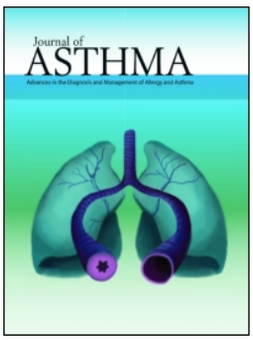

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Controller adherence following hospital discharge in high risk children: A pilot randomized trial of text message reminders

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ABSTRACT

Objective: To assess the feasibility of a mobile health, inhaled corticosteroid (ICS) adherence reminder intervention and to characterize adherence trajectories immediately following severe asthma exacerbation in high-risk urban children with persistent asthma. *Methods:* Children aged 2–13 with persistent asthma were enrolled in this pilot randomized controlled trial during an asthma emergency department (ED) visit or hospitalization. Intervention arm participants received daily text message reminders for 30 days, and both arms received electronic sensors to measure ICS use. Primary outcomes were feasibility of sensor use and text message acceptability. Secondary outcomes included adherence to prescribed ICS regimen and 30-day adherence trajectories. Group-based trajectory modeling was used to examine adherence trajectories. *Results:* Forty-one participants (mean age 5.9) were randomized to intervention ($n = 21$) or control ($n = 20$). Overall, 85% were Black, 88% had public insurance, and 51% of the caregivers had a high school education or less. Thirty-two participant families (78%) transmitted medication adherence data; of caregivers who completed the acceptability survey, 25 (96%) chose to receive daily reminders beyond that study interval. Secondary outcome analyses demonstrated similar average daily adherence between groups (intervention = 36%; control = 32%, $P = 0.73$). Three adherence trajectories were identified with none ever exceeding 80% adherence. *Conclusions:* Within a high-risk pediatric cohort, electronic monitoring of ICS use and adherence reminders delivered via text message were feasible for most participants, but there was no signal of effect. Adherence trajectories following severe exacerbation were suboptimal, demonstrating an important opportunity for asthma care improvement.

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KEYWORDS
Mobile health; inhaled corticosteroids; medication adherence; trajectory modeling

Abbreviations

ED	Emergency Department
ICS	inhaled corticosteroids
cACT	child Asthma Control Test
GBTM	group-based trajectory modeling
BIC	Bayesian information criterion
AV	audiovisual

Introduction

Asthma is a leading cause of childhood illness and hospitalization in the U.S. Non-Hispanic Black children with asthma have higher rates of emergency department (ED) visits, hospitalization, (1) and repeat hospitalization (2,3) compared with children of other races or ethnic backgrounds. The reasons for these outcome disparities are numerous (4,5), but poorer adherence to daily controller medication is one important contributor (5). While general estimates of adherence to prescribed inhaled corticosteroid (ICS) medication regimens for childhood asthma are around 50% (6), studies in urban minority pediatric populations demonstrate considerably lower rates of 11 to 37% (7–11).

One potential window of opportunity to boost adherence would be when a child with asthma either visits the ED or is hospitalized. While adherence to controller therapy for childhood asthma has been studied extensively (6,12,13), little is known about adherence behaviors immediately following severe exacerbations. Prior work has shown that filling inhaled corticosteroids in a timely manner following ED or hospital discharge

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is associated with lower rates of revisits (14,15) and at least one prospective study demonstrated improved outcomes when discharge medications were provided for children and their families prior to leaving the hospital (16). Methods for assessing daily medication use trajectories have been applied to specific intervals for other pediatric chronic conditions (17,18), yet how families take asthma medications following ED or hospital discharge has not been characterized. Further, mobile health reminder strategies that have shown considerable effects on enhancing ICS adherence in other countries (19,20) may be feasible and efficacious for high-risk U.S. populations during this period of heightened risk.

This study sought to assess use and acceptability of electronic inhaler sensors, as well as a limited assessment of ICS adherence with and without a daily text message reminder intervention in a cohort of high-risk children with a recent asthma-related ED visit or hospitalization. Additionally, we examined ICS adherence trajectories and associated child and family characteristics in the month following ED or hospital discharge.

Methods

Participants

Detailed descriptions of eligibility criteria, recruitment methods, conceptual model, measures assessed, and the intervention description have been previously published (21). Briefly, participants and their parent or legal guardian were recruited from the ED or inpatient setting between December 2015 and July 2016. Eligibility criteria included age 2 to 13 years, a diagnosis of persistent asthma, a prescription for a daily ICS in the last year listed in the child's electronic health record, a prescribed ICS medication at discharge that was compatible with the electronic monitoring sensor, and current residence or primary care in a Philadelphia ZIP code with high child asthma hospitalization rates. A parent or legal guardian also needed a cellular plan with unlimited text messages. Participants were excluded if they had comorbid conditions that may influence asthma treatment (e.g., chronic lung disease such as cystic fibrosis or structural heart disease requiring ongoing treatment), were prescribed an incompatible ICS, had significant developmental delays, were non-English speaking, or had an open social services case, as determined by their hospital care team. Families who provided informed consent were enrolled following child assent for patients >7 years of age. The protocol for the conduct of this study was approved by the institutional review board at our institution and is registered on ClinicalTrials.gov (NCT02615743).

Randomization and intervention

Eligible participants and caregivers were randomized into either the control or intervention group using a computer-generated random number sequence and 1:1 block randomization scheme based on location of enrollment (inpatient or ED block size = 5). Each participant received an electronic sensor (Propeller Health, Madison WI) for data collection purposes only; therefore audiovisual reminders were not activated. For both study conditions, the study team member either attached the sensor to the ICS inhaler directly or, if the participant's ICS medication was at home, provided instructions on how to attach the sensor, pair, and synchronize (sync) the device with a mobile app or cellular hub. Study staff contacted participants whose sensors were not attached at discharge if the sensor did not sync or did not register initial actuation within 24–72 hours of discharge. Participants with smartphones from both arms downloaded a research "control" version of a mobile application, which was used for data transmission purposes only. No intervention or interaction was delivered via the app. If the participant did not have a smartphone, the participants were provided with a cellular hub that was paired with the sensor they received to transmit data. Participants in both study arms received text messages on days 3 and 27 to remind them to sync their sensors with their app or cellular hub.

The active intervention phase began the day of discharge and lasted for 30 days (Figure 1). Those in the intervention group received one of seven rotating automated text message reminders to take their ICS medications from the Way to Health platform (waytohealth.org), a behavioral research intervention platform. The text message reminders each included a brief tip about the value of regular controller use, described in greater detail elsewhere (21). Those in the control group received only two reminders to sync their sensors. Participants could select a preferred time of day to receive text messages from the Way to Health platform. At 30 days, all participants were contacted to arrange a 10-minute follow-up telephone survey. For those in the intervention group, a questionnaire assessing intervention acceptability and preferences was also administered. At the end of the call, all participants were given the option to continue receiving (intervention group) or start receiving (control group) text message medication reminders for an additional 30 days. At 60 days, participants were contacted to set up a study completion call and all text messages ceased. During this final call, participants completed another 10 minute-survey. For those who were initially in the control group and opted to receive text messages for the second 30 days, the study team administered the intervention acceptability and preferences questionnaire

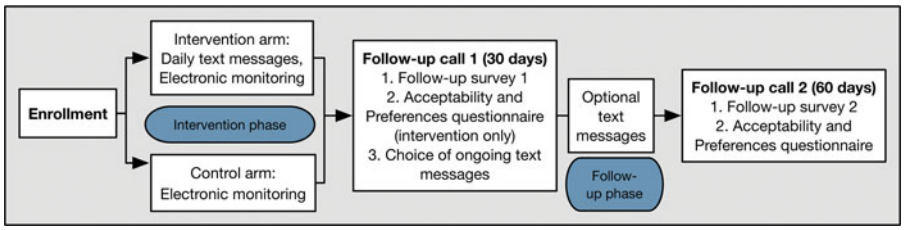

Figure 1. Study flow diagram.

during this second call. Participants were compensated $20 for enrollment and each completed follow-up call.

Outcomes

The outcomes were intervention feasibility (primary) and limited assessment of ICS adherence (secondary) (22). Feasibility was assessed in two ways: (1) the retention of participants in the study phases, determined by duration of electronic sensor syncing, and (2) the usefulness, acceptability, and preferences of text messages determined via questionnaire. For limited evaluation of efficacy, percent ICS adherence was determined (observed ICS actuations divided by prescribed ICS actuations multiplied by 100 over the 30-day active intervention phase) by electronic monitoring and change in asthma control was calculated as the difference between the parent-reported portion of the child Asthma Control Test (cACT) at 30 days compared to enrollment; however, the study was not powered for these outcomes. Inhaled controller medication use was measured in both groups using electronic sensors (23,24). Adherence trajectories were calculated for the 30-day period for all participants based on the daily medication use data.

Statistical analysis

To assess retention, we calculated the percentage of participants who synced their devices throughout the active intervention interval and the average number of days participants synced sensors with smartphones or hubs. We used summary statistics to describe Likert-based intervention acceptability and preferences question responses were dichotomized as follows: "Strongly agree"/"Agree" and "Uncertain"/"Disagree"/"Strongly disagree".

We compared raw ICS adherence rates between the intervention and control groups using student t-tests. To control for age and unbalanced baseline covariates, we used a multiple linear regression model. Daily adherence percentages were calculated for each participant and then averaged within each study condition by day. Participants were considered to have evaluable adherence data if they had at least 2 weeks of sensor syncing in the active intervention phase and at least one inhaler actuation during that interval. These criteria were defined a priori. Of note, this study was not powered to detect statistically significant differences in ICS adherence between the two groups; results were intended to provide preliminary adherence estimates with and without the intervention.

We used group-based trajectory modeling (GBTM) (25,26) to assess for qualitatively different post-hospitalization adherence patterns. We examined solutions with 2 to 5 distinct groups and compared solutions based on model fit (i.e., lowest Bayesian information criterion (BIC)) and, when the BIC was only marginally different, conceptual and clinical meaning. Based on these characteristics, we selected 2 and 3 group solutions. With the identified trajectories, we used multinomial regression to assess whether several exposures (study condition, caregiver education, and prior ED or hospital use) were associated with specific trajectories.

Results

Of the 130 who screened eligible via chart review, 80 children had a legal guardian by the bedside, who our team approached for consent. Of those approached, 41 (51%) consented to the study and were randomized (Figure 2). Equal numbers of participants from each arm ($n = 3$) never synced their sensors with the app or cellular

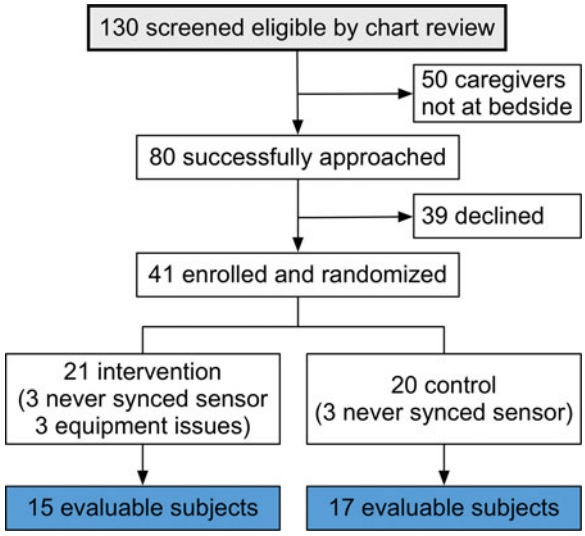

Figure 2. Study consort diagram.

Table 1. Demographic characteristics and baseline asthma control and past adherence of participants ($n = 41$).

Characteristics	Entire cohort ($n = 41$)	Intervention group ($n = 21$)	Control group ($n = 20$)
Child age (mean)	5.9 (2.1)	6.1 (2.1)	5.8 (2.1)
Child gender male	22 (54%)	12 (57%)	10 (50%)
Child's race			
Black	35 (85%)	20 (95%)	15 (75%)
Other	6 (15%)	1 (5%)	5 (25%)
Child's ethnicity			
not Hispanic	39 (95%)	21 (100%)	18 (90%)
don't know/prefer not to answer	1 (5%)	0	2(10%)
Child's health insurance			
Private	5 (12%)	1 (5%)	4 (20%)
Public	36 (87%)	20 (95%)	16 (80%)
Number of caregivers in home, mean (std)	2.2 (0.9)	2.2 (0.87)	2.3 (0.88)
Primary caregiver age, mean (std)	34.6 (10.0)	34.6 (8.9)	34.6 (11.6)
Primary caregiver marital Status			
Married	9 (22%)	4 (19%)	5 (25%)
Single/Unmarried	32 (78%)	17 (81%)	15 (75%)
Caregiver education level			
High school or less	21 (51%)	14 (67%)	7 (35%)
Some college and above	20 (49%)	7 (33%)	13 (65%)
Annual family income level			
≤$30,000	27 (66%)	15 (71%)	12 (60%)
>$30,000	14 (34%)	6 (29%)	8 (40%)
Baseline caregiver asthma knowledge questionnaire Score, mean (std)	93% (8.5)	93% (8.7)	92% (8.4)
Baseline child asthma control test score, mean (std)	17.3 (4.4)	17.8 (4.3)	17.2 (4.6)
Baseline prior adherence (caregiver-reported), mean (std)	64% (24%)	65% (23%)	62% (25%)
Baseline adherence intent, mean (std)	8.5 (2.1)	9.0 (1.7)	8.0 (2.3)
Prior asthma-related ED visits in year before enrollment, mean (std)	1.0 (1.5)	1.0 (1.5)	1.0 (1.6)
Prior asthma-related hospitalizations in year before enrollment, mean (std)	0.4 (0.7)	0.3 (0.6)	0.5 (0.8)

hub. An additional 3 participants (all in the intervention arm) experienced equipment issues that were eventually resolved but only after the active intervention phase of the study.

The demographic composition of the enrolled cohort and each study condition is provided in Table 1. Baseline child Asthma Control Test score was 17.3, indicating that, on average, children enrolled in the study had uncontrolled asthma. Baseline caregiver reported adherence to prescribed ICS regimen was 64%, and caregivers intended to give 85% of prescribed doses of ICS during the intervention period. There were no statistically significant differences between the intervention and control group, except for caregiver education level (Table 1).

Feasibility, acceptability, and preferences

ICS sensor data was available for 32 of the 41 randomized participants (78%). The mean number of days synced was 40.6 (std 23.4) and all but six participants who initially synced their devices synced throughout the 30-day active intervention interval.

We successfully contacted 32 of the 41 enrolled caregivers (78%) for the follow-up call at 30 days and 26 caregivers completed the acceptability and preferences survey at either 30 or 60 days. Participants who completed the survey were similar to those who did not, with two exceptions: education and marital status. A lower proportion of caregivers completing the survey had some college education or more (35% vs 73%, $p = 0.02$) and were not married (65% vs 100%, $p = 0.01$), compared to those who did not complete the survey. Of the caregivers who completed the acceptability and preferences survey, all found text message reminders helpful to avoid missing doses (100%) and 25 (96%) chose to receive daily text reminders beyond that study interval. Of those who completed the acceptability and preferences survey, 11 caregivers (42%) would have liked to have seen a report of their child's medication use, and nine (35%) thought that an incentive would have helped improve their child's medication adherence. Fifteen caregivers (58%) felt that text messages were the best way to receive information or reminders about their child's asthma care, 4 (15%) would prefer in-person conversation, 2 (8%) would prefer a mobile app, and 2 (8%) preferred phone conversation.

Adherence and adherence trajectories

Raw adherence rates in the 30-day intervention interval were 34% in the intervention group and 40% in the control group ($P = 0.56$). After adjusting for age and

Table 2. Unadjusted and adjusted average ICS adherence rates during 30-day intervention period.

		Unadjusted			Adjusted		
	n	Means	95% CI	*p*-value	Means	95% CI	*p*-value
Case status				0.56			0.73
Control	17	0.40	(0.25, 0.55)		0.32	(0.16, 0.48)	
Intervention	15	0.34	(0.18, 0.50)		0.36	(0.20, 0.52)	
Age				0.10			0.14
<5 years old	10	0.25	(0.06, 0.43)		0.26	(0.07, 0.44)	
5+	22	0.43	(0.31, 0.56)		0.43	(0.30, 0.55)	
Educational level				0.10			0.15
High school /Some college	16	0.29	(0.14, 0.43)		0.26	(0.10, 0.41)	
College and above	16	0.46	(0.31, 0.60)		0.43	(0.26, 0.59)	

parental education, there remained no significant difference between mean adherence between intervention and control group (control = 32% vs intervention = 36%, P = 0.73) (Table 2).

Mean daily medication adherence trends over the 30-day intervention interval were also similar between the two groups, with broadly overlapping standard deviations (Figure 3). Similarly, mean change in parent-reported portion of the cACT score over the 30 days of the intervention was not statistically significantly different between controls (3.1) and intervention (1.2) ($P = 0.16$).

Group-based trajectory models

Three distinct adherence trajectories were identified. The two-group linear solution performed best with regards to the BIC criteria (−724.32), whereas a three-group linear model with a marginally higher BIC (−696.23) identified a clinically important third group – participants with sharply declining adherence in the month following hospitalization (Figure 4). Of note, nearly 44% of participants in the two-group model and 35% in the three-group model were in the "sustained" trajectory, though this group never exceeded the 80% threshold goal for ICS adherence. Study condition was not associated with specific trajectories in the two-group, multivariable logistic regression model. Lower education level, however, was associated with higher odds of "lapsed" trajectory (OR 6.75, 95% CI [1.04, 43.67]).

Discussion

In this pilot study, we examined the feasibility and limited assessment of ICS adherence with and without a text message-based daily medication reminder intervention in the month immediately following childhood asthma ED visit or hospitalization. The study demonstrates that an intervention strategy that leverages mobile health technology to provide medication reminders was feasible and acceptable among most caregivers of children from this high-risk demographic. Caregivers generally perceived the intervention as acceptable, reporting that text messages were helpful to avoid missing doses. While the study was not powered for the adherence outcome, we did not demonstrate a signal of impact due to the text message intervention. ICS adherence was low, on average, with wide variation in daily adherence percentage within study arms, as well as across the study population. Group-based trajectory models based on adherence data collected via electronic sensors provided additional novel

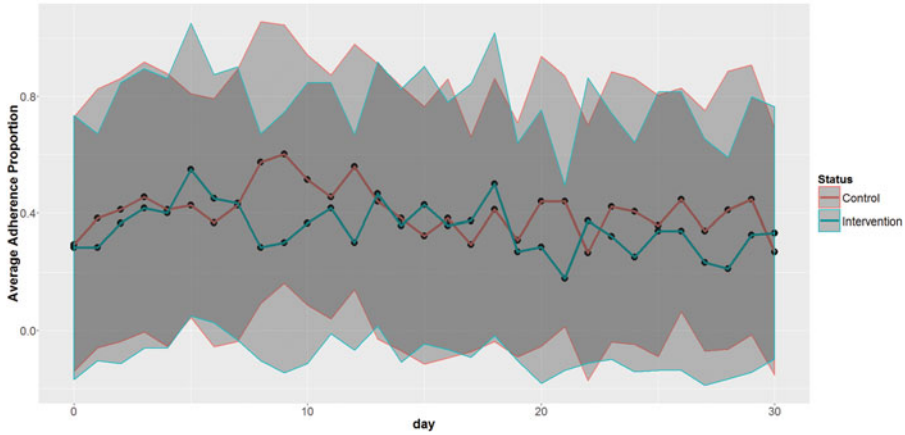

Figure 3. Average daily ICS adherence trends over 30-day intervention comparing intervention and control groups.

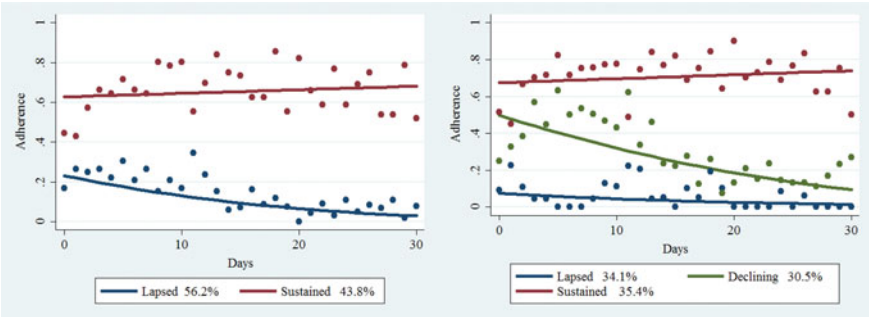

Figure 4. Two- and three-group adherence trajectories.

insight into actual medication use patterns following hospital discharge, evaluating daily medication-taking behavior that has not been previously reported.

While adherence interventions in children with asthma have traditionally shown at best modest effects (13,27,28), two studies of electronic asthma medication reminder interventions in other countries demonstrated robust improvements in medication adherence (27% and 54% higher than contemporary controls, respectively), as well as impact on certain disease outcomes (19,20). The first study recruited late adolescents and adults on daily inhaled steroids from general practice providers and specifically excluded patients who had an exacerbation in the preceding month (19) and the second recruited children aged 6–15 four weeks after presenting to an ED with asthma symptoms (20). In addition to differing recruitment settings and patient characteristics, these studies used dose-specific audiovisual (AV) reminders generated from the affixed monitoring devices, as opposed to daily text message reminders, and in the case of Foster, et. al., integrated the intervention into primary care (19).

These differences may – at least in part – explain the differential findings. While reminders generated by an affixed sensor remind everyone in the sensors vicinity of an upcoming or missed dose, sending text message reminders to a single caregiver presumes that that caregiver is always nearby the child and his/her medicines. Although we were able to program the reminders to arrive at a convenient time for caregivers and instructed them to forward the reminders to the caregiver who was with the child, the coordination of these logistics may be challenging for children of families with shifting daily schedules or who split time with different caregivers. Timing and logistics considerations may also help explain the observed discrepancy between caregiver perception of helpfulness and lack of evidence of behavior change. Alternatively, reminders alone may not be enough to prompt action. Accomodations for these issues may be particularly important for high-risk, minority pediatric populations, as prior studies of medication adherence in high risk urban pediatric populations demonstrate that low adherence is about more than "just forgetting" (13,29,30).

Based upon the findings from the current study, individualized participant feedback and child-oriented incentives may provide additional opportunities to engage participants beyond text message reminders. Prior studies have demonstrated improved use of controller medications with personalized adherence feedback in high-risk children (9,31). While adherence-oriented incentives have not been widely evaluated in childhood (32), certain incentive strategies (specifically conditional payments and regret lotteries) have led to behavior change in low-income, minority adults with other chronic conditions (33). Future studies should assess how these incentive strategies may improve adherence in children prescribed daily asthma medications. Additional intervention components that have demonstrated promise in other studies include AV reminders on the inhaler sensors, participant and clinician real-time access to medication use data, and further integration of mobile-health strategies with existing care with consistent provider education, inhaler technique training, and shared decision-making (30,34). Judicious selection and combination of these intervention components will be key to future adherence efficacy and effectiveness studies.

Lastly, while at least one prior adult study has measured the decay in asthma medication taking immediately following hospitalization (35), to our knowledge this is the first study demonstrating the analogous kinetics of medication use following a severe exacerbation in children with persistent asthma. Our results reveal that even among a cohort of children with persistent asthma and their caregivers who are potentially motivated by a recent hospital discharge, average adherence to prescribed ICS doses in the month following a severe exacerbation was only 34–40%.

Our trajectory analysis findings further revealed even the 44% of our cohort with sustained daily adherence never exceeded the recommended adherence threshold of 80% (36) and the majority of children and families lapsed shortly after hospital discharge. Caregivers with less than a high school education had higher odds of lapsed trajectory, delineating a potentially important risk factor for future nonadherence. Trajectory analysis has

been used in other pediatric chronic conditions with similar groupings (17,18,37). Future, fully powered studies should aim to detect other characteristics associated with lapsed trajectories to help better target adherence interventions to those who are likely to struggle with medication use the most (26). Additionally, future studies could leverage this approach to better understand what factors lead to more optimal adherence in "sustained" trajectory groups. These observations are now possible with electronic monitoring of medication use.

Given that the primary outcome was feasibility, findings should be interpreted in light of the study's limitations. First, our assessment of perceived acceptability to participants was limited in two ways. Participants who were lost to follow-up ($n = 9$) may have perceived the intervention less favorably, and participants who completed the survey may have been influenced by social desirability bias. That said, those who completed the acceptability and preferences questionnaire were similar to those that did not with respect to race, payor, income, and baseline asthma control. Second, our sample size was small and the study was not powered to detect a statistically significant difference in adherence or change in asthma control, but to provide a limited evaluation of efficacy data to inform future study design (22). Efficacy estimates from small feasibility or pilot studies are more likely than not to overestimate or underestimate the actual effect sizes (38) and must be interpreted with caution.

Third, we included preschool children with persistent asthma in this study, a group for whom the diagnosis of persistent asthma may be more uncertain and the value of daily ICS less universally accepted. As Table 2 demonstrates, children aged <5 had, on average, an 18% lower adherence proportion (unadjusted) than older children which approached statistical significance ($P = 0.10$), suggesting that there may be additional challenges in promoting ICS use, if it is truly indicated, in children of this age category. Lastly, the study interval was only 30 days and there was no run-in interval. Though adherence was similarly low in both groups, there may have been an observation (Hawthorne) effect given that participants had a monitoring device on their ICS inhaler. This effect would have been present in both study conditions and may have led to a less accurate estimate of post-discharge adherence in its natural state.

Conclusions/key findings

In conclusion, text messages and electronic monitoring of inhalers were a feasible and acceptable way to communicate about and monitor adherence in most study participants. Enhancing adherence to controller medications in high-risk children with asthma following ED or hospital discharge is one potential strategy to attempt to prevent readmissions and improve asthma outcome disparities. This study demonstrates low average adherence to ICS in the 30 days following ED visit or hospitalization, indicating that even during a period of recent heightened disease activity, there is dramatic room for improvement in ICS adherence. Further, we identify several distinct trajectories of adherence that should be better characterized with larger, fully powered studies to help target and tailor interventions for those at risk of lapsed or declining adherence.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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