

BREATHES:

Bringing Respiratory Education for Improved Adherence and Technique Home Through E-Interventions for Self-management

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BACKGROUND

Chronic obstructive pulmonary disease (COPD) results in nearly 750,000 hospitalizations annually and is the third leading cause of 30-day hospital readmissions in the United States.^{1,2} Improving the quality of care for hospitalized COPD patients has recently become a national priority through the Centers for Medicare and Medicaid Services' Hospital Readmissions Reduction Program.^{3,4} A key element of improving care quality is translating existing evidence into improved practice.^{5,6} Extensive evidence exists to support the efficacy of inhaled medications to control and reduce COPD symptoms and to improve patient outcomes.⁷⁻¹⁷ However, the real-world effectiveness of these medications is often limited due both to poor inhaler technique and to insufficient adherence to treatment plans.^{10,11,18-26} Most interventions for hospitalized patients with COPD focus on medication reconciliation, treatment optimization, and inhaler technique education prior to being discharged home.²⁷⁻²⁹ However, after discharge home, patients quickly lose inhaler technique skills, have difficulty adhering to complex regimens, and lack tools to aid adherence, such as lung function response to their treatment regimen.^{8,10,11,30,31} Interventions to reinforce skills and support adherence are needed across care transitions to reduce the risk of deleterious health outcomes.

Simple and feasible at-home interventions to provide skills training and adherence support are needed. Our novel idea is to pair at-home inhaler skill training with at-home spirometry measurements to comprehensively support both medication skill and adherence. I propose testing a novel at-home self-management support program called "BREATHES" (Bringing Respiratory Education for improved Adherence and Technique Home through E-interventions for Self-management) Program. BREATHES will include two main components: first, self-directed inhaler skill training sessions through the virtual Teach-To-Goal (V-TTG) intervention I developed and tested during my K23^{32,33} and, second, a handheld lung function device to provide physiologic feedback and capture medication adherence called SpiroPD.^{34,35} TTG is a patient-centered strategy that uses cycles of assessment and demonstration tailored to patients' self-management needs; my research shows *in-person* TTG is effective for teaching inhaler technique and reduces acute care utilization.^{10,11,18,31,36} *Virtual*-TTG delivers the key features of TTG using virtual patient-directed lessons through novel adaptive technology that provides tailored self-assessment and training.^{32,33} My studies demonstrate participants' willingness to use V-TTG at-home for post-discharge booster education and show that V-TTG is effective and may be non-inferior to in-person TTG in significantly reducing inhaler misuse among *hospitalized* patients.³²⁻³³ However, it remains unknown whether *at-home* V-TTG sessions will maintain self-management skills over the longer term and how direct physiologic lung monitoring support can impact medication adherence. The proposed studies will determine whether combining at-home skill training with objective measurements of lung function and adherence monitoring through the BREATHES Program improves self-management skills and medication adherence in the first 30 days after hospitalization for COPD.

PURPOSE & HYPOTHESIS

Our central hypothesis is that patients hospitalized for COPD who subsequently complete the at-home BREATHES Program with V-TTG skill training and SpiroPD adherence support will retain increased medication knowledge, skill, self-efficacy, and adherence that otherwise decays substantially by 30 days post-discharge. To test this hypothesis, I propose the following specific aims:

SA1. Determine the feasibility of, adherence to, and efficacy of at-home V-TTG for ongoing inhaler skill training. Hypothesis: Participants who complete both in-hospital and at-home V-TTG will have a significantly increased likelihood of demonstrating effective respiratory inhaler technique within 30 days after hospital discharge compared to in-hospital technique.

SA2. Determine the feasibility of, adherence to, and efficacy of at-home SpiroPD for COPD medication adherence support. Hypothesis: Participants' use of SpiroPD (PMD Healthcare) will significantly improve their COPD medication adherence.

METHODS OVERVIEW

We will voluntarily enroll 70 inpatients admitted to the University of Chicago Medicine over the course of 12 months into the at-home BREATHE Program. After obtaining informed consent, participants will complete in-hospital skills, lung function, and medication adherence assessments followed by the BREATHE at-home V-TTG inhaler learning program with self-monitoring and adherence support through the SpiroPD device. Participants will be trained on V-TTG and SpiroPD use in the hospital. The V-TTG intervention uses novel adaptive learning features that allow learners to participate in tailored educational sessions. They will begin every-other-day lung function assessments using the SpiroPD device in the hospital and continue on discharge. At 48-72 hours after discharge, participants will receive a unique username and password to complete the at-home V-TTG sessions on any of their own desktop or handheld devices; they will complete the V-TTG session at least one time in the first 30 days. Participants will receive reminders for completion of the V-TTG inhaler training and daily lung function monitoring via text messaging. Adherence to the at-home V-TTG session (captured through the Smart Sparrow platform), lung function monitoring (captured via the SpiroPD device), and objective inhaler medication adherence (captured via Propeller Health Bluetooth objective monitoring; only 30 of these 70 patients will have objective medication adherence captured) will be assessed throughout the 30-days after discharge via the HIPAA compliant interface. Participants will return at 30 days post-hospital discharge for an in-person evaluation of their inhaler skills, lung function, and acute care utilization.

RECRUITMENT

Admission logs (EPIC) at the University of Chicago will be examined each day to screen for potentially eligible inpatients. The treating physician will be contacted for verbal assent using standardized text. Among patients whose physician provides assent, medical records will be reviewed to ascertain eligibility and informed consent will be sought from eligible patients. Approximately 70 patients will be recruited at the University of Chicago Medicine over 12 months.

Study Schema

Table 1: Data Collection Tools		Hospital	Home	30-day
V-TTG adherence	Smart Sparrow platform data capture	-	X	-
Inhaler technique	Validated inhaler checklists	X	-	X
Inhaler knowledge, efficacy, skills	Inhaler step <i>knowledge</i> , applied inhaler use <i>skill</i> , and <i>attitudes</i> for inhaler self-efficacy assessed through short-answers.	X	X	X
Lung function	KoKo® portable spirometer: lung function (FEV1 %predicted).	X	-	X
	Handheld SpiroPD device (up to daily, at home)	X	X	X
Treatment Adherence	Self-reported: Medication adherence report scale (MARS); dose-counter on applicable devices; optional medication diary on the SpiroPD device	X	-	X
	Objective: Propeller Health® Bluetooth devices.	-	X	X
Self-efficacy	"I am confident that I know how to use [inhaler] correctly, (5-point scale).	X	X	X
Quality of life (QOL)	The Airway Questionnaire (AQ-20) 20-item tool assesses effect of current symptoms in everyday life for patients with COPD.	X	-	X
Symptoms	Modified Borg Dyspnea Scale; COPD Severity Score.	X	-	X
Health Literacy	Short Test of Functional Health Literacy in Adults: 36 item tool.	X	-	X

Data Collection Time Points

1. *In-Hospital Baseline Assessments.* Research Assistant (RA) will assess participants' baseline inhaler technique, inhaler self-efficacy, lung function, and self-reported adherence to their treatment regimen.
2. *In-Hospital Education:* Research Assistant (RA) provides in-person TTG inhaler training and training on how to use the V-TTG and lung function monitoring at home.
3. *In-Hospital Post-Education Assessments.* RA will obtain post-education assessments.¹⁰
4. *Post-Discharge At-Home BREATHES Program with V-TTG education and lung function monitoring.* The participant will complete up to daily lung function (goal of every other day) and medication adherence diaries using the SpiroPD device. The RA will give a unique username and password to each participant to access the V-TTG inhaler training after they have been discharged home. The V-TTG should be completed at least once within the first 30 days after discharge. The RA will send up to three reminders for completion of the lung function monitoring and V-TTG via text messaging. Participants will use their own device (tablet, laptop or desktop computer, or smartphone) for V-TTG use at home. For some patients, data will be collected each time they use their inhaled medication as prescribed. This data will be collected automatically when medication is utilized via a Propeller Health device attached to the inhaler. Patients should use their medication as they are instructed by their provider; no specified usage will be provided by the research team. Only data from regular use will be collected for this portion of the study.
5. *Post-Discharge Assessments.* Thirty days (+/-7 days) after discharge, participants will return for an in-person study visit to assess inhaler technique, adherence measures, lung function, and other assessments.

Device Data Collection

The SpiroPD device will record participant use and lung function scores. These measurements are stored in a HIPAA compliant server over wifi and are available to the participant and research team. Data from the V-TTG educational modules will be collected via the Smart Sparrow platform. For a subset of approximately 30 patients, a device by Propeller Health will measure objective medication use and adherence. This device will collect only use of an inhaler medication and does not require the participant to use their treatment any differently than prescribed by the clinician. This data will be stored in a HIPPA compliant server only available to the research team.

Survey Data Collection

Trained research staff will assess the following at the initial enrollment and the 30-day follow-up visit:

- Demographics
- Self-reported treatment adherence
 - o MARS
- Self-reported self-efficacy (5-point Likert scale)
- Quality of Life
 - o The Airway Questionnaire (AQ-20) 20-item tool assesses effect of current symptoms in everyday life for patients with COPD
- Symptoms
 - o Modified Borg Dyspnea Scale

- COPD Severity Tool
- Health Literacy
 - Short Test of Functional Health Literacy in Adults: 36 item tool.

Spirometry

Spirometry will be performed during the initial visit and during the follow up visit using the portable KoKo spirometer and the SpiroPD device.

DURATION

Participants will be enrolled in the at-home BREATHE Program for 30 days after discharge from the hospital. They will be in the study for 30 days (with a window of +/- 1 week for the 30 day visit) from the time of enrollment.

LOCATION

The study will take place at the University of Chicago Medicine as well as at patient homes.

TYPE AND NUMBER OF EXPERIMENTAL SUBJECTS

We will enroll 70 study participants from patients admitted to the University of Chicago Medicine. Only 30 of these 70 subjects will utilize the Propeller Health device to objectively measure medication adherence. This subset of 30 patients will be chosen based on the patients' prescription of a Propeller-compatible inhaler device (as not all inhalers will be compatible with this technology) as well as their willingness to verbally assent to this portion of the study.

Inclusion Criteria

1. Age 18 years and older
2. Physician-diagnosed COPD (prior to or during hospitalization)
3. Owns a wifi-enabled device (desktop, laptop, tablet, smartphone, etc.)
4. Discharged with a rescue and/or controller MDI
5. Visual acuity of at least 20/50 in at least one eye (with or without corrective lens provided by the research team for study purposes)

Exclusion Criteria

1. Currently in an intensive care unit
2. Physician declines to provide consent
3. Patient unable to provide consent (e.g., history of cognitive impairment, unable to understand English) or declines to provide consent

STATISTICAL ANALYSES

We will use means, medians, proportions, scatterplots, and histograms to describe the data. We will test for group differences using the *t*-test, the Wilcoxon rank sum test, Pearson's chi-squared test, or Fisher's exact tests, as appropriate. The primary outcomes for Aim 1 are at-home V-TTG adherence and inhaler technique and for Aim 2, at-home lung function testing adherence and medication adherence. McNemar's chi-squared tests will be used to compare 30 day post-discharge vs. pre-discharge adherence to the devices, prevalence of inhaler misuse ($\leq 10/12$ steps correct), and medication adherence. Secondary outcomes will include change in

self-efficacy for inhalers, symptom burden, self-reported utilization of health care services, and QOL. A two-tailed p-value less than 0.05 will define statistical significance.

POTENTIAL RISKS AND BENEFITS

The subject may be uncomfortable answering some interview questions. All subjects will be told that they can refuse to answer any question.

Loss of confidentiality. To help ensure that patients' health information remains private, we will restrict access to data collected for our study to study personnel only (via use of password-protection and locked cabinets for study documents). Study ID numbers will be generated and will be used when discussing and/or reviewing data at study meetings. Also, study reports will report results in aggregate and not contain information that can be used to identify individual patients.

Spirometry is safe and is commonly used to measure disease severity but can cause some minor chest soreness or lightheadedness.

DATA SAFETY MONITORING PLAN

A *Data and Safety Monitoring Board* will be formed to protect the safety of study subjects to ensure that they are not exposed to undue risk and to assure that the quality of the research data generated is acceptable and protected. The DSMB will operate without any conflicts of interest and/or undue influence from interested parties including the study investigators and funder.. The DSMB members' primary responsibilities will be to ensure sufficient progress and implementation of the project and to ensure safety of the participants. This work will include evaluations of patient accrual rates during the recruitment period, patient safety including adverse and/or unplanned events, and the integrity of the data collection and management during this study. All serious adverse events will be forwarded to the IRB and DSMB within 48 hours of being recognized by study staff. The DSMB will have authority to recommend modifications to the clinical investigations or to stop these investigations if there are concerns with patient safety or the integrity of the study.

Study investigators will communicate with the DSMB members about the study only as needed to make decisions related to meetings and meeting materials. Communication between DSMB members will be initiated by the DSMB chair. Communication with NHLBI will be led by the DSMB chair and/or PI depending on the circumstances of the required communication such as communication regarding the DSMB report. This DSMB will consist of 3 members, including two faculty at the University of Chicago and one from Northwestern, who will be involved with the safety and monitoring of this study: Kenzie Cameron, PhD, Peter O'Donnell MD, and Matthew Churpek MD, PhD. All board members will meet our institution's requirements for declaring conflicts of interest. The DSMB will convene initially to review, provide feedback on, and ultimately approve the data safety monitoring plan prior to beginning enrollment. The board will then meet half way through the enrollment period or when we reach 50% enrollment, whichever comes first. The NHLBI Program Office will be notified of scheduled meeting in advance should the program manager and/or delegate wish to monitor the meeting. A report of these minutes will be forwarded to the PI and to NIH NHLBI staff. A summary of DSMB deliberations and recommendations will be submitted to the IRB. Additional DSMB meetings may be scheduled as needed.

POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE PARTICIPANTS AND OTHERS

Although we do not believe that participants will directly benefit from this study, beyond potential improved adherence, self-monitoring, and inhaler technique skills, the risks are reasonable in

relation to the benefits because the proposed studies could help us learn about better ways to patients to self-assess their lung function and continue to learn self-management skills after they transition home post-discharge.

CONFIDENTIALITY

We understand the importance of protecting the confidentiality of information from our research participants. We will use unique alphanumeric identifiers for the data collection process. These unique codes will link all related participant information. All case report forms will be stored in locked file cabinets. All electronic data will be secured using password-protected files. Access to these data will be restricted to the research staff only. Analytic files will not contain any identifying information. All reports/manuscripts will be prepared in such a way that individual patients will not be identifiable. Additional specific details are described above.

COMPENSATION

Participants will receive compensation for their time (\$25 inpatient, \$50 30-day in-person visit).

Additionally, study participants will receive the SpiroPD for use during the study and will be able to keep this device for their personal use upon completion of the study; this device is valued at \$500.

INFORMED CONSENT

Medical records at the University of Chicago will be examined each day to screen for potentially eligible patients. The treating physician will be contacted for verbal or written assent using standardized text. To reduce the burden on busy clinicians of individual pages/phone calls for assent, we will also provide additional options for assent ahead of clinical rotations (see X). Among patients whose physician provides assent, medical records will be reviewed to ascertain eligibility and written informed consent will be sought from eligible patients.

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