Original Paper

A Digital Respiratory Ecosystem for People Living With Asthma: Mixed Methods Pilot Study

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Abstract

Background: Digital health technologies (DHTs) offer potential to improve asthma management and treatment concordance with international clinical practice guidelines.

Objective: The aim of the study was to develop the Breathe Digital Ecosystem (Breathe DE) and evaluate its usability, acceptability, feasibility, and preliminary effects on asthma symptoms and control, medication adherence, medication administration technique, and health status.

Methods: Breathe DE was co-designed from January 2021 to September 2022. Modified from a former model, it was built on a single smartphone app with Bluetooth-enabled hardware components (Medical International Research spirometer and FindAir ONE smart inhaler cap). Breathe DE supports diagnostics, inhaler adherence and technique, short-acting beta-agonist (SABA) rescue inhaler overuse, environmental trigger avoidance, self-management action plan, and spirometry. A prospective observational mixed methods pilot study to evaluate Breathe DE was conducted in Southwestern Ontario from September 2022 to March 2023. A convenience sample of participants was recruited from primary care, and the study duration was 12 weeks (90 days). Participants were adults diagnosed with asthma, using a daily maintenance inhaler (Enerzair/Atectura) and an as-needed SABA rescue inhaler. Quantitative summary statistics and graphical presentation of longitudinal app interactions, inhaler technique assessment, medication adherence, asthma control, and health status were used to describe participant engagement with Breathe DE. Semistructured exit interviews were analyzed using combined deductive and inductive codebook thematic analysis to assess perceived usefulness, acceptability, and feasibility.

Results: Of the 21 participants enrolled in the study, 17 completed the exit interview at week 12. The study population was predominantly female (18/21, 86%) and younger than 65 years of age (16/21, 76%). Engagement with the app was variable and waned over follow-up. Per-participant median frequencies of app interaction were 35 (IQR 26-71) days, daily medication logging was 21 (IQR 12-49), rescue inhaler use was 4 (IQR 0-15) doses, and spirometry was performed a median of 6 (IQR 2-24) times. Longitudinally, asthma control (symptoms, SABA use, and Asthma Control Questionnaire), health status indicators (mini Asthma Quality of Life Questionnaire), and medication adherence indicated possible improvement in participants with complete data. Overall, participants felt that Breathe DE could be useful for symptom management and improving medication adherence.

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Acceptability as a tool for self-management was dependent on the participant's degree of asthma control and self-management abilities. Feasibility was impeded by some technological issues and physical barriers.

Conclusions: We developed one mobile health platform combining all major guideline-directed best practices for successful asthma management. Breathe DE created a comprehensive viewing portal into the day-to-day experience of asthma. Integration of the data types highlighted an opportunity for DHTs as a tool prescribed by the health care practitioner to facilitate partnership with the patient, giving valuable and comprehensive insights to inform individualized optimal asthma management.

Trial Registration: ClinicalTrials.gov NCT05594654; https://clinicaltrials.gov/study/NCT05594654

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KEYWORDS

mHealth apps; mobile health; smartphone; digital health technologies; asthma; guideline-directed therapy; self-management

Introduction

Background

Asthma is a globally significant noncommunicable respiratory disease [1]. In Canada, in 2023, the prevalence of asthma was 11.8%, and in Ontario, Canada's most populous province and where this study took place, there are over 2 million people living with Asthma [2]. Characterized by chronic airway inflammation and variable expiratory airflow limitation, asthma is defined by a history of symptoms that include dyspnea, wheezing, coughing, and chest tightness [3]. Asthma can have a substantial impact on a person's quality of life and financial implications for the health system due to potentially avoidable health care resource use events (hospital admissions, emergency department visits, physician visits, and prescription medication use) [4,5]. Most commonly, these events are due to exacerbations or episodes of symptom worsening that could be averted with appropriate guideline-directed asthma management [3].

Approximately, half of people diagnosed with asthma have symptoms that are not well controlled, an indication of unmet clinical need [6-8]. Key factors associated with poor asthma control include misdiagnosis [9,10], suboptimal adherence to medical therapies [11], incorrect inhaler technique [12,13], exposure to environmental triggers [9], and overuse of short-acting beta-agonists (SABAs) [14,15]; few individuals have been taught self-management strategies and have an action plan available to activate in the event of an exacerbation [8]. The use of innovative disease-specific technological solutions could be used to aid diagnosis and support successful asthma management [16-18].

Availability and the use of digital health technologies (DHTs) are growing rapidly, and mobile health (mHealth) apps are the fastest-growing form of DHT [16,17,19]. DHTs can aid in accurate diagnosis [18], and a review of the current evidence suggests that the use of interactive DHTs can improve therapeutic adherence, lung function, asthma control, and quality of life [17,20-22]. Multidimensional interventions involving more interactive features are associated with better outcomes [16]. A review evaluating 7 mHealth apps for chronic lung disease identified features that included motivational support, education, self-management, asthma action plans, medication reminders, medication use tracking, inhaler technique coaching, and symptom tracking [23]. Collectively, these mHealth apps featured most of the important components deemed necessary for successful asthma management; however, each individual mHealth app only had 2-3 of these features incorporated, and therefore not supporting all aspects of guideline-directed asthma management. Furthermore, it has been identified that not all mHealth apps are compliant with existing evidence-based, guideline-directed therapies [19,24].

The heterogeneity of these evolving digital innovations further complicates evaluation, limiting generalizability [20,25]. Evaluation challenges identified include marked variability in the interventions compared, follow-up durations, target populations, and outcome measures [20,21,25,26]. Other identified limitations of DHTs currently include accessibility, sustaining engagement, cost-effectiveness, and specificity to disease rather than patient groups [21,25,27]. It is evident that for DHTs to advance and succeed, there is a need for robust evidence of effectiveness, demonstrated economic benefit and accessibility, sustained user engagement, integration into clinical pathways, and a well-defined target population [21,25]. Successful asthma management is multifaceted, and to our knowledge, there are no single mHealth platforms that assimilate multiple features across the spectrum of guideline-concordant asthma management.

Breathe, a prior version of the mHealth app centered in this study, included a self-management asthma action plan, daily and weekly symptom assessment, medication information, visualization of user data for review and trend analysis, and alerting functions to warn users of changes in their asthma control zone. Despite demonstrating good usability and assessment of asthma control, Breathe required participants to manually enter a substantial amount of information, did not capture medication adherence, and did not incorporate spirometry insights into the determination of asthma control [28].

In this study, we developed and evaluated the Breathe Digital Ecosystem (Breathe DE). Built from the previous Breathe app version, Breathe DE is an integrated, interactive, holistic mHealth platform designed to address all aspects of guideline-concordant care.

Objectives

Specific study objectives were as follows:

- Development: (objective 1) To build Breathe DE, a modified integrated, interactive mHealth app that combines

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all the essential components of successful guideline-directed asthma therapy.
- Evaluation: (objective 2) To investigate participant engagement with Breathe DE by (a) assessing frequency and type of user interactions with the different incorporated features and hardware components and (b) examining longitudinal changes in the frequency of user interactions and in participant health status over the 12-week follow-up period; and (objective 3) to investigate the participant's experience, perception, and satisfaction with using Breathe DE.

Methods

Study Design

The study was conducted using a multistage mixed methods framework [29]. In stage 1, an expert panel informed the development of Breathe DE using a convergent iterative process (objective 1). In stage 2, Breathe DE was evaluated quantitatively over a 12-week follow-up period (objective 2) and qualitatively at the end of the study (objective 3). Integration of the data collected in stage 1 was iterative, and Breathe DE was developed over a 20-week period. The qualitative and quantitative data collected in stage 2 were integrated during the analysis phase of the study.

Development (Objective 1)

A systematic human-centered co-design process (January 2021 to September 2022) was used to develop a user flow and wireframe creation for the extended and modified Breathe DE app. The user flow and wireframe creation were designed by the Centre for Digital Therapeutics product team, University Health Network (UHN), Toronto, in consultation with the not-for-profit Asthma Research Group Windsor-Essex County Inc (ARGI-Best Care) and Novartis. The design team involved technology and clinical experts, including a project manager, a human factors/user interface/user experience designer, software developers, quality management specialist, primary care providers, respiratory therapists, and respiratory specialists. These individuals were selected based on their involvement in the earlier Breathe app version and relevant expertise in product development, design, technical implementation, and clinical asthma management.

The design team met weekly (1-hour time slots) over the development phase, with format varying by project phase. Early meetings focused on information gathering and understanding user and clinical needs, followed by working sessions to review and refine initial designs, and later demonstrations of evolving wireframes, workflows, and product features to support iterative feedback and refinement. Breathe DE was designed to be compatible with iOS only, due to budget constraints. Breathe DE was classified by Health Canada as a class II medical device, and development adhered to the requirements of ISO 13485:2016 [30,31].

Evaluation (Objectives 2 and 3)

A prospective, observational mixed methods study was conducted to assess the utility of Breathe DE in patients with asthma from 24 primary care clinics across Southwestern Ontario. All participating primary care clinics were part of the ARGI-Best Care network, and recruitment was assisted by clinical educator-case managers who, as part of Best Care chronic disease management programs, are embedded in primary care clinics working collaboratively with the patient and their primary care provider [32,33]. Potential participants were identified by the clinical educator-case manager or primary care provider, and if interested in participating, they were assessed for study eligibility. The clinical educator-case manager was a member of the Breathe DE study team, and from hereon, will be described as the research assistant (RA). Participants were recruited between September 2022 and March 2023 with a convenience sampling goal of 30 participants. The study duration was 12 weeks.

Ethical Considerations

This study was approved by the Research Ethics Board Veritas Independent Review Board (120844) and University Health Network Research Ethics Board (CAPCR ID: 21-5770). All participants signed written consent before participating in the study. The study was registered with ClinicalTrials.gov (NCT05594654).

Participants

Participants were included if they were at least 18 years of age, had a clinical diagnosis of asthma, were categorized as Global Initiative for Asthma Step 3-5 [3], had been prescribed daily maintenance medication of indacaterol acetate, glycopyrronium bromide, and mometasone furoate (Enerzair) or indacaterol acetate and mometasone furoate (Atectura) for at least 2 weeks before enrollment, had been prescribed salbutamol rescue medication administered through a pressurized metered dose inhaler, and had an iPhone 7 (iOS 14) or above, connected to an active cellular data plan. An active cellular plan was preferred to having Wi-Fi connection only, so that access to the app and notifications were continuous and consistent for all participants. Participants were required to be on Enerzair or Atectura as part of their routine care, a minimum 2-week buffer was to ensure that a daily maintenance medication routine had been established. Participants were excluded if they were under the care of a certified respiratory educator or had a diagnosis of another chronic disease that could interfere with their ability to use the intervention.

Study Procedure

All participant contacts were conducted by the RA. During the initial in-person study visit, T0, participant informed consent was obtained, baseline data and questionnaires were collected, and participants were guided through Breathe DE set-up (Figure 1). The participants were asked to use Breathe DE at least once a day when they were taking their maintenance medication, and as needed to manage their asthma symptoms. Frequency of spirometry was not specified but was guided by the RA at the initial visit during set-up. A 2-week follow-up telephone call was conducted by the RA to provide as-needed technical support. At the 12-week, T1, in-person visit, inhaler technique was reassessed, formal spirometry was performed, questionnaires were repeated, and a participant experience,

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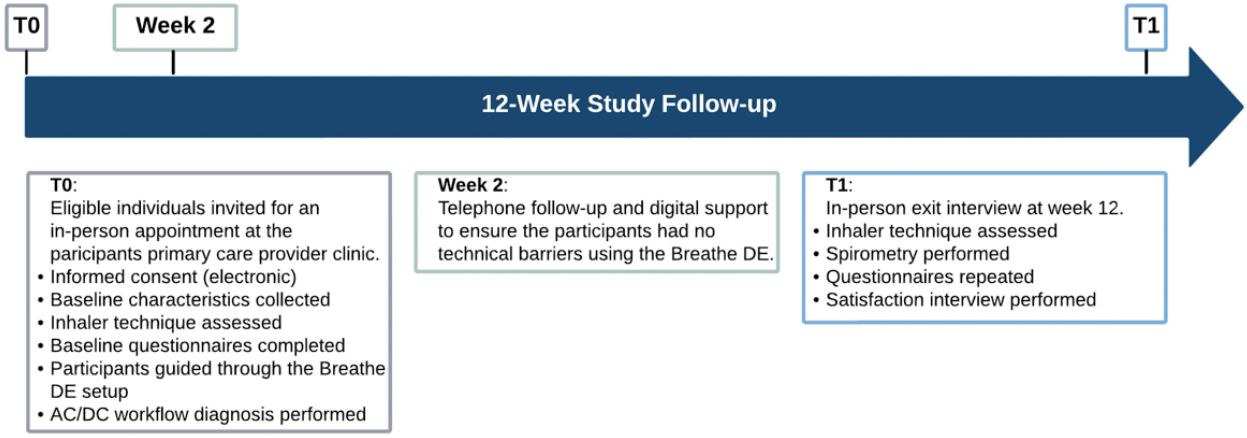
perception, and satisfaction interview was conducted (Figure 1).

Figure 1. Data collection and participant contact time points. AC/DC: Asthma COPD Differentiation Classification; Breathe DE: Breathe Digital Ecosystem.



Data Collection

Informed consent, baseline data, and questionnaires were collected electronically on the CliniOps platform (a digital clinical trials management system). The RA provided the CliniOps platform to the participant on a tablet or laptop. Once the consent form was signed, the RA assisted the participant to set up a CliniOps account, and all study data were collected on the CliniOps platform. Baseline characteristics were self-reported by participants at T0. Demographic and clinical characteristics included sex, age, ethnicity, marital status, age at clinical diagnosis of asthma, education level, employment status, household income, acute prior 3-month health service use, vaccinations, current medication, and smoking status (Multimedia Appendix 1). Participant device and mHealth app characteristics included preference, comfort and frequency of use, activities, digital service access, and number of mHealth wellness apps.

Assessments performed at T0 included an inhaler technique assessment to capture Breezhaler errors and rescue inhaler technique [34], and support for the participant to activate and record the Asthma COPD Differentiation Classification (AC/DC) workflow diagnosis. At T1, assessments included inhaler technique, formal spirometry, and dose counting from empty packaging for the Atectura or Enerzair capsules. Inhaler technique assessments and formal spirometry were conducted by the RA.

Questionnaires were completed by the participants at T0 and T1. The Asthma Control Questionnaire (ACQ) is a 7-item, validated questionnaire to measure adequacy of asthma control [35,36]. Scores range from 0=totally controlled to 6=severely uncontrolled, and a change in score of 0.5 is considered the minimally clinical important difference (MCID) [35,36]. The mini Asthma Quality of Life Questionnaire (mAQLQ) is a 15-item, validated questionnaire to measure disease-specific quality of life [37]. Scores range from 1=severe impairment to 7=no impairment, and the MCID is 0.5 [38].

Semistructured exit interviews were conducted by the RA at T1 (study exit). The interview invited participants to share their experience of using Breathe DE, how Breathe DE may have changed their asthma management, any aspects of Breathe DE they found challenging or would change, and using Breathe DE into the future. They were audio-recorded and took approximately 15-30 minutes to complete (Section S1 in Multimedia Appendix 2).

Quantitative Data Analysis

Participant characteristics at baseline (T0) and engagement with Breathe DE, user interactions, medication adherence, and inhaler technique assessment over follow-up were presented using summary statistics (frequencies and percentages, median with IQRs, and mean and SD). Diagnostic results from the AC/DC algorithm performed at T0 were reported. Point estimates (mean and SD) for the ACQ and mAQLQ at T0 and T1 were presented to investigate change in health status. Statistical software Stata/MP (version 17.0; StataCorp) was used for quantitative analyses.

User interactions with the app were quantified from 4 main features, and any one of the 4 activities was considered a user interaction: Breezhaler assistant and the log of daily administration of the Breezhaler controller medication, the log of spirometry tests performed using the handheld Medical Information Research (MIR) spirometer, the log of rescue inhaler use captured by the peripheral smart inhaler cap, and reported asthma zone based on completion of the symptom questionnaire (cough, difficulty breathing, chest tightness, wheezing, and shortness of breath) within Breathe DE. Breathe DE user interactions (Breezhaler, spirometry, rescue inhaler use, and chatbot interactions) aggregated for the whole study cohort were presented graphically to describe the longitudinal trends over the 12-week follow-up period.

Qualitative Data Analysis

Interview audio recordings were transcribed verbatim on a rolling basis using UHN's instance of Microsoft 365 external transcription service and reviewed by study team members for accuracy. The analysis took a pragmatic orientation consistent with the user-centered design practice of the study team [39,40], with the aim of describing how participants experienced Breathe

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DE and what their accounts implied for its refinement and future implementation.

The reporting domains for the qualitative findings were specified in advance. Interpretation was organized around the implementation outcomes framework [41], a taxonomy of 8 implementation outcomes (acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability) developed by Proctor et al [41] to describe how well an intervention is received and used in practice. The framework was selected because the aims of this pilot were implementation questions about early-stage DHT rather than questions of clinical effectiveness. Three outcomes matched the study objectives and were used as reporting domains. Acceptability and feasibility were applied as defined in the framework, and appropriateness, the perceived fit and relevance of an innovation for its users, is reported here as perceived usefulness. Because these domains were defined a priori, the qualitative findings are reported within them rather than presented as themes that emerged solely from the data.

Coding combined deductive and inductive approaches in a codebook thematic analysis [42], following the hybrid approach described by Fereday and Muir-Cochrane [43]. An initial codebook was scaffolded deductively from 4 constructs, the participant's individual experience of asthma self-management, their experience with Breathe DE, the acceptability of Breathe DE, and their impressions of its design. These constructs were derived from the study objectives and from the domains of the semistructured interview guide (Section S1 in Multimedia Appendix 2), which asked participants about their self-management habits, their experience and expectations of Breathe DE, difficulties with the app and its connected devices, and their intention to continue use. Each construct was operationalized as codes and subcodes with written definitions and annotation notes to standardize their application across coders. The full codebook is provided in Section S2 in Multimedia Appendix 2.

Two coders first coded the same 2 transcripts independently in NVivo (QSR International) and compared their coding to test and refine the code definitions. Once the team reached consensus on the codebook, the remaining transcripts were divided between the coders. Segments that did not fit the existing codes were proposed as new inductive codes and discussed at team meetings; when agreed, they were added to the codebook, and earlier transcripts were rereviewed against the updated version. Coding queries and disagreements were resolved through these consensus discussions rather than through statistical testing of intercoder agreement, consistent with published guidance for consensus-based coding [44]. Coded text within each reporting domain was then condensed into the findings and presented in a table format. Participant counts reported with the qualitative findings are the number of the 17 interviewed participants whose transcript contained content coded to that finding. They are reported to convey how widely a view was expressed and do not constitute a quantitative content analysis. The qualitative methods and results are reported in accordance with the Standards for Reporting Qualitative Research [45], and the completed checklist is provided in Multimedia Appendix 3.

Data Integration

Individual participant "journeys" were presented graphically to describe the longitudinal trends in app interactions (Breezhaler, spirometry, and rescue inhaler use) and patient-reported symptoms to derive asthma zone of control from chatbot interactions over the 12-week follow-up period. To create a synthesized perspective from both the qualitative and quantitative data, we reviewed the quantitative longitudinal participant journey alongside the qualitative feedback from the participant to integrate the user-reported experience with the app engagement.

Results

Development (Objective 1)

The final iteration of Breathe DE integrated 6 key features to assist in the delivery of 7 elements of guideline-directed asthma management that could be incorporated into 1 mHealth platform: addressing accurate diagnosis, symptom monitoring and self-management action plan, controller inhaler technique evaluation and feedback, inhaler adherence support, rescue medication tracking and feedback, guided spirometry to assist asthma control, and environmental trigger avoidance (Figure 2). The main features of Breathe DE are outlined in Table 1. Modified features included the chatbot and Breezometer air quality. New features included the Breezhaler assistant, Breezometer air quality, and the diagnosis decision aid (AC/DC algorithm) and Bluetooth-enabled hardware components, the smart inhaler cap and the MIR digital spirometer (Table 1, Figure 3, full descriptions and technical details included in Multimedia Appendix 4).

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Figure 2. Breathe Digital Ecosystem, a single platform across the spectrum of guideline-directed asthma management. AC/DC: Asthma COPD Differentiation Classification; MIR: Medical Information Research.

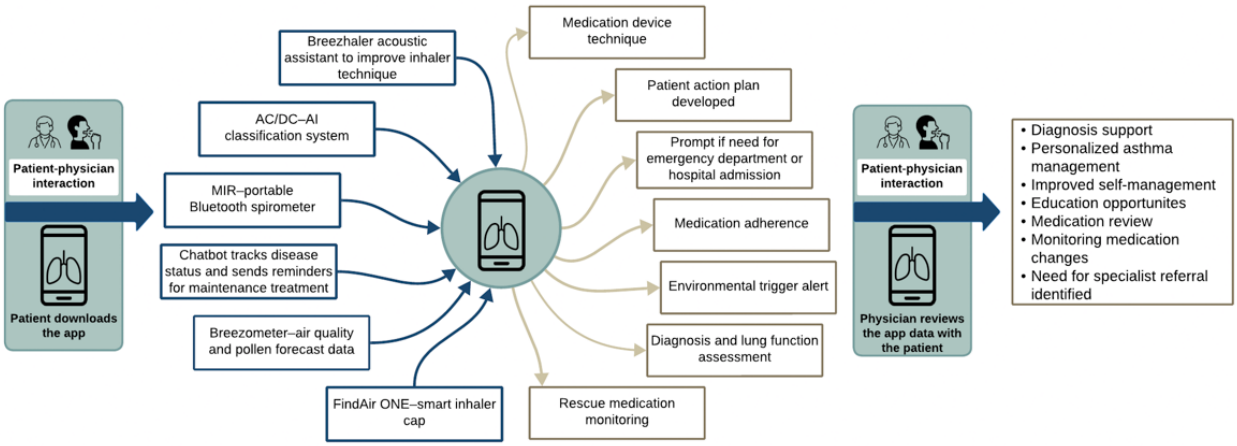

Table 1. Main features of the modified Breathe Digital Ecosystem (Breathe DE) smartphone app and asthma management delivered.

Breathe DE features	Description	Asthma management	New or existing feature
A. Chatbot	The main feature of Breathe DE and the control center for all of the integrated features. The user can interact with the chatbot to receive reminders, take their daily inhaler medication, receive specific instructions on how to administer the Breezhaler inhaler, answer questions about their current asthma symptoms, scan their smart inhaler cap to upload their reliever inhaler use, assess their current zone of control, and instruct on how to manage their symptoms based on that zone [46].	Asthma control and self-management action plan	Existing but modified
B. Breezhaler assistant	Records the date, time, accuracy, and number of doses administered. Works for Atectura and Enerzair. A built-in algorithm software feature uses the iPhone microphone to detect the distinct rattling or whirling noise that the Breezhaler device makes, assessing whether the daily medication was effectively administered.	Medication administration and adherence	New feature
C. FindAir ONE smart inhaler cap	Smart inhaler cap sensors track the use of the rescue inhaler by collecting the date, time, and number of doses administered. These data are integrated into the rules-based exacerbation algorithm to guide correct and regular use of the inhaler, track reliever use, and monitor the user's zone of control [47].	Rescue medication use	New feature
D. MIR[a] digital spirometer	A Bluetooth-based device that allows users to conduct spirometry testing. There are guided step-by-step instructions on how to accurately administer the digital spirometry test. To ensure that acceptability and reproducibility criteria are met, the user is directed to take spirometry readings to identify their best lung function values and change over time to support their diagnosis and action plan [48-50].	Asthma diagnosis and control	New feature
E. Breezometer air quality	Breezometer Air Quality Health Index database to compare the air quality and pollen of the user's location to the national air quality standards [51].	Environmental trigger avoidance	Modified feature
F. Diagnosis decision aid (Asthma COPD Differentiation Classification algorithm)	Aids in the differential diagnosis of asthma, chronic obstructive pulmonary disease (COPD), or asthma-COPD overlap using values from the digital spirometer (FEV_1[b] and FEV_1/FVC[c]), as well as the users' symptoms (dyspnea, wheeze, and cough), smoking history and status, age, BMI, and diagnosis of allergic rhinitis (chronic or acute) [18,52].	Accurate diagnosis	New feature

[a]MIR: Medical Information Research.

[b]FEV_1: forced expiratory volume in the first second of exhalation.

[c]FVC: forced vital capacity.

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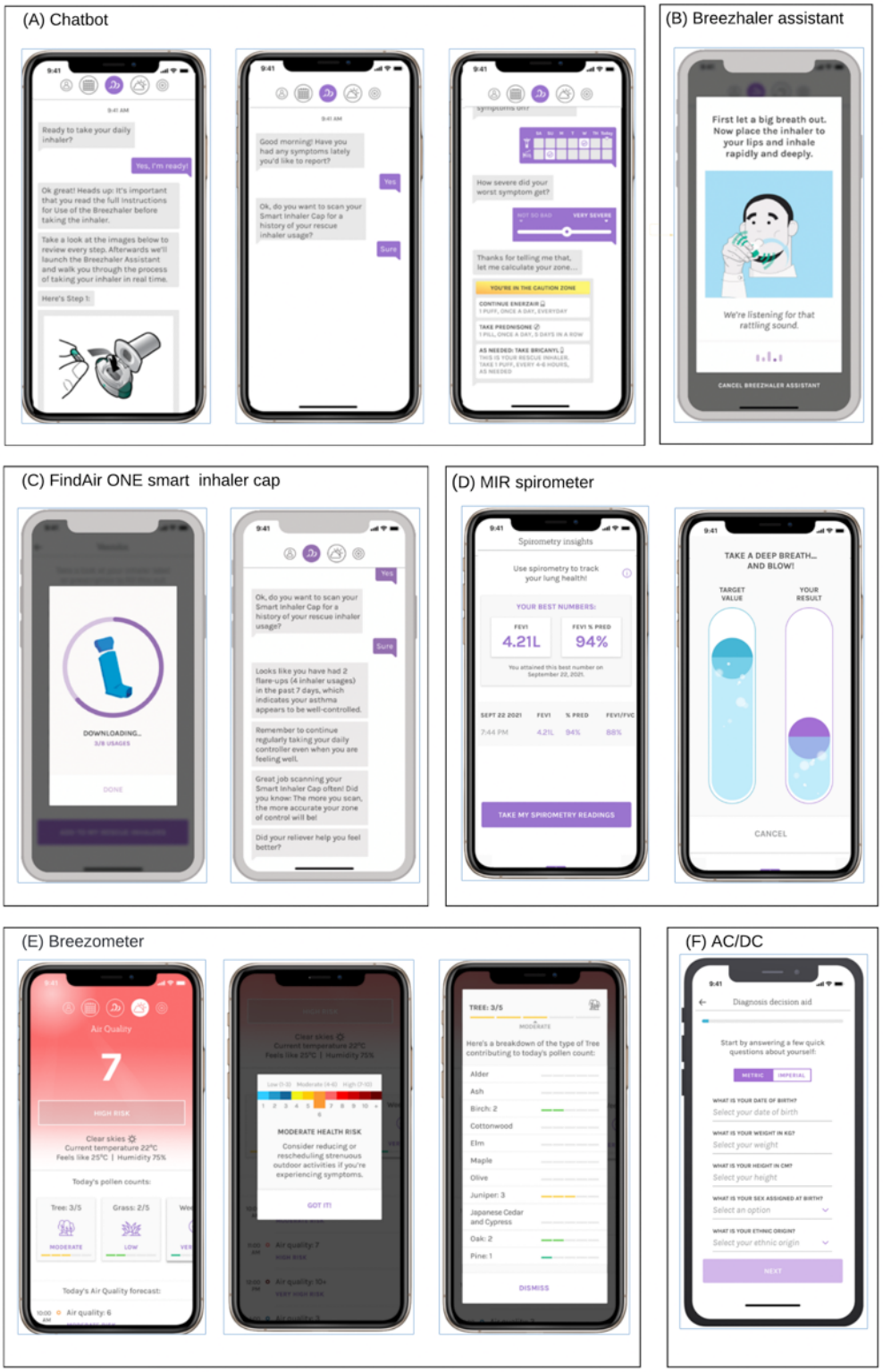
Figure 3. Screen captures from the app of each component of the Breathe Digital Ecosystem. (A) Chatbot, (B) Breezhaler assistant, (C) FindAir ONE smart inhaler cap, (D) MIR digital spirometer, (E) Breezometer air quality, and (F) diagnosis decision aid (AC/DC). AC/DC: Asthma COPD Differentiation Classification; MIR: Medical Information Research.



Evaluation (Objectives 2 and 3)

Participant Characteristics

Of the 21 patients enrolled from 12 primary care clinics, 17 (81%) completed the study, and 4 participants did not complete the exit questionnaire at T1 (3 lost to follow-up and 1 dropped out; Figure 4). The study population was predominantly female (18/21, 86%) and younger than 65 years of age (16/21, 76%). The most preferred digital device was a smartphone (14/15, 93%), which most participants reported using frequently (10/11, 93%; Table 2). The AC/DC algorithm determined that 71% (15/21) had asthma, 5% (1/21) had asthma-chronic obstructive pulmonary disease (COPD) overlap, 14% (3/21) had COPD, and was unable to classify 2 participants.

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Figure 4. Patient recruitment and study flow.

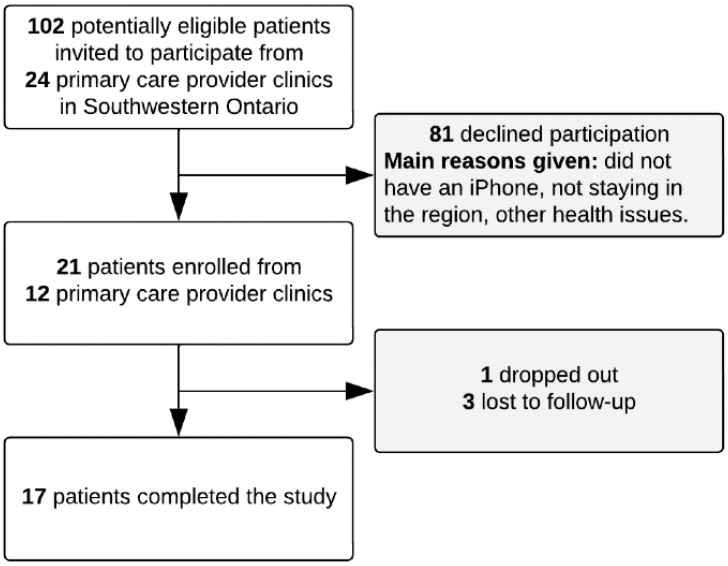

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Table 2. Baseline characteristics of the study cohort[a].

Characteristics	Values
Demographic and clinical characteristics (n=21)	
Sex, n (%)	
Female	18 (86)
Age (years)	
Mean (SD)	51 (16.5)
Age range (years), n (%)	
18-40	6 (28)
41-65	10 (48)
>65	5 (24)
Marital status (n=14) , n (%)	
Married or common-law union	10 (71)
Racial ethnic group (n=16) , n (%)	
White	15 (94)
Education level (n=12), n (%)	
College, trade or technical diploma	6 (50)
University undergraduate degree	4 (33)
University postgraduate degree or professional designation	2 (17)
Employment status (n=14), n (%)	
Work full time	7 (50)
Retired	4 (29)
Other	3 (21)
Age at diagnosis (years) (n=20)	
Mean (SD)	27 (20)
Median (IQR)	19 (9-43)
Smoking status, n (%)	
Never smoked	18 (86)
Health service use and exacerbations (3 months prior) (n=19)	
Unscheduled physician visits (events), n	17
Unscheduled physician visits (participants), n (%)	7 (37)
Emergency department visits, n (%)	1 (5)
Hospital admissions, n (%)	0 (0)
Number of exacerbations requiring prednisone (events), n	6
Number of exacerbations requiring prednisone (participants), n (%)	4 (21)
Digital characteristics (n=15)	
Most preferred device, n (%)	
Smartphone (vs tablet or desktop) as most preferred device	14 (93)
Frequency of using preferred device, n (%)	
Frequent (few times per day) (n=11)	10 (93)
Comfortable using preferred device (very comfortable or comfortable) (n=14)	12 (86)
Number of health and wellness apps used (n=13)	
Mean (SD)	2.2 (1.1)

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Characteristics	Values
Median (IQR)	2 (2-2)

[a]Some baseline characteristics are not presented due to very low participant responses.

Participant Engagement

Overall, participants interacted with the app a median of 35/90 (IQR 26-71) days. In total, 86% (18/21) used the Breezhaler assistant feature of Breathe DE at least once, and median daily use was 21/90 (IQR 12-49) days. Of the participants assessed using the Breezhaler device, the proportion of participants making an error, observed by the RA, decreased from 29% (5/17 participants observed) at T0 to 6% (1/16 participants observed) at T1. For the empty capsule counting at T1, the mean number of controller doses taken per participant was 73 (SD 19.8), with 81% adherence. Approximately half of the administered doses were digitally logged (Table 3).

Table 3. Medication administration and spirometry captured by Breathe Digital Ecosystem (Breathe DE) and assessed by the certified respiratory educator[a].

	Values
Breezhaler	
Breezhaler daily maintenance use captured by Breathe DE over 12 weeks of follow-up	
Captured at least once, n (%)	18 (86)
Number of days, median (IQR)	21 (12-49)
Technique assessment by RA[b] at T0[c] and T1[d]	
Number of errors observed at T0 (n=17)	7 errors by 5 (29%) participants
Number of errors observed at T1 (n=16)	1 error by 1 (6%) participant
Adherence (dose counting) at T1	
Number of doses taken per participant (n=14), mean (SD)	73 (19.8)
Adherence above 80% (n=14), n (%)	7 (50)
Rescue inhaler	
Rescue inhaler use captured by Breathe DE over 12 weeks of follow-up	
Captured at least once, n (%)	13 (62)
Number of doses, median (IQR)	4 (0-15)
Number of days used, median (IQR)	2 (0-6)
Inhaler technique assessment by RA at T0 and T1	
Correct technique at T0, n (%)	6 (29)
Score at T0 (%), mean (SD)	78 (19.0)
Correct technique at T1 (n=16), n (%)	10 (59)
Score at T1 (%) (n=16), mean (SD)	94 (9.0)
Spirometry	
Spirometry performed and captured by Breathe DE over 12 weeks of follow-up	
Used at least once, n (%)	21 (100)
Number of times, median (IQR)	6 (2-24)
Overall engagement with any feature of Breathe DE over 12 weeks of follow-up[e]	
Number of days, median (IQR)	35 (26-71)

[a]N=21 unless otherwise specified.

[b]RA: research assistant.

[c]T0: initial visit.

[d]T1: final visit.

[e]Any feature=Breezhaler assistant, rescue inhaler smart cap, Medical Information Research spirometry, and chatbot interactions to assess asthma zone of control.

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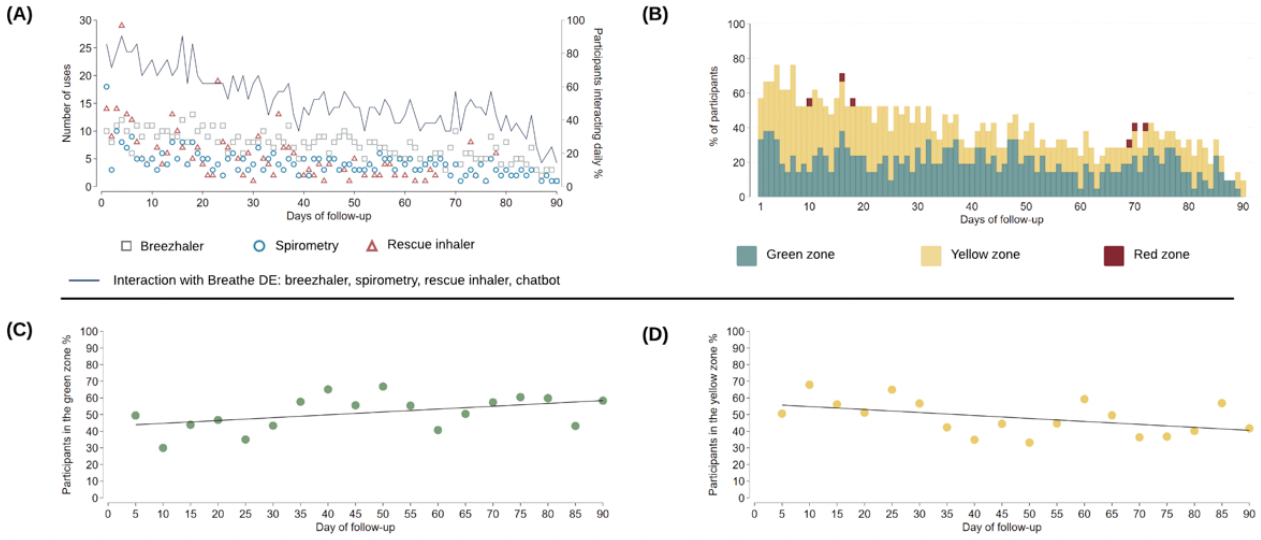
Participant rescue inhaler use was recorded at least once by 13 (62%) of the participants, and the median number of doses administered over follow-up was 4 (IQR 0-15). Rescue inhaler technique improved from a mean score of 78% (SD 19.0%) at T0 to 94% (SD 9.0%) at T1 (Table 3).

All 21 participants used the Bluetooth-connected spirometry at least once; the median number of times spirometry was performed by the participants was 6 (IQR 2-24; Table 3).

The number of Breathe DE interactions decreased over the 12-week period, as did the proportion of participants interacting with Breathe DE (Figure 5A). The proportion of participants in the yellow zone on any 1 day decreased and in the green zone remained more constant over the 12 weeks of follow-up (Figure 5B). The proportion of participants (classified into zone of control) in the green zone increased over time and, by corollary, the proportion in the yellow zone decreased (Figures 5C and 5D).

Figure 5. A longitudinal description of the Breathe Digital Ecosystem use over 12 weeks of follow-up for the whole study cohort: (A) the frequency of Breezhaler use, reliever inhaler use, and participant performed spirometry per day and the percentage of participants interacting with any component of the app per day (N=21); (B) the percentage of participants using the app to determine their zone of control, green, yellow, or red; (C) the mean percentage of participants interacting with the app in the green zone over intervals of 5 days; and (D) the mean percentage of participants interacting with the app in the yellow zone over intervals of 5 days.



Change in Health Status

The number of participants completing the surveys was low, ACQ 48% (10/21) and mAQLQ 52% (11/21). However, for those who did, the mean ACQ score changed from 1.6 (SD 1.3) to 1.0 (SD 0.9), and the mAQLQ from 4.7 (SD 1.08) to 5.3 (SD 0.92).

The Participant Perspective

Overview

The qualitative findings are reported under the 3 predefined domains of usefulness, acceptability, and feasibility (Table 4).

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Table 4. Qualitative findings reported under the 3 predefined domains of usefulness, acceptability, and feasibility of Breathe Digital Ecosystem (Breathe DE) from exit interviews and the connection to the quantitative data collected by Breathe DE.

Consideration	Findings	Supporting quotes and patient journey[a]
Usefulness: the perceived utility of Breathe DE in managing asthma symptoms [41]	Breathe DE can be an effective tool for habit-building and information sharing. Breathe DE provided insight on the patient's inhaler technique and displayed management patterns (zones) that they may not have known before. Participants (n=6) shared that the routine notification reminders they set in the app were useful to help them establish routine or control over their symptoms. In total, 4 participants reported never receiving notifications, and delivery stopped or became intermittent for 2 others. A total of 7 participants had an established medication routine before the study and found the daily reminder redundant rather than additive to their self-management routine; 2 of them disabled the reminders.	• "I never forgot, and I took it every morning. Now I had it set up pop up at 10:00 AM as the notification ... I'll bet you I didn't forget once" [P02] (Patient journey J: regular medication adherence after day 9). • "I found that most of the time it was useful. Just if you didn't complete all the steps within that day, when you would go on the next day, it would try and finish what you were doing the day before, so then you couldn't go on to do your breathe portion of it because it kept saying like, see you later. And then just the Breathe cap wouldn't connect. I couldn't get it to connect, but other than that, the information on there was good as to how to take the capsules and how long to wait and the proper noises you're supposed to hear like that was all pretty good" [P26] (Patient journey S: no evidence of rescue inhaler use). • "So the app it was helpful at first, but I really haven't used it all that much in the past couple of months because I've been in my Green Zone, so it was helpful. Interesting to look at, but it's not something I've practiced every day" [P04] (Patient journey O: used until day 43). • "I was using it quite regularly at the beginning of the study, and then I found it very redundant. Like I found that it was the same information and a lot of times the information that the Breathe app was giving me was intuitive. I kind of could tell just based on weather patterns or other elements of my life how my asthma is being controlled" [P07] (Patient journey G: stopped using the app after day 32). • "I've been doing-it usually just in the morning. I did set the reminder to come up for 8:00 AM and it was coming up every day. I would answer the questions every once in a while, but it became really repetitive. I didn't feel like I needed to do that every day, so I haven't done it for a little while and quite honestly, I would forget if it didn't pop up" [P04] (Patient journey O: intermittent use and stopped using the app after day 3).
Acceptability: the extent to which the participant appears to accept Breathe DE for asthma self-management [37]	Acceptability of Breathe DE was dependent on participants' current asthma symptoms and their self-management routine prior to using Breathe DE. Participants (n=6) who experienced improved control over their symptoms during the study period shared that they would continue to use Breathe DE for self-management. Meanwhile, participants (n=8) who had well-controlled asthma, were nonsymptomatic, or had an existing self-management regimen would not. Similarly, those who were undecided about their future use of Breathe DE (n=3) stated that their decision to use Breathe DE is dependent on the severity of their symptoms.	• "I would say yes and the reason being is that I feel that I've had more control of my breathing than I have in the past, just as I mentioned earlier. Just being able to control it a little bit more utilizing the Ventolin as much as I used to. And even though I went through the one capsule of Ventolin during the three-month period, that's an improvement for me. So I think I'm on the right route" [P08] (Patient journey E: stayed in the green zone after day 23, high rescue inhaler use for 2 days and no other captured use). • "To be honest the app kind of made me not want to be using my puffers because I felt like I was not doing what I was supposed to be doing when I would take my puffer without using the app, so I felt guilty. I feel that I have much better adherence when I am responsible for it on my own and not having an app to remind me" [P03] (Patient journey R: used the Breezhaler assistant quite frequently up until day 62). • "I guess if my symptoms are worse—I would maybe go to it. I mean, I know I've got to take my Ventolin that's my go to. If I'm in a yellow zone, I take my Ventolin. But maybe it would be helpful if I wanted to do spirometry again, even though I know I've got to send it back or to look at the air quality. Maybe that would be helpful for me to kind of put the pieces together as to why I'm having more symptoms. But I know on my own without an app telling me that if I have more symptoms, I take Ventolin. I know that I'm taking the device properly. I hear it spinning. I taste it, I rinse and gargle so I know I'm getting the medication, so I don't know what else on top of that again for a well controlled-asthmatic what more is that going to offer me other than use my Ventolin" [P04] (Patient journey O: in the green zone for every day used. Stopped using the app at day 43).

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Consideration	Findings	Supporting quotes and patient journey[a]
Feasibility: the extent to which Breathe DE can be successfully used for asthma management given resource or skill requirements [37]		
Technological	Patients (n=8) reported connectivity issues between hardware (smart cap and spirometer) and software (Breathe app) components of Breathe DE. Consequently, users were unable to track all aspects of engagement (i.e. use not recorded or registered). Patients also shared concerns around Wi-Fi "dead zones" and a lack of data plans. Breathe DE relies on internet connection to consistently upload information or send reminder alerts. Individuals who do not have internet access would not be able to use Breathe DE as intended.	• "It was very good actually with the Breathe app. I had no issues other than the venting (Ventolin) and recording and so forth, but everything else was straightforward and easy to load (...)" [P08] (Patient journey E: used all features throughout follow-up, rescue inhaler use was only recorded on 2 days). • "I'm quite familiar with spirometry and I felt that even someone who was familiar with spirometry had difficulty using it, and so I found that to be quite frustrating because you're blowing, blowing, blowing, but then it's telling you to keep blowing and I'm like at 12 seconds, nothing left to come out and it's not recognizing" [P03] (Patient journey R: only 1 recorded spirometry captured by the app). • "Yeah, it was not detecting my breaths. It got a little bit better over time. But yeah, the first time it was making me do it over and over and over again, which kind of made me feel like the results weren't going to be accurate because after, yeah, I'm tired after using it" [P26] (Patient journey S: spirometry captured 4 times by the app). • "I think a couple times because I wasn't in a Wi-Fi zone or I wasn't using my data and once I remembered, ohh I gotta put my data on. You know what, I mean then it was OK" [P19] (Patient journey T: used app frequently throughout the follow-up period but >20 days with no data captured).
Physical	Challenges related to dexterity and low vision are major deterrents to the sustained use of Breathe DE. In addition, a few participants (n=3) reported that considerable physical force is required to attach the smart cap properly. Overall, 8 participants mentioned trouble with attaching the smart cap properly.	• "I mean the adaptive technology aspect. [It] fails that aspect because I use larger text and I can't see a lot of the text in the Breathe app because of my use of adaptive tech. So that needs to be fixed right away" [P06] (Patient journey P: used the app very regularly over follow-up). • "I found it very hard—it was hard for me to push the inhaler with the cap on, but I do have some strength issues in my hands, so that might have been the issue" [P18] (Patient journey U: rescue inhaler use captured on 6 days on follow-up). • "I always carry my Ventolin with me, whether it's my coat or my pant pocket and the CAP would always come off after a period of time. I realized when it was coming off, but after it's been in my pant pockets or coat pockets it would slip off. So then I'm struggling with getting it back onto the inhaler because it is tight to get it on" [P08] (Patient journey E: rescue inhaler use was only capture by the app on 2 days of follow-up).

[a]Patient journey illustrations for all participants are included in Multimedia Appendix 5.

Usefulness

Reminders and routine were discussed in all 17 interviews, with divided views. In total, 6 participants described the app notifications as useful for building a medication routine or regaining a sense of control over their symptoms. A total of 7 found the daily reminders redundant or annoying because they had an established medication routine before the study, and 2 of them disabled the reminders. The remaining 4 participants reported receiving no alerts at all. Delivery was also inconsistent for participants in the first 2 groups, with alerts arriving intermittently for one participant and stopping after approximately 1 month for another. Beyond reminders, participants valued Breathe DE as a source of information they did not previously have. One participant learned of rescue inhaler overuse they had been unaware of, and another used a low home spirometry reading to decide to seek care for what proved to be pneumonia. Several others described improved awareness of their inhaler technique and of environmental triggers.

Acceptability

Intention to continue using Breathe DE depended on participants' current symptoms and on the self-management routine they brought to the study. In total, 6 participants intended to continue, generally those who had experienced improved control over their symptoms during the study period. A total of 8 did not intend to continue, most often because their asthma was well controlled or because the app duplicated a self-management routine they already had; one of these participants also felt that the app undermined the sense of personal responsibility that supported their adherence. A total of 3 participants were undecided and said that future use would depend on the severity of their symptoms.

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Feasibility

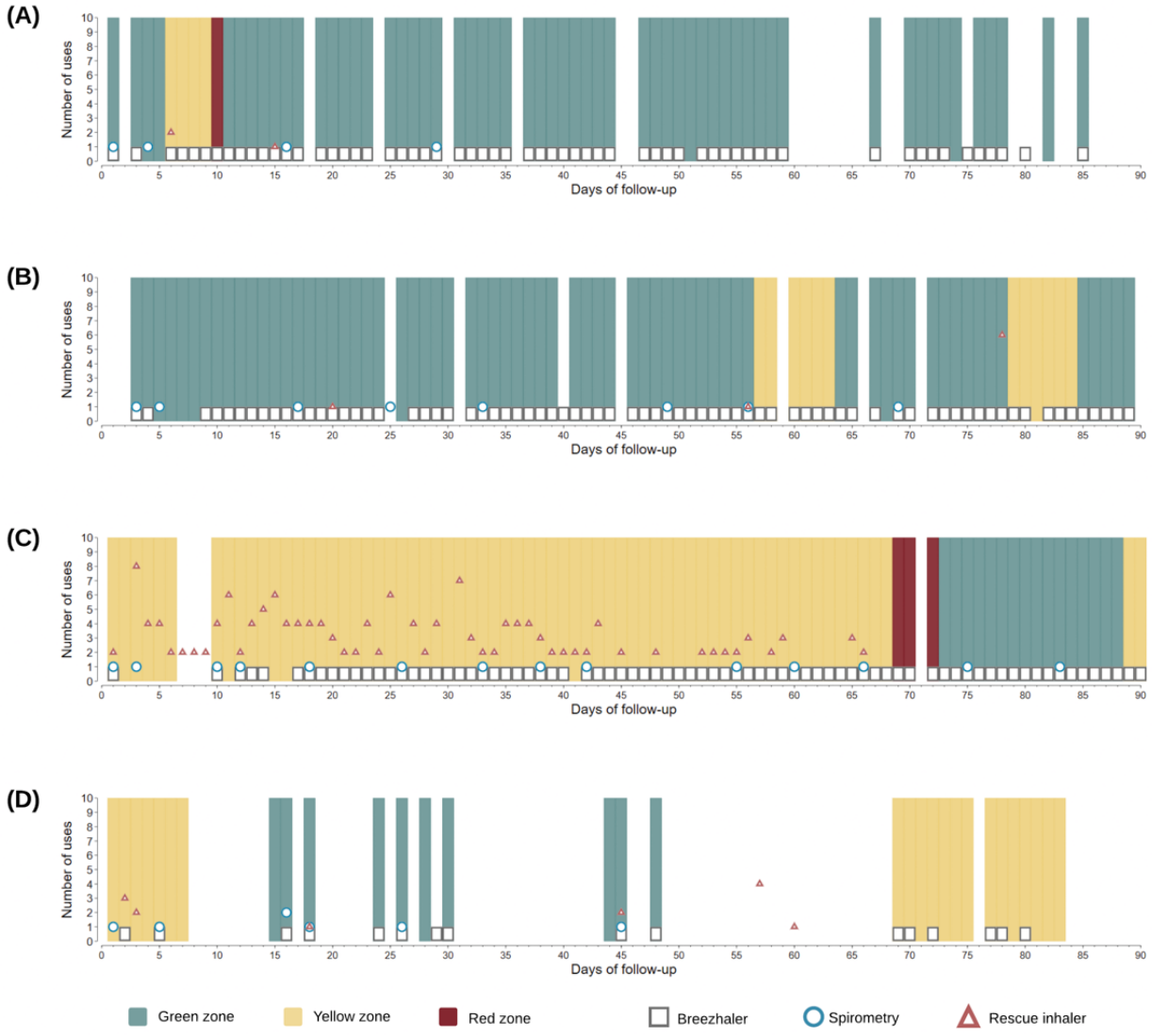
Reports fell into 2 categories, technological and physical. In total, 8 participants reported connectivity failures between the hardware components (smart cap and spirometer) and the app, with the result that inhaler use or spirometry they had performed was not recorded. A total of 2 participants raised the app's dependence on internet access, noting that mobile data are costly and that coverage dead zones made the app unusable when traveling. On the physical side, 8 participants had difficulty attaching or pressing the smart cap, and for 3 of them, this required considerable force, a particular barrier for participants with reduced hand strength or arthritis. One participant who used adaptive large text for low vision could not read screens where the enlarged text was cut off.

Across the 3 domains, the perceived value of Breathe DE tracked symptom state. Participants who were managing active or newly recognized symptoms used the app as a source of guidance and reassurance, while participants with well-controlled asthma and settled routines experienced it as duplicating what they already did. Technical failures of the connected hardware cut across both groups and reduced participants' confidence that the recorded data reflected their actual medication use.

Data Integration

Each participant journey was described graphically (Multimedia Appendix 5), and Table 4 links specific patient quotes to their documented journey. Figure 6 shows the journey of 4 participants with higher app activity and integrates the findings from these participants' qualitative data.

Figure 6. A patient journey: a longitudinal description of the Breathe Digital Ecosystem use over 12 weeks of follow-up for participants (A-D).



The participant from Figure 6A with Breathe DE on 65/90 days and logged daily maintenance adherence 60 times. They documented 58 days in the green zone, 3 days in the yellow zone, and 1 day in the red zone, and 3 doses of rescue inhaler administered. They performed spirometry 4 times over the follow-up period. This participant reported an overall positive experience of using Breathe DE, they found it straightforward to use, and they liked the support that it gave during episodes of symptom worsening and overall felt their self-management skills were improved. They did report good adherence to their daily maintenance inhaler prior to using the app, and so did not

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feel that medication administration reminders were useful to them.

The participant from Figure 6B similarly had high Breathe DE engagement (82/90 days) and 74 days of documented daily maintenance adherence. They spent 68 days in the green zone and 12 days in the yellow zone, administering 8 doses of rescue inhaler and performing spirometry 8 times. From the qualitative data, this participant reported that the alerts worked well for them and improved their asthma management routine. They felt that their asthma was well-controlled, and that Breathe DE may be useful to people with asthma that is poorly controlled. From a more technological perspective, they found Breathe DE to be rigid, with a lack of adaptive technology and limits to symptom recording.

The participant from Figure 6C engaged with Breathe DE 89/90 days, with 77 days of documented daily maintenance adherence. They experienced poorer symptom control, spending 16 days in the green zone, 67 days in the yellow zone, and 3 days in the red zone. They administered a documented 164 doses of rescue inhaler and performed spirometry 14 times. This participant felt that Breathe DE was very helpful in tracking symptoms, lung function, and medication use, and they had not realized that they were using their rescue inhaler so much. This participant reflects that Breathe DE advised them to activate their action plan and course of oral corticosteroids, but they were hesitant and subsequently went to the emergency department. They felt that some of the prompts could be bypassed for regular users, as it became repetitive.

Finally, the participant from Figure 6D interacted with Breathe DE on 34/90 days of follow-up and documented 16 days of daily maintenance adherence. They were in the green zone for 10 days and the yellow zone for 21 days, administering 13 doses of rescue inhaler and performing spirometry 7 times. This participant felt that Breathe DE was educational, and that they had learnt a lot from interacting with it. However, they found some of the prompts and instructions cumbersome and were frustrated with the spirometer, as they always got the same readings despite how they were feeling.

Discussion

Summary of Key Findings

We demonstrated that creating an asthma digital ecosystem to address 7 major barriers to good asthma disease control was feasible. Built on a single smartphone app, Breathe DE provided diagnostics, inhaler adherence support, controller inhaler device technique evaluation and feedback, real-time environmental trigger avoidance information, feedback in B2-agonist overuse, a self-management action plan to support early intervention to restore disease control, and a spirometer to measure asthma control objectively. Then, using a mixed methods study design generated panoramic insights into the utility of Breathe DE. Although many participants were able to use the multiple components of Breathe DE, both physical and technological challenges were reported. Engagement was variable between participants and waned over time. Participants were most inclined to interact with Breathe DE when symptomatic or asthma was poorly controlled, and it was considered somewhat redundant by participants with good asthma control. Breathe DE data and participant self-report suggested that some patients experienced tangible improvements in asthma control, quality of life, and inhaler technique. The app generated profiles that define each participant's personalized disease journey and may be helpful to a physician who is trying to understand and improve disease control.

Engagement With DHTs

Engagement with Breathe DE was good, with participants interacting with the app at least once per day for a median of 35 times during the 12 weeks of follow-up. The highest interactions were seen with the Breezhaler features monitoring daily maintenance inhaler use. Interactions aggregated for the whole study cohort decreased over 12 weeks. Of 11 studies published in the last 10 years evaluating asthma mHealth apps for adults, with follow-up ranging from 1 to 12 months, 4 reported app use temporally [28,53,54]. All 4 studies observed decreasing use over time, with substantial decline after only 1 month of engagement [28,55-57]. These studies attribute the decline in engagement to mastery of self-management, design issues such as repetitive content or technical failures, perceived disease control, and an absence of physician input [28,55-57]. Likewise in this study, participants felt a greater relevance of Breathe DE for patients with uncontrolled asthma, and green zone control appeared to improve over time. A goal of Breathe DE is to increase self-management skills and patient autonomy; some participants reported technological difficulties, and repetition in instructions and prompts potentially influencing continued app engagement. Furthermore, our data were inclusive of those lost to follow-up or who withdrew from the study, contributing to the observed decline. Investigators have examined ways to increase and sustain app engagement through mHealth app design features such as limiting repetition, using social media to promote the app, and incorporating game-like features; however, despite these design modifications, engagement still waned over time [55-57]. Accordingly, it may be prudent to accept that mHealth apps are not all designated for continuous use but rather are a time-limited health care support tool prescribed for patients experiencing "difficult to control disease," "new diagnoses," or other defined disease presentation.

A Breathe DE Prescription for Difficult to Control Asthma or Diagnostic Insights

The patient journey documented by Breathe DE from Figure 6C demonstrated extremely high rescue inhaler use that even the participant was not aware of; this is a valuable insight for both the patient and health care practitioner and one that would not have been revealed by the patient in a routine consultation. Further to this, the practitioner can examine the personalized journey with the patient to assess adherence to maintenance medication and symptom control and measure lung function parameters to better understand contributors to poor control and more accurately inform therapeutic interventions.

A review comparing unsupervised spirometry to spirometry performed in clinic concluded that they were not interchangeable [58]. Of the 28 studies included in the review, 6 used the MIR

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spirometer, and although not tested on asthma, interestingly, all 6 studies did report a high correlation of home versus hospital spirometry results. In this study, home spirometry can be reviewed alongside asthma zone of control, medication adherence, and SABA use, strengthening the interpretation of unsupervised spirometry for health care practitioners.

Kocks et al [18] conducted a study to investigate the average diagnostic accuracy of the AC/DC tool and found that compared to primary care physicians and pulmonologists, the diagnostic accuracy was 73%, 50%, and 61%, respectively. In this study, the AC/DC classification system provided diagnostic insights that supported an asthma diagnosis in 76% of participants, 71% with asthma and 5% with asthma-COPD overlap but suggested that 14% were misdiagnosed and in fact had COPD. This may lead a physician to re-examine a patient's diagnosis. Breathe DE highlights the capabilities of DHTs as tools that can be "prescribed" by the health care practitioner and work in conjunction with in-person consultations to gain valuable and comprehensive insights into the individual disease experience.

Observed Outcomes

Despite the vast heterogeneities between mHealth apps for asthma in adults, in general, consistent benefits in asthma control, quality of life, and adherence have been reported, although findings of lung function improvement are less consistent [19,20,53-55,59-61]. Likewise, in this study, improvements were observed in inhaler technique, quality of life, and asthma control for participants using Breathe DE and who completed the study assessments. However, there were not complete data from these metrics and so we can only conclude that for some participants, there were improvements suggesting better asthma control and fewer days with moderate symptoms.

Limitations

The strength of this study was the mixed methods study design that facilitated the collection of a plethora of data at an individual level, documenting the patient's day-to-day disease experience. However, due to the small sample size, a convenience sampling strategy, and large variability in participant engagement, there was bias susceptibility in the data reported. For example, the sample was 86% (18/21) female participants, Breathe DE was only available for iPhone users, and the dataset was small with incomplete data.

While the data showed some improvement in trends and outcomes and the changes from baseline observed for the ACT and mAQLQ questionnaires were favorable, the changes were not assessed for significance; furthermore, change in health status was only documented for half of the study sample. Likewise, in the longitudinal data, we can assess trends, but as participants were not engaging with the app every day, the potential for bias is high. Participants with well-managed asthma may potentially interact differently from participants with less controlled asthma. Finally, the sound-based detection Breezhaler assistant algorithm was tested using validation datasets (Multimedia Appendix 4) but has not been tested extensively on a real-world population.

Future Direction and App Utility

The comprehensive data captured by Breathe DE, as illustrated in the longitudinal description, provide a granular view of patient engagement and respiratory health trends over time. The observed patterns and changes in app interactions, medication use, and symptom reporting offer valuable insights for health care practitioners, emphasizing the potential of DHTs in chronic disease management and patient empowerment; however, future versions of Breathe DE must include adaptive technology features and be tailored for users living with low vision or limited dexterity. The Breathe DE AC/DC diagnostic tool and home-based patient-performed spirometry could be a valuable tool for practitioners for patients with difficult-to-control asthma, giving a more holistic understanding of the disease at an individual level, allowing treatment tailored to the disease as experienced by the patient. Future larger studies to assess Breathe DE, designed in a way to maximize generalizability, would be valuable, given the promising quantitative and constructive qualitative data collected in this acceptability study.

Conclusions

Breathe DE, a multidimensional digital asthma self-management system combining software and hardware components, provided an all-encompassing insight into the day-to-day disease experience for someone living with asthma. By combining these insights with the patient-reported experience, Breathe DE could provide key application opportunities in respiratory clinical practice. Future work with larger, more diverse study populations to explore how this tool could work in real-world clinical settings could promote guideline-concordant best practices that are accurately tailored to individual patient need.

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Funding

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Data Availability

The datasets generated and analyzed during this study are not publicly available due to confidentiality and ethical concerns. However, data availability requests can be made to the author of correspondence (CL).

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Authors' Contributions

CL, QP, JC, PM, CR, MF, and AH contributed to the conceptualization and codevelopment of Breathe Digital Ecosystem (Breathe DE). All authors contributed to the study design. CL, QP, CR, MF, DN, and AH contributed to the study conduct and coordination and data curation. Data analyses were conducted by AH, SS, CR, DN, QP, MY, and FAG. All authors were involved in the interpretation of the results, manuscript preparation, and manuscript revisions and editing.

Conflicts of Interest

PM was an employee of Novartis at the time of the study. FI is a former employee of Novartis and current shareholder. CL reports research grants, professional fees, or honoraria from AstraZeneca, Novartis, and GlaxoSmithKline. No other authors have conflicts to declare.

Multimedia Appendix 1

Baseline questionnaire.
[DOCX File , 36 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Qualitative data supplementary files: S1. Interview guide; S2 Analysis codebook.
[DOCX File , 44 KB-Multimedia Appendix 2]

Multimedia Appendix 3

SRQR checklist.
[DOCX File , 17 KB-Multimedia Appendix 3]

Multimedia Appendix 4

Breathe Digital Ecosystem features.
[DOCX File , 37 KB-Multimedia Appendix 4]

Multimedia Appendix 5

Patient journeys.
[DOCX File , 750 KB-Multimedia Appendix 5]

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Abbreviations

AC/DC: Asthma COPD Differentiation Classification
ACQ: Asthma Control Questionnaire
Breathe DE: Breathe Digital Ecosystem
COPD: chronic obstructive pulmonary disease
DHT: digital health technology
mAQLQ: mini Asthma Quality of Life Questionnaire
MCID: minimally clinical important difference
mHealth: mobile health
MIR: Medical Information Research
RA: research assistant
SABA: short-acting beta-agonist
UHN: University Health Network

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