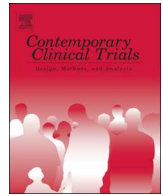




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Methodology and baseline characteristics of a randomized controlled trial testing a health care professional and peer-support program for patients with chronic obstructive pulmonary disease: The BREATHE2 study

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ABSTRACT

Background: Self-management support (SMS) for patients with COPD can improve health-related quality of life (HRQOL). However, it remains unclear what SMS strategies are most effective. Using peer support to advance self-management is promising, as peer supporters possess credibility and can serve as role models.

Methods: We conducted a single-blinded RCT comparing the effectiveness of two strategies to support patients with COPD. The strategies were ‘Health Care Professional (HCP)’ and ‘HCP Plus Peer’ support. Peer support was provided by patients with COPD who have stopped smoking, completed an acute pulmonary rehabilitation program, and met the requirements for becoming a peer supporter. We enrolled patients receiving treatment at inpatient and outpatient settings. Patients were encouraged to invite one family-caregiver to enroll with them. The primary outcome measure was the change in HRQOL at 6 months post enrollment. Secondary outcomes included COPD-related and all-cause hospitalizations and ED visits. Caregiver outcomes included preparedness for caregiving, caregiver stress, and coping.

Results: A total of 292 patients as well as 50 family-caregivers were enrolled. The average patient age was 67.3 yrs. (SD 9.4), 61% were female and 26% were African-Americans. The majority of caregivers were females (68%) and were a spouse/partner (58%).

Discussion: This study tested a dual strategy for providing support to patients with COPD that incorporates peer and health care professional support. The study had minimal exclusion criteria. If shown effective, the study offers a program of peer support that can be readily implemented in health care settings.

1. Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a chronic progressive condition that results in substantial mortality, morbidity, and

disability [1–3]. COPD is the fourth leading cause of death in the United States and a leading cause of hospitalizations [3]. Patients with COPD report unmet needs for information about their disease and guidance on how to manage and cope at “intellectual, emotional, and social levels”

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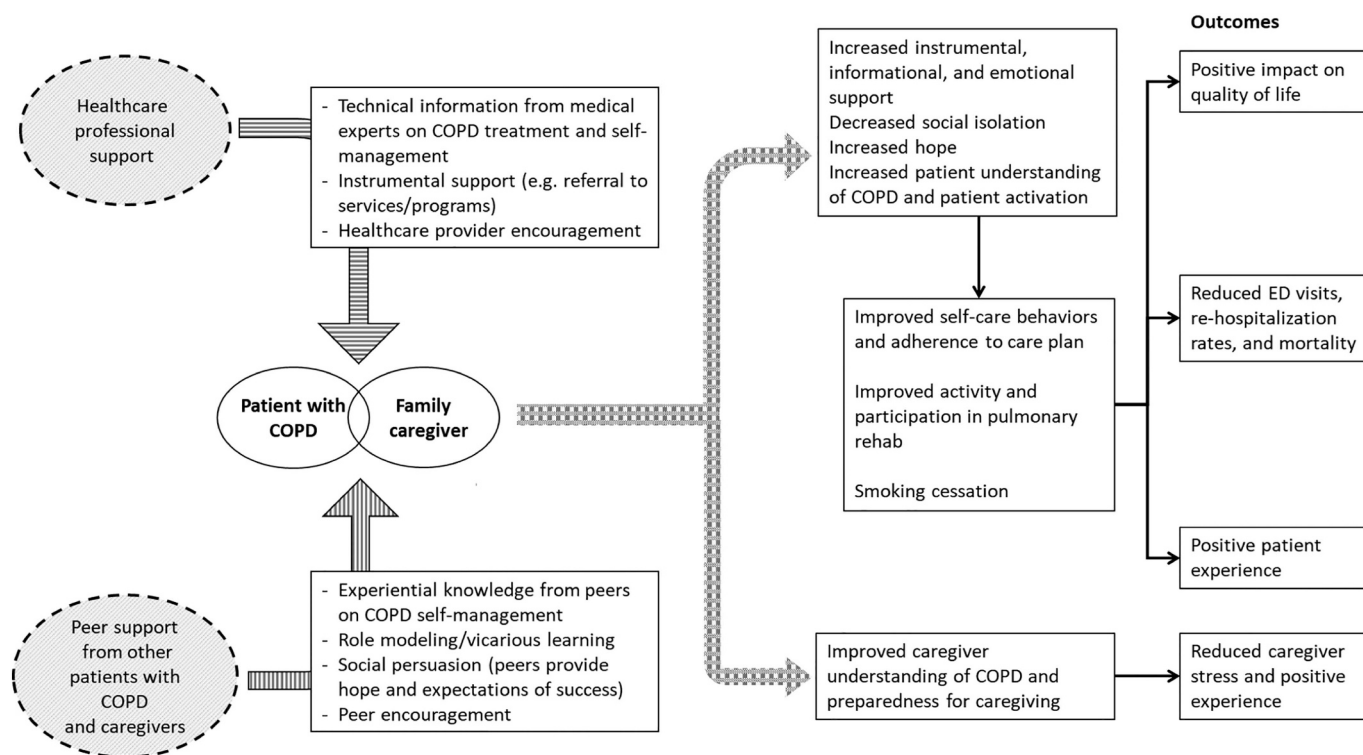


Fig. 1. BREATHE2 conceptual model.

[4–6]. Many patients with COPD lack the information and skills to correctly use inhaled medications [7,8], manage breathlessness episodes, and recognize early signs of COPD exacerbation [9,10].

One strategy for addressing these needs is self-management support (SMS) interventions. Among patients with COPD, SMS interventions have resulted in improved health-related quality of life (HQROL) while reducing hospitalizations, and emergency department (ED) utilization [11]. Yet it remains unclear how to most effectively provide SMS to patients with COPD and their caregivers in health care settings so that an improvement in patient outcomes may be realized [12,13].

Peer support (i.e. support provided by a peer with a similar medical condition) has been utilized to provide SMS. Studies using peer support for patients with obesity, mental health issues, addiction, diabetes, and cancer have shown increased self-efficacy and self-care behaviors as well as improved clinical outcomes and quality of life [14–26]. Examples of these programs include peer-led support groups, dyadic peer-to-peer mentorship, and online networks. Peer support has been provided using multiple channels including in-person and phone. Peer support benefits are attributed to the provision of emotional, informational, and appraisal support (i.e. peer affirmation of the “appropriateness of one’s emotions, cognitions, and behaviors”) [27].

Peer support benefits both people who provide it and those receiving it. Utilizing peer support to improve self-management is particularly promising because peer supporters (or peer mentors/ persons providing support) have credibility as people ‘who understand, been there, and done that’. Peer supporters can also model desirable health behaviors. These elements are key to achieving behavior change, according to the Social Learning Theory [28,29]. Peer support strengthens patients’ social support while reducing isolation. The latter is particularly relevant to patients with COPD whose medical illness often makes them reluctant to go out with family and friends because of functional limitations and the need for portable oxygen. Among persons with COPD, social support has been associated with reduced hospitalizations, fewer exacerbations and better health status [30–32].

Family members play important roles as caregivers for patients with COPD. Their support becomes increasingly important as patients

become more dependent [33,34]. As caregivers, family members may positively affect patients’ health care behaviors (e.g. encouraging adherence), [35] or have a negative impact (e.g. being overprotective, which can lead patients to be less active) [36]. Studies show that caregivers of patients with COPD experience distress that may negatively influence their own emotional wellbeing, professional life, and overall quality of life [34,36,37].

This manuscript describes the methodology and baseline participant characteristics of a randomized controlled trial comparing effectiveness of SMS interventions that incorporate health care professional and peer support on health-related quality of life and acute care use for patients with COPD and their caregivers.

2. Methods

2.1. Study overview and conceptual model

The Better Respiratory Education and Treatment Help Empower-2 (BREATHE2) Study was a single-blinded randomized controlled trial (RCT) comparing the effectiveness of two health communication and dissemination strategies that engaged patients and family-caregivers in the self-management of COPD in health care. One strategy relied on the healthcare professional (HCP) as the primary communicator about COPD self-management (HCP support); the other strategy used a dual approach involving HCP and peer supporters to deliver a tailored COPD self-management support intervention (HCP Plus Peer support). Both strategies aimed to: advance patient and caregiver understanding of COPD, treatment options, and self-care; and enable adoption of positive health behaviors, including adherence to treatment plans, smoking cessation, participation in pulmonary rehabilitation programs, and active lifestyles.

The study’s conceptual model presented in Fig. 1 displays mechanisms by which health care professionals and peers can support patients with COPD and their family-caregivers, and help them adopt recommended self-management strategies and behaviors to improve patient outcomes and empower caregivers in their role.

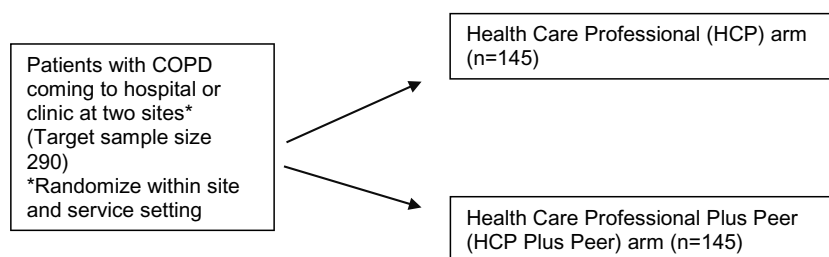


Fig. 2. Schematic of study design.

The traditional medical expert model involves healthcare professionals providing information about COPD, referring patients to treatment services and programs (e.g. pulmonary rehabilitation, smoking cessation programs, etc.), and providing encouragement and support to implement recommended self-care practices and desired behaviors. Though all of the above healthcare professional contributions are essential to caring for patients with COPD, they may be insufficient to induce and maintain positive behavior changes particularly among patients who are often overwhelmed with the diagnosis and do not have access to information. According to Social Cognitive Theory, self-efficacy mediates behavior change and achieving self-efficacy requires practice and mastery of necessary skills, modeling of desired behaviors, and social persuasion [28]. Patients who are successfully managing their COPD—e.g., patients who have stopped smoking and completed a pulmonary rehabilitation program—are well-positioned to help other patients with COPD and their caregivers via sharing information about their experiences in managing COPD and dealing with the challenges that it imposes on their daily life. More importantly, these peers are uniquely equipped to provide other patients with COPD what health care professionals cannot: role modeling of desired behaviors, and a hopeful and persuasive message that these behaviors are achievable.

The conceptual model depicts respective contributions that health care professionals and peer supporters can provide to patients with COPD and their family-caregivers. Combined approach using health care professional services and peer support allows patients to: (1) receive the technical information that they need along with referrals to services that will enable them to adopt recommended behaviors, and (2) obtain peer support that increases the likelihood that they will become more motivated, activated, and achieve the self-efficacy needed to successfully manage COPD.

2.2. Study hypotheses

We hypothesized that compared to the HCP support, patient participants who receive the dual strategy of HCP Plus Peer support will have better health-related quality of life at 6 months post enrollment into the study. Our secondary hypotheses stated that compared to the HCP support, patient participants who receive the dual strategy of HCP Plus Peer support will have better health-related quality of life at 3 and 9 months post enrollment; and reduced numbers of COPD-related hospital and ED visits at 3, 6, and 9 months. Additionally, we expected that the participants will have improved activation, self-efficacy, and self-care behaviors; a higher level of informational, instrumental, and emotional support; and, less social isolation compared to the group receiving HCP support alone. We also hypothesized that caregiver participants would report a higher level of understanding of COPD and preparedness for caregiving.

2.3. Study design

The study used a randomized controlled trial design with two arms in which patient participants were randomized to receive either HCP support alone (from a trained respiratory care professional), or HCP

Plus Peer support. Each patient participant was invited to have one adult family-caregiver enroll with them in the study; however, family-caregiver participation was not a requirement for study enrollment.

Patient and caregiver participants could not be blinded to their study group assignment due to the design of the intervention, however data collectors and outcome assessors were blinded to participants' arm allocation. Based on sample size calculation, our target sample size for patient participants was 290. No enrollment target was set for family-caregiver participants, as caregiver enrollment was at the invitation of patients. Caregivers were assigned to the study arm that their patient was randomized to. All study participants received a one hour session and future contact option with a respiratory care practitioner, and participants randomized to the HCP Plus Peer support arm were also invited to join the peer support program.

The study was approved by the Johns Hopkins Institutional Review Board and written consent was obtained from all the study participants. The study was registered at [ClinicalTrials.gov](https://www.clinicaltrials.gov/ct2/show/study/NCT02891200) (NCT NCT02891200). A schematic of the planned study design is shown in Fig. 2.

2.4. Study setting

The study was conducted at two sites within the Johns Hopkins Health System—Johns Hopkins Bayview Medical Center (JHBMC) and Howard County General Hospital (HCGH)—and their affiliated pulmonary and primary care clinics. JHBMC is an academic center in Baltimore, Maryland with 550 inpatient beds that serves an urban population with a large percentage of low-income patients. HCGH is a 300-bed community hospital in Columbia, Maryland that serves a more affluent suburban population. Both sites have pulmonary specialty clinics on campus and large pulmonary rehabilitation programs. The two sites also serve patients with pulmonary disease receiving care at primary care clinics that are part of the Johns Hopkins Community Physicians network.

2.5. Study population and eligibility criteria

The study population included patients 40 years of age or older who have been diagnosed with COPD by a physician and are currently receiving treatment at a hospital or clinic. Exclusion criteria were: non-English speaking; cognitive dysfunction impairing ability to provide informed consent and follow instructions; active substance abuse or unstable major psychiatric condition; terminal illness (i.e. less than 6 months life expectancy) that is non-COPD related; planning to move from area; living at a facility, such as hospice or nursing home; and inability to provide contact information.

2.6. Recruitment and randomization

A proactive approach was used to systematically inform all patients with COPD who were admitted to the two study site hospitals about this study. Materials about the study were distributed at the outpatient clinics and providers were encouraged to refer their eligible patients to this study. For hospitalized patients, we used patient census and

diagnosis lists to identify potential candidates. These patients were then approached by a study team member who shared information about the study and asked about their interest in participating. Those interested were enrolled prior to their hospital discharge whenever possible. The study start date for participants enrolled from the hospital was established as the date of their hospital discharge. Interested patients who could not be enrolled prior to discharge were subsequently contacted by phone to schedule an enrollment visit.

At the outpatient clinics, recruitment materials were available in waiting areas, and for health care providers to give to patients. Interested patients filled out an information card and a study team member contacted potential candidates by phone to determine eligibility and to schedule an enrollment visit. Study team members were available at select outpatient sites to approach patients referred to the study by their health care provider. Additionally, patients with COPD who visited the pulmonary clinic at one study site were mailed a letter informing them about the study. If a patient participant had an adult family member involved in their health care, they were encouraged to invite their family member to enroll with them into the study. Upon approval from the patient participant, the family-caregiver was approached for consent to participate in the study. Family-caregivers were consented at the hospital, at the enrollment visit with the patient, or at a separate enrollment visit, depending on their availability.

After patient consent was obtained, baseline data was collected, a cognitive assessment and spirometry testing were conducted, and patients were randomized in a 1:1 ratio to one of the study groups based on a pre-generated sequence of assignments. To avoid bias and predictability, randomization was stratified by 4 site-setting strata (JHBMC inpatient, JHBMC outpatient, HCGH inpatient, and HCGH outpatient), and a computer algorithm was then used to perform a blocked randomization assignment within strata with randomly selected block sizes of 2, 4, or 6. If a patient had a family-caregiver enrolled with them into the study, that family-caregiver was consented and assigned to the same study group as the patient participant.

2.7. Intervention description and procedures

2.7.1. Intervention components

Patient and family-caregiver participants in both study arms (the ‘HCP’ and ‘HCP Plus Peer’ arms) were provided with a written guide on COPD self-management and received HCP support. The guide was co-developed with patients and family-caregiver members as part of an earlier study and is described elsewhere [38]. Patient participants who were randomized to the ‘HCP Plus Peer’ arm were also invited to participate in a Peer Support Program with their enrolled family-caregiver. Below, the HCP support and peer support activities are described.

2.7.2. HCP support arm

All participants in the study received standardized HCP support that was provided by a trained respiratory care practitioner who was hired from within the healthcare system and was familiar with the available local resources. The respiratory care practitioner held a one-hour individual session with each patient participant and, when applicable, their family-caregiver. The session was held at the study site where the participant usually receives their care. In these sessions the HCP discussed COPD self-management and reviewed COPD medication use, inhaler technique, and discussed oxygen devices as applicable. The sessions took place in person within 2 months of patient enrollment into the study. If a patient missed their session, they were scheduled for another appointment. If they missed the second appointment, the HCP reached out to them and offered to hold their session via phone. At the end of the session, the HCP provided a telephone number and email address to the study participants and encouraged them to contact her with any questions or concerns during the study period.

2.7.3. HCP plus peer support arm

Participants randomized to this study arm received the same session and follow up support from the respiratory care practitioner as in the HCP arm. In addition, they were invited to join a peer support program for a six-month period. The peer support program offered patients and caregivers peer support services that are delivered via multiple modalities including one-on-one support and group conversations. In this study arm, participants were invited to meet other people who have COPD and their family-caregivers in a series of group meetings (called “Get-Togethers”) and they were matched with a peer support mentor (called a “BREATHE Pal”). The program was coordinated by a licensed clinical social worker who provided training, supervision, and support to the BREATHE Pals, and matched them with the study participants. The matching occurred based on preset criteria with the goal of matching participants, to the extent possible, with BREATHE Pals based on 1) study site; 2) patient and family-caregiver status (i.e. patient participant is matched with a peer mentor who has COPD, and family-caregiver participant is matched with a peer mentor who is a family-caregiver of someone who has COPD); 3) use of oxygen therapy; 4) gender. The BREATHE Pals communicated with the social worker about any surfaced study participants' needs, and the social worker provided counseling to these participants and connected them with resources in the community. The BREATHE Pals talked with the participants at Get-Together events, by phone, or both based on participant preference and attendance of events. The Get-Together events, which were held at each individual study site, were co-led by 2 BREATHE Pals and facilitated by the social worker. At the Get-Together events, select topics about COPD self-management were discussed, and the messages delivered by the respiratory care practitioner were reinforced (see Table 1 for discussion topics). The program coordinator carefully monitored each BREATHE Pal's level of comfort with program activities and their number of matched participants so s/he was not burdened by their role.

Table 1
Get-Together themes and discussion topics.

Theme	Topics description
Theme #1 Ways to Breathe Easier	Performing daily activities with less shortness of breath Pursed-lip breathing Experiences with COPD and providing/receiving help and support
Theme #2 Recognizing Signs of a Flare-up	COPD exacerbations and how to manage them Action plans and how to use
Theme #3 Coping with COPD	COPD impact on life Managing shortness of breath Managing anxiety and depression COPD treatments
Theme #4 Getting the Most of Your COPD Medications	Inhaler use Rescue inhalers vs. maintenance inhalers; Nebulizers Managing medication costs
Theme #5 Getting Acquainted with Oxygen Usage	Oxygen therapy: when needed and how to use safely Traveling with oxygen Getting comfortable using oxygen in public
Theme # 6 Becoming More Active	Importance of staying active Becoming more active Pulmonary rehabilitation and its benefits
Theme #7 Lifestyle Modification with COPD	Nutrition Planning a daily routine and pacing yourself Support for smoking cessation Staying proactive
Theme #8 Preventing Breathlessness	Irritants you should avoid Protecting yourself from infections

2.7.4. Peer supporters (BREATHE Pals) identification, role, training, and supervision

The BREATHE Pals were individuals with COPD who have successfully stopped smoking and completed an acute pulmonary rehabilitation program. Family-caregivers of individuals who met BREATHE Pal criteria were also eligible to become BREATHE Pals. Prospective BREATHE Pals were nominated by a pulmonologist or a pulmonary rehabilitation center team member, and then interviewed by the program coordinator (licensed clinical social worker). The prospective BREATHE Pals were asked to acquire formal volunteer status at the respective study site which included completing required training on privacy, infection prevention, and emergency preparedness. They then completed peer support program training on how to provide peer support to others with COPD. The training focused on general peer mentoring skills, and COPD-self management. It was offered in four 3-h sessions. Topics included engaged/active listening, empathy and maintaining non-judgmental attitude, effective communication skills, building trust and partnership, recognizing red flags and crisis situations, sharing personal stories and experiences, as well as discussion of common questions and challenges with COPD self-management. Teaching methods included group discussion, storytelling, and role-playing. Throughout the intervention period, the BREATHE Pals received ongoing support and guidance from the program coordinator/social worker in person and via phone. The social worker ensured that the BREATHE Pals followed program procedures which included not giving medical advice and remaining non-judgmental. She also helped facilitate difficult conversations in the group events. Whenever needed, the BREATHE Pals could communicate with the Peer Support coordinator about any surfaced study participants' needs and the social worker would talk to these participants and connect them with community resources.

BREATHE Pals received a nominal amount of compensation for their services.

2.7.5. Peer support delivery

BREATHE Pals called the study participants that they were matched with to introduce themselves, discuss their role, and commonalities in their experiences with COPD.

The BREATHE Pal ascertained whether the patient had any unique needs such as assistance with transportation to Get-Togethers, mobility limitations, or dietary requirements. If the patient used oxygen, they were advised to bring a full oxygen tank. Prior to Get-Togethers, the BREATHE Pal called to confirm the participant's attendance, and if a family-caregiver will be joining them.

Peer support group conversations occurred at 8 Get-Together events spanning a 6-month period. Each Get-Together has a specific theme. If a participant missed a Get-Together for any reason (e.g. personal preference or health status), they had the option to attend a similarly themed monthly group call to catch up on the missed event conversations. Additionally, their BREATHE Pal called them to check in, update them on conversations that took place at the Get Together that they missed, answer any questions, and encourage them to attend the next event. These ongoing communications helped the BREATHE Pals to develop individual relationships with each person with whom they were matched.

At the group events (Get-Togethers and group calls), the peers and BREATHE Pals discussed COPD and shared their experiences in coping with and managing it. Event themes and topics are listed in Table 1. The Get-Together events followed a sequence of themes from 1 to 8 and then repeated. A participant could join the event sequence at any time and continue for 8 Get-Togethers, thus getting to participate in all 8 themed events. If at any point the number of participants attending events at a site exceeded 20, a new group was initiated. Attendance of Get-togethers was strongly encouraged but not a requirement to participate in this study. The peer support delivery format was flexible (via group or one-on-one individual call with the BREATHEPal) to help meet

participants' varied needs and preferences.

Table 1 depicts Get-Together events' themes and topics.

Each Get-Together lasted 90 min. The social worker and BREATHE Pals had a set of suggested ice breaker activities and opening questions for use at these sessions. Examples included sharing a personal story related to the meeting topic or sharing coping strategies such as pursed lip breathing to start the discussion. Participants were also encouraged to discuss any COPD-related issues that were affecting them. Time was reserved for participants to socialize at the end of each meeting (approximately 30 min). This was an informal way for participants to network and bond together. Any individual participant concerns were discussed separately between the participant and their BREATHE Pal and/or the social worker at the end of the meetings, and lunch was provided at the meetings.

The Get-Togethers provided an open forum for patients and their family-caregivers to share their experiences with COPD, and how they managed its various impacts on their lives. The Get-Togethers had a set of engagement rules for participants (group agreements) that were revisited periodically and posted in the room. They included: "What is said in the group stays in the group; We listen to, support, and learn from each other; everybody's opinion is important; When someone is talking, we allow the person to complete what they are saying before we speak; There are no right or wrong questions; We reduce distractions (cell phones, computers, iPads, notebooks are not permitted – necessary calls may be made outside the room); We start and end on time".

2.8. Study measures and data collection

Table 2 depicts the BREATHE2 study measures and the data collection schedule. The primary study outcome measure was the change in HRQOL as measured by the St. George's Respiratory Questionnaire (SGRQ) Total score at 6 months compared to baseline. The SGRQ is a validated standardized, self-reported instrument to measure health-related quality of life among people with respiratory conditions. It consists of 76 items divided into three domains: Symptoms, Activity, and Impacts. A total score is calculated to determine the impact of disease on overall health status. The total score ranges from 0 to 100, with 100 indicating the worst possible quality of life [39].

Secondary patient outcomes included the change in SGRQ scores at 3 and 9 months and the combined number of all-cause and COPD-related hospitalizations and ED visits per patient at 6 months post-intervention start. We also measured patient activation using the Patient Activation Measure (PAM) [40]; patient-reported health status; PROMIS (Patient-Reported Outcomes Measurement Information System) measures for Informational support, Emotional support, Anxiety, Depression, and Social isolation [41–43]; and the Herth Hope Index [44]. Other process/impact measures included medication adherence, joining pulmonary rehabilitation, smoking cessation, and patient perceptions of caregiving.

Family-caregiver outcomes included preparedness for caregiving [45], caregiver stress and coping [57,58]; and the PROMIS measures for the domains of Informational and Emotional support.

We collected data on patient demographics, disease severity, comorbid conditions, health literacy, health care utilization, and anxiety and depressive symptoms. For family-caregiver participants, we collected data on age, gender, employment, relationship to patient, caregiving responsibilities, health status, and means of transportation.

All patient participants were interviewed in-person by a trained study team member upon enrollment, prior to randomization. Subsequently, they were interviewed via phone by a research team member who is blinded to their study arm assignment at 3, 6, and 9 months post enrollment. Up to 6 attempts were made to reach participants at each follow-up data collection period. Information was also collected on patient visits to the ED or hospital during the study period and the reasons for these visits. Family-caregiver participants were also interviewed upon enrollment and subsequently at 3, 6, and 9 months

Table 2
BREATHE2 Study Variables and Data Collection Schedule.

Variable	Baseline	3 months	6 months	9 months
Outcomes – Patient				
Health-related quality of life as measured by St. George's Respiratory Questionnaire: total, symptom, activity, and impact scores [39]	I		T	T
Patient Activation Measure [40]	I	T	T	T
Self-efficacy and self-care behaviors [46,47], patient report on physical activity	I	T	T	T
Smoking status and readiness to quit [48]	I	T	T	T
Medication Adherence [49]	I		T	
Patient perceptions of caregiving	I		T	T
Participation in pulmonary rehabilitation	I	T	T	T
Post-enrollment ED visits and readmissions (COPD-related and all-cause)		T,M	T,M	T,M
mMRC Dyspnea Scale [50–52]	I	T	T	T
PROMIS support measures [41–43], with 4 domains used: 1) Social isolation 2) Informational support 3) Emotional support 4) Instrumental support	I	T	T	T
Herth Hope Index with 3 subscales [44]	I	T	T	T
Mortality		T,M	T,M	T,M
Covariates – Patient				
Age, gender, marital status, race/ethnicity, living alone, education, income, occupation, insurance, health literacy [53]	I			
Lung function measures via spirometry (FEV1 and FEV1/FVC)	I			
Addiction to drugs or alcohol, mental health diagnosis	I			
Medical history (height, weight, previous PFTs, oral steroid use, class of inhaler treatment)	M			
No. of years since receiving COPD diagnosis, no. of hospitalizations in prior year, time since last hospitalization, depression treatment, cognitive status [54]	I			
Home oxygen use	I		T	T
Self-reported health status	I	T	T	T
Functional status	I		T	T
Anxiety and depression [55]	I		T	
Charlson Co-morbidity Index [56]	M		T	
Major life events during study period			T	
Patient participation in study intervention, other programs			D	
Outcomes – Family				
Family-caregiver preparedness for caregiving [45]	I	T	T	T
Caregiver stress and coping [57,58]	I	T	T	T
PROMIS support measures [41–43], with 2 domains used: 1) Informational support 2) Emotional support	I	T	T	T
Patient and caregiver satisfaction and experience			T	
Covariates – Family				
Age, gender, relation to patient, employment, health, and smoking status	I			

I = Interview administered in-person; T = Interview administered via telephone; M = Medical record review; D = Study documentation.

post-enrollment. Patient and family-caregiver participation in Get-Together events as well as the number of calls with the BREATHE Pals and the topics discussed were tracked.

2.9. Statistical plan

The main analysis approach for assessing the change in the primary outcome measure from baseline, as well as changes in secondary outcome measures from baseline, consist of analyses of the treatment effect between the two study groups under intention to treat, adjusted for baseline measure, site, and recruitment setting (inpatient versus outpatient).

For all hypotheses, the main independent variable is the treatment group assignment. The prespecified analytic plan includes evaluating the primary hypothesis with a mixed random effects (RE) model where the main test of the hypothesis is of the interaction term of arm and baseline to 6-month measurements on the SGRQ. The mixed RE model reflects the study's interest in comparisons of change at the individual level, where the changes may be subject-specific and reflective of potentially unmeasured variables. Estimates of the intervention effect over time are evaluated, both unadjusted and adjusted for patient characteristics such as age and gender.

Given the nature of the study interventions, it is not possible to guarantee full adherence from all participants. As a result, traditional intent to treat statistical methods might be affected by the effect of non-adherent participants (those who did not participate in intervention). To correct for this bias, we will also conduct a sensitivity analysis to explore the effect of adherence on the change in HRQOL. For this

analysis, we will stratify the patients randomized to the HCP Plus Peer support arm into adherent and non-adherent participants. We will define as adherent participants all those patient participants who have at least 4 or more encounters with their peers or BREATHE Pal either by attending a group event or having a phone conversation with their BREATHE Pal. Additional sensitivity analysis will be performed using different definitions of intervention adherence: 1) those participants with at least 2 encounters with their peers/ BREATHE Pals; and 2) those participants who experienced at least 4 or more encounters with their peers either by attending a group event or by having a phone conversation with their BREATHE Pal that included discussion of COPD-related issues.

2.10. Sample size

The sample size calculation was based on an overall comparison of the change between the baseline and 6-month measurements of patients on the St. George's Respiratory Questionnaire (primary outcome) in the two arms (interaction term). The unadjusted per-arm sample size was based on a power of 0.80, alpha of 0.05, a minimum clinically significant SGRQ score change of 4 points, and a meta-analysis estimate of variability. The estimated sample size was 145 patients per arm, after accounting for a 15% attrition rate, assuming a within-patient correlation between measurements of 0.8.

3. Results

Between April 2017 and December 2018, we screened 1464 patients

for eligibility. Among those, 1172 did not meet eligibility criteria, 434 declined to participate, 335 patients could not be reached for enrollment, and 292 were enrolled and randomized. The 335 candidates who could not be reached for enrollment were inpatient candidates who were screened while they were hospitalized, expressed interest in the study, and wanted to be contacted after they were discharged. Post their discharge, however, they could not be reached despite multiple attempts. See Appendix Fig. 1A for Patient flow chart and Table 1A for the demographic characteristics of eligible, enrolled, and declined patients. The main reasons for declining to participate included lack of time and interest, concomitant medical problems and family issues. Reasons for excluding participants included: no COPD diagnosis by a physician or not receiving daily treatment for COPD ($n = 79$), severe cognitive dysfunction ($n = 65$), unstable major psychiatric condition ($n = 26$), smoking history less than 10 pack-years ($n = 50$; this was an exclusion criteria at study start and was removed in July 2018 to expedite recruitment timeline), active substance use ($n = 45$), and not living at home/living in a facility ($n = 39$). Among patients randomized into the study, 145 were randomized to the HCP arm and 147 to the HCP Plus Peer arm. Fifty family-caregiver participants were enrolled and assigned to the same study arm that their patient was randomized to (21 in the HCP arm, 29 in the HCP Plus Peer arm). Table 3 summarizes the baseline characteristics of enrolled patient and caregiver participants.

Thirteen BREATHE Pals (10 patients and 3 caregivers) were recruited, trained, and participated in study interventions. The average age of the BREATHE Pals was 68 years, and 69% were female. There were 3 males among patient BREATHE Pals, and one male family-caregiver BREATHE Pal. Among the patient BREATHE Pals, 5 were current users of home oxygen therapy.

4. Discussion

This study was designed to compare the effectiveness of health care professional support to health care professional plus peer support among a heterogeneous sample of patients with COPD and their family-caregivers. The patient participants are representative of patients with COPD who are seeking health care services in a real-world clinical setting. The selected study sites allowed for recruitment of diverse study participants living in both urban and suburban locations. We had few exclusion criteria and recruited participants regardless of their comorbidities. Realizing that some patients who have COPD seek only emergency care services (due to being homebound, on continuous oxygen, or struggling with anxiety and depression) and are, therefore, unlikely to be recruited in clinic settings, we conducted recruitment activities in both inpatient and outpatient settings. We followed a systematic approach in informing all patients with COPD who were hospitalized, regardless of reason for their hospitalization about this study. Many, however, declined to participate due to other 'pressing' comorbidities at the time that interfered with their ability and interest in joining this study.

Self-management support interventions which involve "collaboratively helping patients acquire and practice the skills needed to carry out disease-specific medical regimens, change their health behavior to adjust their roles for optimal function, improve day-to-day control of their disease, and improve their well-being" [12], have been demonstrated in clinical trials to improve health-related quality of life among patients with COPD [11]. However, it is still unclear which self-management support strategies employed in a health care setting with a broadly diverse patient populations are most effective in engaging, motivating, and enabling patients to successfully follow recommended treatments, adopt desired health behaviors, and achieve the desired improvements in health outcomes [11].

In this study, select patients with COPD and their family-caregivers served as peer supporters, providing peer-to-peer support to help study participants self-manage COPD and minimize its impact on their quality

Table 3
Participant baseline characteristics.

Patient characteristics ^a	N = 292
Enrollment Site	
Enrolled from HCGH Inpatient, n(%)	67 (23.0)
Enrolled from HCGH Outpatient, n(%)	55 (18.8)
Enrolled from JHBMC Inpatient, n(%)	124 (43.5)
Enrolled from JHBMC Outpatient, n(%)	46 (15.8)
Age, mean (sd)	67.3 (9.4)
Race	
White, n(%)	207 (70.9)
African-American, n(%)	76 (26.0)
Other, n(%)	9 (3.1)
Gender	
Female, n(%)	179 (61.3)
Male, n(%)	113 (38.7)
Education	
8th grade or less, n(%)	16 (5.5)
Some high school, n(%)	41 (14.0)
High school grad or GED, n(%)	86 (29.5)
Some college and above, n(%)	149 (51.0)
Income (n = 286) ^b	
\$20,000 or less, n(%)	116 (40.6)
\$20,001 - \$40,000, n(%)	63 (22.0)
> \$40,001, n(%)	107 (37.4)
Continuous oxygen treatment, n(%)	77 (26.4)
Currently smoking, n(%)	72 (24.7)
Living alone, n(%)	85 (29.1)
Breathlessness grade 3 and 4 ^c , n(%)	174 (59.6)
PROMIS Measures ^d	
Social Isolation, mean (sd)	45.7 (10.3)
Emotional Support, mean (sd)	54.4 (9.6)
Informational Support ^e , mean (sd)	56.5 (10.9)
Instrumental Support, mean (sd)	54.7 (10.4)
Moderate to Severe Anxiety ^f , n(%)	90 (30.8)
Moderate to Severe Depression, n(%)	54 (18.5)
Herth Hope Index ^g , mean (sd)	38.3 (5.0)
Charlson Comorbidity Index, mean (sd)	1.0 (1.3)
Self-reported health status ^h , mean (sd)	
Physical, mean (sd)	3.7 (0.9)
Emotional, mean (sd)	2.8 (1.1)
Participated in pulmonary rehabilitation, n(%)	72 (24.7)
Extremely confident in filling out medical forms, n(%)	175 (59.9)
Family-Caregiver Characteristics	N = 50
Gender	
Female, n(%)	34 (68.0)
Male, n(%)	16 (32.0)
Relationship to participant	
Spouse/Partner, n(%)	29 (58.0)
Daughter/Son, n(%)	10 (20.0)
Daughter/Son-in-law, n(%)	3 (6.0)
Sister/Brother, n(%)	2 (4.0)
Friend or Neighbor, n(%)	1 (2.0)
Other, n(%)	5 (10.0)

^a Randomization was stratified by enrollment site/setting. Participants were enrolled from Howard County General Hospital inpatient, outpatient, Johns Hopkins Bayview Medical Center inpatient, and outpatient

^b Six patients declined to provide information on income.

^c mMRC Breathlessness grades: Grade 3 = I stop for breath after walking about 100 yards or after few minutes on level ground; Grade 4 = I am too breathless to leave the house or I am breathless when dressing.

^d Higher PROMIS® scores for emotional, informational, and instrumental and lower PROMIS® scores for anxiety, depression, and social isolation represent better outcomes.

^e Three patients failed to answer all of the instrument's questions needed to compute a score ($n = 289$).

^f Moderate to severe depression and anxiety based on PROMIS depression and anxiety domains with scores higher than 60.

^g Higher HERTH Hope Index scores represented more hope.

^h Self-reported health status: 1 = Excellent; 2 = Very good; 3 = Good; 4 = Fair; 5 = Poor.

of life. The patient peer supporters, who have successfully stopped smoking and completed an acute pulmonary rehabilitation program, served as realistic role models providing success stories, hope, and

evidence of a person's capacity to cope with COPD. Given their lived experience with COPD, the peer supporters also possess credibility and experience with practical ways to cope with COPD in daily life that health care professionals usually lack. The peer support program included flexible features, offering study participants various peer support modalities, according to their preferences, including connecting via telephone calls or attending Get-Together events.

Many patients with COPD are socially isolated. In this study 29% of patient participants lived alone. Anxiety, concern about breathlessness episodes, and running out of oxygen supply results in many patients being reluctant to leave their homes. The study's peer support program connected these patients with other peer supporters who face similar struggles, something that health care professionals cannot typically do. The BREATHE Pals encouraged the study participants to leave their homes and join the Get-Togethers. They also provided support for participants via phone, thus helping to reach participants who were unable or reluctant to leave their homes. In doing so, they sought to empower patients with COPD to become more active and informed participants in their treatment and advocate for themselves.

This study tested a dual strategy for providing support to patients with COPD and their caregivers that paired peer support with health care professional support to help improve HRQOL and reduce acute care use. If shown to be effective, this strategy could be readily used outside of research settings to help patients with COPD and their family-caregivers, and inform the health care systems that are evaluated for their health outcomes.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.cct.2020.106023>.

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