

A Randomized Controlled Trial of Electronic Medication Monitoring (EMM), Patient Mobile App and Health Care Provider Feedback compared to EMM alone on Inhaled Corticosteroids (ICS) and Short-Acting Beta₂-Agonist (SABA) Utilization and Asthma Control in Adult Patients with Uncontrolled Asthma

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Rationale

- Digital platforms for asthma have been FDA-cleared since 2010.
- Further research demonstrating clinical benefit is still needed before generalized adoption.
- This study aimed to determine the benefit of a digital inhaler platform, plus asthma nurse feedback, on SABA and ICS utilization.

Methods

- Adults 25-65 years of age with uncontrolled asthma (defined as ACT ≤ 19 and/or per NHLBI EPR-3 criteria) and prescribed ICS and SABA inhalers were enrolled.
- Participants' ICS and SABA inhalers were fitted with an EMM (Propeller Health, USA) to track real-time medication usage.
- After a 14-day baseline period, participants were block randomized (3:1) to the treatment group (TG) with medication reminders and feedback via a smartphone app, or attention control group (ACG) with no reminders or feedback. TG participants also received monthly asthma nurse phone calls. The nurse monitored the Propeller Health web dashboard for real-time inhaler medication use. After consultation with an asthma specialist the nurse provided adherence feedback and coaching.
- Linear mixed models compared the percentage of days of SABA use and ICS use during baseline vs. the last 14 study days, defined as the two weeks prior to the final study visit or last two weeks of sync.

Table 1. Baseline characteristics of 100 randomized participants

Characteristic	Attention Control n = 25	Treatment n = 75
Age, mean years (SD)	46.1 (14.3)	49.3 (11.6)
Male gender, n (%)	5 (20.0)	15 (20.0)
Race, n (%)		
Black or African American	7 (28.0)	19 (25.3)
Asian	3 (12.0)	3 (4.0)
White or Caucasian	15 (60.0)	53 (70.7)
ICS containing medications, n (%)*		
ICS monotherapy	7 (28.0)	11 (14.7)
ICS and LABA combination therapy	18 (72.0)	63 (84.0)
ICS and LABA and LAMA combination therapy	1 (4.0)	0 (0.0)
Uncontrolled asthma defined by ≥ 1 criteria below†		
EPR-3 asthma guidelines, n (%)	19 (76)	62 (82)
ACT score ≤ 19	17 (68.0)	49 (65.3)
≥ 2 courses of oral corticosteroids for an asthma exacerbation	17 (68.0)	30 (40.0)
≥ 1 ED visit or hospitalization for an asthma exacerbation	10 (40.0)	18 (24.0)

*Ten participants were on both ICS and ICS/LABA medications, and all reported that their primary controller medication was the ICS/LABA. In these cases, only their ICS/LABA inhaler was fitted with an EMM.

† Criteria for uncontrolled asthma extracted and/or verified by EMR review.

Table 2. Change in SABA-free days (%) and ICS adherence (%) from baseline to study end

	Baseline	Study end	Δ (95% CI)*	P*	ACG vs. TG Δ (95% CI)*†	N
SABA-free days						
ACG	75	81	6 (-3, 14)	0.18	13 (1, 26)	23§
TG	58	77	19 (12, 26)	<0.001		68§
ICS adherence						
ACG	68	51	-17 (-26, -8)	0.001	15 (4, 25)	23¶
TG	70	68	-2 (-7, 3)	0.402		73¶

*Estimated using linear mixed models that accounted for repeated measures.

† Δ (95% CI) is for the interaction term between the intervention group and study period, interaction P values for SABA-free days was 0.038 and for ICS adherence was 0.005

§ Note, n does not equal 100. Instead, n = 91 due to early withdrawal (n=1), final study visit not completed (n=2), first synced their ICS and SABA EMM after baseline (n=2) and did not have an EMM on their SABA inhaler (n=4).

¶ Note, n does not equal 100. Instead, n = 96 due to early withdrawal (n=1), final study visit not completed (n=2), and first synced their ICS and SABA EMM after baseline (n=1).

Results

- 100 participants (80% female, mean age 48.5 years, 60% completed college, 80% privately insured) were enrolled.
- From baseline to study end, a statistically significant increase in the percentage of SABA-free days in the TG but not in the ACG (19% vs. 6%, P=0.038) was demonstrated.
- From baseline to study end, a smaller decline in ICS adherence (-2% vs -17%, P=0.005) in the TG vs. ACG was demonstrated.

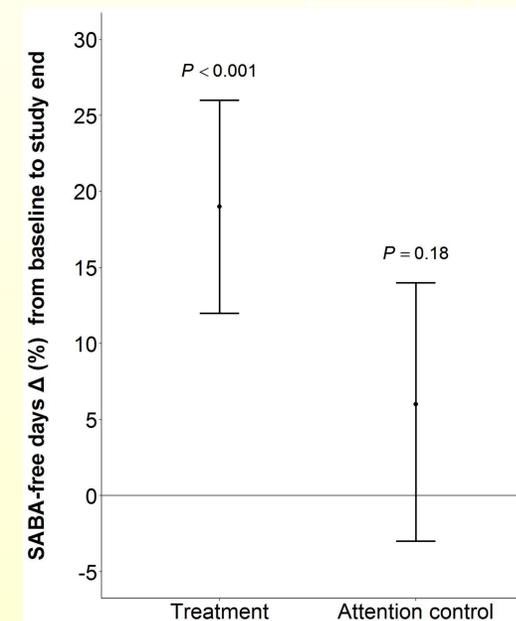


Figure 1. This figure depicts the change in SABA-free days from baseline to study end in the TG and ACG. There was a statistically significant increase in the percentage of SABA-free days in the TG but not in the ACG.

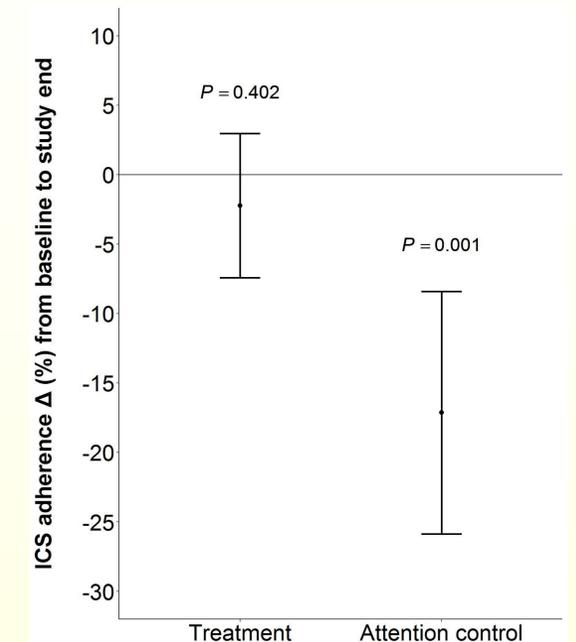


Figure 2. Figure depicts the change in ICS adherence from baseline to study end in the TG and ACG. The decline in ICS adherence was statistically significant in the ACG but not in the TG.

Conclusion

- In a randomized controlled trial of patients with uncontrolled asthma, use of a digital self-management platform, plus asthma nurse adherence feedback, demonstrates promise for decreasing SABA rescue use and increasing ICS adherence.

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