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CLUSTER RANDOMIZED TRIAL SHOWS TELEPHONE PEER- COACHING FOR PARENTS REDUCES CHILDREN'S ASTHMA MORBIDITY

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Abstract

Background—Childhood asthma morbidity remains significant, especially in low-income children. Most often, asthma management is provided by the child's primary care provider.

Objective—To evaluate if enhancing primary care management for persistent asthma with telephonic peer-coaching for parents reduced asthma impairment and risk in children 3–12 years old.

Methods—Over 12-months peer-trainers provided parents with asthma-management training via telephone (median 18 calls) and encouraged physician partnership. The intervention was evaluated in a cluster-randomized trial of 11 intervention and 11 usual care pediatric practices (462 and 486 families respectively). Patient-outcomes were assessed by telephone interviews at 12- and 24-months conducted by observers blinded to intervention assignment and compared using mixed effects models controlling for baseline values and clustering within practices. In a planned subgroup analysis, we examined heterogeneity of intervention effect by insurance type (Medicaid vs. other).

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Results—After 12-months, intervention participation resulted in 20.9 more symptom-free days/child (95% confidence interval [CI] 9.1 to 32.7) than the control group, and there was no difference in ED visits. After 24-months, ED visits were reduced (difference in mean visits/child 0.28, 95%CI –0.5 to –0.02), indicating a delayed intervention effect. In the Medicaid subgroup, after 12-months, intervention participation resulted in 42% fewer ED visits (difference in mean visits/child –0.50, 95%CI –0.81 to –0.18), and 62% fewer hospitalizations (difference in mean hospitalizations/child –0.16, 95%CI –0.30 to –0.014). Reductions in healthcare use endured through 24-months.

Conclusions—This pragmatic telephone-based peer-training intervention reduced asthma impairment. Asthma risk was reduced in children with Medicaid insurance.

Trial Registration—ClinicalTrials.gov: NCT00860834 (<http://clinicaltrials.gov/ct2/show/NCT00860834?cond=Asthma&rank=622>)

Keywords

Asthma; randomized controlled trial; self-management; peer-training; telephone care

INTRODUCTION

Childhood asthma affects one in ten children in the United States (U.S.), with greater morbidity in low-income children (the high-risk population).(1) Daily asthma symptoms limit activities and disease flare-ups result in missed school, missed work, Emergency Department (ED) visits and hospitalizations. The estimated direct annual cost of asthma is more than \$15 billion. (2)

The child's primary care physician (PCP) usually provides asthma care.(3) National guidelines recommend a collaborative partnership between the family and the PCP with visits at least every 6-months to monitor and adjust the treatment plan as needed.(4) However, many parents find managing their child's asthma to be demanding and stressful, (5) and manage asthma outside of the clinical care system,(2) with few office visits to optimize preventive treatment. (6–8) Although many interventions to improve asthma management have been developed, both patient- and provider-focused, few have been evaluated for impact on patient outcomes in large randomized controlled trials. Of those interventions that have been rigorously evaluated, most failed to reduce symptom days (median 0 days, range 0–24) or ED visits (median 6.5% reduction, range 0 to 62%), and all failed to reduce hospitalizations.(9–23) Pragmatic approaches to support parents in asthma management are needed.

Building on our prior work using lay coaches to provide tailored education and social support for parents to reduce childhood asthma morbidity,(24–26) we developed a scalable, theory-based intervention delivered exclusively by phone and integrated into primary care. We hypothesized the intervention would improve asthma outcomes for the child by improving the parent's asthma management and partnership with the PCP. The objective of this randomized controlled trial was to test this hypothesis in both the general and high-risk asthma populations. To minimize contamination of PCP care we chose a cluster randomized

design, randomizing PCP practices, and assessing the intervention effect on patient-level outcomes.

METHODS

Design and Setting

The PARTNER intervention was evaluated in a cluster randomized design, stratified on practice location (urban or suburban) to minimize imbalance of socio-demographic factors across study groups. Clusters were primary care pediatric practices in the St. Louis metropolitan area. For the primary analysis, we examined the intervention effect after 12-months on three patient-level outcomes: 1) symptom-free days (SFDs) for the child, 2) the parent's disease-specific quality of life score (pQOL), and 3) the number of asthma-related emergency department/urgent care visits (ED visits). Participants were followed for 24-months and reassessed to identify sustained and/or late intervention effects. The study protocol was approved by the institutional review board at Washington University.

Participants

Eligibility

Clusters: Eligible practices were community-based primary care practices providing asthma care to 40 children.

Participants: Eligible families within study practices had a child between 3 and 12 years old with a physician diagnosis of asthma, and in the past year had been prescribed a daily controller medications or had 1 acute exacerbation that required an unscheduled office visit, a course of oral steroids, an ED visit or hospitalization, or had persistent asthma symptoms.(4)

Recruitment and Randomization—All potentially eligible practices received a written invitation to participate. The Principal Investigator (PI) met with practice physicians to explain study participation requirements and obtain written consent from one PCP/practice. Each practice used billing data to provide the study team with a list of potentially eligible families (those who had received asthma care in the past 2 years, usually identified by ICD9 493.XX). Subsequently, the practice was randomized to one of two study groups by the statistician using a stratum-specific randomization scheme developed using computer generated random numbers. Following randomization, study investigators, PCPs and parents were aware of study group assignment. All potentially eligible families were contacted by the study team by mail and phone to invite participation, assess eligibility, and complete the consent process. Parents who provided written consent and completed the baseline interview were enrolled in the study. Each family was paid \$20 for the initial interview and \$25 subsequent interviews and each practice was paid \$100 to compensate for administrative time required for study tasks.

After 12 months with 350 families recruited, we extended patient eligibility to include children 3 and 4-years old to enable us to reach our recruitment milestones. This required us to change our primary measure of asthma impairment from the Asthma Control

Questionnaire (not valid if completed by the parent or children < 6 years old)(27) to symptom-free days that were reported for all trial participants. These changes were approved by the Data and Safety Monitoring Board.

The Intervention

The content and implementation of the peer-training intervention for the parent was informed by social cognitive theory(28) and the Transtheoretical Model of behavior change (TTM),(29, 30) built on our prior research,(24–26, 31) and was delivered exclusively by phone. Core constructs of the TTM include the stages of change, a series of five ordered categories along a continuum of readiness for behavior change (pre-contemplation, contemplation, preparation, action, and maintenance). Movement along the behavior change continuum is influenced by cognitive and behavioral processes of change, self-efficacy and the relative pros and cons for the desired behavior change, and can occur in both directions. (30) Targeted asthma management behaviors for the PARTNER intervention included 1) effective use of controller medications, 2) effective use of quick-relief medications and 3) monitoring the child's asthma.

Four peer-trainers were recruited from the target population and three had experiential knowledge of asthma care. Their initial training occurred over 4 weeks and covered asthma pathophysiology, asthma management, the TTM, building rapport, reflective listening and communication skills. The peer-trainers learned to “stage” a parent for their readiness for each of the targeted behaviors, and tailor the intervention to that assessment. Training activities included small group discussions, experiential learning, and role-play. On-going training continued with weekly review of taped calls.

An introductory letter and educational materials for use during the intervention were mailed to the parent at the beginning of the program. The assigned peer-trainer called within one week of enrollment to provide an overview of the program goals and content, enquire about the child's asthma history, asthma treatment and treatment goals, and assess the child's level of asthma control (well, partially, or not-well controlled) using four questions about the frequency of asthma symptoms and use of quick-relief medications in the past 4 weeks.(4) The parent was asked to read a booklet about asthma in the next week and to provide a confidence score from 1 to 10 to indicate the likelihood this short-term goal would be reached. In this way, the peer-trainer introduced study processes used during the intervention to facilitate successful behavior change. The second call occurred one week later when the trainer determined if the parent had achieved their short-term goal and further described the program and the three targeted asthma management behaviors. In subsequent calls, guided by staging questions and a program manual, the peer-trainer provided tailored education, skill training and support for the three targeted asthma management behaviors. Monthly, the trainer assessed the child's level of asthma control and discussed this assessment with the parent. They encouraged PCP visits for routine asthma management at least twice a year and when problems occurred, helped the parent prepare for these visits, and, with the parent's permission, provided the PCP a one-page summary of the child's asthma prior to each visit and after 6- and 12-months in the program. If needed, the peer-trainer provided the parent with contact numbers for community resources.

The program was implemented in a flexible manner as determined by the parents' needs, circumstances and preferences, and the child's asthma condition. Calls varied in frequency from weekly to monthly, were scheduled at times convenient for the parent and occurred during office hours from Monday to Friday, with evening appointments available until 8pm one night per week. Calls were audiotaped and reviewed by the study team to ensure program quality and reviewed by the peer-trainers (self and peer review) as a learning resource.

Additional features of the intervention targeted the PCPs who provided asthma care. Study physicians (JG and RCS) conducted two site visits to each intervention practice, the first to describe the intervention and determine their preferred communication plan with the peer-trainer, and the second to discuss management of common problems in asthma care identified by the peer-trainers. Asthma management information was also provided in eight newsletters.

The comparator or control condition

All PCPs in both intervention and control practices were provided with access to the web-based Education in Quality Improvement for Pediatric Practice (EQIPP) from the American Academy of Pediatricians designed to improve asthma care(32) and a flow chart for recommended administration of albuterol for worsening symptoms. Children in the control group received usual care from their pediatrician for their asthma.

Measurement

Measures were obtained at the individual patient-level. Measurement occurred during telephone interviews conducted at baseline and 12- and 24-months by trained research assistants (RAs) blinded to study group assignment. In addition, a study physician (RCS) audited PCP charts using a structured audit form to assess maintenance asthma visits during the 12 months prior and following enrollment.

SFDs were estimated from the frequency of asthma symptoms in the prior 2 weeks(10, 33) and parental QOL was measured using the Pediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ).(34) This instrument uses a 7-point scale, with a higher score indicating a better QOL. A change of 0.5 units is considered clinically significant.(35) The parent reported the number of ED visits, hospitalizations, and oral steroid courses in the prior 12-months; and their attitudes towards, confidence using, and current use of asthma medications.(36) Collaborative partnership with the PCP was defined as having 2 asthma maintenance visits/year (4) or a parental report of PCP review of a written asthma treatment plan in the past 12-months.(37)

PCPs completed surveys to indicate practice characteristics and use of EQIPP. Those in the intervention group answered questions about the utility of program components.

Statistical Analysis

Using pilot data, we determined that 11 practices per study arm with an average of 42 families per practice would allow us to detect a difference in PACQLQ scores of at least 0.3

units with alpha level 0.017 and power of at least 89% (assuming sd of change in PACQLQ score 0.91, intraclass correlation coefficient, ICC 0.02).(26)

For the primary analyses, we used cluster-specific methods to evaluate the intervention effect on patient-level outcomes because practices rather than patients were randomized. All subjects who provided outcome data were included in their randomized group. We used mixed models to compare patient-level outcomes between study groups at 12- and 24-months adjusting for baseline differences in socio-demographic and outcome variables and season of enrollment, and accounting for the interdependency of outcomes among individuals in the same practice.(38) To estimate the ICC we used a variance component model to partition the total variance of each baseline outcome into within- and between-practice components. We also compared the mean value of each of the three primary outcomes at the cluster (practice) level between the two study groups in an unadjusted analysis using the Wilcoxon test. We used Medicaid insurance as a surrogate for the low-income, high-risk group for a planned subgroup analysis to investigate heterogeneity of intervention effect, and we conducted exploratory analyses to examine mechanisms through which the intervention might exert its effect using generalized linear mixed models.

For the three primary patient-level outcomes, $p = 0.017$ was used to establish statistical significance to control for multiple comparisons. For secondary and exploratory analyses, $p = 0.05$ was used. All tests were two-sided. Continuous variables are reported as the mean (sd) if normally distributed, or median (inter-quartile range, IQR) otherwise, and categorical data as percent. All statistical analyses were done using SAS (SAS Institute. 2007. The SAS System version 9.12, Cary, NC).

RESULTS

Study Population

Between March 11, 2009 and May 19, 2011, 948 families were recruited from 22 pediatric practices (Median subjects/practice, 35, IQR 25 to 69)(Figure 1). Of those eligible, the participation rate was 75.8%, with no difference by study group (intervention 75.6%, control 77.6%, $p=0.76$). Follow-up interviews were completed for 883 (93.1%; intervention 90.9%, control 95.3%) at 12-months and 869 (91.7%; intervention 89.4%, control 93.8%) at 24-months (Figure 1).

There were no differences in practice size, type, and location between intervention and control practices (see Table E1 in the Online Repository). Nine PCPs (14.8%) participated in EQIPP with no difference between study groups. Intervention families ($n=462$) were more likely than usual care families ($n=486$) to have lower baseline values for SFD and PACQLQ scores, use Medicaid insurance, be African American, single parent, low-income and have a younger index child (Table I). A comparison of the high-risk subgroup (Medicaid) and the general asthma population (other insurance) is provided in Table E 2 in the Online Repository.

Implementation and acceptance of the intervention

The median duration of peer-training/family was 3.8 hours (IQR 2.8 to 5.2 hours), with median calls/family 18 (IQR 14 to 21). Most parents discussed all three targeted behaviors (controller medications 95.2%, quick-relief medications 95.2%, and monitoring 96.3%). Sixteen parents (3.5%) withdrew from peer-training (4, 2 calls; 5, 3–4 calls; 7, 6–13 calls; 5 Medicaid, 11 other insurance), most often because they were too busy to participate.

Parents were willing to recommend the intervention to others (64.6% extremely willing, 20.4% very willing, 11.2% willing, 3.8% fairly/not willing). PCPs would recommend the program to patients (90.5%) and colleagues (90.5%) and reported they learned useful information from the patient faxes (71.4%), newsletters (79.0%) and site visits (85.0%).

Program Effectiveness

Primary Analyses—Details of the comparison between patient-level outcomes in the two study groups at 12- and 24-months are provided in Table I. At 12-months, children in the intervention group reported an average of 20.9 more SFDs (95%CI 9.1 to 32.7; ICC 0.04) than those in the control group. The increase in PACQLQ scores associated with the intervention, albeit significant, was not clinically meaningful (ICC 0.05), (34, 35) and there was no between-group difference in ED visits (ICC 0.11)(Table II).

Findings from the unadjusted cluster-level comparisons for these three primary outcomes showed an average intervention benefit of 24.1 SFDs (95%CI 10.0 to 38.2), with no difference for PACQLQ scores (difference 0.07 units, 95%CI –0.16 to 0.02) or ED visits (difference 0.45, 95%CI –0.09 to 1.0).

Additional Analyses of Patient-Level Outcomes—At 12-months, there were no meaningful changes in the frequency or content of asthma maintenance visits or PCP-partnership (Table II). Exploratory analyses suggest increased SFDs in the intervention group were at least partially mediated by increased parental self-efficacy for use of quick relief medications and increased expectation for asthma control, but not by increased use of controller medications (Table III).

At 24-months, there were fewer ED visits in the intervention group than in the control group (difference in mean ED visits/child, –0.28, 95%CI –0.5 to –0.02), indicating a delayed intervention effect (Table I).

Subgroup Analysis—At 12-months, the intervention increased SFDs in both the Medicaid and other insurance subgroups (Table IV). In addition, there were significantly larger intervention effects in the Medicaid subgroup on healthcare use, with 42% fewer ED visits (difference in mean ED visits/child –0.50, 95%CI –0.81 to –0.18), and 62% fewer hospitalizations (difference in mean hospitalizations/child –0.16, 95%CI –0.30 to –0.014) with sustained effects or further reductions in healthcare use at 24-months (Table IV).

DISCUSSION

The peer-training program evaluated in this large, community-based RCT is theory-based and provides a patient-centered approach to asthma management that recognizes that behavior change is complex, and occurs at different rates among individuals.(20) About four hours of what we call peer-training delivered via telephone over 12-months reduced asthma impairment for children from both the general and high-risk asthma populations. Insurance type moderated the intervention effect on risk outcomes, with participation in the peer-training program resulting in significant reductions in ED visits and hospitalizations in the Medicaid subgroup that were sustained at 24-months. These improvements were larger than other interventions to improve asthma management targeting this high-risk group,(9, 11, 15–19, 23) and occurred using lay interventionists and without any face-to-face interactions, home visits, environmental remediation, or PCP training. These findings suggest this peer-training intervention may be an effective strategy to reduce disparities in asthma outcomes. (39, 40)

Several features of the intervention likely contributed to the high level of program retention in both the general asthma population and the traditionally hard to reach high-risk group. Delivering the intervention by phone allowed anonymity, was time and cost-efficient for the patient,(41) and circumvented families reluctance for home and office visits for education. (16, 42, 43) Rather than delivering a prescribed curriculum, the peer-trainer's focus was on meeting parental treatment goals, developing their skills and confidence to provide effective asthma management, and addressing their specific practical and psychological barriers to asthma management.(44) The longitudinal and non-hierarchical nature of the peer-trainer-parent relationship allowed sharing of information and experiences about social and other factors that can undermine effective asthma care. This friendly, empathetic relationship has been noted in other peer-coaching studies,(24, 39) and may explain the lower attrition rate seen here compared to interventions with similar goals delivered by medically trained personnel.(16, 26, 45, 46) Importantly, program quality was maintained by providing call review and ongoing support for the peer-trainers.(26)

Exploratory analyses suggest the intervention improved asthma control at least in part by improving parental self-efficacy for using quick-relief medications and increasing expectations for asthma control. Other studies have demonstrated that increasing self-efficacy and outcome expectancy can improve asthma self-management.(20, 28) While the intervention resulted in a small increase in reported use of controller medications, our exploratory analyses suggest this change did not mediate the increase in SFDs. Further studies with more reliable measures of medication adherence are needed to better understand these relationships. Disappointingly, there was no evidence that interactions with an empowered, informed parent improved PCP-partnership. Consumer demand can improve the quality of care,(47) and may have marginally increased the frequency of asthma maintenance visits in the short-term. However, planned visits for treatment monitoring and adjustment were infrequent, limiting opportunities for the PCP to provide education and support.

Strengths of this study include the community-based approach, the cluster randomized design to minimize contamination of PCP care likely with individual level randomization, blinding for outcome assessment, and the high rate of long-term follow-up. Regression to the mean is an unlikely explanation for our findings as we did not selectively enroll patients when their asthma was poorly controlled (e.g., in the ED), and we controlled for baseline differences in outcome measures among study groups in the regression models. However, several study limitations should be noted. Although the sample was large, the study was performed in one mid-western metropolitan area, and findings may not generalize to other populations. There were several potential sources of bias that may impact study findings: for pragmatic reasons, randomization of clusters occurred before subject recruitment. Although this raises the possibility of post-randomization selection bias,(48) we think this unlikely as the participation rate among eligible families was the same in both study groups. Parents were not blinded to study group assignment and most outcome data were assessed by self-report. Although we achieved a high follow-up rate in both study groups (>89%), follow-up rates were ~5% lower in the intervention group and subjects who did not complete follow-up may have had worse outcomes. Our analytic approach controlled for clustering within practices and seasonal effects yet these differences may have contributed to the measured intervention effect. Finally, we did not control for differential contact between study groups and it is possible that the observed improvements in patient outcomes were simply due to frequent contact with the peer-trainer. We think this unlikely as reductions in healthcare use occurred in the intervention group 12-months after contact ceased and did not occur in the control group.

Reductions in expensive asthma-related ED visits and hospitalizations occurred among children with Medicaid insurance suggesting telephone-based peer-training might be a cost-effective way to reduce asthma disparities. We estimate the ROI (return on investment) for this program for children with Medicaid insurance to be 1:3 and recommend that the intervention be implemented at a system level (such as an Accountable Care Organization or insurance provider), rather than an individual practice level. A centralized approach for program delivery would facilitate ongoing monitoring, training and support needed to maintain program quality, and cost savings from reduced ED visits and hospitalizations could pay program costs. In addition, the Patient Protection and Affordable Care Act allows States to choose to provide Medicaid reimbursement for non-medical providers to deliver preventive services such as asthma skill training. To aid implementation, we have developed a program manual and a training program to support implementation (<http://partnerstudy.wustl.edu/Pages/Default.aspx>).

In conclusion, evidence from this large randomized trial suggests that a peer-training program delivered exclusively by telephone was effective in improving children's asthma control, and was popular with parents and physicians. We recommend this intervention be implemented for children with Medicaid insurance who have poorly controlled asthma. Future study will determine if this novel approach to augment the primary care management of childhood asthma reduces disparities in asthma outcomes and healthcare costs as suggested by findings from this study.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations

AAP	Asthma action plan
CI	Confidence interval
ED	Emergency Department
EQIPP	Education in Quality Improvement for Pediatric Practice
ICC	Intraclass correlation coefficient
ICS	Inhaled corticosteroids
Intv	Intervention
IQR	Interquartile range
LTRA	Leukotriene receptor agonist
OR	Odds ratio
PACQLQ	Pediatric asthma caregiver's quality of life questionnaire
PCP	Primary care provider
PI	Principal Investigator
pQOL	Parental quality of life
QOL	Quality of life
RCT	Randomized controlled trial
ROI	Return on investment

SD	Standard deviation
SFD	Symptom-free days
U.S	United States

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Clinical Implications

Telephonic peer-training for parents reduced childhood asthma impairment. Significant, sustained reductions in ED visits and hospitalizations occurred in children with Medicaid, suggesting this approach may reduce disparities in asthma outcomes.

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Figure 1.
Participant Recruitment and Flow Through the Study

Table 1

Description of outcome measures at baseline, 12- and 24-months by intervention group (mean, sd or %), with adjusted differences (intervention – control) at 12- and 24-months

	Baseline		After 12-months			After 24-months		
	Intv	Control	Intv	Control	Difference (95%CI)	Intv	Control	Difference (95%CI)
Primary Outcomes								
Symptom free days/child	N=462 253.3 (116.3)	N=486 276.9 (103.2)	N=420 315.8 (79.6)	N=463 301.8 (89.9)	20.9** (9.1, 32.7)	N=413 313.6 (84.5)	N=456 311.7 (83.6)	9.0 (-4.0, 21.9)
Parent QOL, PACQLQ score ^a	6.2 (1.0)	6.5 (0.8)	6.9 (0.4)	6.8 (0.5)	0.1* (0.02, 0.19)	6.9 (0.4)	6.9 (0.4)	0.06* (0.009, 0.11)
ED visits/child	0.7 (1.3)	0.7 (1.5)	0.4 (1.1)	0.4 (1.3)	-0.06 (-0.20, 0.09)	0.2 (0.6)	0.3 (1.1)	-0.28* (-0.53, -0.02)
Secondary Outcomes								
Hospitalizations/child	0.09 (0.4)	0.10 (0.4)	0.04 (0.2)	0.06 (0.5)	-0.04 (-0.14, 0.05)	0.05 (0.3)	0.06 (0.4)	-0.008 (-0.06, 0.05)
Oral steroid courses/child	1.5 (1.8)	1.4 (1.7)	1.0 (1.7)	1.0 (1.6)	-0.04 (-0.31, 0.22)	0.6 (1.2)	0.7 (1.1)	-0.15 (-0.30, 0.006)

The reported difference between intervention and control group is adjusted for baseline values, Medicaid insurance, maternal race, family income, single parent family, child age, and season of enrollment.

* indicates p<0.05;

** indicates p<0.001 for adjusted comparisons

^a Parents' QOL was measured by the Pediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ) scored 1 to 7, with a higher score indicating a better outcome.

Abbreviations: Intv Intervention, Control Usual Care; sd standard deviation; OR odds ratio; CI confidence interval; SFD symptom-free days; QOL Quality of Life; PACQLQ Pediatric Asthma Caregiver's Quality of Life Questionnaire (34); ED Emergency Department.

Table II

Office-based asthma care (mean, sd, or %) by intervention group, with adjusted difference (intv-control) at 12-months

	Baseline		After 12-months		Adjusted difference at 12-months (Intervention - Control)	
	Intv	Control	Intv	Control	Difference	95% CI
Asthma maintenance visits/child ^a	1.26 (0.6)	1.31 (0.6)	1.30 (0.6)	1.25 (0.6)	0.14	-0.05 to 0.33
2 asthma maintenance visits/year ^b	14.5%	15.2%	17.3%	13.0%	OR 0.66*	0.44 to 0.97
Visits/child with element of maintenance asthma care documented						
Level of asthma control assessed	0.59 (0.6)	0.60 (0.7)	0.69 (0.7)	0.58 (0.6)	0.12	-0.08 to 0.33
Asthma education provided	0.38 (0.6)	0.28 (0.5)	0.43 (0.6)	0.29 (0.5)	0.09	-0.04 to 0.21
Reviewed AAP with PCP in past 12- months	50.8%	46.6%	32.9%	43.8%	OR 0.65	0.38 to 1.10
PCP Partnership ^c	55.2%	58.1%	71.7%	60.3%	OR 1.64	0.97 to 2.78

The reported difference between intervention and control group is adjusted for baseline values, Medicaid insurance, maternal race, family income, single parent family, child age, and season of enrollment.

* indicates p<0.05

^a An asthma maintenance visit was defined as a visit in which asthma symptoms, medications, or management were documented and no acute care was provided.

^b Recommended minimum frequency for asthma maintenance visits is every 6 months, with more frequent visits for poorly controlled asthma.

^c Partnership was defined as 2 asthma maintenance visits/year by chart audit or parental report that they reviewed AAP with PCP in past 12-months.

Abbreviations: Intv Intervention, Control Usual Care; sd standard deviation; OR odds ratio; CI 95% confidence interval; PCP Primary care provider; AAP Asthma Action Plan.

Table III

Exploratory analyses to identify mediating factors for the interventions' effect on symptom free days (SFDs) at 12-months

	Effect of intervention on variable at 12-months		Effect of variable on SFDs	
	Estimate of between group difference	P-value [*]	Estimate	P-value [*]
Possible mediators				
Related to self-efficacy				
Concern about controllers score ^a	0.25	0.003	4.09	0.07
Confidence to use quick relief medication ^b	0.27	0.002	5.30	0.07
Asthma-related stress ^c	OR 0.66	0.02	-44.40	<0.001
Expectations for asthma control ^d	-0.53	<0.001	-10.04	<0.001
Using controller medication ^e	OR 1.81	<0.001	-27.45	<0.001
PCP partnership ^f	OR 1.64	0.06	-4.64	0.45
Overall effect of intervention on SFDs at 12- months				
Without controlling for possible mediators	20.89	<0.001		
Controlling for all possible mediators	16.14	0.007		

^{*} P-value for the effect of the baseline variable and the 12-month outcome generated using mixed models adjusted for baseline values, Medicaid insurance, maternal race, family income, single parent family, child age, and season of enrollment.

^a General concerns about controller medications were assessed as the sum of agreement scores (strongly agree, 1 to strongly disagree, 4) for two statements. One affirmed their concern about medication dependence and the other their worry about the longterm effects of ICS medications. Scores ranged from 2 to 8 with lower scores indicating less concern.

^b The average confidence score for two questions was used - confidence to initiate albuterol use and confidence to administer albuterol at correct frequency. Confidence score ranged from 1, not confident to 10, very confident.

^c Asthma-related stress was defined as a parental report of being worried about the child's asthma all or most of the time. Parents rated their frequency of worry about their child's asthma in the past 2-months with a five-point response scale ranging from all the time to none of the time.

^d Expectations for asthma control was assessed as the sum of agreement scores (strongly agree, 1 to strongly disagree, 4) for four statements that the child can be symptom free most of the time, attend school, fully participate in activities, and have no ED visits or hospitalizations due to asthma. Scores ranged from 4 to 16 with lower scores indicating higher expectation for good control.

^e Parental report of use of a controller medication in the past 7 days.

^f Partnership was defined as 2 asthma maintenance visits/year by chart audit or parental report that they reviewed AAP with PCP in past 12-months

Abbreviations: SFD symptom-free days; PCP Primary care provider; OR odds ratio

Table IV

Description of outcome measures at baseline, 12- and 24-months by intervention group (mean, sd or %), with adjusted differences (intervention – control) at 12- and 24-months by insurance group

	Baseline		12-months			24-months		
	Intv	Control	Intv	Control	Difference [#] (95%CI)	Intv	Control	Difference [#] (95%CI)
Symptom free days/child								
Medicaid	225.0 (131.4)	243.7 (117.0)	308.1 (85.6)	281.9 (89.1)	32.7* (7.0 to 58.4)	299.9 (101.1)	288.7 (95.0)	8.7 (–18.1 to 35.6)
Other insurance	263.7 (108.6)	285.5 (97.8)	318.2 (77.6)	306.6 (89.6)	17.9* (4.8 to 30.9)	318.0 (78.2)	317.1 (79.8)	8.9 (–5.6 to 23.4)
p-value for interaction variable* insurance group					0.31			0.99
Parent QOL, PACQLQ score ^a								
Medicaid	5.8 (1.2)	6.3 (0.9)	6.8 (0.5)	6.7 (0.8)	0.13 (–0.02 to 0.28)	6.8 (0.6)	6.7 (0.7)	0.16* (0.05 to 0.28)
Other insurance	6.4 (0.9)	6.5 (0.7)	6.9 (0.3)	6.8 (0.4)	0.10* (0.005 to 0.19)	6.9 (0.3)	6.9 (0.3)	0.04 (–0.02 to 0.09)
p-value for interaction variable* insurance group					0.67			0.05
ED visits/child								
Medicaid	1.3 (1.8)	1.4 (2.5)	0.65 (1.5)	1.2 (2.5)	–0.50* (–0.81 to –0.18)	0.31 (0.9)	1.2 (2.2)	–0.88** (–1.21 to –0.55)
Other insurance	0.53 (1.1)	0.45 (1.0)	0.30 (0.9)	0.22 (0.7)	0.05 (–0.11 to 0.21)	0.15 (0.5)	0.14 (0.4)	–0.07 (–0.31 to 0.16)
p-value for interaction variable* insurance group					0.002			<0.001
Hospitalizations/child								
Medicaid	0.15 (0.5)	0.18 (0.4)	0.10 (0.3)	0.26 (1.1)	–0.16* (–0.30 to –0.01)	0.10 (0.5)	0.23 (0.8)	–0.11* (–0.22 to –0.004)
Other insurance	0.07 (0.3)	0.08 (0.3)	0.02 (0.2)	0.02 (0.1)	–0.008 (–0.10 to 0.09)	0.04 (0.2)	0.02 (0.1)	0.02 (–0.04 to 0.07)
p-value for interaction variable* insurance group					0.05			0.04

[#]The reported difference between intervention and control group is adjusted for baseline values, maternal race, family income, single parent family, child age, and season of enrollment.

* indicates p<0.05;

** indicates p<0.001 for adjusted comparisons

^aParents' QOL was measured by the Pediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ), scored 1 to 7, with a higher score indicating a better outcome.

Abbreviations: Intv Intervention, Control Usual Care; sd standard deviation; CI confidence interval; QOL Quality of Life; ED Emergency Department; SFD symptom-free days

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