1. Title Page

Title of Project
Integrating Patient-Reported Outcomes into Routine Primary Care: Monitoring Asthma Between Visits

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2. Structured Abstract

Purpose: The goal of this study was to develop, implement, and rigorously evaluate a clinically integrated remote symptom monitoring intervention for asthma patient-reported outcomes (PROs) in primary care.

Scope: The study was conducted between January 2019 and April 2022 at seven primary care clinics affiliated with a large academic health center in Boston, MA. RCT participants included adults with asthma who were receiving treatment from a PCP affiliated with one of the included clinics.

Methods: We employed user-centered design methods, including design session interviews, a PCP survey, and iterative prototyping to our intervention for use with Spanish- and English-speaking patients in primary care. We collected quantitative data on usage of the mHealth app, clinician dashboard, and call-back requests; and qualitative data through exit interviews with patients, PCPs, and nurses. The primary outcome was defined as the 12-month change in a patient-reported asthma-related quality of life score (MiniAQLQ).

Results: Through our design session interviews (15 patients, 6 providers) and survey (55 PCPs), we identified and implemented numerous requirements. For the RCT, 413 patients were enrolled and 366 (87 percent) completed the 12-month study. The average weekly questionnaire completion rate for intervention patients was 72 percent. We identified a statistically significant improvement in MiniAQLQ among intervention patients compared to those in usual care. The mHealth app and practice model proved feasible and useful in supporting patients in monitoring of asthma PROs between visits as part of routine care.

Key Words: remote symptom monitoring, mHealth, user-centered design, intervention design, patient-reported outcomes, asthma

3. Report

Purpose

The purpose of this project was to adapt a simple mobile health (mHealth) app and health IT-enabled practice model, used successfully for between-visit asthma symptom monitoring in pulmonary subspecialty care, for use in primary care, the setting in which most asthma patients are treated. Specifically, our objectives were as follows:

1. Adapt our mHealth app and health IT-enabled practice model for asthma symptom monitoring using patient-reported outcomes (PROs) to a primary care population that included a diverse population of Spanish-speaking and English speaking patients, including those with low health literacy;
2. Implement the adapted mHealth app and health IT-enabled practice model in primary care community clinics affiliated with our accountable care organization, identifying a cohort of eligible asthma patients to participate and training primary care providers (PCPs) and clinical staff (nurses); and
3. Rigorously evaluate the impact of this new health IT-enabled practice model on asthma-related patient-reported quality of life and healthcare utilization in a randomized controlled trial (RCT) study in which we sought to enroll 500 asthma patients (250 intervention, 250 usual care).

Scope

Background, Incidence, and Prevalence

Asthma is a chronic condition that affects more than 25 million individuals in the United States, and its incidence is increasing.[1] Poorly controlled asthma can severely impair quality of life and is associated with a higher frequency of asthma-related emergency department visits and hospitalization.[2] Uncontrolled asthma causes substantial suffering– disproportionately among Hispanic/Latinx patients and those of lower socioeconomic status[3]— and often results in the use of emergency medical services and/or hospitalization.[4] Asthma-related hospitalizations and reduced asthma-related quality of life are disproportionately more common among Hispanic/Latinx patients than non-Hispanic white patients, and this relationship may be mediated in part by low income and low health literacy.[5, 6] Yet poor health outcomes from inadequate asthma control are preventable, especially with the provision of more timely treatment and adherence to clinical practice guidelines that call for clinicians to adjust treatment based on serial monitoring of patients' reported symptoms.[1, 7-11]

In fact, adhering to clinical guidelines has been shown to improve health outcomes that are important to patients.[10, 12] In contrast to relying on clinical measures such as lung function (which do not directly reflect patients' lived experience) routine collection of asthma symptoms in the form of PROs could focus treatment on what matters most to patients–their symptoms and quality of life. Unfortunately, intensive symptom monitoring and serial measurement is largely not happening.[13, 14] Though clinicians are increasingly collecting asthma-related PROs immediately prior to a patient visit, there has been little progress in collecting PROs during the interval *between* visits. Interventions that facilitate monitoring of asthma symptoms during this interval offer a promising strategy to improve symptom control and quality of life, as well as reduce healthcare utilization for patients with asthma.

Context

In our previous AHRQ-funded work, we demonstrated the success of a simple health IT-enabled practice model developed to facilitate asthma symptom monitoring via a clinically integrated mHealth app installed on patients' smartphones during the interval between subspecialty clinic visits in the ambulatory setting. We used an iterative, user-centered design process to ensure our health IT tools maximally engage patients between visits, and to identify optimal clinic practice workflow to minimize burden on clinicians.[15] As smartphone adoption—now exceeding 81 percent of the U.S. population—continues to increase, an mHealth strategy for collecting PROs as we describe is ready for scale and spread. Specifically, an intervention comprised of our health IT-enabled practice model was well-suited to be adapted to the primary care setting to facilitate PRO collection between visits for a larger population of patients with the goal of improving guideline-concordant monitoring of asthma symptoms.

Through our user-centered design in this previous work, we identified requirements for our remote asthma monitoring intervention to be delivered in primary care. First, we determined that a weekly lookback period would be necessary for monitoring of asthma PROs, as less frequent monitoring can be subject to recall issues and would be less likely to improve asthma self-management. We knew that our PRO measure needed to be short (5 items at most), since longer questionnaires were too burdensome and could negatively impact patient adherence. To meet the needs of patients and PCPs in low resource settings, we sought a PRO measure that is low cost and easily accessible (i.e., does not require a license to use). When we did not identify any validated PRO measure that met these requirements, we decided to adapt the Asthma Control Measure (ACM) from a one-month lookback period to a one-week lookback period, and conduction validation our modified ACM against the 5-item Asthma Control Questionnaire (ACQ-5).[16]

Setting

The design phase was conducted between January 2019 and November 2020. Design session interviews and surveys were conducted at five primary care clinics affiliated with Brigham Health, a large academic health center affiliated with Mass General Brigham (MGB) in Boston, MA. Also during the design phase, we recruited subjects using Amazon Mechanical Turk (MTurk) – an online marketplace that connects freelance workers with available work – to participate in a survey to evaluate the validity of our modified ACM against the ACQ-5 to use as our PRO measure. The RCT study was conducted between April 2020 and April 2022 at seven primary care clinics affiliated with Brigham Health, including the five clinics that participated in the design stage as well as two additional clinics that were added later to support recruitment efforts.

Clinics ranged in number of physicians (8 to 37 per clinic), physician clinical effort (part-time vs full-time), patient populations (majority Spanish vs English-speaking), and clinic type (teaching vs non-teaching). All clinics used a commercial EHR system (Epic Systems, Inc.) and were a part of Brigham Health's Primary Care Practice-Based Research Network. All patients could enroll in MGB's patient portal, Patient Gateway, which is powered by MyChart (Epic Systems, Inc.) and was available in Spanish as well as other languages. The Institutional Review Boards of MGB and the RAND Corporation approved all study procedures.

Participants

During the design phase, we conducted design session interviews with 15 patients and 6 providers, and analyzed results of 55 PCP survey respondents (55 of 78 PCPs at participating clinics; response rate of 71 percent). We gathered additional input through informal meetings with clinic medical directors, nurses, and 2 nurses in system leadership positions. Also during the design stage, we evaluated our modified ACM against the ACQ-5 using by fielding a survey to 498 subjects recruited through MTurk.

For the RCT, potentially eligible adult patients (18 years or older) from these clinics were identified by querying MGB's electronic data warehouse at any time during the 24 months prior to study initiation (April 2020), and from subsequent data refreshes during the recruitment period (April 2020 to April 2022) if they were assigned to a PCP affiliated with one of the seven primary care clinics and had either one of the following criteria: 1) a prior diagnosis of asthma (ICD-10 code defined as J45.xx) either on their EHR problem list or specified during a subspecialty, inpatient, or emergency department encounter; or 2) a diagnosis of asthma and a referral to an Allergy or Pulmonary subspecialist. Potentially eligible patients who were not considered appropriate (e.g., complex mental health or social issues) for the study per their PCP or clinic medical director were excluded. Of note, patient portal enrollment, defined by an "activated" status in the EHR, was not used to identify this initial cohort.

Methods

Study Design

In the design phase of the study, we employed user-centered design methods, including patient and provider interviews, surveys, stakeholder meetings, and iterative prototyping to adapt our novel mHealth app and practice model for use with Spanish- and English-speaking patients in primary care. We worked with an expert on consumer-facing informatics tools (Adriana Arcia, PhD, RN) on optimal display of PRO data for patients with low health literacy, and consulted with a human factors and usability expert (Ms. Pamela Garabedian, MS) on health IT design and usability. We also engaged the expertise of several advisors. After recruiting practice leads from each clinic to serve as liaisons during user testing, we identified a sample of physicians, nurses, and patients to engage in user testing at each practice. We developed high-fidelity mockups of the app and EHR dashboard and performed beta testing of new features, employing rapid, iterative prototyping for user interface design changes to the mHealth app. Specifically, we interviewed patients to ask about frequency of PRO collection, display of PRO history, and ability to request a phone call from a nurse. We interviewed PCPs to get feedback on all components of the practice model, including types of patients that might benefit, workflow for inviting patients to participate in the study, frequency of PRO collection, format of PRO availability within Epic, and preferences for being contacted between visits for patients with worsening symptoms. We also interviewed nurses to understand their information needs and identify potential workflows for responding to notifications from patients.

For the RCT, we implemented the intervention with 7 primary care clinics affiliated with the practice-based research network at Brigham and Women's Hospital, a large academic medical center. We worked closely with PBRN and clinic leadership and other stakeholders in the design, planning, initial testing, and implementation. The app was available in Spanish as well as English to accommodate the Spanish-speaking patient population at study clinics. We worked

with a data analyst to identify potential patient participants from each clinic, and worked with PCPs to facilitate recruitment. We recruited patients using multiple digital and non-digital strategies, including mailed letters, patient portal messages, follow-up phone calls, targeted phone calls (prior to an upcoming PCP appointment), targeted in-person recruitment, '1-click' referrals (i.e., a method for PCPs to refer patients to participate in the study communicated via a digital workflow in the EHR), and 'huddle notes' (i.e., electronic notes in the EHR to remind clinicians to recruit specific eligible patients scheduled for a clinic appointment that day). Also at the outset of the clinical trial, we trained PCPs and nurses at all participating clinics on the practice model, workflows, and the mHealth app used by patients, as well as the EHR-integrated PRO dashboard used by PCPs. We supported PCPs, nurses, and clinic staff in implementation of the intervention throughout the RCT, providing additional trainings to new providers or as a refresher when needed.

Intervention

The intervention implemented and evaluated in this work was previously developed using user-centered design methods,[17] tested for feasibility in subspecialty care,[17] and adapted for implementation in primary care with scalability in mind.[18] Briefly, the intervention consists of remote symptom monitoring via a patient-facing mHealth app, clinician-facing dashboard, and a practice model (i.e., clinic workflows needed to support the symptom monitoring).[18] Patients using the mHealth app complete an initial 5-item baseline questionnaire and then a similar weekly patient reported outcome (PRO) questionnaire for the one-year study period.[16] If the PROs show problematic symptoms, defined as worse compared to baseline or previous week by 3 points in the ACM scale, the app gives the patient the option to request a call from a nurse. Patients receive reminders prior to a visit to bring their phone and discuss their asthma with their PCP. The app also allows patients to enter notes, triggers, and peak flow values; view their data as a graph; and watch educational videos such as how to use their inhaler. PCPs have access to the dashboard in the EHR and receive EHR inbox messages prior to a visit with a participating patient reminding them to view the data in the dashboard. We implemented the intervention at seven primary care clinics, working closely with clinical leadership, clinicians, and staff in the design, planning, initial testing, and implementation.

Data Sources/Collection and Measures

We used quantitative and qualitative methods to assess the potential for an intervention consisting of an mHealth app and integrated clinical practice model to achieve sustained adoption in clinical care.

We collected quantitative data on usage of the mHealth app, clinician dashboard, and callback requests among patients, PCPs, and nurses, respectively. We also collected qualitative data through exit interviews with patients, PCPs, and nurses. To structure our research questions and inform our data collection and analysis, we used the non-adoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technology (NASSS) framework. NASSS is designed specifically to predict and evaluate the scalability and sustained use of health and care technology innovations.[19] We focused on NASSS domains most relevant to evaluating our intervention and its implementation: the condition or illness, the technology, the value proposition, the adopter system, and the organization.

For the RCT, the primary outcome was defined as the change between baseline and 12-month endpoint of the 15-item Mini Asthma Quality of Life Questionnaire (MiniAQLQ). The MiniAQLQ is a validated, patient-reported measure that is available in Spanish and English, takes roughly four minutes to complete, and offers a comprehensive assessment of quality of life across four sub-domains: symptoms (5 items), activity limitations (4 items), emotional function (3 items), and exposure to environmental stimuli (3 items).[20, 21] The MiniAQLQ score is calculated as an average across these domains, and the minimum clinically important difference is 0.5.[20] As a secondary outcome, we analyzed the number of asthma-related emergency department (ED) visits, urgent care visits, and hospitalizations identified in the EHR during the 12-month study period. We included ED visits, urgent care visits, and hospitalizations in the EHR with asthma coded as a primary or secondary diagnosis. For our primary and secondary outcome analysis, we used robust linear regression models with treatment arm as the only covariate, clustering by PCP using generalized estimating equations (GEE). Linear regression using GEE to compare mean scores between treatment and control groups is robust to non-normality of the outcomes. While we anticipated that baseline covariates (patient characteristics) will balance out across the two arms due to randomization, we also adjusted for baseline characteristics that differed across arms for our primary and secondary analyses.

We also conducted additional exploratory analyses on baseline and demographic characteristics of patient participants. From the EHR, we analyzed age, sex assigned at birth, race/ethnicity, marital status, primary language, education, socioeconomic status (median income by zip code), insurance status, clinic, PCP type, patient portal status, smoking status, visits to subspecialist 12 M before baseline, number of asthma medications at time of enrollment, presence or environmental or seasonal allergy or allergic rhinitis comorbidity based on problem list at time of baseline. From patient-reported REDCap study assessments, we analyzed smartphone type (e.g., iPhone, Android), baseline ACM score, baseline PAM score, baseline Health Literacy Score (SLS), study start date, and time between completion of baseline and final surveys. We also counted the number of unique PCPs with at least one patient in each arm of the study, and the average number of patients per PCP in each arm.

Limitations

Our study has several limitations. First, our remote symptom monitoring intervention was limited to a single condition, and additional use case data is needed to understand requirements for other chronic medical conditions. Second, EHR users were associated with one academic health center, and requirements for other health systems and EHR vendors may differ. Third, our app is also dependent on smartphone ownership and use by patients, and some patients may experience difficulty using the app (though we found that many may have a caregiver or family member who use a smartphone and can provide assistance). Also, the PRO data was stored in the app server and not written back to the EHR database, and thus requires manual entry in the EHR by PCPs if it is to be tracked within PCP visit notes. Importantly, the functionality of EHRs with respect to PROs is constantly evolving, and the user requirements for providers and patients may change as a result. With respect to our validation of the modified ACM, we only assessed participants once, our inclusion criteria were based on patient-reported asthma, and our respondent population was younger, white, and more educated than the general population.

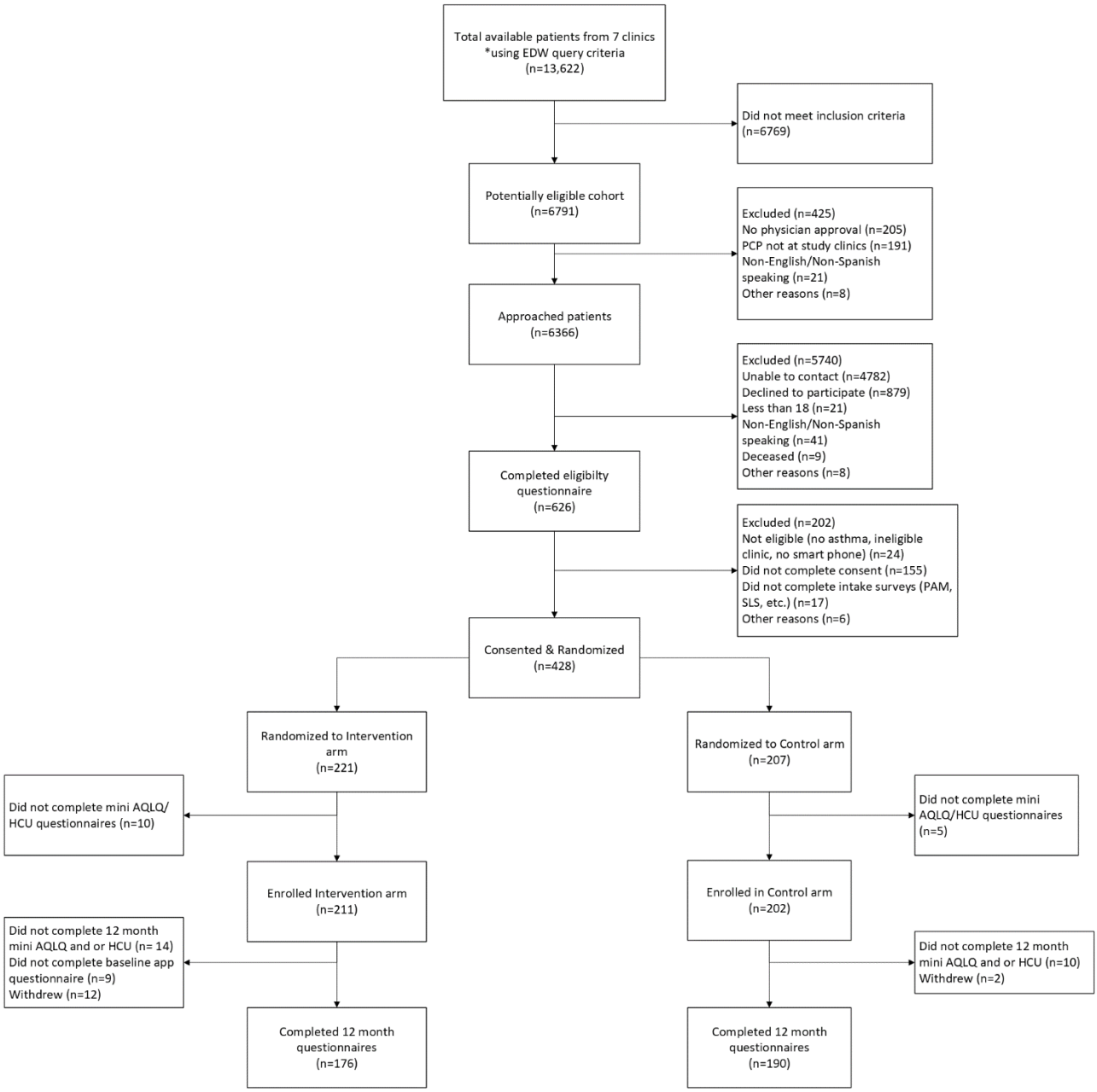
Results

Principal Findings

During the design stage, our analysis of 21 design sessions (15 patients, 6 providers), and survey responses from 55 PCPs (71 percent of 78) were used to identify intervention requirements. Patient-facing requirements included: 1- or 5-item symptom questionnaires each week, depending on asthma control; option to request a callback; ability to enter notes, triggers, and peak flows; and tips pushed via the app prior to a clinic visit. PCP-facing requirements included a clinician-facing dashboard accessible from the EHR and an EHR inbox message preceding the visit. PCP preferences diverged regarding graphical presentations of PROs. Nurse-facing requirements included callback requests sent as an EHR inbox message. Requirements were consistent for English- and Spanish-speaking patients. EHR integration required use of custom application programming interfaces (APIs).

Patients in our RCT study were identified from the EHR and recruited on the basis of asthma diagnosis. Of the 6,366 potentially eligible patients who were approached, 627 completed the eligibility questionnaire, 445 patients consented to participate, 413 were enrolled, and 366 completed the 12-month study without dropping out (Figure 1). Of the 210 patients randomized to the intervention arm, 190 used the app at least once and did not withdraw from the study. The latter is the population of patients that are included in our primary analysis.

Figure 1. Participant Flow Diagram



Baseline characteristics of patients randomized to the intervention and control group were similar (Table 1).

Table 1. Baseline Participant Characteristics

Characteristic	All enrolled patients (N=413)	Intervention Group (N=211)	Usual-Care Group (N=202)	Completed 12-month AQLQ Intervention Group (N=176)	Completed 12-month AQLQ Usual-Care Group (N=190)
Age in years–mean (SD)	52.2 (15.4)	51.9 (15.5)	52.6 (15.4)	52.4 (15.3)	52.1 (15.5)
Sex assigned at birth- female–no. (%)	333 (77.8)	157 (74.4)	164 (81.2)	125 (71.0)	155 (81.6)
Race–no. (%)					
White Non-Hispanic	231 (54.0)	116 (55.0)	110 (54.5)	106 (60.2)	105 (55.3)
Black Non-Hispanic	86 (20.1)	37 (17.5)	45 (22.3)	28 (15.9)	42 (22.1)
Hispanic	83 (19.4)	42 (19.9)	35 (17.3)	29 (16.5)	32 (16.8)
Other/Missing	28 (6.5)	16 (7.6)	12 (5.9)	13 (7.4)	11 (5.8)
Marital Status – no. (%)					
Partnered	174 (42.1)	98 (46.5)	76 (37.6)	86 (48.9)	72 (37.9)
Single	236 (57.1)	111 (52.6)	125 (61.9)	88 (50.0)	117 (61.6)
Unknown	3 (0.7)	2 (1.0)	1 (0.5)	2 (1.1)	1 (0.5)
Primary language – no. (%)					
English	407 (95.1)	202 (95.7)	192 (95.1)	169 (96.0)	183 (96.3)
Education – no. (%)					
8th grade or some high school but did not graduate	28 (6.5)	14 (6.6)	13 (6.4)	10 (5.7)	10 (5.3)
Graduated high school or GED	122 (28.5)	56 (26.5)	62 (30.7)	40 (22.7)	58 (30.5)
Graduated college	229 (53.5)	118 (55.9)	102 (50.5)	109 (61.9)	97 (51.1)
Unknown	49 (11.5)	23 (10.9)	25 (12.4)	17 (9.7)	25 (13.2)
Socioeconomic status[a] – no. (%)					
Less than or equal to $73,585	110 (25.7)	54 (25.6)	52 (25.7)	39 (22.2)	51 (26.8)
$76,586 to $108,824	106 (24.8)	50 (23.7)	53 (26.2)	42 (23.9)	49 (25.8)
$108,825 to $137,102	106 (24.8)	53 (25.1)	49 (24.3)	48 (27.3)	44 (23.2)
Greater than $137,102	106 (24.8)	54 (25.6)	48 (23.8)	47 (26.7)	46 (24.2)
Insurance status – no. (%)					
Commercial	251 (58.6)	136 (64.5)	110 (54.5)	118 (67.1)	106 (55.8)
Medicaid	77 (18.0)	31 (14.7)	41 (20.3)	19 (10.8)	39 (20.5)
Medicare	98 (22.9)	43 (20.4)	50 (24.8)	38 (21.6)	44 (23.2)
Unknown/Self-pay	2 (0.5)	1 (0.5)	1 (0.5)	1 (0.6)	1 (0.5)
PCP type – no. (%)					
Physician	418 (98.4)	206 (97.6)	198 (99.0)	173 (98.3)	186 (98.9)
Nurse Practitioner	7 (1.7)	5 (2.4)	2 (1.0)	3 (1.7)	2 (1.1)
Patient Portal Status [c] – no. (%)					
Activated	406 (99.8)	202 (95.7)	191 (94.6)	171 (97.2)	180 (94.7)
Login Date within 6 months	101 (23.6)	49 (23.2)	46 (22.8)	39 (22.2)	42 (22.1)
Phone type[b] – no. (%)					
Android	101 (24.5)	47 (22.3)	54 (26.7)	40 (22.7)	51 (26.8)
iPhone	279 (67.6)	141 (66.8)	138 (68.3)	127 (72.2)	132 (69.5)
Other	4 (1.0)	4 (1.9)	0 (0.0)	4 (2.3)	0 (0.0)
I don't know	2 (0.5)	2 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	27 (6.5)	17 (8.1)	10 (5.0)	5 (2.8)	7 (3.7)
Smoking Status – no. (%)					
Current smoker	24 (5.6)	9 (4.3)	15 (7.4)	8 (4.6)	14 (7.4)
Former smoker	125 (29.3)	62 (29.5)	55 (27.2)	48 (27.4)	52 (27.4)
Never smoker	278 (65.1)	139 (66.2)	132 (65.4)	119 (68.0)	124 (65.3)
Asthma subspecialist care in 12 M before baseline[d] – no. (%)					
Zero visits	262 (63.4)	127 (60.2)	135 (66.8)	103 (58.5)	127 (66.8)
1 to 5 visits	117 (28.3)	65 (30.8)	52 (25.7)	55 (31.3)	48 (25.3)

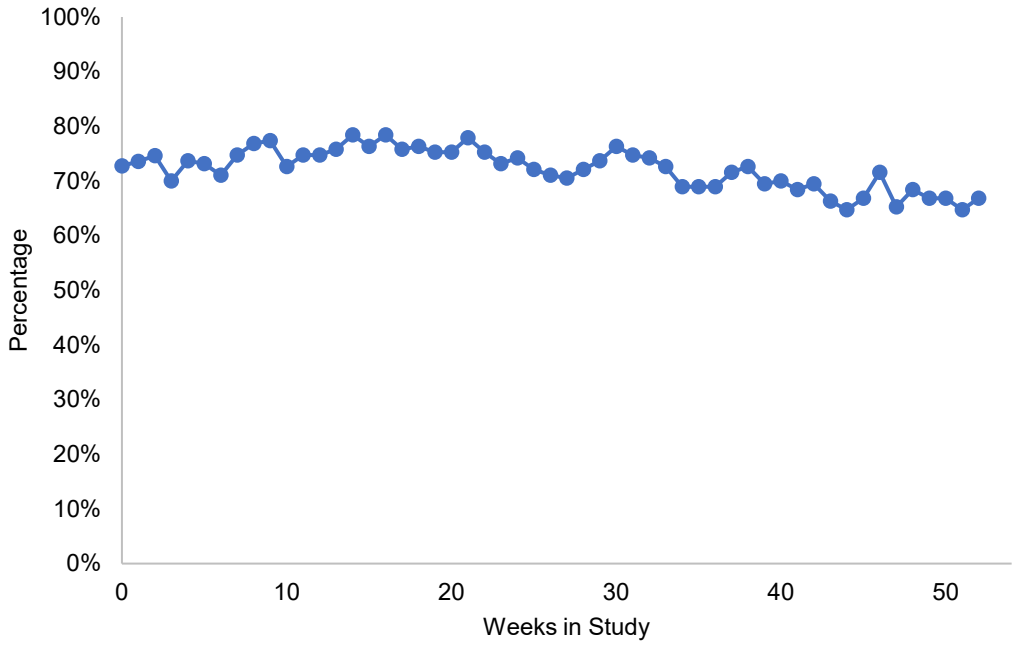
Characteristic	All enrolled patients (N=413)	Intervention Group (N=211)	Usual-Care Group (N=202)	Completed 12-month AQLQ Intervention Group (N=176)	Completed 12-month AQLQ Usual-Care Group (N=190)
6 to 39 visits	34 (8.2)	19 (9.0)	15 (7.4)	18 (10.2)	15 (7.9)
Asthma exacerbation - 12 M before baseline (Yes) – no. (%)	130 (31.5)	68 (32.2)	62 (30.7)	59 (33.5)	59 (31.1)
Specific medications (e.g., ICS, ICS/LABA, LAMA, asthma biologics, LTRA, SABA) – at time of enrollment – no. (%)					
Zero	348 (84.3)	178 (84.4)	170 (84.2)	144 (81.8)	160 (84.2)
1 to 10	49 (11.9)	26 (12.3)	23 (11.4)	25 (14.2)	21 (11.1)
11 to 40	16 (3.9)	7 (3.3)	9 (4.5)	7 (4.0)	9 (4.7)
Baseline allergy comorbidity[e] – no. (%)	396 (95.9)	204 (96.7)	192 (95.1)	171 (97.2)	180 (94.7)
General health					
Charlson comorbidity score at baseline – mean (SD)	1.7 (1.5)	1.7 (1.4)	1.8 (1.6)	1.7 (1.4)	1.8 (1.7)
Obesity at baseline[d] – mean (SD)	30.8 (7.8)	31.2 (8.0)	30.5 (7.7)	30.8 (8.0)	30.6 (7.8)
Baseline ACM score[b] – mean (SD)	5.0 (3.9)	4.9 (4.0)	5.1 (3.8)	4.6 (4.0)	4.9 (3.7)
Baseline PAM score level[b] – no. (%)					
1	18 (4.4)	8 (3.8)	10 (5.0)	7 (4.0)	9 (4.7)
2	36 (8.8)	18 (8.6)	18 (8.9)	10 (5.7)	15 (7.9)
3	123 (29.9)	67 (32.1)	56 (27.7)	60 (34.1)	53 (27.9)
4	234 (57.0)	116 (55.5)	118 (58.4)	99 (56.3)	113 (59.5)
Baseline Health Literacy (SLS)[b]	13.8 (2.2)	13.8 (2.0)	13.7 (2.4)	14.0 (1.8)	13.8 (2.4)

SOURCE: Authors' analysis.
NOTES: All data came from the EHR unless denoted otherwise. [a]Median income by zip code. [b]REDCAp Data. [c]Patient portal enrollees = defined as having an "activated" status in the EHR. [d]Defined as obesity based on BMI score around the time of baseline (i.e., within the prior 12 months). [e]Defined as environmental or seasonal allergy or allergic rhinitis comorbidity based on Problem List at the time of baseline.

Our analyses of exit interviews with patients and providers revealed that the app, clinician dashboard, and integrated practice model were feasible to use. Most patients did not report any barriers in installing the app, and most reported that it did not take them long to complete their weekly questionnaires. PCPs and nurses reported that the ASTHMA data tab and inbox messages with requests for a call were relatively simple to use and interpret, with little need for training or support.

Among participants enrolled in the intervention arm who used the app at least once and did not drop out of the study early (n = 190), the average number of weekly PRO questionnaires answered was 72 percent (65-78 percent; Figure 2). Questionnaire completion and retention rates by demographic characteristic are summarized in Table 2. We found that patient participation rates were relatively strong. Over half of patients (66 percent) completed at least one weekly questionnaire per month for all twelve months of the study, and the majority (79 percent) completed at least one questionnaire in the final four weeks of the study.

Figure 2. Weekly Questionnaire Completion Rate



SOURCE: Authors' analysis.
NOTES: Reflects weekly mHealth app questionnaire completion rates for patients enrolled in the intervention arm of the study (*n* = 190).

The number of unique patients who reviewed their asthma PRO data in the app after completing their weekly questionnaire, either by navigating to the History tab or by clicking 'view graph,' was 169 (89 percent) and 171 (90 percent) respectively. A total of 29 patients requested a call back from the nurse in the app after completing their weekly questionnaire on 35 occasions. For the majority of these call requests (*n* = 26; 74 percent), follow-up encounters with a nurse or other provider at their respective clinics occurred within 1.1 (2.2) calendar days. Most patients who utilized this feature reported that it was valuable in helping them to better manage their asthma.

Table 2. Overall mHealth App Usage

Category	Number of App Users[a]	Answered Questionnaires (Completed/ Available (%))	Number of app users who completed at least 1 questionnaire per month for all 12 Months N (%)	Number of app users who completed at least 1 questionnaire within final 4 weeks of study (retention) N (%)
Overall	190	7162/9922 (72.2)	126/190 (66.3)	150/190 (78.9)
Age Categories				
18 – 33	36	1124/1885 (59.6)	17/36 (47.2)	22/36 (61.1)
34 – 48	48	1773/2509 (70.7)	32/48 (66.7)	35/48 (72.9)
49 – 64	64	2447/3337 (43.3)	43/64 (67.2)	52/64 (81.3)
65 +	42	1818/2191 (83.0)	34/42 (81.0)	41/42 (97.6)
Ethnicity				
Hispanic	45	1051/2042 (51.5)	15/33 (45.5)	21/33 (63.6)

Category	Number of App Users[a]	Answered Questionnaires (Completed/ Available (%))	Number of app users who completed at least 1 questionnaire per month for all 12 Months N (%)	Number of app users who completed at least 1 questionnaire within final 4 weeks of study (retention) N (%)
Non-Hispanic	136	5583/7099 (78.6)	103/136 (75.7)	118/136 (86.8)
Unknown/Missing	21	528/781 (67.6)	8/21 (38.1)	11/21 (52.4)
Education				
No High-School Degree	8	181/419 (43.2)	3/8 (37.5)	3/8 (37.5)
High-School Degree or GED	15	383/788 (48.6)	4/15 (26.7)	7/15 (46.7)
Some College	23	950/1200 (79.2)	16/23 (69.6)	18/23 (78.3)
2-Year College	15	422/785 (53.8)	7/15 (46.7)	10/15 (66.7)
4-Year College	52	2135/2707 (78.9)	39/52 (75.0)	46/52 (88.5)
More Than 4 Year College	77	3091/4023 (76.8)	57/77 (74.0)	66/77 (85.7)
Sex				
Male	57	2178/2712 (80.3)	41/57 (71.9)	45/57 (78.9)
Female	133	4984/7210 (69.1)	85/133 (63.9)	105/133 (78.9%)
Language				
English	184	6952/9610 (72.3)	123/184 (66.8)	145/184 (78.8)
Spanish	6	210/312 (67.3)	3/6 (50.0)	5/6 (83.3)
Race				
American Indian or Alaska Native	1	27/52 (51.9)	1/1 (100.0)	1/1 (100.0)
Asian	8	356/418 (85.2)	6/8 (75.0)	6/8 (75.0)
Black	36	1321/1879 (70.3)	20/36 (55.6)	31/36 (86.1)
More than one race	15	398/943 (42.2)	5/15 (33.3)	9/15 (60.0)
Native Hawaiian/Other Pacific Islander	1	52/52 (100.0)	1/1 (100.0)	1/1 (100.0)
White	115	4730/6107 (77.5)	90/115 (78.3)	97/115 (84.3)
Unknown/not reported/ missing	14	278/471 (59.0)	3/14 (21.4)	5/14 (35.7)
Smartphone				
Android	45	1763/2402 (73.4)	29/45 (64.4)	34/45 (75.6)
iPhone	135	5285/7310 (72.3)	96/135 (71.1)	114/135 (84.4)
Other	10	114/210 (54.3)	1/10 (10.0)	2/10 (20.0)

NOTES: [a]Includes the 190 patients in the intervention arm who completed the baseline ACM questionnaire in the app and who did not withdraw from the study.

The mean change in miniAQLQ score between baseline and 12 months was 0.35 point improvement for intervention group participants and 0.13 point improvement for participants in the usual care group (Table 3).

Table 3. Primary and Secondary Analyses

	Intervention Group (N=176)	Usual-Care Group (N=190)	Unadjusted Effect Size	p	Adjusted Effect Size	p
Primary analysis						
Change in Mean MiniAQLQ between baseline and 12M	Baseline: 5.34 (1.16) 12M: 5.69 (1.05) Difference: 0.35 (0.78)	Baseline: 5.08 (1.28) 12M: 5.21 (1.29) Difference: 0.13 (0.90)	0.22 (0.04, 0.40)*	0.02	0.25 (0.07, 0.43)*	0.01
Secondary analysis	**Intervention Group (N=221)**	**Usual-Care Group (N=207)**	**Unadjusted Effect Size**	**p**	**Adjusted Effect Size**	**p**
No. asthma-related emergency utilization in 12M study period [a]	0.55	0.81	-0.39 (-0.81, 0.02)	0.06	-0.23 (-0.63, 0.17)	0.26

NOTES: Clustered and unclustered analyses yielded the same results. [a] Includes usual care visits, emergency department visits, and hospitalizations.

Discussion and Conclusions

Through a user-centered approach to design and iterative prototyping, we determined user and EHR integration requirements for a clinically integrated remote symptom monitoring intervention for asthma using PROs. We found that the mHealth app developed for remote patient monitoring of asthma in primary care was successful in supporting patients in tracking and self-reporting of their asthma symptoms and improved asthma-related quality of life. The integrated practice model proved feasible and allowed PCPs, nurses, and clinic staff to successfully monitor asthma PROs between visits as part of routine care. Our evidence shows that our mHealth app has the capabilities of being implemented at a larger scale and becoming the standard of care.

List of Publications and Products

Rudin RS, Perez S, Rodriguez JA, Sousa J, Plombon S, Arcia A, Foer D, Bates DW, Dalal AK. User-centered design of a scalable, electronic health record-integrated remote symptom monitoring intervention for patients with asthma and providers in primary care. *J Am Med Inform Assoc*. 2021 Oct 12;28(11):2433-44.

Rudin RS, Qureshi N, Foer D, Dalal AK, Edelen MO. Toward an asthma patient-reported outcome measure for use in digital remote monitoring. *J Asthma*. 2022 Aug;59(8):1697-702.

Rudin RS, Sulca Flores J, Sousa J, Foer D, Dalal AK. Making COVID-19 Screening Part Of Routine Symptom Monitoring. *Health Affairs Forefront*. [Internet]. 2021 Oct 20. Available from: https://doi.org/10.1377/forefront.20211018.47378

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