

A Pilot Study of the Effect of an Educational Web Application on Asthma Control and Medication Adherence



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What is already known about this topic? Adherence monitoring used in combination with identification of barriers and/or implementation of adherence strategies delivered with advanced communication skills may improve adherence and/or asthma control. This is consistent with the Asthma Adherence Management Model.

What does this article add to our knowledge? This study demonstrates that electronic adherence monitoring of metered-dose inhalers along with a web app, which identifies adherence barriers, provides effective adherence strategies, and trains clinicians in motivational interviewing can promote adherence and improve asthma control.

How does this study impact current management guidelines? Expert Panel Report 3 and Global Initiative for Asthma 2018 Guidelines promote adherence to improve asthma control. This study facilitates and provides uniformity with the effective use of technology, electronic monitors, and educational web app, to achieve adherence and asthma control.

BACKGROUND: An Asthma Adherence Pathway (AAP) application, which is an Internet application that combines patient and clinician education strategies to promote adherence to asthma therapy, has been developed.

OBJECTIVE: The primary objective of this pilot study was to evaluate the effectiveness of the AAP application with electronic adherence monitors on asthma control. Secondary objectives evaluated the effect of AAP and monitors on medication

adherence, asthma symptoms, quality of life, psychosocial factors, and barriers to treatment.

METHODS: Adult patients with asthma were randomly assigned either to intervention ($n = 19$) or control ($n = 20$) groups in this 3-month prospective study, and they completed the Asthma Control Questionnaire (ACQ). Intervention patients completed the AAP software and were given barrier-specific motivational interviewing adherence strategies and a SmartTrack device to monitor mometasone furoate/formoterol (MF/F) use. Clinicians in the interventional group received adherence management training. Interventional patients were given feedback regarding adherence findings at each visit. Treatment adherence was determined by the mean of 4 measures of doses taken over 3 months. Control patients were not monitored for MF/F adherence.

RESULTS: The mean MF/F adherence in the intervention group was 81%. The intervention and control groups did not differ on the mean baseline ACQ. Thirteen intervention patients achieved the minimal important difference (defined as an improvement ≥ 0.5 units on the ACQ) compared with 6 control patients ($P = .016$). The intervention group showed greater improvement in the ACQ (0.75) than the control group (0.19) representing a moderate-to-large effect size of $d = 0.638$.

CONCLUSIONS: The AAP was effective in promoting adherence and helped to improve asthma control. These findings provide preliminary validation of the AAP model. © 2019 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2019;7:1497-506)

Key words: Asthma Adherence Pathway Application; Dulera; Mometasone furoate/formoterol; Adherence; Asthma control

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Abbreviations used

AAP- Asthma Adherence Pathway

ACQ- Asthma Control Questionnaire

EPR- Expert Panel Report

FEV₁%- Percentage of forced expiratory volume in 1 second

MF/F- Mometasone furoate/formoterol (Dulera)

MIAS- Motivational interviewing adherence strategies

QOL- Quality of life

RM-ANOVA- Repeated-measures analysis of variance

The annual economic cost of asthma in 2013 was more than \$81.9 billion, including medical costs and loss of work and school days.¹ Nonadherence to asthma therapy is conservatively estimated in both children and adults to be 30% to 50%.^{2,3} Cost estimates of nonadherence are not precise because prescription refill measures, a widely used method, assume that: (1) prescription refilling patterns correspond to medication-taking behavior and (2) medication is taken exactly as prescribed.⁴ Electronic measures of adherence give an accurate account of doses taken as well as pattern of use but are not routinely available because of cost.⁵ Nonadherence in patients with asthma is associated with increased oral corticosteroid use,⁶ emergency department visits,⁷ hospital care,⁸ mortality,⁹ and cost of care.¹⁰ Studies have identified multiple barriers leading to nonadherence, including patient-related (forgetting, concerns about side effects, disagreement with the diagnosis, and need for treatment), clinician-related (poor communication skills and insufficient time spent with the patient), and health-system-related (cost, frequency of visits, and multiple providers) barriers.¹¹

Earlier childhood asthma adherence management studies led to the development of a model to promote adherence and asthma control, which included objective monitoring/feedback, identification of barriers, barrier-specific intervention, and patient-centered communication.^{5,12,13} In addition, microprocessors and Bluetooth technology have led to the ability to accurately measure patient medication use outside the clinic in real time.¹⁴ Asthma applications have been designed for patient use to improve self-management and to provide education and aids for symptom control (log daily symptoms, rescue medication use, peak flow values, triggers, and asthma action plans).^{15,16} Web-based asthma self-management systems have been found to improve quality of life (QOL),¹⁷⁻¹⁹ self-reported asthma symptoms,¹⁸⁻²⁰ lung function,^{18,19} reduction in asthma symptoms and exacerbations,^{18,19} and self-reported adherence for adults.^{18,19} However, they do not include adherence-focused education/interventions for the clinician. This research group has developed the Asthma Adherence Pathway (AAP) application, an Internet application that combines patient and clinician education strategies to promote adherence to asthma therapy.²⁰ It assists clinicians in identifying asthma barriers, delivering tailored clinical decision support strategies specific to the identified barrier, and providing training in motivational interviewing to assist clinicians in acquiring enhanced communication skills to effectively deliver the strategies.²⁰

The primary objective of this pilot study was to evaluate the effectiveness of the AAP application with electronic adherence monitors on asthma control. Secondary objectives evaluated the

effect of AAP and monitors on medication adherence, asthma symptoms, QOL, psychosocial factors, and barriers to treatment.

METHODS**Study design**

This was a randomized clinical trial conducted between April 2015 and July 2017 and was approved by Institutional Review Board at Allegheny General Hospital, Pittsburgh, Pa.

Patients

Patients 18 years or older from the Allergy/Clinical Immunology and Pulmonary departments were recruited consecutively and included if they had suboptimal asthma control (Asthma Control Questionnaire [ACQ] score >1.0) and were prescribed an inhaled corticosteroid or an inhaled corticosteroid/long-acting β -agonist for at least 1 month before screening. Patients were excluded if they had: (1) intermittent asthma; (2) asthma exacerbation over the past 3 months; (3) serious uncontrolled medical conditions; or (4) a diagnosis of any other chronic pulmonary disease. Patients were withdrawn from the study if they had an untoward reaction to the study medication mometasone furoate/formoterol (MF/F) (Dulera; Schering Corporation, a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ), were lost to follow-up (ie, did not report to the clinic for the scheduled visit), or withdrew consent. All patients who did not complete the protocol were replaced.

Patients were reimbursed for participation. They received \$50 for each completed study visit, up to a maximum of \$300 if all 6 visits were completed.

Clinicians

Three allergists/clinical immunologists (2 board certified and 1 physician's assistant) and 4 pulmonologists (2 board certified and 2 fellows in training) from Allegheny General Hospital were recruited for the study. All clinicians followed the Expert Panel Report 3 (EPR-3).²¹ Each subspecialty group treated 20 patients: 10 intervention and 10 control patients. Intervention and control physicians exclusively treated either intervention or control patients, respectively. Five clinicians received adherence management training, whereas those in the control group did not. The intervention and control group clinicians evaluated subjects in different areas of the medical center and were asked not to discuss study interactions with each other.

Motivational interviewing

Before study initiation, clinicians in the intervention group received 10 hours of training to implement the motivational interviewing adherence strategies (MIAS).⁵ The curriculum included articles, video examples, and role-playing. An essential component of motivational interviewing was to address patient ambivalence.

Asthma Adherence Pathway application

The AAP Internet application is an Asthma Adherence Disease Management Program that guides patients and clinicians through the adherence interventions.⁵ It was designed to improve adherence to asthma medication and management of behaviors that affect asthma control. It identifies attitudes, behaviors, and barriers about disease management. After completing the AAP survey, patients would reflexively receive 2 forms of feedback: (1) written, 1 or 2 paragraphs at the sixth grade level, addressing the response, and (2) 30- to 60-second video reinforcing the written response. The clinician would review the patient's responses to the survey and follow clinical decision support recommendations within the software for each barrier identified. The



FIGURE 1. SmartTrack device (Nexus6, Auckland, New Zealand).

clinician would apply the motivational interviewing technique to address patient ambivalence. Within the platform, both patients and clinician had access to supplemental educational material regarding adherence and asthma. Clinicians could refer to a motivational interviewing module, which included video examples within the software that were initially presented in the training before the clinical phase. The AAP gave the patient an opportunity to identify barriers to care, QOL, psychosocial concerns, and management behaviors that may affect adherence to treatment.

For clinicians, AAP provides an analysis of the patient's response in the form of "prompts" as a clinical decision-making tool. It gives the provider recommendations on delivering MIAS. The adherence barriers that patients can identify include:

- *Ineffective management*: not following the asthma medication plan; delaying symptom treatment; not removing self from an area causing symptoms; not following instructions to treat an asthma attack; not measuring peak flow.
- *Negative attitudes about treatment*: do not need medication; medicine does not work.
- *Symptoms during distressing emotional states*: angry; upset; frustration; depression; anxiety.
- *Lack of comprehension of care instructions*: uncertain when to use which medication; not understanding how to use prescribed medication, especially the inhalation technique; not understanding how to use a peak flow meter.
- *QOL disruption*: sleep, recreational activities, home activities, work, school.
- Lack of agreement by significant other with the treatment plan.
- Cost, side effects, forgetfulness.

Questions were asked requiring a response to a 3-point Likert scale (never, sometimes, often) or Yes, No. Depending on the

wording of the question, a "significant barrier" was identified by the provider and reviewed with the patient.

SmartTrack device

Each patient in the intervention group was given a SmartTrack device (Nexus6, Auckland, New Zealand; [Figure 1](#)) that clipped onto their MF/F 100 and albuterol sulfate (Proventil HFA; Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Northridge, Calif) inhalers. After the device was activated during the baseline visit, it recorded the date/time of all actuations. Each time the subject returned to the clinic for evaluation, the data were uploaded to a secure website and clinicians reviewed adherence and delivered adherence strategies as needed.

Medications and office visits

At initial screening, patient-informed consent was obtained. Medical history, complete physical examination, and spirometry were performed, and the metered dose inhaler technique was reviewed. Patients also completed the ACQ. Enrolled patients were followed for asthma care per EPR-3 Guidelines and were directed to take 2 inhalations of MF/F 100 twice daily and 2 inhalations of albuterol sulfate every 4 hours as needed for rescue therapy. Patients in both the intervention and control groups, who were identified as symptomatic while on MF/F 100/5, were given MF/F 200/5.

Patients returned in 2 weeks for a baseline visit and were randomized in an alternating process to the intervention or control group. As with any behavioral intervention, blinding of clinicians and patients to their own intervention(s) was not possible. Both intervention and control patients completed the ACQ.²² Patients in the intervention group: (1) were given MF/F 100/5 and albuterol hydrofluoroalkane (HFA) with SmartTrack devices and were informed that it would measure and record metered dose inhaler use that would then be reviewed at each subsequent visit; (2) completed the AAP software to identify specific barriers to adherence; and (3) received barrier-specific MIAS as determined by AAP results.

At the follow-up visits, the ACQ was completed by patients in both groups. After the baseline visit, control patients were followed at 1-month intervals for a total of 4 repeated assessments. Intervention patients were asked to return in 2 weeks and 4 weeks to evaluate the ACQ and adherence and were then followed at 1-month intervals. However, if a patient in the intervention group was found to be nonadherent (<60% MF/F), he or she was asked to return in 2 weeks for another assessment.

For patients in the intervention group, assessment and feedback of MF/F adherence were performed at follow-up visits. Adherence data from the SmartTrack device were uploaded to www.hailie.com (Adherium North America, Inc, San Mateo, Calif), which displayed the data graphically. The data were reviewed with the patient. [Figure 2](#) delineates specific patient interventions in the intervention group based on the data received from the SmartTrack device and ACQ. Nonadherent subjects with elevated ACQ or increased albuterol use received barrier-specific intervention using MIAS techniques and were asked to return in 2 weeks for follow-up. Adherent subjects with elevated ACQ or albuterol use received a higher dose of MF/F. Control patients received usual asthma care. Of note, ACQ scores ≤ 0.75 were defined as well controlled, whereas those above ≥ 1.50 were not well controlled. Those patients with an ACQ between 0.75 and 1.50 were classified as indeterminate and were further analyzed by evaluating their usage of albuterol. If nonadherent patients used albuterol ≤ 2 days/week, they were removed

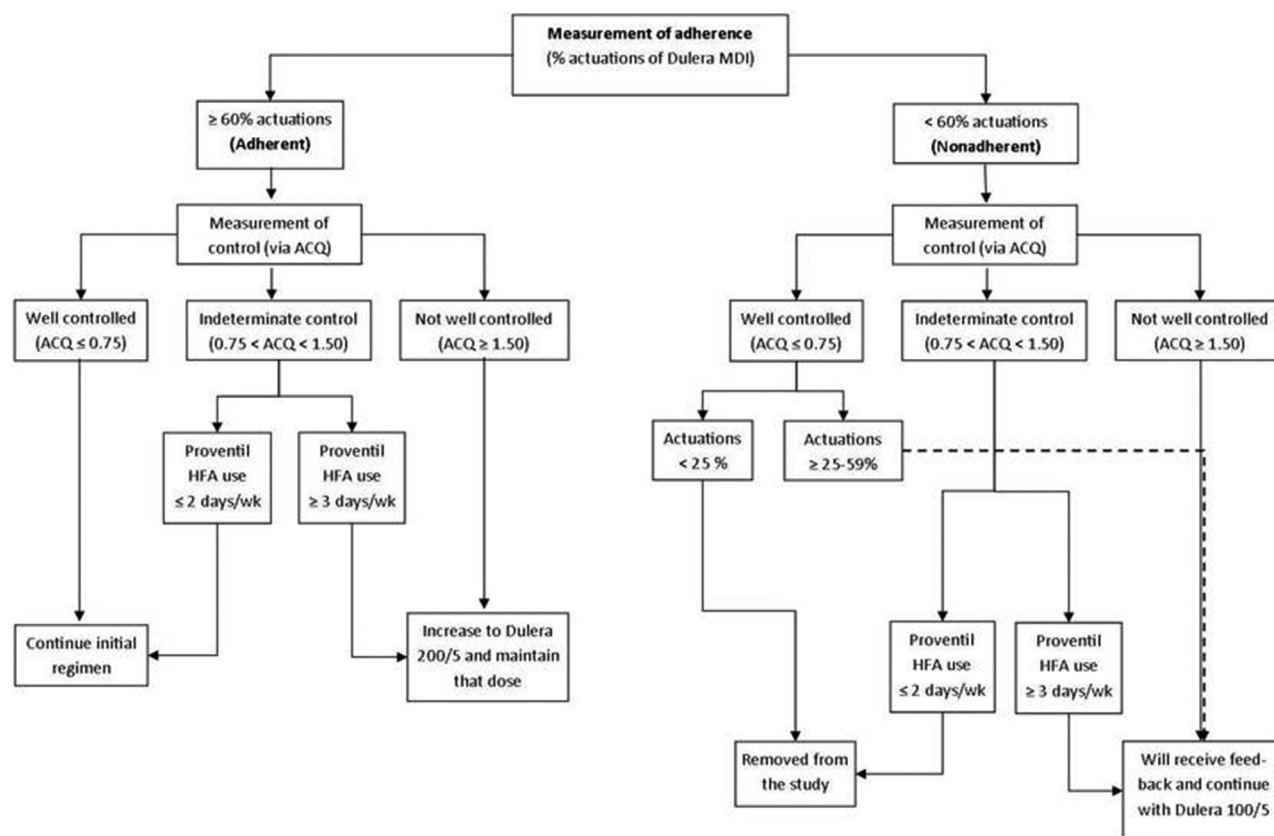


FIGURE 2. Adherence flowchart. ACQ, Asthma Control Questionnaire; HFA, hydrofluoroalkane; MDI, metered-dose inhaler.

from the study, because they were not dependent on medications. If they used it ≥ 3 days a week, they continued on in the study.

Primary outcome measure

The primary outcome for the study was a change in the ACQ score over 3 months. The score is inversely related to asthma control with a high score indicating poor control.²²

Secondary outcome measures

Adherence to MF/F in the intervention group was calculated for each visit, both morning and evening doses, and recorded as a percentage. This was calculated by dividing the number of doses taken by the number of doses prescribed and then multiplied by 100. The daily adherence was capped at 100% to avoid falsely increased values due to dose dumping. Nonadherence was identified as $< 60\%$ adherence with MF/F during the interval. The overall interval figure was a mean of each daily percent.

A difference in scores between the self-reported 3-month measure and the baseline measure of asthma symptoms over each 4-week period was calculated at each follow-up visit to correlate asthma control with adherence. Asthma symptom scores were derived from a patient's self report based on a 3-point Likert scale within the AAP (I am having asthma symptoms: never; sometimes; often). Positive scores on this difference score indicated a worsening of symptoms from the start to the end of treatment. This difference was correlated with the mean score on adherence over the treatment period.

Difference scores between patient-reported 3-month measures and baseline measures based on using rescue medication over each 4-week period were calculated at each follow-up visit to correlate adherence with rescue medication. Rescue medication scores were derived from a patient's self-report based on a 3-point Likert scale within the AAP (In the past 4 weeks I have used my rescue medication [albuterol]: never; sometimes; often). Again, positive scores indicated worsening symptoms. This difference was correlated with the mean score on adherence over the treatment period.

QOL measures (sleep, recreation, family activities, and work) and psychosocial indicators (frustration, controlled by asthma symptoms, dependence on treatment, anxiety, and depression) were scored on a 3-point Likert scale (The following are ways that asthma may affect your QOL. Check any that apply to you [never, sometimes, or often]; interferes with sleep; interferes with work; interferes with family activities; interferes with recreational activities; causes frustration; controls my life; I feel too dependent on asthma medication; my asthma has made me anxious; my asthma has made me depressed). To correlate a change in symptoms over the course of treatment (emphasizing status at the end of treatment accounting for where a patient started), a change in ACQ scores was analyzed, which were calculated by taking the difference between the 3-month ACQ measure and the baseline ACQ measure of asthma symptoms. Lower scores on this ACQ change score indicated a reduction of asthma symptoms from the start to the end of treatment. Change scores on QOL and psychosocial indicators were calculated by taking the difference between the

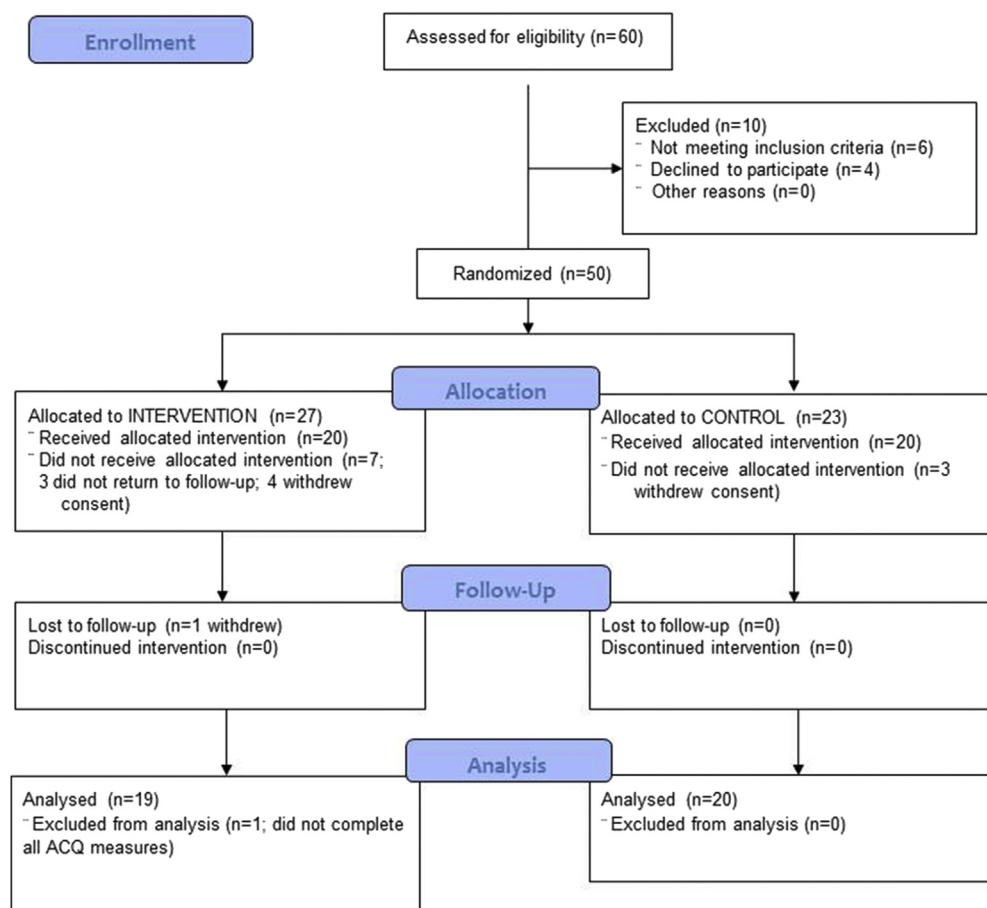


FIGURE 3. Consort 2010 study patient flow diagram. *ACQ*, Asthma Control Questionnaire.

3-month measure and the baseline measure for the particular indicator. Higher QOL change scores indicated an improvement in functioning for that particular QOL indicator over the course of the study.

Percentage of forced expiratory volume in 1 second ($FEV_1\%$) was calculated and adjusted for age, sex, height, and baseline value.

Statistical analyses

The ACQ consists of 7 questions scaled from 0 (best asthma control) to 6 (worst asthma control). Assuming a large treatment effect (ie, a difference of 0.8 standard deviation units in the outcome) reflecting an absolute change in the asthma control outcome, small-to-moderate levels of intraclass correlation, 40 patients nested within 8 clinicians in each condition, and alpha of 0.05, statistical power for the test of the primary hypothesis exceeds 0.80. The *a priori* power analysis was based on a variance estimate of 0.70 and a score change of 0.50 in the ACQ being a minimal important difference.²² The study was designed to enroll up to 60 patients to allow for 40 total patients to complete the study.

The primary analysis of change on the 4 measures of the ACQ over time over 3 months was conducted using repeated-measures analysis of variance (RM-ANOVA) to determine whether the intervention group differed on average compared with the control group. In addition to *F* tests and *P* values, we also report the associated effect size for between-groups change in ACQ.²³ The primary endpoint was the third month

measure of the ACQ. Statistical analyses were conducted using SPSS (version 24.0, IBM Corporation, Armonk, NY).

RESULTS

Baseline disposition and demographics

A total of 60 patients were assessed for eligibility, of whom 6 patients did not meet the inclusion criteria and 4 patients declined to participate (Figure 3). Of the remaining patients, 27 and 23 patients were randomized to the intervention and control groups, respectively. In the intervention group, all 27 patients received treatment, but 7 discontinued before study completion (3 did not return for follow-up clinic visit and 4 withdrew consent). One intervention patient did not complete all ACQ assessments. Of the 23 patients in the control group, 3 patients withdrew consent. Baseline data from the dropout groups were not included in the analysis. There were no statistically significant differences between the intervention and control groups with regard to baseline demographics or disposition (Table I).

ACQ score

Of the 40 enrolled patients, 19 and 20 patients in the intervention and control groups, respectively, completed the ACQ at 4 time points and were included in the intention-to-treat analyses. At 3 months, 6 control patients and 13 intervention patients had clinical improvement as measured by the minimal

TABLE I. Baseline demographics and patient disposition

Patient data	Control (n = 20)	Intervention (n = 19)	Total (N = 39)
Mean age, y	39	41	40 (range 23-69)
Sex (female), n (%)	15 (75)	25 (60)	27 (60.7)
Mean ACQ (SD)	2.14 (1.02)	2.31 (0.94)	2.315 (± 0.96)
Mean FEV ₁ % (SD)	0.70 (0.18)	0.76 (0.13)	0.728 (± 0.16)
Inhaled corticosteroid use over past 1 y, n (%)	19 (95)	19 (95)	38 (95)

ACQ, Asthma Control Questionnaire; FEV₁%, percentage of forced expiratory volume in 1 s; SD, standard deviation.

TABLE II. ACQ score over 3-month study period

ACQ measures	Intervention group	Percentile range (10% to 90%)	Control group	Percentile range (10% to 90%)
ACQ at baseline ($\pm$ SD)	1.86 (± 0.92)	(1.0-2.86)	1.59 (± 0.84)	(0.57-1.87)
ACQ at 1 mo ($\pm$ SD)	1.79 (± 1.36)	(0.57-4.0)	1.58 (± 0.86)	(0.57-3.14)
ACQ at 2 mo ($\pm$ SD)	1.35 (± 1.18)	(0.14-3.29)	1.49 (± 0.95)	(0.48-2.85)
ACQ at 3 mo ($\pm$ SD)	1.11 (± 0.81)	(0.29-2.57)	1.41 (± 0.76)	(0.43-2.71)

ACQ, Asthma Control Questionnaire; SD, standard deviation.

Although intervention and control groups did not differ at any individual time point, the change in ACQ from baseline to 3 mo was significantly greater for the intervention group (as detailed in the Results section).

important difference $\chi^2(1) = 5.757$ ($P = .016$). The minimal important difference for the ACQ was 0.50 units.

The 4 repeated measurements on the ACQ are summarized in Table II. Both intervention and control groups had lower ACQ at 3 months than at baseline. An RM-ANOVA using within-subjects (study entry vs study end) and between-subjects (intervention vs control) factors was performed on the ACQ outcome. The time by group interaction was significant, $F(1, 37) = 4.26$, $P = .046$, indicating that the intervention group showed greater improvement from baseline to 3 months (0.75 ACQ units) as compared with the control group (0.19 ACQ units). This difference in change between groups represents a moderate-to-large effect size of $d = 0.638$.²⁴

Adherence

All 19 patients in the intervention group used the SmartTrack device and had data recorded on adherence. Six patients experienced device failure, and data were lost for the 1-month interval. Data from counters on the metered dose inhaler were used to assess adherence for these patients. Accuracy during the device failure interval was limited because there was no objective measure, and could have been enhanced by the patient. Replacement devices were given.

The mean MF/F adherence was 81% over the course of the study, with adherence being greatest (88.75%) at week 2 and gradually reducing to 76.8% at 3 months (Figure 4). Five patients had <60% mean adherence at 3 months.

Correlation of adherence with asthma control and with rescue medication

The association between difference scores of asthma control and average adherence was $r = -0.526$ ($P = .012$), indicating that those patients who had lower mean adherence over the course of the study tended strongly to also report greater increases in symptoms from the start to the end of treatment (Table III). The association of mean adherence with difference scores of rescue medication was $r = -0.508$ ($P = .026$),

indicating that those patients who had lower average adherence over the course of the study tended strongly to also report greater increases of rescue medication from the start to the end of treatment.

QOL and psychosocial indicators

Table III details the correlation between difference scores (capturing change from the study entry to the end point) on ACQ and difference scores on QOL and psychosocial indicators. For example, the correlation between QOL sleep and ACQ change scores was $r = -0.67$ ($P < .01$), indicating that patients who reported greater improvements in sleep over the course of treatment also tended to show greater reductions in asthma symptoms. A similar pattern of correlation can be seen across the various QOL and psychosocial indicators, specifically family activities, frustration, controlled by asthma symptoms, and dependence on treatment.

FEV₁%

There was no evidence of change in FEV₁% from baseline to month 3 for either the intervention group (0.760 and 0.776 at baseline and month 3, respectively) or the control group (0.697 and 0.732 at baseline and month 3, respectively).

DISCUSSION

Persuasive data are available to show that educational interventions to overcome adherence barriers can improve asthma self-management,²⁵ reduce wheezing,²⁶ promote adherence to asthma therapy,²⁷ help families adjust to the demands the disease imposes on family life,²⁸ improve school attendance and performance,²⁶ and change the use of health services, primarily reducing emergency visits and hospitalizations.²⁹

The asthma adherence management model involves the concomitant application of objective electronic monitoring devices with clinician feedback, identification of adherence barriers, utilization of specific adherence strategies to overcome these

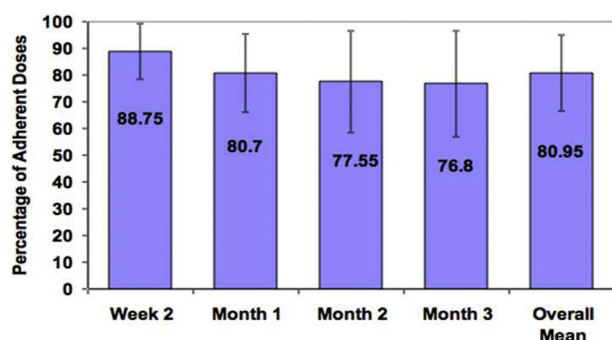


FIGURE 4. Mean MF/F adherence over 3 months in the intervention group. MF/F, Mometasone furoate/formoterol.

TABLE III. Correlation coefficients between changes in ACQ scores and asthma outcomes, self-reported QOL, and psychosocial indicators in the intervention group

Asthma outcomes, QOL, and psychosocial measures	ACQ difference score
Asthma outcome difference scores	
Mean adherence	−0.53 [†]
Rescue medication use	−0.51 [†]
QOL indicator difference scores	
Sleep	−0.67*
Work	−0.28
Family activities	−0.62*
Recreation	−0.41
Psychosocial indicator difference scores	
Frustration	−0.51 [†]
Controlled by asthma symptoms	−0.48 [†]
Dependence on treatment	−0.67*
Anxiety symptoms	−0.31
Depressed symptoms	0.04

ACQ, Asthma Control Questionnaire; QOL, quality of life.

* $P < .01$.

[†] $P < .05$.

barriers, and application of patient-centered communication skills to maximize interventions.⁵

An important technological component of this study that sets it apart from previous studies is the use of a scalable web application with a database that can accommodate small and large number of users. It incorporates: (1) asthma adherence self-management principles; (2) patient questionnaire and education program; (3) barrier-specific clinical decision adherence support strategies; and (4) asthma, adherence, and MIAS education and training for the clinician.

This pilot study demonstrated the effectiveness of the AAP Internet application and electronic monitoring device in improving asthma control and promoting adherence. Patients in the intervention group achieved an 81% adherence rate to doses of MF/F100/5 and MM/F 200/5 and had greater improvement in asthma control and in ACQ minimal difference scores as compared with the control group. There were strong correlations between improvement in asthma control and greater levels of adherence and lesser use of β_2 -agonists for acute symptoms.

Investigators have attained different outcomes (adherence and asthma control) using electronic monitoring with varying components of the asthma adherence management model (Table IV).^{2,30-33} One study demonstrated improvement in asthma control and adherence;³¹ 2 improved adherence but not asthma control;^{2,30} and 2 improved adherence but did not measure asthma control.^{32,33} Although some investigators used direct feedback to patients from electronic monitoring devices,^{2,30-32} others had physicians review data from the monitoring device directly with patients.^{2,30,33} One investigator trained physicians to deliver patient-centered adherence strategies;³⁰ 1 commented that physicians provided patient-centered practices;² and one did not describe physician counseling skills.³³

Given the multiplicity and varying interventions and outcomes listed above, in the present study, we examined adherence and asthma control outcomes with physicians following uniform MIAS interventions from a web app within the context of the asthma adherence management model.

Barriers/MIAS

MIAS has been shown to be efficacious across a wide variety of health behavior change areas, including asthma.^{34,35} In the current study, clinicians received 10 hours of asthma, adherence, and MIAS training in the form of lecture/handouts, video, and role-playing. It included specific motivational interviewing skills that can be briefly and easily implemented in medical settings.³⁶ By applying these MIAS skills and interweaving asthma adherence strategies with patient feedback of medication use, study clinicians were successful in addressing patient adherence barriers achieving positive asthma outcomes.

Electronic monitoring device

Electronic monitoring devices attached to metered dose inhalers serve multiple functions. First, this device identifies the date and time of medication use and establishes patient adherence. Secondly, it serves as a reminder via a visual and/or auditory signal that is preset by the clinician to encourage actuation.^{31,37} Direct-to-patient reminders about medications can help patients with chronic illness to establish medication-taking routines and increase engagement with self-management.^{31,37} In the present study, we did not activate electronic monitoring device reminders, but rather used the device to collect medication use to give feedback to the patient.

Clinician feedback to patients

Objective, personalized, feedback data on patterns of medication use provided by electronic monitoring devices can open discussions between the health professional and the patient.³⁸ When feedback is given sensitively and with respect that incorporates patient autonomy, it can optimize treatment routines.^{37,39} Two different approaches have been used for electronic monitoring device–based adherence promotion: face-to-face (health professional-to-patient) discussion based on electronic monitoring data and direct-to-patient monitoring device reminders for missed doses. Feedback in the present study generally took the form of reviewing printouts of inhaler use, followed by a constructive discussion, with problem-solving or goal-setting sessions. Emphasis was placed on identification of ambivalence and resolving ambivalence about medication administration. The overall impact of the adherence feedback on asthma control and adherence was favorable and included improvement in QOL (sleep and family activities). Psychosocial

TABLE IV. Comparison of with previous studies

Study	Design	Medication	Monitor type	Reminder	Feedback	Communication	Asthma control	Adherence	Clinical outcome	Self-reported
Present study: Weinstein et al	3-m, randomized, controlled trial in 40 adult patients with moderate-to-severe asthma	MF/F	SmartInhaler 12% device failure/replacement	None	Clinician monthly	MIAS 10-h training: in-person and on AAP AAP application to identify barriers and assist clinician decision support	ACQ improved compared with control	Adherence in Intervention group 81% Not measured in control group	None reported	Improved sleep, family activities, recreation Less frustration, less control by asthma, less dependent on asthma medication
Foster et al ³⁰	6-mo pragmatic cluster 2 × 2 factorial parallel group, randomized controlled trial of 4 groups: usual care; usual care with counseling; reminder feedback; reminder feedback with counseling 129 adult patients with moderate-to-severe asthma	Fluticasone/salmeterol	SmartTrack 4% failure/replacement	Electronic audio twice daily; subject had choice to turn off ringer	Mandatory at first month with clinician and then monthly as needed No specific follow-up for feedback for patients after 1 mo Patients had access to adherence data	2 groups received 2-h patient-centered communication to assess barriers; set goals Incorporated the information-motivation-behavioral skills model	Measured by ACT; no significant difference in ACT score during the study among the 4 intervention groups	Significantly higher adherence in the 2 reminder/feedback groups than in the 2 nonreminder groups (73% vs 46% of daily prescribed doses)	None reported	All groups had improved quality of life and anxiety
Morton et al ¹²	1-y multicenter, randomized, open-label, parallel-group controlled study with an allocation of 1:1 in 77 patients aged 6-16 y with moderate-to-severe asthma	Budesonide/formoterol Fluticasone/salmeterol	SmartTurbo SmartTrack Reported broken: 50% intervention devices (37% replaced) and 19% control devices (5% replaced)	Electronic audio twice daily	Clinician every 3 mo	Nonspecified patient-centered communication No clinician training	No difference in ACQ between control and reminder/feedback group	Adherence was 70% in intervention group vs 49% in the control group	Reduction in corticosteroid bursts and hospitalizations	Both intervention and control groups reported improved quality of life

Chan et al ³¹	6-mo randomized, controlled trial in 220 patients aged 6-15 y with moderate-to-severe asthma	Fluticasone/salmeterol	SmartTrack audiovisual reminder Failure not reported	Electronic audio twice daily	None	None	ACT scores improved significantly in intervention group as compared with control group	Adherence was 84% in the intervention group vs 30% in the control group	None	None
Charles et al ³²	6-mo randomized, open-label, parallel-group study in 110 patients aged 12-65 y with moderate-to-severe asthma	Fluticasone	SmartInhaler audiovisual reminder Failure not reported	Electronic audio twice daily	None	None	Not measured	Adherence was 93% in the intervention group vs 74% in the control group	None	None
Burgess et al ³³	4-mo randomized trial in 26 patients aged 6-14 y with moderate-to-severe asthma	Fluticasone/Fluticasone/salmeterol	SmartInhaler Failure not reported	None	Clinician monthly	Nonspecific	Non-specific	Adherence was 79% in the intervention group vs 58% in the control group	Decreased use of β_2 -agonist Improved FEV ₁	None

AAP, Asthma Adherence Pathway; ACQ, Asthma Control Questionnaire; ACT, Asthma Control Test; M/F/F, mometasone furoate/formoterol; M/AS, motivational interviewing adherence strategies.

factors (frustration; controlled by asthma; and dependence on medication) were impacted to a lesser extent.

Limitations

Because of limited funding, adherence data for the control group were not collected. Other less accurate and expensive methods to measure metered dose inhaler adherence that were considered but not selected were dose counters and measuring canister weight.

Other limitations included lack of baseline adherence data; a study population that achieved high adherence possibly due to self-selection of motivated volunteers in research environments; free medication; and monthly study visits. Awareness of adherence monitoring may have also inflated adherence, although evidence suggests that this only lasts for approximately 7 days.³⁷ Future research should assess adherence and clinical impact at a minimum over 1 year, especially in real-world practice populations, as done by Morton et al.²

Feasibility data are needed from normal clinical settings, because significant barriers to implementation of adherence feedback interventions may be concealed in research studies. In research: (1) patients and clinicians are actively recruited and reimbursed for participation; (2) technical support is provided for device checking and data handling; and (3) trained clinicians have time to deliver appropriate counseling. By contrast, in clinical practice: (1) patients, particularly those from disadvantaged populations, may fail to attend clinic visits and lose the electronic monitoring device; (2) health care professionals may lack the skills, resources, and time to review patients' adherence data and provide counseling;⁴⁰ (3) cost of the device and data transfer services as well as the diverse software and web platforms used by different manufacturers may make it difficult to assess adherence across available medications;⁵ and (4) there is lack of reimbursement for devices, staff time, training, and patient counseling.⁶

CONCLUSIONS

In clinical practice, the most promising indications for the asthma adherence management model using technology lie in the management of severe asthma, which is associated with high health costs.⁴¹ Large adult population studies and smaller pediatric studies have shown that adherence rates of 75% to 80% are required to significantly improve asthma control^{8,42,43} and cost.⁴⁴ In the present pilot study, findings suggested that the AAP was effective in achieving 81% adherence and helped to improve asthma control. To determine scalability of any asthma adherence management program, large-scale implementation studies in a range of populations and health contexts are needed for a robust examination of the components, including cost-effectiveness, feasibility, and acceptability. Such evidence would potentially support reimbursement. Medicare has recently created and reimbursed remote monitoring Current Procedural Terminology (CPT) codes (CPT codes 99453, 99454, 99457 (2019 Medicare Physician Fee Schedule), which should encourage application of asthma adherence management.^{45,46} Asthma adherence management programs in general are currently considered to be too complicated, time consuming, and expensive to incorporate into routine clinic practice. With rapidly improving technology, suitably trained clinicians (specialized nurses or pharmacists) will have the opportunity to implement these programs in both large practices and health

plans. A Delaware Medicaid health plan has begun to introduce the AAP within a telehealth format including remote medication monitoring. This program, which will be delivered by asthma subspecialists caring for patients with severe asthma, is anticipated to reduce emergency visits and hospital care as well as costs.

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