



Pictorial versus written asthma action plans for youth: initial impact on regimen knowledge, medication adherence, symptom control, and family satisfaction

Lisa Hynes, PhD^a , Kristine Durkin, MS^a , Thomas Ewell, MS^a , Christa Lilly, PhD^b , Desiree N. Williford, PhD^a , Corrine Ahrabi-Nejad, MS^a , Destiny Noel, BS^a, Viral Kothari, MD^c , David Skoner, MD^c , and Christina L. Duncan, PhD^a 

^aDepartment of Psychology, West Virginia University, Morgantown, WV, USA; ^bDepartment of Biostatistics, School of Public Health, West Virginia University, Morgantown, WV, USA; ^cDepartment of Pediatrics, School of Medicine, West Virginia University, Morgantown, WV, USA

ABSTRACT

Objective: Asthma action plans (AAP) are recommended to guide asthma management. Written AAPs (WAAPs) are under-utilized and can be difficult to understand. Our study designed and tested a simplified pictorial AAP (PAAP). We hypothesized that better outcomes would be obtained for youth with the PAAP.

Methods: One hundred and sixty-nine (169) youth (aged 8–17; AAP-naïve) were screened for this pilot, 2-arm randomized controlled trial. Feasibility, usability and preliminary efficacy of PAAP compared to a WAAP, for improving outcomes (inhaled corticosteroid (ICS) adherence, symptom control, AAP knowledge, AAP satisfaction) were assessed quantitatively. Youth received an AAP from their physician after completing baseline measures and completed measures at three additional time points (1-, 3-, and 6-month).

Results: Forty-five youth were recruited (PAAP = 22; WAAP = 23). Youth AAP knowledge was higher for the PAAP group compared to the WAAP group ($p=.017$). ICS adherence did not differ between groups, over time, or based on prescribed dosing; however, for WAAP participants, adherence was lower with a higher daily prescription (4 puffs) relative to a lower dose ($p=.006$). Symptom control improved with both AAPs, but the change was not statistically significant. Lung function did not change significantly by AAP type or time, and literacy variables were not related significantly to outcomes. Youth satisfaction with AAP improved significantly for the PAAP group compared to the WAAP group ($p=.03$).

Conclusions: Higher AAP knowledge and satisfaction among youth in the PAAP group suggests that structured education from a physician using a PAAP is beneficial. Intervention and study design insights gained will guide future research.

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Introduction

Adherence to inhaled controller medication among children with asthma is a significant challenge that has persisted despite improvements in asthma treatment and awareness of factors influencing adherence and outcomes (1–3). Determinants of asthma treatment non-adherence are complex, including factors such as family routine and comprehension of the condition and treatment instructions (2). A recent systematic review (3) reported adherence rates to inhaled corticosteroid (ICS) treatment (daily preventive or controller medication) to be between 28% and 67% based on data from objective (e.g. electronic monitoring) and subjective (self-report) measures.

Various adherence interventions were included in this review – for example, individualized care programs, electronic monitoring devices, and communication during pediatric visits. These interventions resulted in improved adherence rates: 49–81% (3). When poorly managed, asthma can result in increased risk of mortality and morbidity, such as increased school absences, asthma exacerbations, and hospitalizations (4).

Effective asthma education is vital to ensure child and family understanding of symptoms and medications, including when to seek urgent medical care (5), and serves as a foundation for treatment adherence. Current asthma care guidelines (5) recommend using asthma action plans (AAPs) to educate youths and

families and to improve self-management and asthma outcomes (6). AAPs are individualized, structured treatment plans that guide youth and families in asthma management, including daily asthma care (e.g. taking preventative medications), how to respond to exacerbations (e.g. taking rescue medication), and when to seek out emergency care. AAPs commonly feature a traffic light format and are given as paper copies to families. The green zone describes daily asthma management, the yellow zone defines response to asthma symptoms, and the red zone details actions to take when symptoms are severe (5). Written AAPs can reduce emergency/acute care visits and improve medication adherence and overall health outcomes over time (7,8). Despite these positive effects, nearly half of youth and families in the US do not receive an AAP (4), with rates of use particularly low in pediatric primary care (i.e. 8–9% for ages 5–11; 2.4% for ages 12–18) (9). Low rates likely contribute to insufficient adherence and self-management skills as well as lower levels of asthma knowledge and self-efficacy around care (10–13).

A frequent barrier to AAP use is readability, with many written AAPs being written at a 7th–9th grade level, making them difficult to understand, navigate, and use (14). Low literacy may also hinder usability and deter providers from using the tool during asthma education (15–17). Written AAPs with inaccessible language and dense text may also deter youth from engaging in asthma education during clinic visits or reduce their confidence in managing their own asthma. Given concerns related to the usability and readability, as well as underutilization of written AAPs, recent research has shifted toward a focus on AAPs with lower literacy demands. Novel AAPs often incorporate images along with simplified written instructions (18,19), or mobile applications (20).

In line with this approach, our Take Action for Asthma Control (TAAC) study aimed to address a critical need to develop a simple, computer-generated, individualized, pictorial AAP for youth and families that reduces literacy demand, enhances usability, and potentially contributes to positive asthma-related outcomes. In this pilot and feasibility randomized controlled trial (RCT), we compared the preliminary relative efficacy of pictorial versus written AAPs with regard to youth and caregiver knowledge of the youth's AAP, adherence to inhaled controller medication, asthma symptom control and lung function, and satisfaction with AAP. We hypothesized that knowledge, medication adherence, and symptom control would improve significantly more over time for the pictorial AAP group than for the written AAP

group. Further, we hypothesized that AAP satisfaction scores would be significantly higher for the pictorial AAP group. Finally, we planned to explore whether youth literacy, and youth and caregiver health literacy would be associated with treatment outcomes.

Methods

Study design

The current study used stratified randomization (age & asthma severity) in a 2-arm, parallel group (pictorial AAP vs. written AAP) design for a pilot and feasibility RCT. Data were collected at four time points: enrollment/baseline, 1 month, 3 months, and 6 months.

Participants

From May 2017 through June 2018, youths (ages 8–17) and their primary caregiver were recruited from two pediatric specialty clinics (Pulmonology Clinic; Allergy & Asthma Clinic), each with its own physician provider, in Morgantown, West Virginia. Youth were eligible to participate in the study if they met one of the following conditions: newly diagnosed with persistent asthma and prescribed a daily controller inhaler that was compatible with our electronic monitoring device (Propeller Health, USA); or had an established diagnosis of persistent asthma, had never received an AAP, had suboptimal asthma control as identified by the physician, and prescribed a daily controller inhaler also compatible for electronic monitoring. Youth were not eligible to participate if they had a disability or cognitive impairment (caregiver or physician-identified) that prevented them from completing study procedures.

A total of 169 youth was screened as potentially eligible for this study. Of those identified, 49% ($N=83$) of the youth could not be approached (e.g. missed appointments) and 15% ($N=26$) did not meet inclusion criteria (e.g. previously received an AAP; not prescribed a controller medication). In total, 60 youth were eligible (36% of screened) and 45 were enrolled (75% of eligible) (see Figure 1). Of those eligible, 15 declined participation citing reasons such as lack of interest and insufficient time.

Procedure

Approval from the institutional IRB was obtained prior to data collection. The procedures are described in detail in the published protocol (21). Eligible participants were identified through clinic records. To

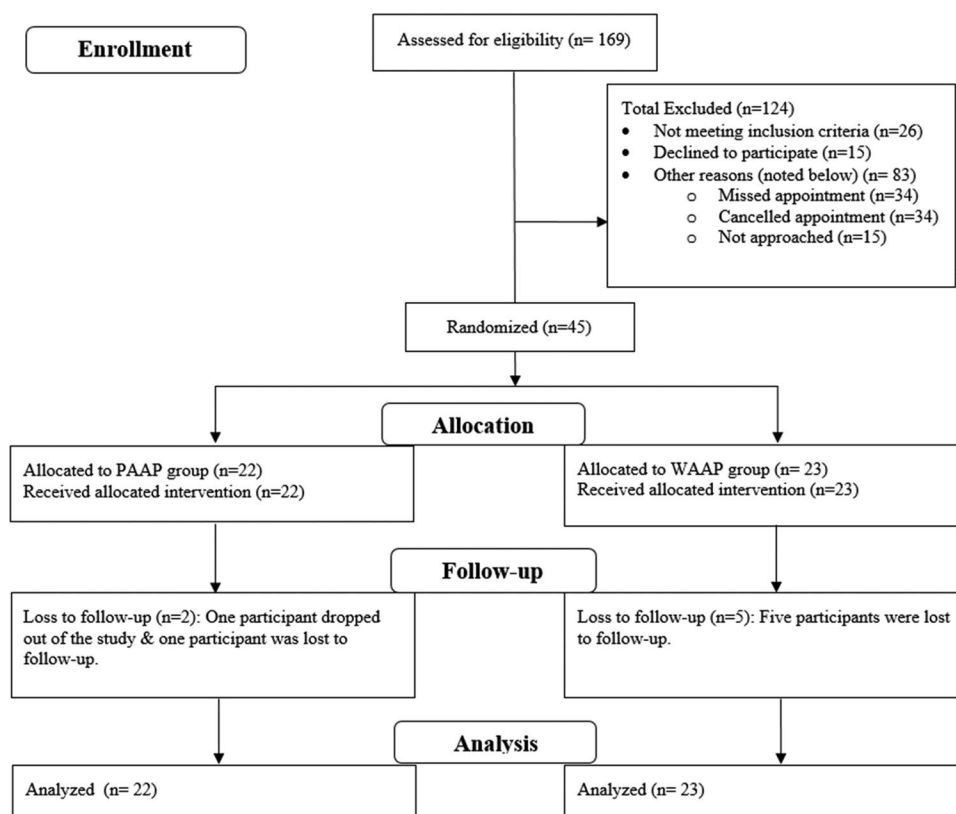


Figure 1. CONSORT flow diagram.

determine interest in the study, these families were called prior to attending their scheduled care appointments and interested participants were invited by their physician to meet with study staff during their visit. Once eligibility and interest were confirmed, youth and their caregiver completed assent and consent forms, respectively. The physician classified each youth's asthma severity as mild, moderate, or severe persistent. Youth were then randomized into one of the AAP groups (pictorial vs. written) based on their asthma severity and age (8–12 vs. 13–17), using a system of pre-filled envelopes designed to place an even number of participants in each group based on asthma severity and age. An envelope was randomly selected by the researcher for each participant. After enrollment and completion of baseline study measures, all youth received copies of their AAP and a brief education session with their physician (see Intervention details). Educations sessions were audio-recorded to allow independent review of content (i.e. fidelity assessment) and duration of these sessions. After the education session, youth and caregivers completed an AAP knowledge interview. Before leaving clinic, youth were provided with a preventative medication inhaler/discus with an electronic monitoring device (Propeller Health, USA) attached; adherence data were monitored by study staff *via* a secure online dashboard.

Youth and caregivers completed study surveys at each of the four time points, measuring variables as follows: (a) enrollment/baseline – asthma symptom control, spirometry, reading comprehension, and health literacy, AAP knowledge (post AAP education); (b) 1-month – asthma symptom control, AAP satisfaction; (b) 3-month – asthma symptom control, AAP knowledge, spirometry; and (c) 6-month – asthma symptom control, AAP knowledge, spirometry, and AAP satisfaction. Six participants were enrolled in the study too late to complete the 6-month follow-up session within the grant funding period; consequently, these individuals completed the final AAP satisfaction measure at the 3-month session.

Intervention

Youth in both the groups received paper copies of their AAP, populated by the physician to reflect the prescribed asthma treatment regimen. Physicians generated PAAPs *via* a simple software program, developed for this project based on the findings of a qualitative study involving youth with asthma, their caregiver, and asthma physicians (22). An example of a completed PAAP is included in Figure 2. For the WAAP participants, the NHLBI template (<https://www.nhlbi.nih.gov/health-topics/all-publications-and-resources/asthma-action-plan-2020>)

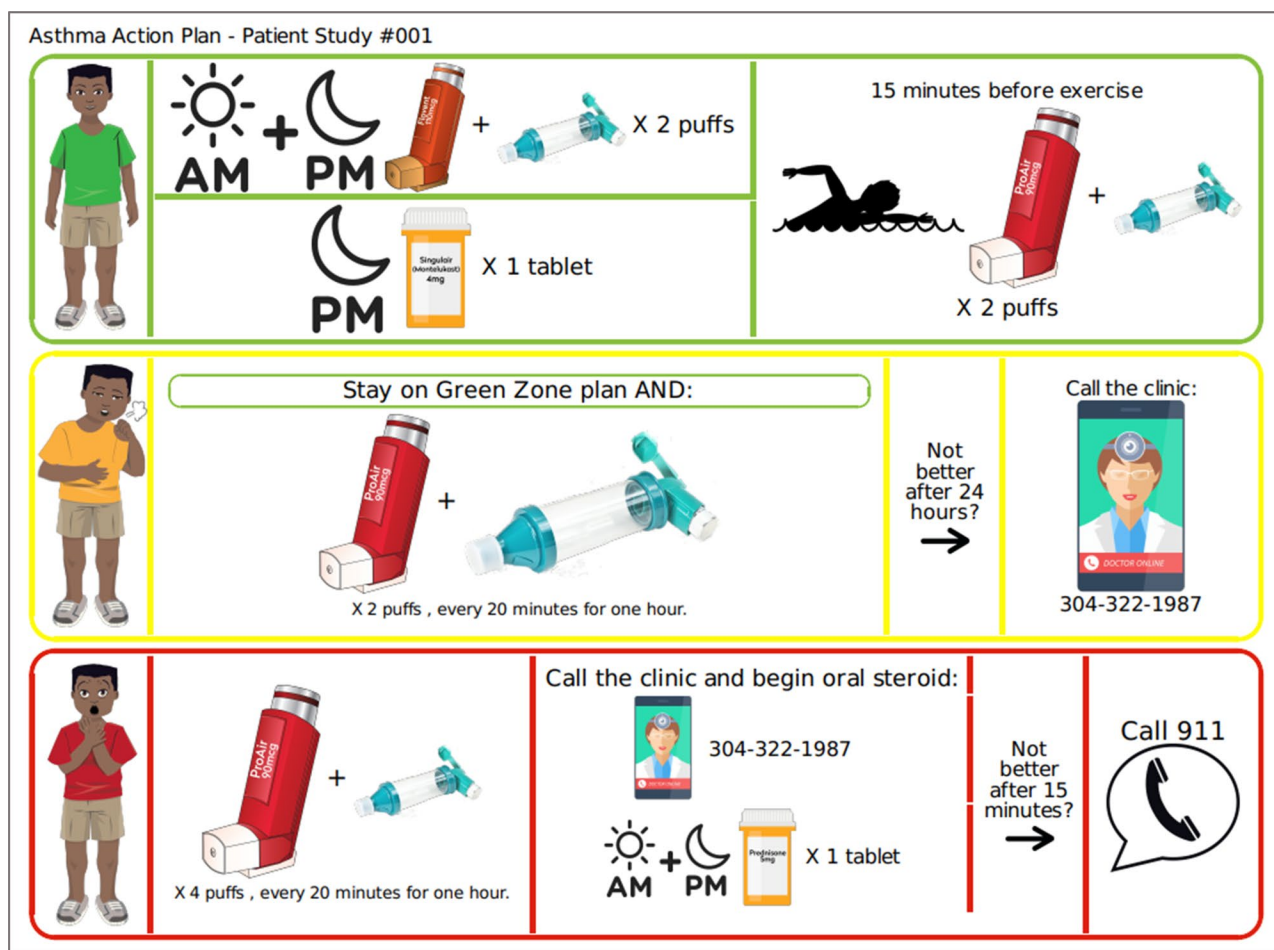


Figure 2. Complete PAAP example.

was used. NIH is a reputable source for asthma treatment guidelines in the United States, and this tool has a horizontal format for the green, yellow, and red zones, similar to our PAAP. The physician completed WAAPs by hand. Physicians were asked to provide similar information to families, regardless of group allocation, when engaging them in the AAP review or education session during the initial enrollment visit in clinic.

Measures

Literacy and health literacy

Three measures of literacy and health literacy were administered at the study enrollment session.

Health literacy. The Short Test of Functional Health Literacy in Adults (23; S-TOFHLA) assessed caregiver and youth ability to read and understand health related information at baseline. This tool consists of 36 items, and a score of <16 indicates low health literacy. Because the S-TOFHLA has been used in studies with adolescents (24), in our study, we administered it with

youth aged 13–17 only. Lack of variability (i.e. ceiling effect) in this measure made it impossible to calculate Cronbach's alpha for our sample.

Youth reading comprehension. Youth of all ages completed the Reading Comprehension subtest of the Wechsler Individual Achievement Test-III (WIAT; 25) as a proxy for literacy. The youth's subtest total raw score was converted to an age-based standard score (Mean = 100; SD=15) for data analyses.

Asthma numeracy. The Asthma Numeracy Questionnaire (ANQ; 26) was administered to caregivers to assess understanding of numerical concepts in asthma treatment instructions. The ANQ includes four items, coded as 1=correct or 0=incorrect, and summed for total score (0–4). The standardized Cronbach's alpha was acceptable ($n=45$, $\alpha=0.61$) and higher than that obtained by the original authors (26).

AAP knowledge. The Asthma Action Plan Knowledge Interview (AAPKI) was developed for the purpose

of this study to measure treatment knowledge as it pertains to the youth's AAP (Tool available from corresponding author). Research staff administered items verbally, and participants were permitted to refer to their AAP when responding. The first section of the structured interview consisted of eight items describing hypothetical situations with asthma symptomology (e.g. coughing and chest tightness) in which the respondent was asked to categorize the child as being in the green, yellow, or red zone of an AAP. To reduce practice effects, the scenarios varied slightly (e.g. child riding bicycle versus child playing basketball) across repeated administrations at different time points. Items were scored as correct (1) or incorrect (0). Two items from the first section were excluded from the total score because the treatment information did not pertain to all youth; one item asked about allergies as a trigger, while the other item asked about albuterol use prior to exercise. Section "average" score was calculated as the sum across six items, divided by 6 (total possible score) and multiplied by 100.

The second section of the structured interview included three open response items asking the respondent to describe the green, yellow, and red zone treatment instructions according to the youth's AAP. Using the youth's individual AAP as a reference, responses were scored on a 4-point scale: 0 = incorrect response or no response (e.g. "I don't know"); 1 = vague response with some correct content, but lacking substantial detail (i.e. missing more than 50% of details); 2 = partially correct response that has many of the details but is missing some key instructions (i.e. missing 25–49% of details); 3 = completely or almost completely correct response that is missing minimal key details (i.e. missing 0–24%). Two independent coders scored these open-ended responses for all available AAPKI interviews for nine participants ($n=26$ interviews each for caregiver and youth). Kappa coefficients were excellent across informant versions and zones: Green – 0.95 caregiver, 0.95 youth; Yellow – 0.74 caregiver, 1.00 youth; Red – 0.85 caregiver, 0.79 youth. Section "average" score was calculated as the sum across three items, divided by 9 (total possible score) and multiplied by 100. To calculate an overall AAPKI knowledge score (separately for caregiver and youth), the average scores for the two sections were totaled and divided by 2. This approach to calculations allowed both sections to be equally weighted (despite different number of items) and expressed in a manner that is more readily interpretable (i.e. percentage 0–100).

Medication adherence

Medication adherence was measured *via* an electronic monitoring sensor (Propeller Health, USA) attached to the youth's prescribed daily controller medication. Sensor activity was monitored using the Propeller Health electronic system, which provided continuous adherence information to the study team and allowed for equipment errors to be detected quickly. Daily adherence was defined as the total number of puffs inhaled divided by total number of puffs prescribed, multiplied by 100, yielding a total adherence percentage. Consistent with recommended prescribing practices (27), youth in our study were prescribed 1–4 puffs (dose) of ICS to be taken 1–2 times each day (schedule). To prevent misrepresentation of "over-adherence," daily adherence was capped at 100% of prescribed dosage. Excess "dumping," defined as instances in which the number of actuations within a minute span met or exceeded 10 puffs (28), were excluded before calculating adherence. Data outputs were carefully reviewed for inappropriate patterns of use and errors consistent with device malfunctions, such as erroneous actuations and device failure. Late adherence (e.g. participant took medication at 11:55 PM on day 1 and then 12:01 AM on day 3) was accounted for within the previous day (e.g. day 2), given the nature of adolescents' variable sleep schedules and activities. Medication adherence was monitored throughout study participation (i.e. enrollment through 6-month follow-up).

Asthma symptom control

The Asthma Control Test (ACT; 29) is a measure of asthma symptom control, including shortness of breath, use of rescue medication, and daily functioning. Two versions were used in this study: Childhood ACT for ages 4–11 years (seven items), and ACT for ages 12 years+ (five items). Respondents rate items using a Likert-type scale; total scores range 0–27 and 0–25 for Childhood ACT and ACT, respectively, with higher scores reflecting better symptom control. A total score less than 20 indicates clinically significant problems with asthma control (25). Consequently, analyses used a binary variable: well-controlled asthma (total >19) versus suboptimal asthma control (total <20).

Lung function

Two spirometry variables were used as a measure of the youth's lung function (30): (i) Forced Expiratory Volume (FEV_1), as an efficacy outcome in analyses, and (ii) FEF_{25-75} , as a sample descriptor. Youth repeated the spirometry test until three valid trials

were obtained; the highest percent predicted FEV₁ value (and corresponding percent predicted FEF_{25–75} value) was analyzed.

AAP satisfaction

The AAP Satisfaction Survey is a study-specific measure assessing satisfaction with the individual's AAP, with parallel versions created for caregiver and youth report. The measure consists of 11 items with a 4-point Likert-type response scale, asking the respondent to rate satisfaction with various aspects of their AAP (e.g. "Very Helpful" to "Not Helpful at All," "Not Clear at All" to "Very Clear"). Five items were reverse coded to discourage response bias patterns. The researcher verbally administered the survey to caregivers and youth, separately, and recorded responses in writing. Item scores were averaged together to generate an overall mean item score, with higher scores indicating higher levels of satisfaction (possible range = 1–4). At 1-month follow-up ($n=44$), the standardized Cronbach's alpha values for caregiver ($\alpha=0.79$) and youth ($\alpha=0.78$) were satisfactory.

Analyses

All analyses were conducted using SAS 9.4. Missing data were addressed through statistical pairwise deletion. Six participants completed satisfaction measures at 3 months instead of 6 months due to having been recruited too late in the funding period to gather 6-month outcomes. Therefore, for satisfaction scores, the 3-month and 6-month time points were combined for pre-post analysis. Otherwise, time was treated as a continuous variable. Descriptive analysis was conducted on enrollment/baseline (0-month) measures for the total sample and by the AAP group. Frequency and valid percentages were used to describe categorical data, means, and standard deviations for continuous data, and medians and interquartile range for non-normal continuous data. Group differences were tested by chi-square, Fisher's exact, Mann-Whitney, or t test, as appropriate for variable type, with odds ratios (OR) and 95% CI of the OR, means by group and t -statistic, or mean score ranks and Z-statistic reported.

Daily adherence data were analyzed using generalized linear mixed model (GLIMMIX) analyses with multinomial response distribution and a cumulative logit link function. This approach was used to model this ordinal outcome measure (0%, 25%, 50%, 75%, & 100% adherence) over time from being prescribed up to 4 puffs per day. Multiple covariance structure models were tested, with an unstructured matrix best fitting by AIC. For this pilot RCT, prescription dose was not

used for block randomization into AAP group. Only one youth had been prescribed one puff per day; all other youth had 2 or 4 puffs prescribed per day. Thus, the youth prescribed only one puff was excluded from adherence analysis. The GLIMMIX models included main effects for prescription type (e.g. 2 puffs vs. 4 puffs per day), Group, Time, and all interaction effects. Effects should be interpreted as modeling the lower adherence category relative to having perfect (100%) adherence. GLIMMIX models with binary response distribution were also conducted for the binary outcome of ACT cutoff ≥ 19 and main effects were reported by Group, Time, and the Group * Time interaction.

Linear mixed models with restricted estimation maximum likelihood estimation and Kenward-Richardson adjustment for the degrees of freedom were used for continuous outcome data (i.e. AAP knowledge, satisfaction). Group, Time, and Group * Time effects were included in the model. Random effects statement included the time, with participants listed by ID. Different covariance structures and intercept inclusion were tests; AIC was used to determine best model fit with the best fitting model including no intercept and an unstructured covariance matrix.

Sensitivity analysis was run to assess relationships between health literacy, asthma numeracy, and youth reading comprehension scores and changes in outcomes by adding in covariates and interaction terms with group and time in the models; there was no statistically significant relationships.

Results

Sample characteristics

Table 1 contains descriptive statistics for total sample, and separated by group, at enrollment. Youth were on average nearly 12 years of age, largely White, and mostly female. Most caregivers had a high school degree or equivalent and had indicators (e.g. annual income, insurance status) of lower socioeconomic status. No statistically significant differences were seen among these demographic variables by group. Mean differences over time and by group are presented in Table 2, and test statistics for these differences are shown in Table 3. Measures of literacy and health literacy and numeracy did not differ between groups and were not related to outcomes.

Feasibility

In this study, 75% of the target sample of 60 was successfully recruited ($N=45$), albeit over a longer period than planned. The study had high levels of participant

Table 1. Descriptive data for total sample by the AAP group.

Variable	N	%	WAAPN (Col% ^a)	PAAPN (Col% ^a)	OR ^b (PAAP)	OR ^b 95% CI	p Value
Group			–	–	–	–	–
WAAP	23	51.11					
PAAP	22	48.89					
Prescription					–	–	–
1 puff daily	1	2.22	1 (100.00)	0 (0.00)			
2 puffs daily	16	35.56	10 (62.50)	6 (37.50)			
4 puffs daily	28	62.22	11 (39.29)	17 (60.71)			
Sex							
Male	18	40.00	9 (39.13)	9 (40.91)	0.93	0.28, 3.06	.90
Female	27	60.00					
Race							
White	42	95.45	22 (100.00)	20 (90.91)	–	–	.49 ^c
School grade							
Elementary (1–4)	13	28.89	6 (26.09)	7 (31.82)	–	–	.75
Middle (5–8)	21	46.67	12 (52.17)	9 (40.91)			
High (9–12)	11	24.44	5 (21.74)	6 (27.27)			
Insurance							
Medicaid/medicare	37	88.10	18 (85.71)	19 (90.48)	1.58	0.24, 10.61	1.00 ^c
Variable	N	M	SD	WAAPM(SD)	PAAPM(SD)	t Test statistic	p Value
Youth age							
Years	45	11.79	2.75	11.87 (2.65)	11.70 (2.91)	0.20	.84
Caregiver age							
Years	45	41.16	8.95	42.26 (9.88)	40.00 (7.92)	0.84	.40
WIAT reading comprehension							
Age based	44	96.30	17.42	95.50 (22.45)	97.09 (10.78)	–0.30	.77
FEV ₁ % predicted	34	91.53	25.52	85.31 (14.25)	97.06 (31.89)	–1.36	.18
FEF _{25–75} % predicted	34	78.45	35.33	72.87 (22.92)	84.03 (44.54)	–0.92	.37
Variable	N	Median	[25th, 75th IQR^d]	Type of AAP	Mean score ranks	Z test statistic	p Value
ANQ	45	4	[3, 4]	PAAPWAAP	22.7523.24	–0.13	.90
Youth S-TOFHLA	18	34	[32, 35]	PAAPWAAP	7.4411.15	–1.48	.14
Caregiver S-TOFHLA	45	35	[35, 35]	PAAPWAAP	25.0921.00	1.19	.23

Note: Group differences tested by chi-square, Fisher's exact, Mann-Whitney, or *t* test as appropriate for variable type.

Possible range for WIAT, FEV₁, and FEF_{25–75} scores is 0–100.

Possible range for Asthma Numeracy Questionnaire (ANQ) = 0–4, Youth S-TOFHLA = 0–36, and Caregiver S-TOFHLA = 0–36.

^aCol%, column percentage.

^bOR, odds ratio.

^cFisher's exact *p* values.

^dIQR, inter-quartile range.

retention, with 98%, 93%, and 73% of participants completing 1-, 3-, and 6-month follow-up, respectively.

Preliminary evidence for intervention efficacy

AAP knowledge

Caregiver and youth scores on the AAPKI each were evaluated by Group, Time, and Group * Time (see Tables 2 and 3). For caregiver AAPKI, all effects were non-significant. For youth AAPKI, there was a significant main effect for Group, $t(79.7) = -14.3$, $p = .03$, such that knowledge was lower for youth in the WAAP group. No statistically significant main effect for Time ($p = .42$) or Group * Time ($p = .89$) were found for youth knowledge.

Medication adherence

According to the sensor data youth in the WAAP group had similar adherence at day 1 (Median = 50, IQR = 50, 75) compared to those in the PAAP group (Median = 50, IQR = 50, 75). The fixed effects are presented in Table 4, and graphical representation of the ICS prescription dose (2 vs. 4 puffs) by Group * Time effect is presented in Figure 3. Analysis

of adherence data revealed no statistically significant differences by Time ($p = .52$), Group ($p = .79$), Group * Time ($p = .14$), Prescription ($p = .39$), and Group * Prescription ($p = .12$). A statistically significant three-way interaction was found for the Time * WAAP * 4 puffs per day prescription [Est. = 0.04, $t(5830) = 3.09$, $p = .002$], demonstrating that youth in the WAAP group that were prescribed 4 puffs per day had a slightly lower adherence rate over time relative to those who were prescribed 2 puffs per day.

Asthma symptom control

At baseline, scores on the ACT ranged from 7 to 23, and 40% of youth had well-controlled asthma (ACT total >19). For the ACT cut off (see Table 3), there were no statistically significant main effects of Group ($p = .07$), Time ($p = .06$), or interaction ($p = .33$), although effects were in the hypothesized direction (see Figure 4(A)). When the groups are combined, well-controlled asthma percentages increased from 40% at baseline, 68.2% at 1-month, 84.6% at 3-months, and 75.8% at 6-month.

Table 2. Descriptive statistics for outcome variables by time/session.

Variable	Group	Session							
		0-month		3-month		6-month		–	
		<i>N</i>	<i>M</i> (SD)	<i>N</i>	<i>M</i> (SD)	<i>N</i>	<i>M</i> (SD)		
<i>Caregiver AAPKI</i>									
Average percent	Total	45	66.79 (16.01)	39	67.24 (14.52)	32	60.50 (10.24)		
	WAAP	23	67.87 (14.60)	19	63.60 (12.25)	16	62.33 (9.78)		
	PAAP	22	65.66 (17.64)	20	70.69 (15.93)	16	58.68 (10.68)		
<i>Youth AAPKI</i>									
Average percent	Total	45	59.51 (19.35)	39	63.82 (15.50)	33	63.72 (15.05)		
	WAAP	23	52.66 (19.00)	19	57.16 (10.16)	17	58.33 (11.37)		
	PAAP	22	66.67 (17.36)	20	70.14 (17.22)	16	69.44 (16.67)		
<i>ACT cutoff >19</i>									
		<i>N</i>	0-month <i>n</i> (%)	<i>N</i>	1-month <i>n</i> (%)	<i>N</i>	3-month <i>n</i> (%)	<i>N</i>	6-month <i>n</i> (%)
	Total	45	18 (40.00)	44	30 (68.18)	39	33 (84.62)	33	25 (75.76)
	WAAP	23	7 (30.43)	22	11 (50.00)	19	16 (84.21)	17	13 (76.47)
	PAAP	22	11 (50.00)	22	19 (86.36)	20	17 (85.00)	16	12 (75.00)
		<i>N</i>	0-month <i>M</i> (SD)	<i>N</i>	3-month <i>M</i> (SD)	<i>N</i>	6-month <i>M</i> (SD)	–	–
	Total	34	91.53 (25.52)	29	96.90 (15.10)	24	98.13 (17.25)		
	WAAP	16	85.31 (14.25)	14	91.29 (12.02)	11	99.09 (20.91)		
	PAAP	18	97.06 (31.89)	15	99.61 (19.82)	13	97.31 (14.31)		
<i>FEF_{25–75}</i>									
% predicted	Total	34	78.45 (35.33)	25	91.73 (23.55)	21	85.30 (25.45)		
	WAAP	17	72.87 (22.92)	13	84.46 (25.10)	10	85.99 (25.45)		
	PAAP	17	84.03 (44.54)	12	99.61 (19.82)	11	84.67 (26.68)		
		<i>N</i>	1-month <i>M</i> (SD)	<i>N</i>	3-month ^a <i>M</i> (SD)	<i>N</i>	6-month <i>M</i> (SD)	Final (combined 3-month/6-month) <i>N</i>	<i>M</i> (SD)
<i>Satisfaction – youth</i>									
	Total	44	3.59 (0.34)	6	3.65 (0.32)	33	3.63 (0.31)	39	3.63 (0.31)
	WAAP	22	3.53 (0.40)	2	3.32 (0.32)	17	3.50 (0.35)	19	3.48 (0.34)
	PAAP	22	3.65 (0.24)	4	3.82 (0.17)	16	3.76 (0.21)	20	3.77 (0.20)
<i>Satisfaction – caregiver</i>									
	Total	44	3.66 (0.33)	6	3.65 (0.37)	32	3.64 (0.32)	38	3.64 (0.32)
	WAAP	22	3.67 (0.30)	2	3.55 (0.51)	16	3.70 (0.28)	18	3.68 (0.30)
	PAAP	22	3.64 (0.37)	4	3.70 (0.37)	16	3.57 (0.35)	20	3.60 (0.35)

Note: AAPKI, Asthma Action Plan Knowledge Interview; ACT, Asthma Control Test; FEV₁, Forced Expiratory Volume; FEF₇₅₋₇₅, Forced Vital Capacity.

Possible range for caregiver and youth AAPKI score is 0–100.

Possible range for FEV₁ and FEF₂₅₋₇₅ scores is 0–100.

Possible range for Satisfaction Survey scores is 1–4.

^aSelect measures had six participants completing at 3-month instead of 6-month session, and so are combined into a final time point.

Lung function

Table 2 displays sample descriptive statistics for percent predicted values of FEV₁ and FEF₂₅₋₇₅. Linear mixed models with a random effects statement for time were used to analyze FEV₁ (percent predicted). No statistically significant main effect of Time ($p=.80$), Group ($p=.08$), or interaction ($p=.29$) was observed (see Table 3).

Satisfaction

Mean scores for satisfaction measured at the end of the intervention (i.e. 3-month/6-month assessment visit) suggested that caregivers in the PAAP ($M=3.60$; $SD=0.35$) and WAAP ($M=3.68$; $SD=0.30$) groups rated their AAP experience as positive, overall (see Table 3). Youth AAP satisfaction reported at 3-month/6-month assessment were also positive for PAAP ($M=3.77$; $SD=0.20$) and WAAP ($M=3.48$;

$SD=0.34$) groups. AAP satisfaction scores for both youth and caregivers were evaluated by Group, Time, and Group * Time. There were no statistically significant main effects observed for caregiver's satisfaction by Time, Group, or Group * Time interaction. Analysis of youth-reported satisfaction scores found no statistically significant main effects of Time or Group. However, results yielded a significant Group * Time interaction ($Est = -0.21$, $t(31.8) = -2.26$, $p=.03$), with lower satisfaction over time being seen for the WAAP group relative to the PAAP group (see [Figure 4\(B\)](#)).

Discussion

We sought to improve the usability of AAPs by implementing a simple, computer-generated, individualized PAAP for youth and their families. Indeed, visual

Table 3. Fixed effects for time by group for knowledge, satisfaction, and asthma control.

Outcome	Effect	Estimate	Standard error	DF	t Value	p Value
<i>Caregiver AAPKI – average percent</i>						
	Intercept	68.53	4.13	71.3	16.58	<.0001
	Group (ref = PAAP)	1.13	5.79	71.5	0.20	.85
	Time	–1.16	1.50	111	–0.77	.44
	Group*Time (ref = PAAP)	–0.74	2.12	111	–0.35	.73
<i>Youth AAPKI – average percent</i>						
	Intercept	65.48	4.30	78.4	15.24	<.0001
	Group (ref = PAAP)	–14.68	6.01	78.4	–2.44	.017
	Time	1.36	1.63	113	0.84	.40
	Group*Time (ref = PAAP)	0.61	2.27	113	0.27	.79
<i>FEV₁ % predicted</i>						
	Intercept	97.35	6.33	52.3	15.38	<.0001
	Group (ref = PAAP)	–16.63	9.26	53.8	–1.80	.08
	Time	0.59	2.33	82.9	0.26	.80
	Group*Time (ref = PAAP)	3.64	3.41	82.8	1.07	.29
<i>Caregiver satisfaction</i>						
	Intercept	3.64	0.07	41.9	51.28	<.0001
	Group (ref = PAAP)	0.02	0.10	42.3	0.21	.83
	Time	–0.02	0.06	36	–0.33	.74
	Group*Time (ref = PAAP)	0.03	0.09	37.2	0.33	.74
<i>Youth satisfaction</i>						
	Intercept	3.65	0.07	42.1	51.19	<.0001
	Group (ref = PAAP)	–0.12	0.10	42.6	–1.16	.25
	Time	0.12	0.06	30.7	1.84	.08
	Group*Time (ref = PAAP)	–0.21	0.09	31.8	–2.26	.03
<i>ACT cutoff >19</i>						
	Intercept	–0.08	0.60	114	–0.13	.90
	Group (ref = PAAP)	–1.57	0.85	114	–1.86	.07
	Time	0.52	0.27	43	1.95	.06
	Group*Time (ref = PAAP)	0.37	0.37	114	0.98	.33

Note: AAPKI, Asthma Action Plan Knowledge Interview; FEV₁, Forced Expiratory Volume; ACT, Asthma Control Test.

Table 4. Fixed effects for daily adherence (*N* = 44; max observations 180), estimates modeling belonging to a lower adherence category.

Effect	Estimate	Standard error	DF	t Value	p Value	Type III p value
<i>Intercept (ref = 100%)</i>						
0%	–1.99	0.46	41	–4.33	<.0001	–
25%	–1.86	0.46	41	–4.05	.0002	
50%	–0.14	0.46	41	–0.31	.76	
75%	0.05	0.46	41	0.12	.91	
<i>Time</i>						
Days	–0.01	0.01	41	–0.65	.52	.002
<i>Group (ref = WAAP)</i>						
PAAP	–0.16	0.60	5830	–0.26	.79	.07
<i>Time*Group (ref = WAAP)</i>						
PAAP	0.02	0.01	5830	1.47	.14	.37
<i>Prescription (ref = 2)</i>						
4 per day	0.43	0.49	5830	0.86	.39	.69
<i>Group*Prescription (ref = WAAP*2 per day)</i>						
PAAP*4 per day	–1.14	0.72	5830	–1.58	.12	.12
<i>Time*Group*Prescription (ref = 2 per day)</i>						
PAAP*4 per day	0.01	0.01	5830	1.00	.32	.006
WAAP*4 per day	0.04	0.01	5830	3.09	.002	
<i>Comparison</i>						
Group WAAP vs. PAAP	Odds ratio	Lower 95% CI	Upper 95% CI			
Unit change of day from mean for PAAP	1.11	0.28	4.36			
Unit change of day from mean for WAAP	1.02	1.01	1.03			
Prescription: 2 vs. 4	1.01	1.00	1.02			
	0.19	0.06	0.61			

health communication tools are associated with better comprehension of information, consumer satisfaction, self-management, and provider-patient engagement (31–33). The PAAP software and tool were developed through a stakeholder engagement process involving qualitative input from youth and caregivers, and

iterative development with asthma providers. The resulting tool was tested in this pilot and feasibility RCT, in line with guidance for intervention development and evaluation (34). Our findings partially confirmed the hypothesis that knowledge, medication adherence, and symptom control would improve

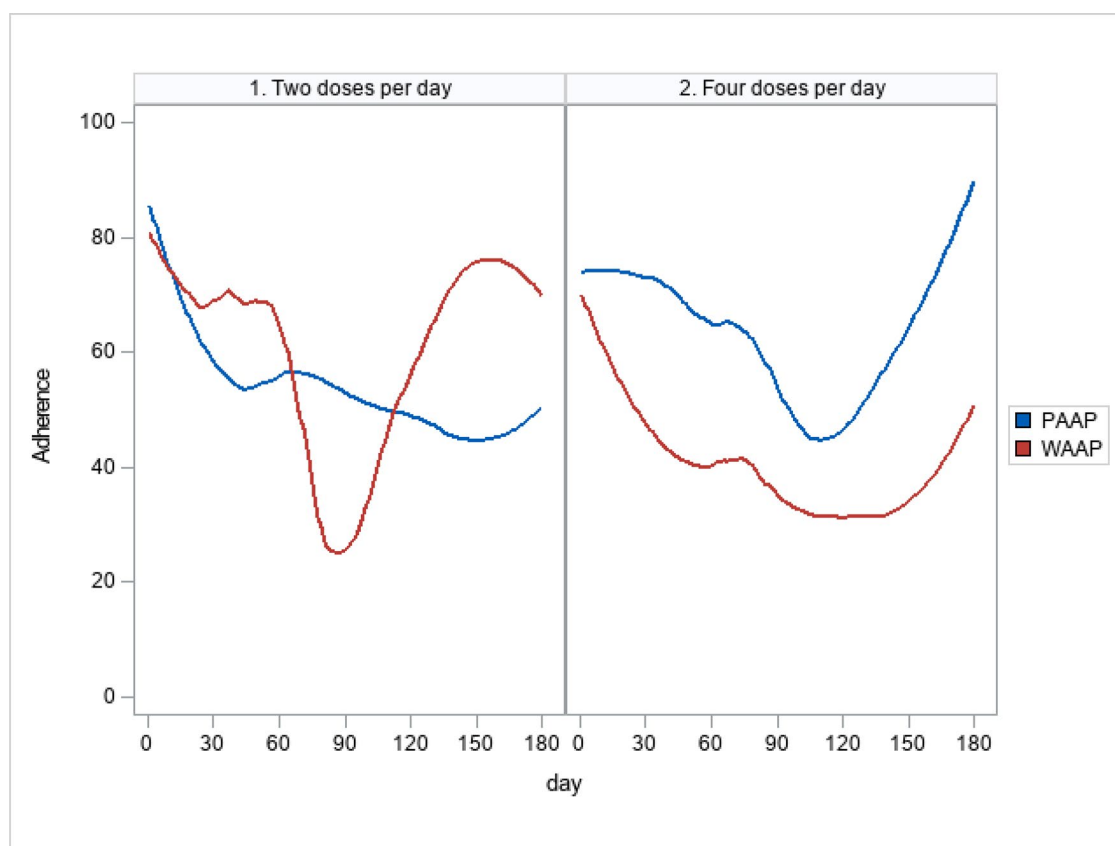


Figure 3. Mean predicted loess line with smoothing for daily adherence, stratified by prescription.

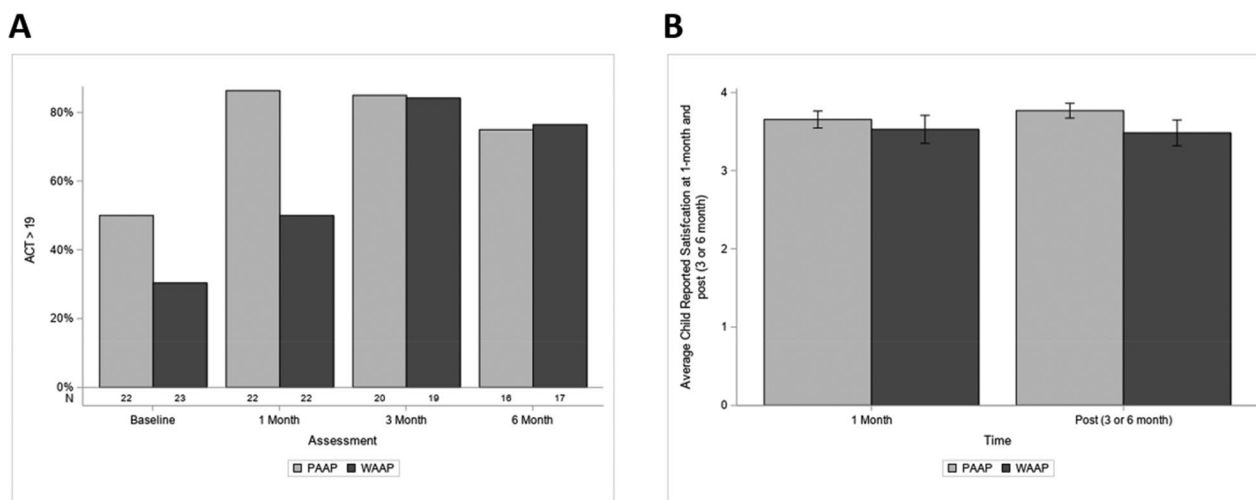


Figure 4. Significant outcomes. Panel A: Percent of participants with good asthma control [i.e. Asthma Control Test (ACT) or Childhood ACT >19] over time and by group. Panel B: Mean differences over time and by group for youth satisfaction.

significantly more over time for those in the PAAP group relative to the WAAP group. Nonetheless, results supported some potential value of PAAPs, as well as the feasibility of evaluating a broader intervention specifically targeting asthma education strategies incorporating PAAPs.

Most youth recruited for this study were not newly diagnosed, aligning with previous research reporting

that AAPs are often not prescribed (4,9) despite being recommended in asthma treatment guidelines (5). This finding suggests that a PAAP may offer a solution to the usability related barriers associated with AAPs reported in previous research (14). AAP knowledge was significantly higher in the PAAP compared to the WAAP group, and youth in the PAAP group were significantly more satisfied with their AAP,

suggesting greater usability and appeal of PAAPs. Ensuring youths with asthma have the necessary knowledge and tools is a fundamental building block for improving medication adherence and health outcomes. This is particularly important given that children begin to take on some responsibility for asthma self-management from the age of 7, possibly assuming 50% of ICS responsibility by age 11 (35). In one study with 6–11 year olds with asthma, they viewed themselves as having significantly more responsibility than their parents believed they had, emphasizing the importance of youth-focused asthma education and empowerment (36).

Our results indicate that youth in the WAAP group taking four puffs of ICS per day had a slightly lower adherence rate compared with those in that group taking two puffs per day. A range of the many inter-related factors found to influence adherence may have played a role here, in addition to the AAP type. However, this finding does align with existing literature that regimen complexity including multiple daily dosing is associated with lower adherence (36). Evidence from individual studies on the impact of once daily dosing versus higher frequency on adherence is variable (37,38). However, it is recommended to prescribe as few doses as possible, and may reduce possible barriers to adherence, such as forgetting or low belief in the effectiveness of medications (38–40).

No relationship was found between AAP type, literacy, and health literacy and numeracy, limiting our ability to make conclusions related to improved comprehension of the PAAP compared with the WAAP. Nonetheless, findings from previous studies linking SES, health literacy and a range of health behaviors and outcomes (41–43) emphasize the need for user-friendly tools such as a PAAP.

Qualitative interviews were conducted with youth, caregivers, and providers involved in the study, and the findings will provide insights into preferences and AAP use. The impact of the PAAP software, which enabled providers in this study to quickly and easily generate individualized PAAP for their patients, will also be examined in the qualitative data, which may indicate whether or not PAAPs can overcome widely reported AAP prescribing barriers from the provider perspective (12). In addition, perceptions of providers related to PAAP usability by patients and families, in comparison to traditional WAAP will also be explored and reported in a future publication.

Addition of an AAP, regardless of written or pictorial format, did not significantly affect adherence to ICS medication or asthma symptom control (measured using self-report and spirometry) in this study.

We did not gather a baseline run-in period of medication adherence monitoring; therefore, we cannot make conclusions about adherence prior to study baseline. However, a sizable proportion of the sample had poorly controlled asthma, implying preexisting concerns with adherence. It is noteworthy that 70% of the WAAP group and 50% of the PAAP group had scores reflecting clinically significant asthma symptoms at baseline. Although not statistically significant, these rates dropped to 23% and 25% for the WAAP and PAAP groups, respectively, at 6-month follow-up. A longer follow-up period in this study would have provided data on the impact of greater AAP knowledge and satisfaction on adherence and health outcomes over time.

Implications for research and practice

Overall, this study's findings suggest youth with asthma may benefit from an education intervention using a PAAP, given that it was associated with better regimen knowledge (relative to a WAAP) and greater satisfaction in using it across time. However, achieving significant improvements in important outcomes such as adherence, symptom control, and lung function is difficult and requires a more intensive, multi-level intervention.

In the next phase of this research, an AAP intervention will be expanded to include evidence-based components addressing a wider range of barriers to ICS adherence among youth with asthma. The COM-B (Capability, Opportunity, Motivation – Behavior) model enables intervention developers to identify barriers to a particular behavior to design intervention components that will bring about change (44). The findings of this study suggest that focusing on capability related factors alone, such as AAP knowledge, was not sufficient to change behavior in terms of daily ICS adherence. Therefore, motivation (e.g. beliefs about capability) and opportunity (e.g. access to resources) related factors will be explored to identify modifiable targets for a future intervention study. For example, a more formal education session format including evidence-based strategies, such as the repetition of key messages at regular intervals (45) may be a useful addition to a future PAAP intervention.

The next phase of the study will also seek to optimize the PAAP tool itself, based on the findings of this study. Key considerations will be the integration of software to generate tailored AAPs within hospital electronic systems, options for pictorial, written, or hybrid AAPs to match preferences and symptoms, and

the ongoing management and review of AAPs by providers and youth through shared decision making. The high rate of retention in this study and positive feedback on the satisfaction survey suggest that a future full-scale RCT, involving electronic monitoring of inhaler adherence, are feasible.

Limitations

This study had some important limitations. First, we encountered challenges in recruiting a sufficient number of pediatric clinics catering to youth with asthma, and as a result, the representativeness of the sample and our ability to recruit the target sample of 60 participants was limited. The sample size is small, despite extending the recruitment period. Although the sample reflected the demographic characteristics of West Virginia, there was minimal racial diversity in this sample. Second, age and asthma severity were accounted for in stratified randomization, but prescription dose was not. Though the two groups were balanced for age and asthma severity, with a larger, more representative sample, future research could examine whether these variables moderate study outcomes. Third, adherence was measured from the baseline visit, at which time youth received their AAP. Therefore, we could not assess adherence to ICS pre-intervention. Fourth, social desirability bias in responding to the verbally-administered satisfaction survey is possible; however, both the groups were assessed in a similar manner. Moreover, the interviewer invited additional feedback from respondents after they had provided their rating, to elicit reasons for the rating and to demonstrate that we valued their honest opinions. Finally, the WAAP group was intended as a usual care group in the protocol for this study. However, it transpired that the majority of youth with asthma assessed for eligibility for this study had never received an AAP, regardless of their duration of diagnosis with asthma. We intended that a considerable proportion of our sample would be newly diagnosed with asthma and naïve to AAPs, and that the provision of a WAAP would reflect usual care. As a result, both arms of this RCT received an education intervention, limiting our ability to make conclusions about the additional contribution of the pictorial format of the PAAP.

Conclusion

This study contributes to a growing literature describing novel, technology-supported AAPs interventions. The iterative, guideline-based, and stakeholder-driven

nature of this research will maximize the likelihood of developing a feasible and acceptable AAP education intervention ahead of a future full-scale RCT. The findings suggest that an electronic PAAP may help to address widely reported barriers to AAP prescription and use in pediatric asthma, based on preliminary usability and satisfaction results. Additional intervention components addressing relevant youth, family, and health service factors are necessary to address the complex, interacting determinants of asthma management and health outcomes. Drawing on the results of this study and guidance for intervention development, we will continue to refine this intervention and its implementation, to provide evidence-based approaches for supporting best practice in pediatric asthma management.

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Declaration of interests

The authors report no conflicts of interest relevant to this article to disclose. The authors alone are responsible for the content and writing of this article.

Author notes

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ORCID

Lisa Hynes  <http://orcid.org/0000-0003-0419-2188>
 Kristine Durkin  <http://orcid.org/0000-0002-7410-7228>
 Thomas Ewell  <http://orcid.org/0000-0002-5885-5189>
 Christa Lilly  <http://orcid.org/0000-0002-0009-0638>
 Desirée N. Williford  <http://orcid.org/0000-0003-1763-5507>
 Corrine Ahrabi-Nejad  <http://orcid.org/0000-0002-3013-0987>
 Viral Kothari  <http://orcid.org/0000-0002-0046-0707>
 David Skoner  <http://orcid.org/0000-0002-5463-0556>
 Christina L. Duncan  <http://orcid.org/0000-0001-5460-7981>

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