Published in final edited form as:

J Allergy Clin Immunol Pract. 2020 ; 8(10): 3466–3473.e11. doi:10.1016/j.jaip.2020.06.058.

Patient Advocates for Low-Income Adults with Moderate to Severe Asthma: A Randomized Clinical Trial

Andrea J. Apter, MD, MSc, MA^{a,b}, Luzmercy Perez, BA^a, Xiaoyan Han, MS^c, Grace Ndicu, AS^a, Anna Localio, MPH^a, Hami Park, BA^a, Alyssa N. Mullen, MHA^d, Heather Klusaritz, PhD^e, Marisa Rogers, MD, MPH^b, Zuleyha Cidav, PhD^f, Tyra Bryant-Stephens, MD^g, Bruce G. Bender, PhD^h, Susan T. Reisine, PhDⁱ, Knashawn H. Morales, ScD^c

^aDivision of Pulmonary, Allergy, & Critical Care Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pa

^bDepartment of Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pa

^cDepartment of Biostatistics, Epidemiology and Informatics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pa

^dTemple Physicians, Inc, Temple University Health System, Philadelphia, Pa

^eDepartment of Family Medicine and Community Health, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pa

^fLeonard Davis Institute of Health Economics, University of Pennsylvania, Philadelphia, Pa

^gChildren's Hospital of Philadelphia, Philadelphia, Pa

^hNational Jewish Health, Denver, Colo

ⁱUniversity of Connecticut Health Center, Farmington, Conn

Abstract

BACKGROUND—Few interventions have targeted low-income adults with moderate to severe asthma despite their high mortality.

OBJECTIVE—To assess whether a patient advocate (PA) intervention improves asthma outcomes over usual care (UC).

METHODS—This 2-armed randomized clinical trial recruited adults with moderate to severe asthma from primary care and asthma-specialty practices serving low-income neighborhoods. Patients were randomized to 6 months of a PA intervention or UC. PAs were recent college graduates anticipating health care careers, who coached, modeled, and assisted participants with preparations for asthma-related medical visits, attended visits, and confirmed participants'

Corresponding author: Andrea J. Apter, MD, MSc, MA, Hospital of the University of Pennsylvania, 829 Gates Bldg, 3600 Spruce St, Philadelphia, PA 19104., andrea.apter@uphs.upenn.edu., 2213-2198.

Conflicts of interest: A. J. Apter is a consultant for UpToDate and an associate editor of the *Journal of Allergy and Clinical Immunology*. K. H. Morales owns stock in Altria Group Inc, British American Tobacco PLC, and Phillip Morris International Inc. The rest of the authors declare that they have no relevant conflicts of interest.

understanding of provider recommendations. Participants were followed for at least a year for patient-centered asthma outcomes: asthma control (primary outcome), quality of life, prednisone requirements, emergency department visits, and hospitalizations.

RESULTS—There were 312 participants. Their mean age was 51 years (range, 19–93 years), 69% were women, 66% African American, 8% Hispanic/Latino, 62% reported hospitalization for asthma in the year before randomization, 21% had diabetes, and 61% had a body mass index of 30 or more. Asthma control improved over 12 months, more in the intervention group (−0.45 [95% CI, −0.67 to −0.21]) than in the UC group (−0.26 [95% CI, −0.53 to −0.01]), and was sustained at 24 months but with no statistical difference between groups. The 6-month rate of emergency department visits decreased in the intervention (−0.90 [95% CI, −1.56 to −0.42]) and UC (−0.42 [95% CI, −0.72 to −0.06]) groups over 12 months. The cost of the PA program was \$1521 per patient. Only 64% of those assigned had a PA visit.

CONCLUSIONS—A PA may be a promising intervention to improve and sustain outcomes in this high-risk population if expanded to address factors that make keeping appointments difficult.

Keywords

Asthma; Asthma control; Asthma-related quality of life; Inner-city asthma; Patient advocate; Health literacy

INTRODUCTION

Despite efficacious medications and national guidelines for management,¹ asthma disproportionately impacts low-income and minority adults, particularly African Americans and Puerto Ricans.^{2,3} Compared with children, adults with asthma, 65% of whom are women, are more likely to die from asthma.^{2,4} Comorbidities including hypertension, diabetes, and obesity, prevalent among low-income adults, increase the complexity of managing asthma and health in general. Although there is a growing evidence base of effective asthma control interventions, few have targeted low-income minority adults.^{5–7}

To ensure health equity, the Institute of Medicine advocated addressing access to health care and patient-provider communication by intervening at several levels: the provider-patient interaction, the culture of the practice, the encompassing health system, the community, and the local and national government.⁸ We report the evaluation of a patient advocate intervention (PAI) that operates at the first 2 levels of intervention.^{8,9}

The PAI was adapted from the Patient Navigator program, which was conceived by Harold P. Freeman, MD, to overcome barriers to diagnosis and initial treatment of cancer for patients living in poverty in Harlem.¹⁰ Variations on this theme have had some partial success in different patient groups (eg, elderly, children, and adolescents) with different acute medical problems (eg, surgery, chronic kidney failure, diabetes, smoking cessation, hospice, cancer screening, and needing a procedure or chemotherapy).¹¹ With input from focus groups of our patients and providers¹² and piloting,¹³ we developed a patient advocate (PA) who coached, modeled, and assisted with preparations for asthma-related medical visits, attended visits with permission of patient and clinician, and confirmed patient understanding of provider recommendations. We evaluated the effect of 6 months of PAI on

the primary outcome (asthma control) and secondary outcomes (asthma-related quality of life, prednisone bursts, emergency department [ED] visits, hospitalizations, and urgent office visits) relative to baseline and compared with usual care (UC). We also evaluated whether such a difference is sustained in the 6 months after the completion of the intervention. We tracked resources used to deliver the intervention, and estimated the associated costs.

METHODS

This parallel-group clinical trial randomized adults with moderate to severe asthma from clinics serving low-income neighborhoods to UC or working with a PA who coached, modeled, and assisted participants with preparations for asthma-related medical visits, attended visits, and confirmed participants' understanding of providers' recommendations. This protocol, Helping Asthma Patients 2 (HAP2), has been detailed previously.⁹ The institutional review boards of the University of Pennsylvania and the Corporal Michael J. Crescenz Veterans Administration Medical Center approved the protocol ([ClinicalTrials.gov: NCT 01972308](https://clinicaltrials.gov/ct2/show/study/NCT01972308)).

Participants

Participants were adults aged at least 18 years, with a physician's diagnosis of asthma, prescribed an inhaled steroid-containing medication for asthma, with evidence of reversible airflow obstruction (either an increase of 15% and 200 mL in FEV₁ with asthma treatment over the previous 3 years or, after 4 puffs of albuterol by inhaler [or 2.5 mg by nebulizer], an increase in FEV₁ or forced vital capacity 12% and 200 mL in FEV₁ within 30 minutes), and with at least 1 appointment scheduled with their asthma (primary or specialty care) clinician from a participating practice during the first 6 months of participation. Patients with comorbidities who met these criteria were included. Past or current smoking was not an exclusion criterion.

Participating practices/recruitment sites

Participating practices/recruitment sites included primary care and asthma-specialty practices from a large academic health center: family medicine, general internal medicine (2), pulmonary (2), allergy-immunology outpatient practice, a pulmonary practice from a Veterans Administration Medical Center; a community-based primary care practice of a federally qualified health center; and a primary care practice serving mainly Spanish-speaking patients. All sites served urban low-income and minority patients from surrounding communities.⁹

Patient advocates

PAs were recent college graduates interested in health care careers.^{9,12,14} Focus groups of patients who had participated in pilot studies for this project recommended these individuals because they had liked working with them previously, felt comfortable, and noticed they were comfortable with clinic staff.⁹ At least 2 of the PAs had lived in patients' Philadelphia neighborhoods; one had worked in other low-income communities, but the other had not worked with such patients previously. The PAs with community knowledge shared their experiences at weekly team meetings. All PAs received on-going education/training on

social determinants of health, community-level barriers to care, and positive asthma outcomes through weekly team meetings. During meetings, cases were reviewed and PAs provided peer education on community-level factors, and study investigators provided guidance.

Recruitment, enrollment, and randomization

Researchers screened electronic or paper health records of participating practices for patients with an asthma diagnosis, upcoming appointments, and inhaled steroid-containing prescription. A researcher then contacted potential participants by phone or in person and requested consent for further screening.

After obtaining consent, baseline data were collected (see Table E1 in this article's Online Repository at www.jaci-inpractice.org). Subsequent quarterly data collection was scheduled. At all visits participants were asked about asthma symptoms and need for urgent care (ED visits, hospitalizations, new or increased prednisone prescriptions ["prednisone bursts"] since the last visit). After initial data collection, participants were randomized 1:1 to either PAI or UC, stratified by practice,⁹ with randomly permuted blocks of varying block sizes. If allocated to the PA arm, the data collector would then review a separate consent form describing the nature, content, and length of this treatment group. Only the principal investigator and biostatistician were blinded to treatment assignment.

Intervention procedures

Upon randomization to PAI, an email informed the patient's asthma clinician of the enrollment, briefly describing protocol activities. The email asked permission for the PA to accompany the participant to an appointment.

A few days before each visit with the asthma clinician, by phone or in person, the PA assisted the patient in updating a medication list to share with the clinician. The patient and the PA discussed any problems with obtaining, refilling, or taking medications. The participant reviewed any questions he or she planned to address with the clinician. The PA prompted the patient to prepare no more than 2 to 3 priorities to address at the medical visit to allow adequate time to address them and those of the clinician. The PA helped the patient obtain and complete needed forms, referrals, or documents.

In the waiting room the PA asked the participant whether he or she had an emergency plan for an asthma exacerbation and encouraged the participant to discuss this with the provider as part of an action plan. The PA helped the participant organize any needed materials (eg, study results, medication lists, and insurance information). The PA used the waiting time (which was sometimes considerable) to get to know more about the patient's life and priorities.

During the medical appointment with permission, the PA accompanied the participant as an observer, taking notes on key information communicated between provider and patient. The PA spoke only if invited by the participant or the clinician.

In primary care practices, other health issues besides asthma were sometimes discussed. The PA protocol included all health issues discussed and afterwards a review of all health recommendations.

Immediately after the appointment, the PA and the participant organized medical and administrative information, scheduled follow-ups, and, when applicable, completed insurance forms or other documents. The PA asked the patient to “teach back,” that is, teach the clinician’s instructions as if the patient were the clinician. If the participant had questions after the teach back, the PA and the participant completed a report of items needing clarification for the clinician or staff.

Between visits, the PA made monthly calls checking on the patient’s general well-being, adequacy of medications, and upcoming appointments.

Usual care

Both UC and intervention participants received asthma care from their clinicians and practices that generally followed asthma guidelines.¹ For UC-assigned participants there were no meetings with PAs; PAs did not accompany participants or play a role in provider visits.

Duration of patient participation

Duration of patient participation was planned for 12 months. For those in PAI, the intervention was scheduled for the first 6 months. Both groups were to be observed in the second 6 months without intervention. Participants who completed this 12-month protocol before the last 12 months of the study expired were invited to be followed for an additional 12 months to assess durability and sustainability of the intervention.

Outcomes

The primary outcome, asthma control, reflecting symptoms over the past week, was measured using the 6-item version of the Asthma Control Questionnaire (ACQ).^{15,16} Each item is scored from 0 to 6, with lower scores indicating better control. Secondary outcomes included asthma-related quality of life, measured with the Mini-Asthma Quality of Life Questionnaire,^{17,18} and the number of prednisone bursts, ED visits, and hospitalizations. Participants reported hospitalizations, ED visits, urgent medical visits (scheduled <24 hours in advance), and prednisone bursts. These were verified, when possible, with medical records. Spirometry was obtained using the American Thoracic Society procedures for FEV1 and forced vital capacity.¹⁹

Research Electronic Data Capture (<https://projectredcap.org/>), a secure web-based application, was used for data entry and management.^{9,20}

Statistical analysis

A power analysis, detailed previously, indicated that a cohort of 300 adults, 150 per arm, has 80% power at the adjusted 2-sided significance level of .025 to observe a group effect of

0.29 and 0.32 in mean change in asthma control across groups at 6 and 12 months, respectively.⁹

The primary analyses were as randomized (intention to treat [ITT]). We applied generalized estimating equations with an independent working correlation structure to the outcomes: asthma control, asthma-related quality of life, ED visits, hospitalizations, urgent visits, and need for prednisone bursts. Because of skewed distributions, gamma models with a log link were used for asthma control; Poisson with a log link for ED visits, hospitalizations, and urgent visits; and binomial with a logistic link for prednisone bursts. The models accounted for correlated longitudinal measurements and missing data, assuming that data were missing completely at random. Time was measured continuously as months from baseline and modeled flexibly with splines. The knots were chosen at 3, 6, 9, 12, and 15 months. Time-by-treatment interactions were included to estimate the ITT effect. Models were adjusted for study site and baseline characteristics that might be related to dropout. Data reduction methods were used for identification of baseline variables and subgroups (see this article's Online Repository at www.jaciinpractice.org).

Because few patients were observed at exactly the time points of interest, and to avoid arbitrary data collection windows, estimated means from longitudinal models were obtained for each outcome at 0, 6, and 12 months and accounted for measurement error as well as variation across patients. We compared changes in individual predictions of outcome at 6 months and 12 months to baseline. Within-group effects, in addition to the ITT (across-group) model-estimated effects, were reported with 95% bootstrap CIs. Observed asthma control scores over time were graphed along with the estimated means for each intervention group. We avoided the use of *P* values whenever possible to keep with current guidance on the importance of estimation and CIs, and therefore did not consider multiple testing corrections. For asthma control, we further counted the number of predictions that improved by at least 0.5, the minimally important difference for asthma control, and those that achieved controlled asthma indicated by an asthma control score less than 1.5.

Secondary analyses described in this article's Online Repository included (1) repeating the models on the subset of participants who were followed for an additional year; (2) instrumental variable approach to estimate what the intervention effect would have been if those randomized to the PAI had 2 PA visits, while controlling for confounding of unmeasured factors; (3) evaluation of potential mediators of the PAI; and (4) exploration of heterogeneous intervention effects using baseline patient characteristics (eg, comorbidities, smoking history, sociodemographic characteristics, and community barriers).

Resource use and costs

We assessed costs and cost offset associated with the 2 study conditions from the perspective of the payer (health care sector). Resources measured were time spent and materials used for training and supervision of PAs, time spent by PAs on intervention delivery, and health care services used by the patients. Travel costs for PAs to distant practices were included. Further details are in this article's Online Repository.

RESULTS

The first of 312 patients was enrolled on December 12, 2013; the last data collection occurred on March 16, 2017. Figure 1 (the Consolidated Standards of Reporting Trials diagram) describes screening, enrollment, randomization, and follow-up. Of 125 patients enrolled for an extra year, the first was enrolled on September 23, 2016, and the last was enrolled on April 9, 2018.

Participant characteristics are presented in Table I. Mean age was 51 years (range, 19–93 years), 69% were women, and 37% received Medicaid. Among the participants, 29% reported at least 1 asthma hospitalization, 43% had an ED visit in the year before enrollment, 54% had hypertension, and 21% had diabetes. Sixteen percent were current smokers, and almost half had smoked. Five patients died during the study's course (1 in the PA group), all unrelated to asthma. Table II presents the number of patients with ED visits, hospitalizations, and urgent visits during the study period.

Of the 312 patients, 227 (73%) patients, independent of randomization assignment, had a visit with their asthma clinician after enrollment. Among 156 randomized to PAI, 99 (63%) had at least 1 medical appointment with PA support. Half of those had only 1 visit; some of these occurred late in the intervention period. Only 15 of the 99 had more than 2 PA visits (see Table E2 in this article's Online Repository at www.jaci-inpractice.org). Thirty (19%) PA-assigned patients did not have any asthma-related visits with a provider during the study compared with 10 (6%) in the UC group; 12 (8%) PA-assigned patients either had appointments rescheduled, canceled, or not attended by patients compared with 18 (12%) in the UC group; 9 (6%) could not be contacted by a PA; and 6 (4%) declined to have a PA, of which 2 were already accompanied to clinic visits by a family member and another by a social worker (Figure 1).

Outcomes

Only 13 (4%) were considered dropouts, but patients frequently rescheduled data collection visits (Figure 2; see also Tables E3 and E4 in this article's Online Repository at www.jaci-inpractice.org). This did not differ between groups. The most frequent reasons for rescheduling appointments were transportation difficulties, work, and the need to care for a family member.

Asthma control, the primary outcome, improved significantly in both groups at 12 months (more in the PA-assigned group), but the differences between groups at 6 months (the end of PA visits for the intervention group) and at 12 months (-0.45 [95% CI, -0.67 to -0.21] for PA vs -0.26 [95% CI, -0.53 to -0.01] for UC) were not statistically significant (Table III; see also Figure E1 in this article's Online Repository at www.jaci-inpractice.org). On the basis of the model-predicted ACQ score, 26 patients in the PA group had improved (decrease of at least 0.5 in the ACQ score) at 12 months compared with 5 patients in the UC group. An equal number of patients in each group (62) had a predicted ACQ score less than 1.5 (considered controlled asthma) by 12 months. The improvement in the ACQ score in the PA group was also sustained in those who were followed for an extra year (see Table E6 in this article's Online Repository at www.jaci-inpractice.org). Asthma-related quality of life

improved in both groups, but there was no statistically significant difference in scores between groups (Table III).

The rate of ED visits and hospitalizations decreased in both groups at 6 and 12 months; the decrease for ED visits was more, approximately twice the decline in the PA compared with the UC group at 12 months (-0.90 per 6 months [95% CI, -1.56 to -0.42] vs -0.42 [95% CI, -0.72 to -0.06]). However, the difference in the decrease between groups did not reach conventional levels of statistical significance (Table III; see also Table E5 in this article's Online Repository at www.jaci-inpractice.org). Urgent office visit rates and risk of a prednisone burst diminished (Table III).

Results of the instrumental variable analysis suggest improvement in asthma control at 12 months for the PA group. Having at least 2 PA visits would have led to a larger difference in improvement among the PA-assigned patients (-0.79 [95% CI, -1.27 to -0.23]) compared with the UC group (-0.28 [95% CI, -0.49 to -0.11]). The ITT effect for asthma control at 12 months for the patients who had at least 2 PA visits (-0.50 [95% CI, -1.00 to 0.11]) is almost 3 times that of the corresponding effect when comparing groups as randomized (-0.18 [95% CI, -0.54 to 0.17]) (see Table E7 in this article's Online Repository at www.jaci-inpractice.org).

In the secondary analyses, no significant mediators or moderators were identified (see this article's Online Repository and Tables E8 and E9 at www.jaci-inpractice.org).

Cost and cost-offset analyses

Treatment effects for ED, hospitalizations, and urgent care service use were not statistically significant between groups (Table III), which suggests no evidence of cost savings attributable to the reductions in health care service use. The annual average cost per patient of the PA program was approximately \$1521 per patient per year (for more details, see Cost Analysis and Table E10 in this article's Online Repository at www.jaci-inpractice.org).

DISCUSSION

We examined whether a PAI improves asthma control and other outcomes compared with UC in adults with moderate to severe asthma, many with reported low incomes and many with comorbidities. Most of the estimated treatment effects for our primary outcomes were in the hypothesized direction (better outcomes for PA-assigned patients), although they were not statistically significant. For example, the point estimate for improvement in asthma control in the PA group was numerically almost twice the improvement in the UC group at 12 months. In addition, the instrumental variable analysis supported benefit of the PA over UC in which we found 3 times more positive effect of the PA albeit not significant. Previous analyses showed that the patients and providers were engaged and the protocol feasible.²¹

In trying to understand why there was improvement in both groups, we noted that there were implicit interventions to which the UC group was exposed during routine data collection. For example, inhaler technique was checked during data collection and if inadequate, the patients were instructed and retested until the technique was adequate. Baseline

questionnaires asked patients about their knowledge of the function of medications. Incorrect answers were corrected. Also, as part of baseline questioning, we defined “controller” and “quick relief” inhalers.

Potentially modifiable factors

Only 15 patients had at least 2 PA visits. Our instrumental analysis suggested that at least 2 PA visits were needed to make a difference. Thus, there was little difference in the amount of intervention compared with control. If we could increase the number of PA visits and follow patients longer, we might see more effect. Given the transportation difficulties and family care obligations of patients, converting some of the PA visits to home visits, where the PA visits the home and reports back to the clinician, may make a difference and may possibly lead to better and more complete recommendations for patients. With video conferencing, these visits could be completely or in part virtual and could include the clinician. Many self-management problems patients described were related to events at home. The home circumstances relative to social determinants of health (housing difficulties, food insecurity, inability to afford medications, lack of heat, electricity, cellphone, violence in the neighborhood) were not addressed in the current intervention and inability to address these may have overwhelmed the benefit of PA activities.

We did not have indications that patients or clinic personnel did not like the PAI.^{21,22} In fact, earlier reports of this project indicated patient acceptability.^{21,22} That there was very little dropout further supports the acceptability of the intervention.

Although they focused on asthma, PAs addressed other chronic illnesses covered in appointments demonstrating the intervention can be useful considering patients’ medical problems in their entirety and in both a specialty and primary care setting. The complexity of participants’ medical problems and lives supports the belief that a longer or more intense participation likely would improve the effectiveness of the intervention. These alterations would increase the cost of the intervention but hopefully also increase the cost-effectiveness.

Other considerations

We included current and past smokers. Smokers are frequently excluded from clinical trials for asthma. Smoking is common even among patients with asthma and it is not known whether smokers benefit from pharmaceutical or behavioral interventions for asthma. In this study, there was no difference in intervention effect of never smokers compared with current smokers. In modifying our intervention, it will be important to continue to include and address tobacco exposure.

There are a few recent clinical trials of older adults with high-risk asthma or tobacco-induced respiratory disease dependent with adequate transfer of information.^{23–26} Our PA protocol is unique in that the PA accompanies the participant on the medical visit, ensuring accuracy of the teach back and subsequent help with navigating. Their attention in the visit to patient and clinician can help solidify and support the relationship between them.

Our study has limitations. First, only 64% of those assigned a PA had medical visits that included the PA’s presence and, as previously mentioned, both groups had irregularity of

follow-up. Lapses in follow-up occurred not because of dropout, which was 4%, but rather difficulties in overcoming barriers such as transportation problems. Second, recent college graduates may not be available in all communities, and the requirement of a college education may not be necessary. What is likely needed is an understanding of the community in which patients live. As noted in earlier studies, patients liked working with these research coordinators.^{22,23} Third, the generalizability may be limited to inner-city older minority patients with asthma similar to that of those who participated in the study. Fourth, the study included more women than men, reflecting the higher prevalence of women than men in asthma behavioral interventions. There is a need for a longer trial, likely with more participants. Fifth, data collectors were not blinded.

CONCLUSIONS

The cost of \$1521 per PA per year is within the range of 1 to 2 ED visits and less than the yearly cost of many drugs. Previously published qualitative research indicates that patients and clinicians found this PAI feasible and acceptable, particularly for patients with severe or complex medical problems and limited socioeconomic resources, who are the very patients most likely to have a poor health outcome.^{22,23} PAs encourage a more detailed picture for clinicians of the social barriers patients face, and PAs also facilitate patient understanding of medical recommendations. A PA's communication is further enhanced if the PA has experience within the community^{23–27} and can facilitate a view of the home environment perhaps with video conferencing. A PA's activities may provide increased understanding of the psychosocial barriers that will result in better communication among all.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgment

We gratefully acknowledge A. Russell Localio for advice during the conduct and data analysis of this study.

This work was supported by the National Institutes of Health/National Heart, Lung, and Blood Institute (grant no. R18 HL116285).

Abbreviations used

ACQ	Asthma Control Questionnaire
ANQ	Asthma Numeracy Questionnaire
ED	emergency department
HAP2	Helping Asthma Patients 2
ITT	intention to treat
PA	patient advocate
PAI	patient advocate intervention

UC usual care

REFERENCES

1. Expert Panel Report 3. Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Institutes of Health, National Heart, Lung, and Blood Institute; 2007.
2. Centers for Disease Control and Prevention, National Center for Health Statistics. Summary health statistics tables for U.S. adults: National Health Interview Survey, 2016, Table A. 2016. Available from: <https://www.cdc.gov/nchs/fastats/asthma.htm>. Accessed October 10, 2018.
3. US Department of Health and Human Services. Office of Minority Health. Asthma and Hispanic Americans. 2020. Available from: <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=60>. Accessed June 3, 2020.
4. Akinbami LJ, Moorman JE, Bailey C, Zahran HS, King M, Johnson CA, et al. Trends in asthma prevalence, health care use, and mortality in the United States, 2001–2010. NCHS Data Brief 2012; (94):1–8.
5. Press VG, Pappalardo AA, Conwell WD, Pincavage AT, Prochaska MH, Arora VM. Interventions to improve outcomes for minority adults with asthma: a systematic review. J Gen Intern Med 2012;27:1001–15. [PubMed: 22798212]
6. Burchard EG. Medical research: missing patients. Nature 2014;513:301–2. [PubMed: 25230631]
7. Ramsay J, Schwindt T, Nguyen T, Margellos-Anast H. Translating a proven pediatric healthy homes asthma intervention to adults. Health Promot Pract 2018;19:222–32. [PubMed: 27794073]
8. Smedley BD, Stith AY, Nelson AR. Unequal treatment: confronting racial and ethnic disparities in health care. Washington, DC: Institute of Medicine, The National Academies Press; 2003.
9. Apter AJ, Morales KH, Han X, Perez L, Huang J, Ndicu G, et al. A patient advocate to facilitate access and improve communication, care, and outcomes in adults with moderate or severe asthma: rationale, design, and methods of a randomized controlled trial. Contemp Clin Trials 2017;56:34–45. [PubMed: 28315481]
10. Freeman HP. Patient navigation: a community centered approach to reducing cancer mortality. J Cancer Educ 2006;21:S11–4. [PubMed: 17020496]
11. McBrien KA, Ivers N, Barnieh L, Bailey JJ, Lorenzetti DL, Nicholas D, et al. Patient navigators for people with chronic disease: a systematic review. PLoS One 2018;13:e0191980. [PubMed: 29462179]
12. Black HL, Priolo C, Akinyemi D, Gonzales R, Jackson DS, Garcia L, et al. Clearing clinical barriers: enhancing social support using a patient navigator for asthma care. J Asthma 2010;47:913–9. [PubMed: 20846085]
13. Apter AJ, Wan F, Reisine S, Bogen DK, Rand C, Bender B, et al. Feasibility, acceptability and preliminary effectiveness of patient advocates for improving asthma outcomes in adults. J Asthma 2013;50:850–60. [PubMed: 23800333]
14. Thompson SC, Nanni C, Schwankovsky L. Patient-oriented interventions to improve communication in a medical office visit. Health Psychol 1990;9:390–404. [PubMed: 2373065]
15. Juniper EF, O'Byrne PM, Guyatt GH, Ferrie PJ, King DR. Development and validation of a questionnaire to measure asthma control. Eur Respir J 1999;14: 902–7. [PubMed: 10573240]
16. Juniper EF, Bousquet J, Abetz L, Bateman ED. Identifying “well-controlled” and “not well-controlled” asthma using the Asthma Control Questionnaire. Respir Med 2006;100:616–21. [PubMed: 16226443]
17. Juniper EF, Guyatt GH, Willan A, Griffith LE. Determining a minimal important change in a disease-specific Quality of Life Questionnaire. J Clin Epidemiol 1994;47:81–7. [PubMed: 8283197]
18. Leidy NK, Chan KS, Coughlin C. Is the Asthma Quality of Life Questionnaire a useful measure for low-income asthmatics? Am J Respir Crit Care Med 1998; 158:1082–90. [PubMed: 9769264]
19. Standardization of spirometry, 1994 update. American Thoracic Society. Am J Respir Crit Care Med 1995;152:1107–36. [PubMed: 7663792]

20. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81. [PubMed: 18929686]
21. Korwin A, Black H, Perez L, Morales KH, Klusaritz H, Han X, et al. Exploring patient engagement: a qualitative analysis of low-income urban participants in asthma research. *J Allergy Clin Immunol Pract* 2017;5: 1625–1631.e2. [PubMed: 28499772]
22. Localio AM, Black HL, Park H, Perez L, Ndicu G, Klusaritz, et al. Filling the patient-provider knowledge gap: a patient advocate to address asthma care and self-management barriers. *J Asthma* 2018;4:1–10.
23. Federman AD, O'Connor R, Mindlis I, Hoy-Rosas J, Hauser D, Lurio J, et al. Effect of a self-management support intervention on asthma outcomes in older adults: the SAMBA study randomized clinical trial. *JAMA Intern Med* 2019;179:1113–21.
24. Kangovi S, Mitra N, Grande D, Huo H, Smith RA, Long JA. Community health worker support for disadvantaged patients with multiple chronic diseases: a randomized clinical trial. *Am J Public Health* 2017;107:1660–7. [PubMed: 28817334]
25. Kangovi S, Mitra N, Norton L, Harte R, Zhao X, Carter T, et al. Effect of community health worker support on clinical outcomes of low-income patients across primary care facilities: a randomized clinical trial. *JAMA Intern Med* 2018;178:1635–43. [PubMed: 30422224]
26. Krieger JW, Takaro TK, Song L, Weaver M. The Seattle-King County Healthy Homes Project: a randomized, controlled trial of a community health worker intervention to decrease exposure to indoor asthma triggers. *Am J Public Health* 2005;95:652–9. [PubMed: 15798126]
27. Bryant-Stephens T, Kurian C, Guo R, Zhao H. Impact of a household environmental intervention delivered by lay health workers on asthma symptom control in urban, disadvantaged children with asthma. *Am J Public Health* 2009; 99:S657–65. [PubMed: 19890172]
28. Baker DW, Williams MV, Parker RM, Gazmararian JA, Nurss J. Development of a brief test to measure functional health literacy. *Patient Educ Couns* 1999;38: 33–42. [PubMed: 14528569]
29. Apter AJ, Cheng J, Small D, Bennett IM, Albert C, Fein D, et al. Asthma numeracy skill and health literacy. *J Asthma* 2006;43:705–10. [PubMed: 17092853]
30. Norman CD, Skinner HA. eHEALS: the eHealth literacy scale. *J Med Internet Res* 2006;8:e27. [PubMed: 17213046]
31. Juniper EF, Guyatt GH, Cox FM, Ferrie PJ, King DR. Development and validation of the Mini Asthma Quality of Life Questionnaire. *Eur Respir J* 1999;14:32–8. [PubMed: 10489826]
32. Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. *Appl Psychol Meas* 1977;1:385–401.
33. Juniper EF, O'Byrne PM, Ferrie PJ, King DR, Roberts JN. Measuring asthma control: clinic questionnaire or daily diary? *Am J Respir Crit Care Med* 2000; 162:1330–4. [PubMed: 11029340]
34. Juniper EF, Buist AS, Cox FM, Ferrie PJ, King DR. Validation of a standardized version of the Asthma Quality of Life Questionnaire. *Chest* 1999;115: 1265–70. [PubMed: 10334138]

What is already known about this topic?

Low-income and minority adults with asthma suffer worse asthma outcomes than more advantaged groups.

What does this article add to our knowledge?

An intervention that addresses patient-clinician communication may be helpful if other barriers such as transportation difficulties can be overcome.

How does this study impact current management guidelines?

This study contributes to the mounting evidence that guidelines must place more emphasis on evaluating and addressing social determinants of health such as communication and transportation.

FIGURE 1.

Participant flow diagram (Consolidated Standards of Reporting Trials). *Attendance at participating clinics was reviewed daily. Thus, some patients' records were reviewed multiple times. †Contacting patients was time-consuming; we scanned clinic records to meet patients when they came for an appointment and could be approached.

FIGURE 2.

Time from randomization to data collection by treatment group. There were 5 data collection sessions scheduled for months 0, 3, 6, 9, and 12 and represented by vertical lines. In the figure we have labeled with numbers when the collection actually took place, indicating a spread of time when collection occurred. For example, the third data collection was to occur at month 6 but actually occurred between months 3 and 21 (for 1 outlier) for those assigned a PA.

TABLE I.

Baseline characteristics of the 312 adults with moderate to severe asthma, assigned randomly 1:1 to PAI or UC

Characteristic	Total (N = 312)	No PA (n = 156)	PA exposed (n = 156)
Sociodemographic			
Age (y)	51 ± 14	53 ± 14	50 ± 14
Range	19–93	19–85	21–93
Sex: female	216 (69.2)	101 (64.7)	115 (73.7)
Ethnicity: Hispanic or Latino	25 (8.0)	14 (9.0)	11 (7.1)
Race			
Black/African American	206 (66.0)	100 (64.1)	106 (67.9)
White	75 (24.0)	40 (25.6)	35 (22.4)
Declined to answer	24 (7.7)	13 (8.3)	11 (7.1)
Household income			
<\$30,000	152 (48.7)	70 (44.9)	82 (52.6)
\$30,000–\$49,999	42 (13.5)	18 (11.5)	24 (15.4)
\$50,000–\$99,999	44 (14.1)	26 (16.7)	18 (11.5)
\$100,000	29 (9.3)	15 (9.6)	14 (9.0)
Declined to answer	42 (13.5)	25 (16.0)	17 (10.9)
Insurance type			
Medicaid	114 (36.5)	56 (35.9)	58 (37.2)
Medicare only	62 (19.9)	33 (21.2)	29 (18.6)
Self-pay	3 (1.0)	2 (1.3)	1 (0.6)
Commercial with or without Medicare	133 (42.6)	65 (41.7)	68 (43.6)
Education attainment (highest level achieved)			
Grade 8 or less	3 (1.0)	0 (0)	3 (1.9)
Some high school	40 (12.8)	11 (7.1)	29 (18.6)
High school graduate or GED	97 (31.1)	57 (36.5)	40 (25.6)
Some college or trade school	79 (25.3)	32 (20.5)	47 (30.1)
College graduate	93 (29.8)	56 (35.9)	37 (23.7)
Literacy			
S-TOFHLA *	29 ± 11	29 ± 11	29 ± 11
Minimum, maximum	0, 36	0, 36	0, 36
ANQ (no. of items correct) †	2.05 ± 1.34	2.19 ± 1.35	1.91 ± 1.31
Minimum, maximum	0, 4	0, 4	0, 4
eHEALS ‡	29.2 ± 6.5	29.5 ± 6.2	28.9 ± 6.8
Minimum, maximum	8, 40	8, 40	8, 40
Asthma severity at baseline			
No. with 1 hospitalization for asthma in past year	90 (29)	48 (31)	42 (27)
No. with 1 ED visit for asthma in past year	135 (43.3)	68 (43.6)	67 (42.9)
FEV ₁ (percent predicted)	68 ± 18	68 ± 19	68 ± 18
Minimum, maximum	15, 112	15, 112	16, 112

Characteristic	Total (N = 312)	No PA (n = 156)	PA exposed (n = 156)
Asthma control [§]	2.3 ± 1.2	2.2 ± 1.2	2.4 ± 1.2
Minimum, maximum	0.0, 5.4	0.0, 4.7	0.0, 5.4
Asthma-related quality of life	4.0 ± 1.5	4.0 ± 1.6	4.0 ± 1.5
Minimum, maximum	1.2, 7.0	1.2, 7.0	1.3, 7.0
Comorbidities			
Hypertension	167 (53.5)	84 (53.8)	83 (53.2)
Diabetes	65 (20.8)	36 (23.1)	29 (18.6)
Body mass index	33.9 ± 8.9	34.2 ± 9.3	33.6 ± 8.5
Minimum, maximum	16.3, 67.2	16.3, 67.2	19.3, 66.4
Ever smoked in the past	152 (48.7)	72 (46.2)	80 (51.3)
Current smoker	51 (16.3)	27 (17.3)	24 (15.4)
Depressive symptoms (CES-D) [¶]	124 (39.7)	59 (37.8)	65 (41.7)

AQLQ, Mini-Asthma Quality of Life Questionnaire; *CES-D*, Center for Epidemiologic Studies Depression Scale; *eHEALS*, eHealth Literacy Scale; *GED*, General Educational Development certificate; *S-TOFHLA*, Short Test of Functional Health Literacy in Adults. Data are expressed as frequency (%) for discrete variables and mean ± SD for continuous variables.

* S-TOFHLA is a reading comprehension test with a range from 0 to 36, with scores ≥ 23 considered adequate.²⁸

† The ANQ is a 4-item validated questionnaire of numerical concepts (arithmetic, percentage).²⁹

‡ eHEALS has 8 items, each ranked on a 5-level scale.³⁰

§ Asthma control is measured by the ACQ. It has 6 items, each scored from 0 to 6, with lower scores indicating better control.^{15,16} The minimally important clinical difference is 0.5. A score of >1.5 is considered inadequate control.¹⁶

|| The AQLQ^{17,31} is a 15-item questionnaire with a 7-point response scale that provides a mean summary score. A 0.5-unit change is considered clinically meaningful.¹⁷ The AQLQ has been shown to be a useful indicator of asthma-related quality of life in low-income adults.¹⁸

¶ The CES-D has a range from 0 to 60, with scores ≥ 16 suggestive of depressive symptoms or general distress.³²

TABLE II.

Number and percent of patients with hospitalizations, ED visits, and urgent office visits for asthma and any cause during study participation *

Treatment	ED visits		Hospitalizations		Urgent office visits		Total patients
	No. (%) of patients (any cause)	No. (%) of patients (asthma)	No. (%) of patients (any cause)	No. (%) of patients (asthma)	No. (%) of patients (any cause)	No. (%) of patients (asthma)	
UC	65 (42)	21 (13)	55 (35)	23 (15)	67 (43)	40 (26)	156
PA	72 (46)	33 (21)	45 (29)	19 (12)	59 (38)	25 (16)	156

* These data are reported at the patient level; "any cause" = asthma or nonasthma event.

TABLE III.

Asthma outcomes at baseline and changes over time, by treatment assignment in 312 adults with uncontrolled asthma

Outcome	Baseline, mean $\pm$ SD		Change in expected values at 6 mo from baseline (95% CI)		Difference between groups at 6 mo (95% CI)		Change in expected values at 12 mo from baseline (95% CI)		Difference between groups at 12 mo (95% CI)	
	PA (n = 156)	UC (n = 156)	PA	UC			PA	UC		
Asthma control [*]	2.23 $\pm$ 1.30	2.04 $\pm$ 1.22	-0.16 (-0.42 to 0.07)	-0.10 (-0.35 to 0.16)	-0.07 (-0.43 to 0.28)		-0.45 (-0.67 to -0.21)	-0.26 (-0.53 to -0.01)	-0.18 (-0.54 to 0.17)	
Asthma-related quality of life [†]	4.0 $\pm$ 1.5	4.0 $\pm$ 1.6	0.12 (-0.09 to 0.34)	0.28 (0.07 to 0.49)	-0.16 (-0.43 to 0.13)		0.32 (0.05 to 0.57)	0.40 (0.14 to 0.65)	-0.08 (-0.44 to 0.27)	
ED visits (rate per 6 mo)	1.20 $\pm$ 3.54	0.78 $\pm$ 1.38	-0.66 (-1.26 to -0.06)	-0.42 (-0.66 to -0.24)	-0.24 (-0.90 to 0.42)		-0.90 (-1.56 to -0.42)	-0.42 (-0.72 to -0.06)	-0.48 (-1.20 to 0.12)	
Hospitalizations (rate per 6 mo)	0.60 $\pm$ 2.10	0.60 $\pm$ 1.62	-0.36 (-0.72 to -0.12)	-0.42 (-0.72 to -0.12)	0.02 (-0.42 to 0.90)		-0.30 (-0.72 to -0.01)	-0.42 (-0.72 to -0.12)	0.06 (-0.42 to 0.54)	
Urgent office visits (rate per 6 mo)	0.48 $\pm$ 1.62	0.66 $\pm$ 1.86	-0.01 (-0.36 to 0.36)	-0.42 (-0.72 to -0.06)	0.36 (-0.12 to 0.90)		-0.24 (-0.54 to 0.06)	-0.42 (-0.72 to -0.12)	0.18 (-0.24 to 0.60)	
Risk of prednisone bursts	0.27 $\pm$ 0.45	0.29 $\pm$ 0.45	0.09 (-0.01 to 0.20)	0.09 (-0.02 to 0.20)	-0.001 (-0.15 to 0.15)		-0.01 (-0.11 to 0.09)	-0.06 (-0.16 to 0.04)	0.05 (-0.09 to 0.20)	

AQLQ: Mini-Asthma Quality of Life Questionnaire.

Models adjusted for clinical site, primary language, specialty vs primary care setting, age, skills supporting asthma management, social support, exposure to violence, trust of medical system, current smoking status, depression severity (CES-D score³²), and asthma severity. No estimates in 21 bootstrap samples in the model for hospitalizations. No estimates in 53 bootstrap samples in the model for urgent visits.

^{*}The ACQ has 6 items, each scored from 0 to 6, with lower scores indicating better control.^{15,16,33}

[†]The AQLQ is a 15-item questionnaire^{17,18,31,34} and it is scored on a 1–7 scale, with higher scores indicating better asthma-related quality of life. The AQLQ is a useful indicator of asthma-related quality of life in low-income adults.¹⁶ For both ACQ and AQLQ, a within-person change of at least 0.5 points is considered clinically meaningful.^{15,16}