additional home visits. Each CHW had an active caseload of approximately 40 to 45 clients.

The CHWs used protocols that specified education content, participant skill development, and participant and CHW actions (eAppendix in the Supplement). They addressed asthma pathophysiology, medication use, self-monitoring, use of an asthma action plan, trigger avoidance, seeking urgent care, communication with clinicians, stress management, receiving influenza and pneumonia vaccines, and accessing community resources. The CHWs provided social support,[22,23] advocated for clients (eg, housing issues, insurance coverage), and made referrals to community resources for childcare, food, employment, and citizenship assistance.

The CHWs placed allergen-impermeable encasements on the participant's bed[24,25] and supplied a low-emission vacuum cleaner,[26-28] 2-layer microfiltration vacuum bags,[29] a home cleaning kit, a plastic medication box, an inhaler spacer, and, if roaches were present, food storage containers. Participants with furry and/or feathered pets in the home and nonsmokers exposed to secondhand smoke received high-efficiency particulate air filters. Community health workers implemented integrated pest management methods[30] to eliminate pest infestations.

The CHWs coordinated with participants' medical homes. They faxed a summary of each visit to the clinic. Clinicians could contact the CHWs with concerns. The project nurse informed the clinic of important medical issues.

The control group received usual care for asthma plus information about community resources for asthma self-management (such as classes and support groups) and educational pamphlets. At the end of the study, participants in the control group received a home visit by a CHW and the intervention group resources.

The project nurse conducted monthly audits of home visit records to assess adherence to protocols and reviewed findings with CHWs. The project manager or nurse observed at least 1 home visit per month per CHW, rated it with a structured tool, and provided feedback.

## Outcome and Other Measures

Primary prespecified outcomes were asthma symptom-free days[31,32] (self-reported number of 24-hour periods during the prior 2 weeks without wheeze, tightness in chest, cough, shortness of breath, slowing down activities, or nighttime awakening because of asthma), Mini Asthma Quality of Life Questionnaire[33] score (range, 1-7, higher score indicating better quality of life, minimum clinically significant difference = 0.5[34]), and number of self-reported asthma-related urgent health care episodes during the past 12 months (emergency department, hospital, or unscheduled clinic visit). We used unweighted and weighted health care episodes in our analyses, with weights based on unit costs from PharMetrics Integrated Outcomes Database.[35]

Secondary outcome measures were night symptoms; asthma exacerbations; pulmonary function[36]; β-agonist use; asthma control level (National Asthma Education and Prevention Program control level and the Asthma Control Questionnaire [ACQ][2,37]); missed work, school, or normal daily activity days; and general health status (SF-12).[38] Data on self-reported participant race were collected to permit assessment of effect heterogeneity.

## Study Power

A sample size of 76 per study arm is needed to detect the minimal clinically important difference of a change in 2 symptom-free days per 2 weeks across the groups with a power of 0.80 and α set at .05 (2-sided). Detection of the minimal clinically important difference for quality of life (0.5 units[34]) and urgent health care events (0.5 events/y) requires sample sizes of 84 and 142, respectively. Given an expected attrition rate of 15% per year in the intervention group and 23% in the control group, we sought to enroll 167 participants in the intervention group and 184 in the control group.

## Randomization and Blinding

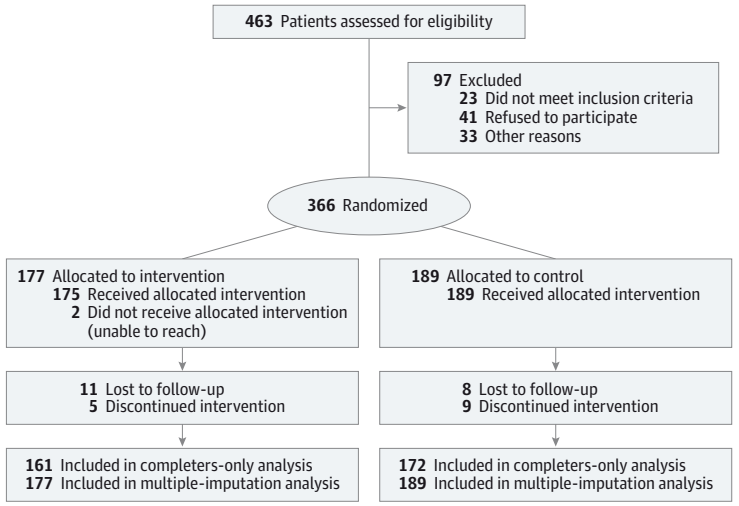
We randomly assigned participants to groups using a permuted block design with varying block size, stratified by age (18-39 vs 40-65 years) and asthma-control level (not well controlled vs very poorly controlled). Randomly generated sequence numbers and group allocation were concealed in sealed, opaque, numbered envelopes that were centrally prepared and sequentially provided to data collectors who used them to assign participants to groups. Data collectors and analysts were blinded to participant study group, but it was not possible to blind participants because of the nature of the intervention.

## Statistical Methods

We examined baseline differences across groups with $t$ or $\chi^2$ tests and used paired $t$-tests or McNemar tests for assessing within-group baseline-to-exit changes. For evaluating intervention effects, we used multivariate linear and logistic regression with the robust option for estimating standard errors using the Huber-White sandwich estimators.[39] The regression models controlled for baseline value of the outcome variable and prespecified demographic covariates: age, sex, race/ethnicity (white, black, Hispanic, and other), and education level. When the distribution of outcome variables was skewed, we used negative binomial regression analysis to confirm the results of the linear models. We used linktest in Stata to examine the specifications and fit of each model. We tested for effect modification of the intervention effect by age, sex, education, and race/ethnicity by creating separate regression models that included an interaction term and used $P < .05$ to define a significant interaction. We computed the number needed to treat for continuous variables, accounting for both improvements gained and deteriorations prevented.[40] We used the Cohen d statistic to measure effect size, dividing the difference in unadjusted mean before-and-after changes across groups by the pooled standard deviation.

We performed complete case and multiple-imputation analyses for each outcome.[41,42] All analyses were by original assigned group. The complete case analysis included only participants for whom baseline and exit data were available. We used multiple imputation (with 10 imputation data sets) to estimate missing exit values of outcome variables for the 33 participants who did not complete the exit questionnaire. The imputation models included baseline outcome variable, covariates in the regression model (age, sex, employment, race, and Hispanic ethnicity), ACQ score (well correlated with outcomes), and employment status (associated with dropping out

Figure. CONSORT Flow Diagram




of the study). In addition, we imputed missing baseline unscheduled health care use for 20 participants (5%). All analyses were 2 tailed and performed using Stata, version 13 (StataCorp). $P < .05$ was considered statistically significant.

## Results

### Participation

We attempted to reach 845 potentially eligible participants, of whom 463 completed eligibility telephone screening (**Figure**). Of the 382 who did not complete telephone screening, 114 were reached and refused, 113 did not return calls, 64 had disconnected telephones, 45 numbers were incorrect, 26 had moved out of King County, and 20 did not answer and/or did not have voice mail. Of the 463 who completed telephone screening, 366 were eligible and enrolled, 74 were eligible but not enrolled (41 refused, 18 were lost to follow-up before enrolling, and 15 had other reasons), and 23 were not eligible.

We randomized 177 participants to the intervention group and 189 to the control group. The study was completed by 161 intervention and 172 control group members (91% of each group). Of the 16 in the intervention and 17 in the control groups who did not complete the study, 11 and 8, respectively, were lost to follow-up, 1 and 5 moved out of the county, 4 and 2 refused to continue, and 2 had other reasons. Those who did not complete the study were similar to those who did with respect to the baseline characteristics listed in **Table 1** except that noncompleters were more likely be Spanish speakers, less likely to be employed, and were more frequent urgent health care users (data not shown).

Baseline interviews were conducted between May 2008 and November 2010. Exit interviews were conducted between June 2009 and October 2011.

### Process Measures

Of the 177 participants in the CHW group, all received an initial CHW intake visit, 2 did not receive any follow-up home visits (1%), 2 received 1 visit (1%), 4 received 2 visits (2%), 21 received 3 visits (12%), 126 received the targeted number of 4 visits (71%), and 22 received 5 visits (12%). Participants received a mean of 3.9 follow-up visits, with a median (range) of 4.0 (0-5). No harms or unintended effects occurred in either group. Audits of home visit encounter records showed that 90% of identified problems on each participant's asthma problem list were addressed with the correct protocol, 86% of mandatory protocols were discussed, and 83% of active problems were addressed at each visit.

### Baseline Data

Table 1 presents baseline participant characteristics by study group. Most participants were aged between 25 and 54 years (73.3%) and female (73.2%). Approximately one-half had a high school or less level of education (57.5%), were working (40.5%), and were Hispanic (46.7%). Asthma morbidity was high. Most participants had very poorly controlled asthma (71.9%), few symptom-free days (a mean of 3.9 per 2 weeks), low quality of life scores, and frequent use of urgent health care (mean, 4.4 episodes in past year). Approximately two-thirds (66.0%) were atopic. The most common allergies were to house dust mite allergen (Der p 1) (38.0%), grass (38.0%), dust mite Der f 1 (28.5%), and cat dander (26.0%). Pest sensitization was also common, with 16.5% allergic to roaches, 10.5% to mice, and 7.5% to rats. The study groups were balanced with respect to demographic, asthma control, and main outcome characteristics.

### Primary Outcomes

#### Main Results

Intervention group participants had significantly greater and clinically meaningful increases in symptom-free days (mean, 2.02 days per 2 weeks more) and quality of life (mean, 0.50 points) than did those in the control group (**Table 2**). The number needed to treat to increase symptom-free days by 2 days per 2 weeks was 7.4. The number needed to treat to improve quality of life by 0.5 points was 2.6. The number of unweighted urgent health care use episodes in the past 12 months

Table 1. Baseline Characteristics of Study Participants

| Characteristic | Control (n = 189) | Intervention (n = 177) | Total (N = 366) | *P* Value[a] |
|---|---|---|---|---|
| Age, y | | | | |
| Mean | 41.3 | 41.2 | 41.3 | .90 |
| % | | | | |
| 18-24 | 10.6 | 9.0 | 9.8 | .77 |
| 25-39 | 33.3 | 36.7 | 35.0 | |
| 40-54 | 37.6 | 39.0 | 38.3 | |
| 55-65 | 18.5 | 15.3 | 16.9 | |
| Female sex, % | 73.0 | 73.4 | 73.2 | .93 |
| Race/ethnicity, %[b] | | | | |
| White | 31.2 | 26.0 | 28.7 | .74 |
| Black | 16.4 | 16.9 | 16.7 | |
| Hispanic | 45.0 | 48.6 | 46.7 | |
| Other | 7.4 | 8.5 | 7.9 | |
| Language, % | | | | |
| English | 62.4 | 61.6 | 62.0 | .87 |
| Spanish | 37.6 | 38.4 | 38.0 | |
| Rent rather than own home, % | 87.3 | 80.8 | 84.2 | .09 |
| Employment, % | | | | |
| Employed | 40.2 | 40.9 | 40.5 | .15 |
| Out of work | 10.6 | 14.8 | 12.6 | |
| Homemaker | 18.5 | 11.4 | 15.1 | |
| Student | 3.7 | 8.5 | 6.0 | |
| Retired | 5.3 | 4.5 | 4.9 | |
| Unable to work | 21.7 | 19.9 | 20.8 | |
| Education, % | | | | |
| Less than high school | 34.4 | 30.7 | 32.6 | .68 |
| High school graduate | 25.3 | 24.4 | 24.9 | |
| Some college | 32.8 | 34.1 | 33.4 | |
| College graduate | 7.5 | 10.8 | 9.1 | |
| Asthma very poorly controlled, %[c] | 73.5 | 70.1 | 71.9 | .46 |
| Main outcome variables | | | | |
| Asthma symptom-free days, mean per 2 wk | 3.7 | 4.2 | 3.9 | .36 |
| Asthma-related quality of life score, mean[d] | 3.8 | 3.7 | 3.7 | .80 |
| Urgent health care use, mean episodes in past year[e] | 4.3 | 4.4 | 4.4 | .87 |
| Atopic, %[f] | 69.5 | 62.9 | 66.0 | .72 |

[a] Comparison of control and intervention groups: *t* test for means and $\chi^2$ for proportions.

[b] White defined as white, non-Hispanic; black as black, non-Hispanic; and Hispanic as Hispanic of any race.

[c] As defined by National Asthma Education and Prevention Program: symptoms throughout the day or nighttime awakenings more than 4 times per week or activity severely limited or daily rescue medication use.

[d] Mini Asthma Quality of Life Questionnaire.

[e] Includes hospitalizations, emergency department visits, and urgent clinic visits for asthma.

[f] Defined as at least 1 positive skin prick test result; percentage is among the 105 intervention group participants and 95 control group participants who received a skin test.

decreased significantly and similarly in both groups (approximately 1.3-1.5 fewer episodes). A model using episodes weighted by their relative estimated cost (unscheduled clinic visit, emergency department visit, and hospitalization weighted at 1, 2, and 50, respectively) also showed similar decreases in both groups (approximately 6-7 fewer weighted episodes). Hospitalization accounted for 16% of urgent care use at baseline; emergency department visits, 38%; and urgent clinic visits, 67%.

Results were nearly identical when we reanalyzed data using estimates for missing data derived from multiple-imputation models (Table 2). Sensitivity analysis of symptom days (which were not normally distributed) using negative binomial regression produced conclusions similar to those observed with the linear regression models (data not shown). The standardized Cohen d effect size for symptom-free days was 0.33 (95% CI, 0.11-0.55) and for quality of life score was 0.53 (95% CI, 0.31-0.75).

### Heterogeneity of Treatment Effects

In separate regression models for each of the 3 primary outcomes, there were no significant interactions between study group and race/ethnicity, sex, educational attainment, or baseline level of asthma control and the primary outcomes.

Two interactions were close to the significance threshold of .05, although after taking into account the multiple comparisons involved in testing for interactions, neither was significant. For symptom-free days, the intervention had an insignificantly greater impact on younger participants (coefficient of interaction term = 0.09, *P* = .06). For urgent health care use, the intervention effect tended to be greater among those with less than high school education compared with those with at

Table 2. Primary Outcomes: Intervention vs Control Groups

| Outcome | Intervention Group[a] Mean Base | Intervention Group[a] Mean Exit | Intervention Group[a] Mean Change (95% CI) | Intervention Group[a] P Value | Control Group[b] Mean Base | Control Group[b] Mean Exit | Control Group[b] Mean Change (95% CI) | Control Group[b] P Value | Intervention Effect (Adjusted)[c] Coefficient (95% CI) | Intervention Effect (Adjusted)[c] P Value |
|---|---|---|---|---|---|---|---|---|---|---|
| **Asthma Symptom–Free Days in Prior 2 Weeks, No.** | | | | | | | | | | |
| Completers | 3.11 | 6.78 | 3.67 (2.75 to 4.59) | <.001 | 2.81 | 4.50 | 1.69 (0.79 to 2.60) | <.001 | 2.02 (0.94 to 3.09) | <.001 |
| Multiple imputation | 3.19 | 6.69 | 3.50 (2.98 to 4.03) | <.001 | 2.68 | 4.52 | 1.84 (1.36 to 2.32) | <.001 | 1.93 (0.88 to 2.98) | <.001 |
| **Mini Asthma Quality of Life Score** | | | | | | | | | | |
| Completers | 3.72 | 4.66 | 0.95 (0.76 to 1.13) | <.001 | 3.83 | 4.19 | 0.36 (0.21 to 0.51) | <.001 | 0.50 (0.28 to 0.71) | <.001 |
| Multiple imputation | 3.73 | 4.64 | 0.91 (0.86 to 1.03) | <.001 | 3.76 | 4.17 | 0.41 (0.33 to 0.49) | <.001 | 0.47 (0.27 to 0.68) | <.001 |
| **Urgent Health Care Use Episodes in Prior 12 Months, No.[d]** | | | | | | | | | | |
| Unweighted | | | | | | | | | | |
| Completers | 3.46 | 1.99 | −1.47 (−2.28 to −0.67) | <.001 | 3.30 | 1.96 | −1.34 (−2.00 to −0.72) | <.001 | 0.07 (−0.60 to 0.75) | .83 |
| Multiple imputation | 3.59 | 2.10 | −1.50 (−2.03 to −0.97) | <.001 | 3.69 | 2.08 | −1.60 (−2.13 to −1.08) | <.001 | 0.09 (−0.59 to 0.73) | .78 |
| Weighted[e] | | | | | | | | | | |
| Completers | 18.26 | 11.14 | −7.13 (−15.26 to 1.01) | .09 | 20.29 | 13.56 | −6.73 (−15.06 to 1.60) | .11 | −1.10 (−10.15 to 7.95) | .81 |
| Multiple imputation | 19.48 | 13.54 | −5.94 (−10.27 to −1.10) | .008 | 24.86 | 16.83 | −8.02 (−14.21 to −1.84) | .01 | −0.91 (−9.77 to 7.45) | .84 |
| **≥1 Episode of Urgent Health Care Use in Prior 12 Months, %** | | | | | | | | | | |
| Unweighted | | | | | | | | | | |
| Completers | 77.70 | 56.08 | −21.62 (−31.58 to −11.67) | <.001 | 76.22 | 61.59 | −14.63 (−23.7 to −0.05) | .001 | 0.83[e] (0.51 to 1.34) | .44 |
| Multiple imputation | 78.79 | 57.99 | −20.80 (−25.26 to −16.34) | <.001 | 77.35 | 63.22 | −14.13 (−19.09 to −9.18) | <.001 | 0.82[e] (0.51 to 1.31) | .40 |

[a] Based on n = 161 participants who completed the study and n = 177 for multiple-imputation analysis.

[b] Based on n = 172 participants who completed the study and n = 189 for multiple-imputation analysis.

[c] Adjusted using linear regression models that included the following covariates: age, sex, race/ethnicity, level of education, and the same outcome variable at baseline.

[d] Includes hospitalizations (weight = 50), emergency department visits (weight = 2), and urgent clinic visits (weight = 1), all for asthma.

[e] Odds ratio from logistic regression models that included the following covariates: age, sex, race/ethnicity, level of education, and same outcome variable at baseline.

least some college education (coefficient of interaction term = −1.74, $P$ = .04).

### Secondary Outcomes

We describe the intervention effect on secondary outcomes for completed participants on the basis of linear and logistic regression models (**Table 3**). Findings were nearly identical with multiple-imputation–based linear and logistic models and negative binomial models. All measures of asthma control improved significantly more in the intervention group, with the exception of use of steroid bursts, which did not change in either group. The ACQ score (higher represents worse control) decreased by a mean of 0.55 more points in the CHW group, exceeding the 0.5-point threshold for a clinically meaningful difference.[37,43] The proportion with very poorly controlled asthma declined 20.1 absolute percentage points more in the intervention group (odds ratio of very poor control in intervention group relative to control group, 0.43), the number of self-reported asthma attacks was a mean of 0.55 fewer per 3 months, and the mean days of rescue medication use in the past 2 weeks was 1.38 fewer. Nocturnal awakening because of symptoms declined significantly more in the CHW group (mean, 1.65 days per 2 weeks). Days of missed work or school declined equally in both groups (mean, approximately 0.6-0.8 days per 2 weeks). Whereas some measures of pulmonary function improved in the intervention group, there were no significant differences in the amount of change across groups. A general measure of physical health status (SF-12) improved more in the CHW group (mean, 4.54 points, a clinically important difference[44,45]), whereas mental health improved equally in both. Among secondary outcomes, no significant heterogeneity in treatment effects among subgroups was present (data not shown).

## Discussion

In-home asthma self-management support provided by CHWs to adults with uncontrolled asthma, compared with a usual care control group, resulted in significantly greater and clinically meaningful increases in symptom-free days (mean, 2.02 days per 2 weeks more) and quality of life (mean, 0.50 points). Urgent care episodes decreased equally in both groups. Most secondary outcomes also improved to a greater extent in the intervention group, including multiple measures of asthma control and general physical health status. There were no significant differences in changes in pulmonary function measures, although only the intervention group demonstrated significant improvements. The intervention was equally effective across age,

Table 3. Intervention Effect for Secondary Outcome Variables

| Outcome | Intervention Group[a] Mean Base | Mean Exit | Mean Change (95% CI) | P Value | Control Group[b] Mean Base | Mean Exit | Mean Change (95% CI) | P Value | Intervention Effect (Adjusted)[c] Coefficient (95% CI) | P Value |
|---|---|---|---|---|---|---|---|---|---|---|
| **Asthma Control Questionnaire** | | | | | | | | | | |
| Completers | 2.77 | 1.63 | −1.14 (−1.30 to −0.98) | <.001 | 2.55 | 2.10 | −0.45 (−0.60 to −0.31) | <.001 | −0.55 (−0.74 to −0.37) | <.001 |
| Multiple imputation | 2.77 | 1.64 | −1.13 (−1.22 to −1.04) | <.001 | 2.59 | 2.10 | −0.49 (−0.57 to −0.41) | <.001 | −0.53 (−0.72 to −0.35) | <.001 |
| **Very Poorly Controlled Asthma, %[d]** | | | | | | | | | | |
| Completers | 70.8 | 39.1 | −31.7 (−41.8 to −21.6) | <.001 | 71.5 | 59.9 | −11.6 (−21.2 to −0.02) | .01 | 0.43[e] (0.27 to 0.68) | <.001 |
| Multiple imputation | 70.1 | 39.0 | −31.0 (−37.0, −25.1) | <.001 | 73.5 | 60.5 | −13.1 (−18.4 to −7.71) | <.001 | 0.41[e] (0.26 to 0.65) | <.001 |
| **Asthma Attacks, 3 mo** | | | | | | | | | | |
| Completers | 2.42 | 1.07 | −1.35 (−1.68 to −1.02) | <.001 | 2.34 | 1.63 | −0.71 (−1.02 to −0.40) | <.001 | −0.55 (−0.87 to −0.24) | .001 |
| Multiple imputation | 2.44 | 1.08 | −1.35 (−1.59 to −1.12) | <.001 | 2.38 | 1.63 | −0.74 (−0.94 to −0.54) | <.001 | −0.54 (−0.87 to −0.21) | .002 |
| **Days Use of Rescue Medication, 2 wk** | | | | | | | | | | |
| Completers | 7.30 | 4.50 | −2.80 (−3.75 to −1.86) | <.001 | 7.40 | 6.08 | −1.32 (−2.23 to −0.41) | .005 | −1.38 (−2.44 to −0.32) | .01 |
| Multiple imputation | 7.46 | 4.59 | −2.87 (−3.38 to −2.37) | <.001 | 7.59 | 6.28 | −1.31 (−1.85 to −0.77) | <.001 | −1.51 (−2.60 to −0.44) | .006 |
| **Nights With Symptoms, 2 wk** | | | | | | | | | | |
| Completers | 6.19 | 2.14 | −4.05 (−4.97 to −3.13) | <.001 | 5.56 | 3.77 | −1.79 (−2.75 to −0.83) | <.001 | −1.65 (−2.59 to −0.72) | .001 |
| Multiple imputation | 6.15 | 2.21 | −3.94 (−4.59 to −3.28) | <.001 | 5.76 | 3.83 | −1.93 (−2.59 to −1.27) | <.001 | −1.65 (−2.61 to −0.70) | .001 |
| **Oral Steroid Bursts, 12 mo** | | | | | | | | | | |
| Completers | 3.94 | 1.16 | −2.79 (−7.20 to 1.63) | .21 | 5.68 | 2.45 | −3.23 (−9.75 to 3.29) | .33 | −1.18 (−4.09 to 1.72) | .42 |
| Multiple imputation | 3.75 | 0.97 | −2.78 (−6.82 to 1.26) | .18 | 5.36 | 2.61 | −2.75 (−7.99 to 2.49) | .30 | −1.63 (−4.61 to 1.34) | .28 |
| **Days Missed Work and/or School in Past 2 wk** | | | | | | | | | | |
| Completers | 1.09 | 0.28 | −0.81 (−1.26 to −0.36) | .001 | 1.01 | 0.46 | −0.56 (−0.98 to −0.14) | .01 | −0.16 (−0.49 to 0.18) | .35 |
| Multiple imputation | 1.00 | 0.30 | −0.70 (−1.04 to −0.36) | <.001 | 1.11 | 0.48 | −0.63 (−0.99 to −0.26) | .001 | −0.13 (−0.48 to 0.22) | .46 |
| **Short Form-12 Physical Health Scale** | | | | | | | | | | |
| Completers | 35.9 | 41.5 | 5.61 (4.07 to 7.14) | <.001 | 37.3 | 37.5 | 0.26 (−1.24 to 1.77) | .73 | 4.54 (2.56 to 6.52) | <.001 |
| Multiple imputation | 36.3 | 41.7 | 5.45 (4.89 to 6.02) | <.001 | 37.0 | 37.1 | 0.09 (−0.49 to 0.67) | .76 | 4.94 (2.90 to 6.99) | <.001 |
| **Short Form-12 Mental Health Scale** | | | | | | | | | | |
| Completers | 41.7 | 44.3 | 2.57 (0.58 to 4.56) | .01 | 40.7 | 43.5 | 2.82 (0.86 to 4.77) | .005 | 0.31 (−1.95 to 2.57) | .79 |
| Multiple imputation | 41.5 | 44.1 | 2.68 (1.57 to 3.79) | <.001 | 40.8 | 43.8 | 2.94 (1.87 to 4.01) | <.001 | 0.08 (−2.28 to 2.44) | .95 |
| **Spirometry Measures** | | | | | | | | | | |
| FEV1 | | | | | | | | | | |
| Completers | 2.50 | 2.56 | 0.06 (−0.01 to 0.14) | .10 | 2.60 | 2.61 | 0.01 (−0.05 to 0.07) | .68 | 0.03 (−0.05 to 0.12) | .44 |
| Multiple imputation | 2.41 | 2.50 | 0.09 (0.06 to 0.11) | <.001 | 2.54 | 2.55 | 0.01 (−0.02 to 0.03) | .55 | 0.05 (−0.03 to 0.14) | .21 |
| FVC | | | | | | | | | | |
| Completers | 3.37 | 3.44 | 0.07 (−0.04 to 0.18) | .21 | 3.43 | 3.46 | 0.03 (−0.07 to 0.12) | .57 | 0.03 (−0.09 to 0.16) | .58 |
| Multiple imputation | 3.28 | 3.38 | 0.11 (0.06 to 0.15) | <.001 | 3.40 | 3.41 | 0.01 (−0.03 to 0.05) | .55 | 0.06 (−0.06 to 0.18) | .34 |
| FEV1 % predicted | | | | | | | | | | |
| Completers | 84.5 | 87.3 | 2.74 (0.00 to 5.47) | .05 | 87.3 | 88.3 | 1.00 (−1.14 to 3.08) | .36 | 0.97 (−2.22 to 4.16) | .55 |
| Multiple imputation | 81.9 | 85.5 | 3.52 (2.52 to 4.52) | <.001 | 85.7 | 86.7 | 0.97 (0.02 to 1.93) | .046 | 1.47 (−1.31 to 4.25) | .30 |
| FEV1/FVC | | | | | | | | | | |
| Completers | 72.9 | 74.3 | 1.36 (−1.07 to 3.79) | .27 | 75.4 | 75.0 | −0.40 (−3.00 to 2.20) | .76 | −0.27 (−2.67 to 2.13) | .82 |
| Multiple imputation | 72.5 | 74.1 | 1.65 (0.19 to 3.11) | .03 | 73.8 | 74.2 | 0.32 (−1.10 to 1.74) | .66 | 0.14 (−2.50 to 2.78) | .91 |

Abbreviation: FVC, forced vital capacity; FEV, forced expiratory volume.

[a] Based on n = 161 participants who completed the study and n = 177 for multiple-imputation analysis.

[b] Based on n = 172 participants who completed the study and n = 189 for multiple-imputation analysis.

[c] Adjusted using linear regression models that included the following covariates: age, sex, race/ethnicity, level of education, and the same outcome variable at baseline.

[d] As defined by National Asthma Education and Prevention Program: symptoms throughout the day or nighttime awakenings more than 4 times per week or activity severely limited or daily rescue medication use.

[e] Odds ratio from logistic regression models that included following covariates: age, sex, race/ethnicity, level of education and same outcome variable at baseline.

sex, and race/ethnicity groups, as well as participants with different levels of asthma control at baseline.

A substantial body of evidence[9,10] supports the use of home visits for improving asthma control among children. To our knowledge, HomeBASE is the largest randomized trial to evaluate the effectiveness of home visits for adults and the first using CHWs. A PubMed search (using medical subject headings asthma and adults and home care services with no date restrictions) yielded 3 studies. A small, short-duration randomized trial of home visits by respiratory therapists or nurses showed improvement in quality of life, fewer hospitalizations but not emergency department visits, and no changes in lung function.[46] A controlled pilot study of CHW home visits and group sessions led by a social worker showed a small improvement in quality of life but not in other clinical outcomes.[47] A small randomized trial of home-based asthma education delivered by a nurse found that it affected neither symptoms nor quality of life.[48]

Our study has limitations. Blinding with respect to group assignment was not possible given the nature of the intervention. To address this potential source of bias, we collected baseline data prior to randomization and used interviewers unaware of group assignment to conduct exit data. However, we note that objective outcomes such as health care use and pulmonary function did not improve more in the intervention arm. The intervention did consistently improve patient-centered outcomes such as symptoms, quality of life, and health status. These measures are recommended by the National Institutes of Health,[31,49] and interest in such outcomes is growing among policy makers and payers.[50,51] The primary outcomes were based on participant self-report, which may be influenced by the intensity of study contact with participants. We used self-reported health care use data because patients received care from multiple delivery systems, making it impractical to collect administrative use data. Self-report of symptoms and quality of life is the standard method for assessing these measures.[31,49] Because it was not possible to perform allergy testing for all participants, we did not tailor environmental interventions on the basis of sensitization. We did not have resources to observe study participants after the intervention to assess durability of effects.

Several study strengths are worth noting. We used patient-centered outcome measures. Randomization succeeded in producing balanced study groups. Quality control mechanisms ensured consistent implementation of home visit protocols. Participant retention was high. We assessed for confounding by multiple factors. We followed participants for a full year, both removing seasonal effects on asthma outcomes and assessing outcomes over a substantial period of time.

We anticipate that this intervention could be readily replicated by health organizations serving diverse, low-income clients, suggesting that it could reduce asthma-related health inequities. Intervention protocols can be implemented without specialized training or resources. The cost per participant was approximately $1300 (2013 US dollars), substantially less than 1 year's supply of an inhaled corticosteroid. It was not difficult to identify eligible participants, and participation and program completion rates were high.

## Conclusions

The HomeBASE study provides evidence that home visits by CHWs can improve asthma control and quality of life among low-income adults. The approach used for home visits is practical and inexpensive, suggesting that, if additional studies confirm our findings, adoption by organizations serving similar populations would be feasible and beneficial.

### ARTICLE INFORMATION

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*Drafting of the manuscript:* Krieger, Song.
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**Additional Contributions:** Michelle DeMicio, MSW, Marguerita Mendoza, and Maria Rodriguez, Public Health–Seattle and King County (project CHWs), delivered the implementation, collected data, and provided field-based feedback on project protocols. Karen Artz, RN, MS, Public Health–Seattle and King County (project nurse), provided clinical supervision to CHWs and was responsible for quality control. Nathan Drain, BA, Public Health–Seattle and King County (project manager), oversaw operations and managed data. All additional contributors were salaried employees of the project.

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