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Glenn Flores, Christina Bridon, Sylvia Torres, Ruth Perez, Tim Walter, Jane Brotanek, Hua Lin and Sandy Tomany-Korman

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Improving Asthma Outcomes in Minority Children: A Randomized, Controlled Trial of Parent Mentors

WHAT'S KNOWN ON THIS SUBJECT: Asthma disproportionately affects minorities, but few studies have evaluated interventions that target minority children with asthma, and none has evaluated the effects of PMs on asthma outcomes for minority children.

WHAT THIS STUDY ADDS: For minority children with asthma and their families, PMs can reduce wheezing, asthma exacerbations, ED visits, and missed parental work days while improving parental self-efficacy. These outcomes can be achieved at a reasonable cost, with net cost savings for high participants.

AUTHORS: Glenn Flores, MD,[a,b] Christina Bridon, BA,[a,b] Sylvia Torres, BA,[c] Ruth Perez, BA,[d] Tim Walter, BA,[e] Jane Brotanek, MD, MPH,[a,b] Hua Lin, PhD, MS,[a] and Sandy Tomany-Korman, MS[f]

[a]Division of General Pediatrics, Department of Pediatrics, UT Southwestern Medical Center, Dallas, Texas; [b]Division of General Pediatrics, Children's Medical Center, Dallas, Texas; [c]Medical College of Wisconsin, Milwaukee, Wisconsin; [d]Center for Urban Population Health, Aurora-Sinai Hospital, Milwaukee, Wisconsin; [e]Shorewood, Wisconsin; and [f]Signature Science, LLC, Austin, Texas

KEY WORDS

asthma, minority groups, children, African-American, Hispanic, randomized, controlled trials

ABBREVIATIONS

ED—emergency department
RCT—randomized, controlled trial
PM—parent mentor
PedsQL—Pediatric Quality of Life Inventory 4.0 Generic Core Scales
QoL—quality of life
PACQLQ—Paediatric Asthma Caregiver's Quality of Life Questionnaire
PAMSES—Parent Asthma Management Self-efficacy Scale
ICER—incremental cost-effectiveness ratio
ITT—intention-to-treat
OR—odds ratio
CI—confidence interval

This study was presented in part as a platform presentation in the American Academy of Pediatrics Presidential Plenary of the 2008 annual meeting of the Pediatric Academic Societies (May 4, 2008; Honolulu, HI); as platform presentations at the 2008 annual meetings of AcademyHealth (June 9, 2008; Washington, DC) and the American Public Health Association (October 27, 2008; San Diego, CA); and as a late-breaking poster at the 2008 annual meeting of the American Academy of Allergy Asthma & Immunology (March 18, 2008; Philadelphia, PA).

This trial has been registered at www.clinicaltrials.gov (identifier NCT00800020).

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Address correspondence to Glenn Flores, MD, UT Southwestern Medical Center, Division of General Pediatrics, Department of Pediatrics, 5323 Harry Hines Blvd, Dallas, TX 75390. E-mail: glenn.flores@utsouthwestern.edu

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abstract

OBJECTIVE: Because asthma disproportionately affects minorities, we evaluated the effects of parent mentors (PMs) on asthma outcomes in minority children.

METHODS: This randomized, controlled trial allocated minority asthmatic children to the PM intervention or traditional asthma care. Intervention families were assigned PMs (experienced parents of asthmatic children who received specialized training). PMs met monthly with children and families at community sites, phoned parents monthly, and made home visits. Ten asthma outcomes and costs were monitored for 1 year. Outcomes were examined by using both intention-to-treat analyses and stratified analyses for high participants (attending ≥25% of community meetings and completing ≥50% of PM phone interactions).

RESULTS: Patients were randomly assigned to PMs ($n = 112$) or the control group ($n = 108$). In intention-to-treat analyses, intervention but not control children experienced significantly reduced rapid-breathing episodes, asthma exacerbations, and emergency department (ED) visits. High participants (but not controls or low participants) experienced significantly reduced wheezing, asthma exacerbations, and ED visits and improved parental efficacy in knowing when breathing problems are controllable at home. Mean reductions in missed parental work days were greater for high participants than controls. The average monthly cost per patient for the PM program was $60.42, and net savings of $46.16 for high participants.

CONCLUSIONS: For asthmatic minority children, PMs can reduce wheezing, asthma exacerbations, ED visits, and missed parental work days while improving parental self-efficacy. These outcomes are achieved at a reasonable cost and with net cost savings for high participants. PMs may be a promising, cost-effective means for reducing childhood asthma disparities. *Pediatrics* 2009;124:1522–1532

Childhood asthma disproportionately affects minority children. The prevalence of asthma in US children is 18.7% in Puerto Rican children, 12.5% in African-American children, and 7.7% in white children.[1] African-American children have an annual asthma hospitalization rate of 57 per 10 000 children, more than triple that of white children, at 16 per 10 000.[2] African-American children are 3 times more likely than white children to seek asthma care in the emergency department (ED).[2] Asthma mortality among African-American children, at 10.1 per million, is almost 5 times higher than for white children, at 2.2 per million.[2] Multiple studies have documented that minority children with asthma frequently receive an inferior quality of medical care.[3–9] In addition, the prevalence, morbidity, and mortality of childhood asthma are greatest in the inner city.[10] These disparities are particularly striking in light of declines in hospitalizations and deaths for most other childhood conditions and recent advances in asthma treatment.

Although asthma disproportionately affects urban minority children, little is known about effective interventions for improving asthma outcomes in this population. We therefore conducted a randomized, controlled trial (RCT) to determine whether parent mentors (PMs) are more effective than traditional asthma care in improving asthma outcomes for minority children.

METHODS

Participants

This RCT enrolled participants between February 2004 and May 2007 from a consecutive series of African-American and Latino children 2 to 18 years old who had a primary diagnosis of asthma and were seen in EDs and inpatient wards of the 4 hospitals that provide care to almost all children with asthma in Milwaukee, Wisconsin. Eligibility criteria included that the child (1) be 2 to 18 years old, (2) be African-American or Latino by parent identification, (3) reside in a Milwaukee zip code, and (4) have asthma as the primary ED or admitting diagnosis. Exclusion criteria were (1) significant comorbidities (other pulmonary conditions, cardiopathologies, renal abnormalities, diabetes, or epilepsy) that might lead to ED visits or hospitalizations, and (2) current enrollment in another asthma study/program.

Baseline Assessment

The child's primary caregiver (hereafter referred to as "parent") completed 2 previously piloted enrollment questionnaires, both orally administered by bilingual research assistants. The first questionnaire consisted of 12 multiple-choice questions regarding parent and household sociodemographics. The second questionnaire, addressing children's characteristics, included 30 open-ended, multiple-choice, and yes/no questions regarding sociodemographics, health care, and asthma. English proficiency was determined by asking parents to rate how well they and their child spoke English by using the following choices: very well, well, not very well, and not at all. Responses other than "very well" were classified as limited English proficiency. The question and response choices were taken verbatim from the English proficiency item used by the US Census.[11]

Randomization

Participants were randomly assigned to the PM intervention or control group by using SAS 9.1.3 (SAS Institute, Cary, NC). The control group received no intervention other than traditional asthma care. Participants and families who were assigned to the intervention were assigned to PMs, in addition to continuing traditional asthma care. PMs were recruited from the Children's Hospital of Wisconsin Asthma/Allergy Clinic and were experienced African-American or Latino parents of children who have asthma and resided in the same communities as participants. PMs were matched with intervention families by race/ethnicity, primary language spoken at home, and (whenever possible) zip code, to maximize matching by socioeconomic status, educational attainment, and other factors. The Spanish proficiency of bilingual PMs was confirmed by bilingual research assistants by (1) asking the parents whether they considered themselves fluent in Spanish, and 2) assessing conversational Spanish fluency by asking PM candidates to provide detailed answers to several questions about childhood asthma in Spanish. Six of 9 PMs were African-American and 3 were Latina.

Intervention

PMs received an intensive 2½-day training session led by a nurse asthma specialist and program coordinator. Training sessions and the 73-page training manual (available in English and Spanish) focused on (1) why asthma is such an important issue for American children, (2) sharing experiences on caring for an child with asthma, (3) keeping children with asthma out of hospitals, (4) details (in lay terms) regarding the PM intervention and study, (5) asthma basics, (6) asthma medications and triggers, (7) regular and follow-up appointments, (8) cultural issues that affect asthma care, and (9) being a successful PM. In addition, PMs received training and resources on insurance programs for uninsured children, locations of free clinics, medication and equipment teaching sheets, and creating reminder calendars for health care provider appointments. PMs also received training and resource manuals on assisting families with unmet needs for health insurance, housing,

food, and other social concerns. English and Spanish versions of the PM training manual are available online at http://www4.utsouthwestern.edu/ParentMentor/. A 34-item test to assess PM knowledge revealed a mean ± SD pretraining score of 77.7% ± 5.0% and mean posttraining score of 89.9% ± 5.0%, a significant increase ($P < .0001$).

PMs were instructed that they would augment children's asthma care by being peer counselors, family advocates, and parent resources collaborating with the clinical team to enhance children's asthma management. PMs met monthly with the study nurse to discuss issues that arose with participants and families. For intervention families, the initial PM contact was a home visit within 3 days of the child's ED visit or hospitalization, including completion of baseline surveys and a contact information form. Thereafter, PMs met monthly with assigned children and families at a community learning center, Boys and Girls Club, church, or family resource center. Meetings included asthma education, meals, opportunities for children and families to interact socially, and the potential for social networking and peer support; a total of 57 meeting were held during the course of the study, with separate meetings at separate venues for the African-American and Latino participants. The pediatric asthma educator gave various informative presentations on 15 topics and answered questions from PMs and participants. PMs telephoned parents monthly until 1 year after the initial ED visit or hospitalization and made second home visits 6 months after the initial ED visit or hospitalization. For families without telephone access, PMs conducted home visits to collect data. PMs were available by telephone to intervention families 24 hours/day (with telephone backup by the asthma nurse) to answer questions, clarify issues, or refer families to appropriate health care providers. In the first home visit and subsequent parent contacts, PMs reviewed each area of emphasis from the initial training session.

Control Group

Control children continued receiving their usual pediatric asthma care. As with intervention families, they were contacted monthly by a blinded research assistant to evaluate outcomes. All families received an initial $50 participation incentive and $10 for each subsequent participation month.

Outcome Measures

A research assistant who was blinded to group allocation assessed 10 outcomes for 12 months by using standardized telephone interview methods with parents. Frequency of the child's symptoms and asthma exacerbations in the previous month were assessed monthly through parent self-report and have been shown to correlate with health care use and health status.[12] Missed school and work days in the previous month were assessed monthly by parental report. Scores on the Pediatric Quality of Life Inventory 4.0 Generic Core Scales (PedsQL) were assessed monthly. This 23-item instrument measures parent-reported health-related quality of life (QoL), by using a 5-point scale (from 0 = never a problem to 4 = almost always a problem).[13] Items are reverse-scored and linearly transformed on a scale from 0 to 100, with higher scores indicating better QoL.[13] PedsQL is valid and reliable and correlates with morbidity and illness burden.[13] Scores on the Pediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ) were assessed monthly. The PACQLQ measures problems that parents experience as a result of their child's asthma. It consists of 13 questions with 7-point response options (1 = severe impairment and 7 = no impairment); has excellent reliability, responsiveness, and validity[14,15]; and is available in 9 different Spanish versions that are customized to specific subgroups.[16] Higher PACQLQ scores indicate better QoL.

ED visits for asthma were assessed monthly by parent self-report and confirmed by medical record review and use of a computerized surveillance system that tracks 1500 children with asthma in Milwaukee. Asthma hospitalizations were assessed monthly by parental report and periodic monitoring of medical records and inpatient admission logs. Scores on the Parent Asthma Management Self-efficacy Scale (PAMSES) were assessed at baseline and study end point (month 12 of follow-up). PAMSES consists of 13 Likert scale items on a 5-point scale (1 = not at all sure and 5 = completely sure) that were designed to measure parent self-efficacy in preventing and managing children's asthma attacks, and it is reliable and valid.[17] Overall PAMSES scores can range from 13 to 65, with higher scores indicating higher parental self-efficacy.[17] Scores on the Asthma Satisfaction Survey were assessed at baseline and study end point. This 10-item questionnaire addresses parental satisfaction with children's asthma care; satisfaction for each item is rated on a 5-point Likert scale (1 = poor and 5 = excellent), and total scores can range from 10 to 50, with higher scores indicating higher satisfaction.[18]

Cost outcomes included costs of personnel, PM stipend payments, supplies, PM training sessions, and monthly meetings with PMs and intervention participants. Costs of care were calculated by using differences between the intervention and control groups in asthma-related charges, including ED and physician visits, hospitalizations, home care, medical equipment, and other asthma-related claims. The cost-effectiveness evaluation used asthma-related medical

costs from the Pediatric Health Information System, a database of inpatient and selected outpatient data from North American pediatric hospitals that are affiliated with the Child Health Corporation of America (Shawnee Mission, Kansas). The incremental cost-effectiveness ratio (ICER) was computed by subtracting total costs for the control group from those for the intervention group, then dividing by the mean difference between the control and intervention groups in reduction of asthma exacerbation days from the first month to the final month of follow-up. Total costs for the intervention group included program costs, direct medical costs, and indirect income costs from missed work days. Program costs were estimated by summing costs for personnel, PM stipends, training, and monthly meetings. Direct medical costs included charges for ED visits and hospitalizations. ICU stay charges were not included because of multiple missing values. Person-level indirect costs of missed work days were obtained by multiplying employed caregivers' missed worked days by the midpoint of the family's income. Total costs for the control group included only direct and indirect medical costs.

Analyses

SAS 9.1.3 for Windows was used for all analyses. χ^2 and Wilcoxon tests were performed to examine baseline intergroup differences.

In addition to intention-to-treat (ITT) analyses, all outcomes were examined by using stratified per-protocol analyses, given the anticipated high attrition rates (because this was a community-based study of impoverished, underserved, urban populations that move frequently) and the focus on counting events appropriate to actually receiving the intervention.[19] Intervention participants were stratified into high-participation and low-participation groups, depending on the extent to which they received PM intervention components. High participants were defined as those who attended ≥25% of scheduled monthly community meetings and completed ≥50% of monthly PM telephone calls; the remaining participants were classified as low participants.

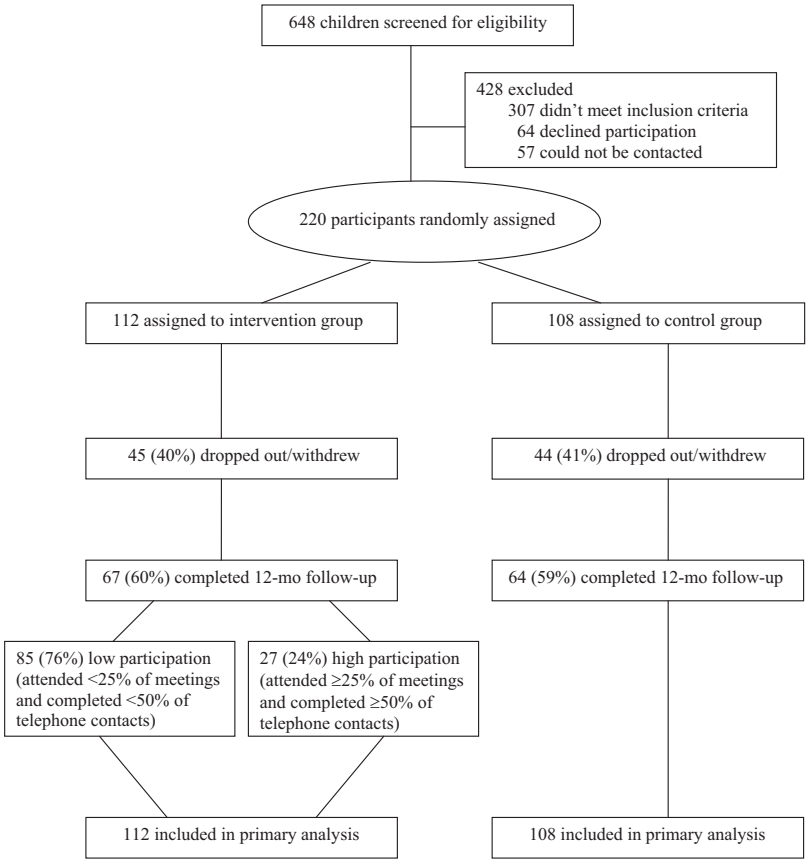

FIGURE 1
Participant flow diagram.

Changes in asthma outcomes from baseline to the study end point (the final 12-month follow-up assessment) were analyzed by using the Wilcoxon, Wilcoxon's paired signed rank, and Fisher's exact tests. For asthma exacerbations, time trends were examined by plotting the mean number of exacerbations over time, followed by logarithmic regression line fitting.

For cost analyses, the percentage effort that project personnel devoted to program implementation was estimated to be 30% for the asthma nurse educator, 60% for the program coordinator, and 15% for each research assistant. Multivariable analyses were performed by using general linear models with nonlinear link functions to examine time trends. Generalized estimating equations adjusted for multiple measurements and family clustering (ie, >1 child per family). Covariates in multivariable models included group assignment, time since study entry, and a time-by-group interaction term.

Using a power = 80%, $\alpha = .05$, $\delta =$ 20%, and an anticipated attrition rate of 40%, we calculated that a total sample size of 220 would detect differences between the intervention and control groups in the co-primary outcomes of at least 2 asthma exacerba-

tions per year, 4 wheezing episodes per year, 0.4 missed school days per year, 0.7 ED visits per year, a 17% difference in the asthma hospitalization rate, $318 in asthma care charges, 0.16 points on the PedsQL, and 0.3 points on the PACQLQ and PAMSES.

Institutional Review Board Approval

The study protocol was approved by the institutional review boards of Children's Hospital of Wisconsin, Aurora Health Care, and Wheaton Franciscan Health Care. Written informed consent and child assent (when indicated) were obtained for all participants.

RESULTS

Study Population

Of 648 families who were screened for eligibility, 428 were excluded because of ineligibility, parents' declining participation, or no response to subsequent contacts (Fig 1). A total of 220 participants were randomly assigned to the intervention (n = 112) or control group (n = 108), with similar dropout/withdrawal rates in both groups; dropouts and withdrawals occurred at a fairly constant rate for both groups across the 12-month follow-up period. Because of institutional review board constraints, the reasons for dropout and withdrawal could not be determined. The families who dropped out or withdrew were more likely than those who completed the study to be African-American (91% vs 76%, respectively; P = .01) and born in the United States (96% vs 85%; P = .01), and less likely to pursue education beyond high school (17% vs 31%; P = .02) or be married and living with the spouse (7% vs 23%; P < .01), but did not differ in age, gender, English proficiency, employment status, or family income. There were no significant differences between completers and

TABLE 1 Baseline Sociodemographic Characteristics of Study Parents (N = 220)

Characteristic	Control (N = 108)	Intervention (N = 112)	P
Age, mean ± SD, y	32.5 ± 9.1	31.3 ± 7.6	.33
Female, %	90.7	91.7	.93
Education beyond high school, %	27.8	23.2	.18
Married, living with spouse, %	18.5	15.2	.75
Race/ethnicity, %			.46
African-American	83.3	79.5	
Latino	16.7	20.5	
Limited English proficiency, %	12.0	13.4	.76
Employed full-time, %	37.0	42.9	.66
Born in United States, %	90.6	89.4	.60
Annual combined family income, %			.23
$0–$2500	17.6	23.4	
$2501–$5000	14.8	12.6	
$5001–$7500	12.0	8.1	
$7501–$17 500	19.4	26.1	
$17 501–$25 000	14.8	11.7	
$25 001–$35 000	11.1	12.6	
$35 001–$45 000	3.7	4.5	
$45 001–$60 000	0.0	0.9	
$60 001–$75 000	1.9	0.0	
More than $75 000	4.6	0.0	

TABLE 2 Baseline Characteristics of Study Children (N = 220)

Characteristic	Control (N = 108)	Intervention (N = 112)	P
Age, mean ± SD, y	7.3 ± 4.4	7.1 ± 4.3	.72
Female, %	47.2	40.2	.29
Limited English proficiency, %	24.1	31.3	.23
Family member in household smokes, %	36.7	46.6	.31
Has primary care provider, %	95.4	89.3	.08
Health status, %			.80
Excellent	12.0	9.8	
Very good	24.1	18.8	
Good	34.3	39.3	
Fair	25.9	26.8	
Poor	3.7	5.4	
Asthma severity, %			.40
Mild intermittent	25.0	28.6	
Mild persistent	17.6	24.1	
Moderate persistent	13.0	13.4	
Severe persistent	44.4	33.9	
Health insurance coverage, %			
Public	79.6	86.6	.52
Private	16.7	9.8	
None	2.8	2.7	
Other[a]	0.9	0.9	
Has asthma specialist, %	15.2	17.9	.73
Has asthma care plan, %	48.1	39.6	.45
Takes prescribed medications, %	94.4	95.5	.70
ED most likely place to be taken for asthma care, %	61.9	64.3	.31
Asthma attacks in previous year, mean ± SD	13.9 ± 42.7	10.4 ± 36.0	.53
Doctor visit for asthma in previous year, mean ± SD	6.7 ± 10.8	4.9 ± 5.8	.13
ED visit for asthma in previous year, mean ± SD	3.4 ± 3.7	3.1 ± 3.4	.49
Hospitalizations for asthma in previous year, mean ± SD	0.6 ± 1.1	1.0 ± 1.9	.11
ICU for asthma in previous year, mean ± SD	0.10 ± 0.48	0.10 ± 0.44	.74
Asthma attacks in previous month, mean ± SD	2.2 ± 4.1	1.8 ± 4.0	.41
Daytime asthma symptoms in previous month, mean ± SD	10.7 ± 13.8	14.1 ± 19.4	.13
Nighttime asthma symptoms in previous month, mean ± SD	12.7 ± 14.4	11.4 ± 17.5	.56
Missed school days in previous year, mean ± SD	8.1 ± 15.5	6.8 ± 10.9	.47
Parental missed work days in previous year, mean ± SD	7.3 ± 14.4	4.8 ± 9.9	.17

[a] Includes combination of public and private insurance.

drop-outs in any of the 22 childhood sociodemographic or asthma characteristics examined.

A total of 67 intervention-group and 64 control-group participants completed the final 12-month follow-up interview. In the intervention group, 85 PM group participants had low participation and 27 had high participation.

No significant baseline intergroup differences existed for any parent (Table 1) or child (Table 2) characteristic. Of note, the annual combined family income was $5000 or less for approximately one third of households and $17 500 or less for approximately two thirds of households. Study children at baseline collectively experienced substantial asthma morbidity, including averaging approximately 1 asthma symptom daily; 1 exacerbation monthly; and 7 missed school days, 6 missed parental work days, 3 ED visits, and 1 hospitalization yearly (these collective data are not shown in Table 2).

There were no significant differences among high participants, low participants, and control subjects in asthma severity categories ($P = .48$ for the 3-way comparison and $P = .47$ for the comparison between high and low participants). In addition, there were no significant baseline differences among the 3 groups for 13 of the 14 asthma outcome measures. The only significant difference noted was for wheezing episodes in the previous month, experienced by 92.0% of high participants, 62.9% of low participants, and 73.3% of control subjects ($P = .02$).

TABLE 3 ITT Analysis of Differences Between Baseline and End Point (12-Month Follow-up) for Study Outcomes Among Control Subjects ($N = 108$) and Intervention-Group Children ($N = 112$)

Outcome	Baseline, Mean (95% CI)	End Point, Mean (95% CI)	*P*
Wheezing episode[a]			
Control group	73.30 (63.70 to 82.80)	61.20 (51.40 to 71.00)	.08
Intervention group	70.70 (60.70 to 80.80)	61.70 (51.70 to 71.70)	.21
Coughing episode[a]			
Control group	100	71.30 (62.60 to 80.00)	<.01
Intervention group	100	64.30 (55.30 to 73.30)	<.01
Difficulty-breathing episode[a]			
Control group	76.70 (67.60 to 85.90)	55.10 (45.10 to 65.10)	<.01
Intervention group	78.00 (68.90 to 87.20)	58.50 (48.40 to 68.70)	<.01
Rapid-breathing episode[a]			
Control group	54.70 (43.90 to 65.40)	45.90 (35.90 to 56.00)	.24
Intervention group	57.30 (46.40 to 68.30)	41.50 (31.30 to 51.60)	.04
Chest-tightness episode[a]			
Control group	40.70 (30.10 to 51.30)	37.80 (28.00 to 47.50)	.68
Intervention group	43.90 (32.90 to 54.90)	44.70 (34.40 to 54.90)	.92
Asthma exacerbations			
Control group	2.30 (1.40 to 3.20)	1.60 (1.10 to 2.10)	.05
Intervention group	2.90 (1.70 to 4.00)	1.80 (1.00 to 2.60)	.01
Missed school days[b]			
Control group	1.90 (1.20 to 2.50)	0.80 (0.40 to 1.20)	<.01
Intervention group	2.20 (1.50 to 3.00)	1.00 (0.60 to 1.40)	.01
Missed parental work days[b]			
Control group	0.80 (0.30 to 1.30)	0.30 (0.02 to 0.50)	.01
Intervention group	1.50 (0.80 to 2.20)	0.60 (0.30 to 1.00)	.04
PedsQL score			
Control group	74.00 (69.40 to 78.50)	83.00 (74.10 to 91.90)	.02
Intervention group	72.30 (66.80 to 77.80)	82.30 (74.10 to 90.50)	.02
PACQLQ score			
Control group	5.10 (4.80 to 5.40)	5.70 (5.50 to 6.00)	.02
Intervention group	5.10 (4.70 to 5.50)	5.80 (5.30 to 6.20)	.04
ED visits for asthma			
Control group	0.30 (0.10 to 0.40)	0.10 (0.06 to 0.21)	.09
Intervention group	0.50 (0.20 to 0.70)	0.10 (0.06 to 0.22)	.03
Hospitalizations for asthma			
Control group	0.07 (0.01 to 0.13)	0.01 (−0.01 to 0.03)	.07
Intervention group	0.20 (0.00 to 0.40)	0.05 (0.01 to 0.10)	.37
Doctor visits for asthma			
Control group	1.00 (0.70 to 1.30)	0.70 (0.50 to 0.90)	.01
Intervention group	1.30 (1.00 to 1.60)	0.50 (0.30 to 0.70)	<.01
PAMSES score			
Control group	55.30 (54.00 to 56.60)	57.50 (55.00 to 60.00)	.07
Intervention group	55.20 (53.40 to 57.00)	58.30 (55.30 to 61.20)	.05
Asthma satisfaction survey score			
Control group	37.90 (36.30 to 39.50)	40.20 (37.50 to 42.90)	.19
Intervention group	39.10 (37.50 to 40.70)	41.00 (38.20 to 43.90)	.27

[a] Unit of evaluation is symptom episode in past month.
[b] In past month.

Outcomes

ITT Analyses

In ITT analyses, intervention but not control children experienced significant reductions in rapid-breathing episodes, asthma exacerbations, and ED visits (Table 3). Per-protocol analyses (Tables 4 and 5) revealed additional significant differences.

Asthma Symptoms

Those with high participation experienced significant reductions from baseline to study end point in wheezing, coughing, and difficulty-breathing episodes (Table 4). For all 3 outcomes, there was a difference of ~30 percentage points between baseline and end point means for high participants. No significant reductions in rapid breathing or chest tightness were noted for high participants. Control subjects experienced reduced coughing and difficulty breathing, and low participants

TABLE 4 Per-Protocol, Stratified Analysis of Differences Between Baseline and End Point (12-Month Follow-up) for Asthma Symptom Outcomes Among Control Subjects ($N = 108$) and Intervention-Group Children With Low ($N = 85$) and High ($N = 27$) Participation

Outcome[a]	Baseline, % (95% CI)	End Point, % (95% CI)	*P*
Wheezing episode			
Control subjects	73.3 (63.7–82.8)	61.2 (51.4–71.0)	.08
Low participation	62.9 (50.5–75.3)	62.3 (50.6–74.0)	.94
High participation	92.0 (84.5–105.5)	60.0 (39.4–80.6)	.01
Coughing episode			
Control subjects	100	71.3 (62.6–80.0)	<.01
Low participation	100	62.4 (51.8–72.9)	<.01
High participation	100	70.4 (52.0–88.8)	.01
Difficulty-breathing episode			
Control subjects	76.7 (67.6–85.9)	55.1 (45.1–65.1)	<.01
Low participation	74.2 (63.0–85.4)	58.0 (46.0–70.0)	.05
High participation	90.0 (75.6–104.4)	60.0 (39.4–80.6)	.03
Rapid-breathing episode			
Control subjects	54.7 (43.9–65.4)	45.9 (35.9–56.0)	.24
Low participation	54.8 (42.1–67.6)	40.6 (28.7–52.5)	.10
High participation	65.0 (42.1–87.9)	44.0 (23.1–64.9)	.17
Chest-tightness episode			
Control subjects	40.7 (30.1–51.3)	37.8 (28.0–47.5)	.68
Low participation	41.9 (29.3–54.6)	43.5 (31.5–55.5)	.86
High participation	50.0 (26.0–74.0)	48.0 (27.0–69.0)	.90

[a] Unit of evaluation is symptom episode in past month.

had significant reductions only in coughing.

Other Outcomes

High participants experienced significant reductions in asthma exacerbations (decrease from baseline mean to end-point mean: 3.0), missed school days (decrease from baseline mean to end-point mean: 2.9), missed parental work days (decrease from baseline mean to end-point mean: 2.6), and ED visits (decrease from baseline mean to end-point mean: 0.6), and significant improvements in PedsQL scores (increase from base-line mean to end-point mean: 15.9) (Table 5). For asthma exacerbations, a time-trend analysis (Fig 2) revealed that the decrease of 3 exacerbations from the baseline mean for high participants was significantly greater than exacerbation reductions among control subjects and low participants. Generalized estimating equation models showed both control subjects (odds ratio [OR]: 1.16; $P < .001$) and low participants (OR: 1.20; $P < .001$) had greater odds over time of asthma exacerbations than high participants. The mean reduction in missed parental work days also was significantly greater for high participants (OR: −3.3 [95% confidence interval (CI): −6.7 to 0.1]) than control subjects (OR: −0.4 [95% CI: −0.70 to −0.02]), but the reduction for low participants (OR: −0.4 [95% CI: −0.9 to 0.2]) did not differ significantly from that of control subjects.

Control subjects had reduced missed school and parental work days and improved PedsQL and PACQLQ scores, but low participants had no changes in any nonsymptom outcome (Table 5). No significant changes were observed for high participants in asthma hospitalizations or in PACQLQ, PAMSES, or asthma satisfaction scores. A significant improvement, however, was noted in the PACQLQ activity-related subscore, although control subjects and low participants also experienced improvements (Fig 3). In addition, 2 significant PAMSES subscale score changes were observed (Fig 4). High participants experienced significant improvements in parental self-efficacy in controlling serious breathing problems at home (although control subjects also did) and in the parent's knowing when a serious breathing problem is controllable at home.

Control children had 3 ICU admissions, and intervention-group children had 2 ICU admissions. Although the asthma nurse for the study regularly was asked questions at community meetings by PMs about assisting families with childhood asthma management, the asthma nurse never received any telephone calls from PMs regarding asthma management.

Costs and Cost-Effectiveness

The PM intervention was relatively inexpensive (Table 6), with an average monthly cost per patient of $60.42. Most monthly costs were for personnel; the next most expensive items were PM stipend payments and meeting costs. The intervention cost $120.84 per child for the first month and the final month of follow-up. The intervention group experienced savings of $361.48 for hospitalizations and $50.33 for ED visits. Income loss as a result of parental missed work days was similar for both groups ($4.36 difference). The mean reduction in asthma exacerbation days was 1.26 days for the intervention group and 0.78 for control subjects. The ICER for the intervention was −$597.10 per asthma exacerbation–free day gained, indicating a total cost savings for intervention participants.

The high-participation group experienced savings of $51.06 for asthma hospitalizations, $120.01 for ED visits, and $28.15 for missed parental work days. The ICER for the high participation group was −$46.16, indicating an overall cost savings.

DISCUSSION

This RCT revealed that a PM intervention for minority children with asthma can significantly reduce wheezing,

TABLE 5 Per-Protocol, Stratified Analysis of Differences Between Baseline and End Point (12-Month Follow-up) for Study Outcomes Among Control Subjects ($N = 108$) and Intervention-Group Children With Low ($N = 85$) and High ($N = 27$) Participation

Outcome	Baseline, Mean (95% CI)	End Point, Mean (95% CI)	*P*
Asthma exacerbations			
Control subjects	2.30 (1.40 to 3.20)	1.60 (1.10 to 2.10)	.05
Low participation	2.10 (1.30 to 2.90)	1.70 (0.70 to 2.60)	.10
High participation	5.20 (1.00 to 9.30)	2.20 (0.80 to 3.60)	.03
Missed school days[a]			
Control subjects	1.90 (1.20 to 2.50)	0.80 (0.40 to 1.20)	<.01
Low participation	1.70 (1.00 to 2.40)	1.00 (0.50 to 1.50)	.06
High participation	3.70 (1.50 to 5.90)	0.80 (0.30 to 1.40)	.03
Missed parental work days[a]			
Control subjects	0.80 (0.30 to 1.30)	0.30 (0.02 to 0.50)	.01
Low participation	1.00 (0.40 to 1.60)	0.80 (0.30 to 1.20)	.41
High participation	2.90 (0.50 to 5.30)	0.30 (−0.10 to 0.60)	.01
PedsQL score			
Control subjects	74.00 (69.40 to 78.50)	83.00 (74.10 to 91.90)	.02
Low participation	72.80 (66.30 to 79.30)	77.10 (66.60 to 87.70)	.64
High participation	70.60 (59.20 to 82.00)	86.5 (73.30 to 99.80)	.04
PACQLQ score			
Control subjects	5.10 (4.80 to 5.40)	5.70 (5.50 to 6.00)	<.01
Low participation	5.10 (4.60 to 5.50)	5.70 (5.50 to 6.00)	.07
High participation	5.20 (4.50 to 5.80)	5.90 (5.50 to 6.40)	.08
ED visits for asthma			
Control subjects	0.30 (0.10 to 0.40)	0.20 (0.06 to 0.21)	.09
Low participation	0.40 (0.11 to 0.63)	0.20 (0.04 to 0.24)	.20
High participation	0.70 (0.15 to 1.20)	0.10 (−0.02 to 0.26)	<.05
Hospitalizations for asthma			
Control subjects	0.20 (0.00 to 0.40)	0.02 (−0.01 to 0.03)	.07
Low participation	0.20 (0.00 to 0.40)	0.10 (0.00 to 0.10)	.38
High participation	0.10 (−0.10 to 0.30)	0.00 (−0.04 to 0.10)	.85
PAMSES score			
Control subjects	55.30 (54.00 to 56.60)	57.50 (55.00 to 60.00)	.05
Low participation	55.40 (53.30 to 57.60)	58.50 (52.60 to 64.30)	.05
High participation	54.50 (51.20 to 57.80)	58.10 (54.90 to 61.30)	.13
Asthma satisfaction survey score			
Control subjects	37.90 (36.30 to 39.50)	40.20 (37.50 to 42.90)	.19
Low participation	39.70 (37.80 to 41.60)	42.70 (37.40 to 48.00)	.18
High participation	37.20 (34.40 to 40.00)	39.60 (36.10 to 43.10)	.15

[a] In past month.

asthma exacerbations, ED visits, and missed parental work days, and improve parental self-efficacy in identifying serious breathing problems that are controllable at home, all at a net cost savings. This is the first RCT (to our knowledge) to examine the effects of PMs on asthma outcomes in minority children. Recent systematic reviews of RCTs of culture-specific asthma programs and self-management education programs by lay leaders for chronically ill patients revealed no published studies on PMs.[20,21]

Although no previous RCTs have evaluated PMs in childhood asthma or other chronic illnesses, 2 studies examined lay-worker interventions for asthma. A small pilot observational study of lay workers who made home visits and attended patients' clinic appointments indicated pre-to-post reductions in asthma ED and follow-up clinic visits.[22] An RCT of adults that compared clinic-based lay educators with nurses indicated comparable outcomes in health care visits, oral steroid courses, and patient satisfaction.[23] The only other published RCT of a PM-like program (to our knowledge) examined monthly home visits to first-time mothers of infants by trained volunteer community mothers.[24] Compared with standard support, the community mothers program resulted in increased infant immunization rates and reading to children and decreased inappropriate dietary practices.

Intervention children but not control subjects experienced significant reductions in rapid-breathing episodes, asthma exacerbations, and ED visits. Stratified, per-protocol analyses additionally revealed that high-intervention children but not control subjects or low-intervention children had reduced wheezing, asthma exacerbations, and ED visits; improved parental self-efficacy in recognizing serious breathing problems that are controllable at home; and greater reduction than control subjects in missed parental work days. For 4 additional outcomes, high participants and either control subjects or low participants experienced significant changes from baseline. Both high participants and control subjects had reduced missed school days and coughing and improved PedsQL scores, and both high and low participants had decreased difficulty breathing. For these 4 outcomes, larger sample sizes and multicenter studies may be required to determine definitively whether PMs can improve outcomes. No changes from baseline were observed for high participants in hospitalizations; rapid breathing; chest tightness; or PAMSES, PACQLQ, or physician satisfaction scores. Additional research is needed to examined whether changes in these outcomes might occur in larger studies or might be achieved only through quality improvement or nurse case management interventions.

For high participants, a motivating factor for more active participation in the intervention may have been the enhanced opportunity for improvement in the child's wheezing frequency. High-participant children were significantly more likely at baseline than low-participant and control children to have

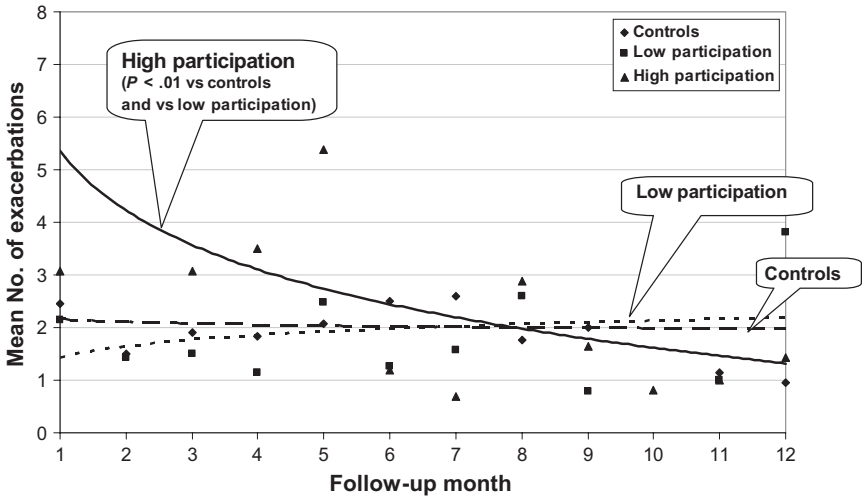

FIGURE 2
Time-trend lines for asthma exacerbations from baseline to study end point (12-month follow-up).

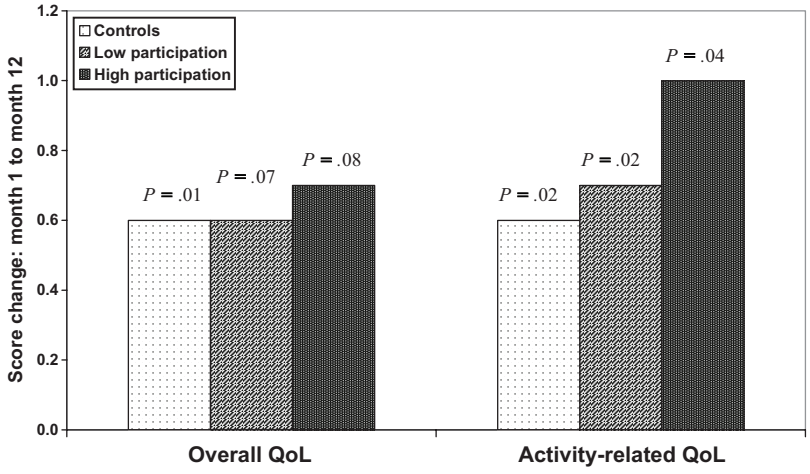

FIGURE 3
Changes in pediatric asthma caregiver's QoL scores (PACQLQ) from baseline to study end point (12-month follow-up).

had a wheezing episode in the previous month (Table 4). This greater likelihood of wheezing might have provided extra motivation for parents to seek assistance, support, and education through the PM program. In future work, we intend to examine parents' reasons for high and low participation to gain a greater understanding of participation characteristics and risk factors, as well as possible mechanisms for enhancing intervention participation.

Certain study limitations should be noted. The study was single- rather than double-blinded, but double-blinding was not possible because of immediate participant awareness of PM assignment. This study was performed in 1 Midwestern city, so findings may not necessarily generalize to other urban, suburban, or rural populations. Only African-American and Latino children were enrolled, so the results may not pertain to other races/ethnicities. Data were not collected on the number of calls to PMs by intervention parents or the call pattern over time. It was not possible to determine and disaggregate whether improvements in parental knowledge and asthma management behavior for the intervention group resulted from asthma educator presentations at the community meetings versus the peer mentor and family advocate influence of PMs (or some combination). The attrition rate was 40%, but this is comparable to attrition in other community-based studies of impoverished minority populations.[25,26] Comparison of dropouts/withdrawals with study completers indicates that future PM RCTs should focus special attention on retention strategies for parents who are African-American and US-born, head single-parent households, and have lower educational attainment.

Certain study strengths also should be noted. This is the first RCT to examine effects of PMs on asthma outcomes in minority children. Multiple clinical outcomes were examined, and several recommendations from recent systematic reviews were addressed.[20,21] The intervention had numerous characteristics of interventions that are successful in eliminating pediatric disparities, including the RCT design, blinding, appropriate comparison groups, and a community-based and culturally and linguistically sensitive approach.[26]

Although additional studies and larger trials are needed to evaluate the impact of PMs on disparities in asthma and other pediatric conditions, we believe that the findings of this RCT have several potential implications for research, practice, and policy. A PM intervention for minority children with asthma can be an effective means of reducing wheezing, asthma exacerbations, ED visits, and missed parental work days while improving parental self-efficacy in recognizing serious breathing problems that are controllable at home, all at a fairly reasonable cost and with net cost savings. Additional benefits include providing PM employment in urban, impoverished,

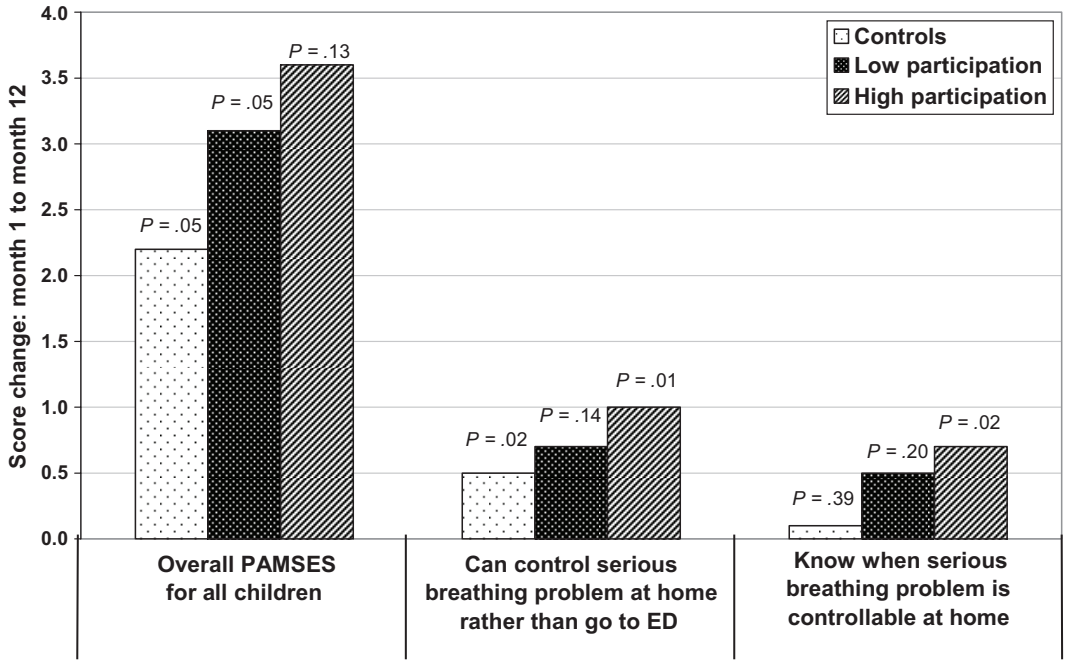

FIGURE 4
Changes in parental self-efficacy score (PAMSES) from baseline to study end point (12-month follow-up).

TABLE 6 Program-Related Costs

Item	Quantity	Unit Cost, $	Average Monthly Cost Per Patient, $
Personnel	1.2 FTE	4555.00/mo	40.67
Payments to PMs	9 mentors	88.00 per mentored family per mentor	16.81
1-time supplies	—	78.94/mo	0.70
3-d training sessions	8 sessions	102.00 per training session	0.18
Monthly meetings	55 meetings	120.05 per meeting	1.49
Bus tickets		63.00/mo	0.56
Total			**60.42**

FTE indicates full-time equivalent.

minority communities, which frequently experience high unemployment, and empowering underserved communities to address their children's health and health care. The results also suggest that a PM program is a cost-effective approach to improving asthma outcomes for minority children who are covered by Medicaid. PM interventions—and analogous peer mentor interventions for adults—might potentially be effective, low-cost approaches to eliminating racial/ethnic disparities for other chronic conditions.

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Dr Flores had full access to all study data and takes responsibility for the data integrity and accuracy of the data analysis and was solely responsibly for study concept and design, critical revision of the manuscript for important intellectual content, and obtaining funding. Dr Flores, Ms Bridon, Ms Torres, Ms Perez, and Mr Walter were responsible for acquisition of data; Drs Flores and Lin and Ms Tomany-Korman were responsible for analysis and interpretation of data; Dr Flores, Ms Bridon, and Dr Lin were responsible for drafting of the manuscript; Dr Lin and Ms Tomany-Korman were responsible for statistical analysis; Drs Flores and Brotanek were responsible for administrative, technical, or material support; and Dr Flores and Ms Bridon were responsible for study supervision. The funding agencies had no involvement in the design or conduct of the study; analysis or interpretation of the data; or preparation, review, or approval of the manuscript.

Improving Asthma Outcomes in Minority Children: A Randomized, Controlled Trial of Parent Mentors

Glenn Flores, Christina Bridon, Sylvia Torres, Ruth Perez, Tim Walter, Jane Brotanek, Hua Lin and Sandy Tomany-Korman

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