Comparing Self-Management Programs with and without Peer Support among Patients with Chronic Obstructive Pulmonary Disease
A Clinical Trial

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Abstract

Rationale: Self-management support (SMS) is an essential component of care for patients who have chronic obstructive pulmonary disease (COPD), but there is little evidence on how to provide SMS most effectively to these patients. Peer support (i.e., support provided by a person with a similar medical condition) has been successfully used to promote self-management among patients with various chronic conditions, yet no randomized studies have focused on testing its effects for patients with COPD.

Objectives: To assess whether adding peer support to healthcare professional (HCP) support to help patients with COPD self-management results in better health-related quality of life (HRQoL) and less acute care use.

Methods: A two-arm randomized controlled trial was performed at one academic and one community hospital and their affiliate clinics. The study population included patients aged ⩾40 years who had been diagnosed with COPD by a physician and were currently receiving daily treatment for it. Two self-management support strategies were compared over 6 months. One strategy relied on the HCP for COPD self-management (HCP support); the other used a dual approach involving both HCPs and peer supporters (HCP Plus Peer). The primary outcome was change in HRQoL measured by the St. George's Respiratory Questionnaire at 6 months (range, 0–100, lower is better; four-point meaningful difference). Secondary outcomes included COPD-related and all-cause hospitalizations and emergency department visits. Analysis was conducted under intention to treat.

Results: The number of enrolled participants was 292. Mean age was 67.7 (standard deviation, 9.4) years; 70.9% of participants were White, and 61.3% were female. St. George's Respiratory Questionnaire scores were not significantly different between the study arms at 6 months. HCP Plus Peer arm participants had fewer COPD-related acute care events at 3 months (incidence rate ratio, 0.68; 95% confidence interval [CI], 0.50–0.93) and 6 months (incidence rate ratio, 0.84; 95% CI, 0.71–0.99).

Conclusions: Adding peer support to HCP support to help patients self-manage COPD did not further improve HRQoL in this study. However, it did result in fewer COPD-related acute care events during the 6-month intervention period.

Clinical trial registered with www.clinicaltrials.gov (NCT 02891200).

Keywords: delivery of health care; health care utilization; health-related behavior

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Chronic obstructive pulmonary disease (COPD) is a major cause of mortality, morbidity, and disability (1–3). Patients with COPD report needing information and guidance on how to manage COPD (4–6). Many are unable to correctly use inhalers (7, 8), manage breathlessness episodes, and recognize exacerbation signs (9–12). Recommendations to improve care for patients with COPD have included focusing on self-management and providing patient-centered support programs (13, 14).

COPD self-management support (SMS) interventions have reduced acute care use and improved health-related quality of life (HRQoL) (15). These interventions aim to help patients adopt desired behaviors, including medication adherence, smoking cessation, and physical activity (16). To help patients adopt desired behaviors, coordinated follow-up from well-trained healthcare professionals (HCPs) is needed, together with services to help patients overcome any met barriers (14, 16). The Global Initiative for Chronic Obstructive Lung Disease recommends SMS (17). However, it remains unclear how to most effectively provide SMS in healthcare settings (16, 18).

Peer support (support provided by a peer with a similar medical condition) has been used 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 and improved clinical outcomes and quality of life (19–31). Using peer support to improve COPD self-management is particularly promising, because the peer supporters have credibility as people who have lived with COPD and who can model desirable health behaviors. These elements promote behavior change, according to social learning theory (32).

The BREATHE2 (Better Respiratory Education and Treatment Help Empower 2) study assessed whether adding peer support to HCP support to help patients with COPD self-management results in better HRQoL and less acute care use.

Methods

The BREATHE2 study was a two-arm single-blinded randomized controlled trial (RCT) comparing two strategies for engaging patients and family caregivers in COPD self-management. One strategy relied on HCPs as primary communicators on COPD self-management (HCP arm); the other strategy used a dual approach involving HCPs and peer supporters (HCP Plus Peer arm). Both strategies aimed to advance understanding of COPD and its treatment options, and adoption of positive health behaviors including medication adherence, smoking cessation, participation in pulmonary rehabilitation programs, and maintaining an active lifestyle. Our primary hypothesis was that HCP Plus Peer arm participants will have a greater improvement in HRQoL than HCP arm participants at 6 months after enrollment. Study methods are detailed elsewhere (33).

The study was approved by the Johns Hopkins Institutional Review Board, and written consent was obtained from all participants. The study was registered at www.clinicaltrials.gov (NCT 02891200). Trial protocol and statistical analysis plans are provided in the data supplement.

Study Design and Setting

Given the nature of study interventions, participants could not be blinded to their arm assignment; however, randomization was concealed from team members conducting data collection. The study was conducted from March 2017 to December 2018 at two sites within the Johns Hopkins Health System: Johns Hopkins Bayview Medical Center (JHBMC) and Howard County General Hospital (HCGH). Both sites have primary care and pulmonary specialty clinics and pulmonary rehabilitation programs.

The study population included patients 40 years or older diagnosed with COPD and receiving daily treatment for it. Exclusion criteria were non–English speaking, cognitive dysfunction impairing ability for informed consent and following instructions, active substance abuse or unstable major psychiatric condition (as determined by patient's healthcare team), terminal illness unrelated to COPD (<6-mo life expectancy), planning to move from the area, living at a facility (hospice or nursing home), or inability to provide contact information. Smoking history of >10 pack-years was initially an inclusion criterion and then removed to streamline recruitment and not deny the request of multiple patients who were nonsmokers and wanted to enroll. We subsequently had 15 participants who never smoked enrolled in this study. Patient participants had the option of having one family caregiver enroll with them.

The peer supporters were patients with COPD and their family caregivers who were nominated by pulmonary clinic and rehabilitation program staff at each study site, completed training on peer support provision, and met all healthcare volunteer requirements at the respective study site. Patient peer supporters had to have COPD, be current nonsmokers, and have finished an acute pulmonary rehabilitation program. Caregiver peer supporters were a family caregiver of a patient who met the patient peer supporter criteria and was not a current smoker. All peer supporters had ongoing support and

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This article has a data supplement, which is accessible from this issue's table of contents at www.atsjournals.org.

supervision from a licensed clinical social worker who served as the peer support program coordinator (33).

Study Arm Description

HCP arm participants received support from a trained respiratory care practitioner (RCP) (a respiratory therapist). The RCP held one individualized hour-long session with each participant on COPD self-management. In these sessions, the RCP discussed COPD self-management, reviewed COPD medication use and inhaler technique, and discussed oxygen devices, as applicable. The sessions took place in person within 2 months of patient enrollment in the study. If patients missed their session, they were scheduled for another. If they missed the second appointment, the RCP reached out to them and offered to hold their session by phone. At the end of the session, the RCP provided a telephone number and e-mail address to the participants, encouraging them to contact her with any questions or concerns during the 6-month study period. The participants also received a written COPD self-management guide (33).

HCP Plus Peer arm participants received the same interventions as HCP arm participants. In addition, they were invited to join for 6 months a peer support program designed for patients with COPD. The program offered peer support via one-on-one and group conversations, held by phone and in person. Participants were invited to meet other people who had COPD and their caregivers in a series of eight group meetings, called get-togethers. They were also matched with a peer supporter, called a BREATHE Pal. The BREATHE Pals met with participants at get-together events or spoke by phone, based on participant preference.

Data Collection

Data were collected using standardized instruments via in-person interview before randomization at baseline and then via phone at 3, 6, and 9 months after enrollment. No 9-month follow-up calls were conducted for participants who were enrolled after Sept 2017 because of the scheduled end of the study period in June 2018.

Information was collected on all participants' visits to the emergency department and all hospital admissions from 9 months before to 9 months after enrollment, together with the reasons for these visits. These data were obtained from the State of Maryland Health Services Cost Review Commission, with the assistance of the Chesapeake Regional Information System for Our Patients (34, 35), and included all acute care visits occurring within the state of Maryland. Data on deaths were verified via death certificate reviews (33).

Outcomes

The study's primary outcome was the change in HRQoL as measured by the St. George's Respiratory Questionnaire (SGRQ) total score at 6 months compared with baseline. The SGRQ is a valid instrument for measuring HRQoL in patients with respiratory disease (total score range, 0 [best] to 100 [worst]) (36). The total score's minimum clinically important difference (MCID) is four points (36).

Prespecified secondary outcomes included *1*) change in SGRQ total score at 9 months from baseline; *2*) COPD-related and all-cause acute care events (hospitalization or emergency department visit) per participant at 3, 6, and 9 months after enrollment. Determination of whether an acute care event was COPD related was conducted using a computer algorithm based on a set of predetermined International Classification of Diseases, 10th edition (ICD-10) discharge diagnoses that indicated COPD-related reasons (33).

Intervention activities, including the number of times participants had sessions with the RCP, attended get-togethers, or had phone calls with a BREATHE Pal, were tracked. Adverse events, including hospitalizations, deaths, and falls resulting in an acute care visit, were monitored.

Statistical Analyses

Sample size was calculated to detect the MCID of four points in SGRQ score between study arms (36), with 80% power and type I error of 0.05 (two-sided).

The estimated sample size was 145 per arm, after accounting for a 15% attrition rate. Main analyses and intervention adherence measures were prespecified (33). The approach for assessing the change in the primary outcome measure from baseline consisted of analyses of the treatment effect between the two study arms under intention to treat, adjusted for baseline measure, site, and recruitment setting (inpatient vs. outpatient). The primary hypothesis was evaluated with a mixed random effects model using all SGRQ scores (baseline, 6 mo, and 9 mo), in which the main test of the hypothesis was of the interaction term of study arm and the 6-month measurements of the SGRQ. Values of 100 (the worst possible SGRQ score) were imputed for patients whose data were missing because of death. No other imputations were made for missing values. For acute care use (COPD-related and all-cause acute care events per participant), we fit negative binomial models for the number of events at each time point. Patients who died were excluded from analyses after the time of death. All models were adjusted first for baseline measure, site, recruitment setting, and then for relevant patient demographic and clinical characteristics.

To assess adherence to study interventions, we measured whether participants had their one-time session with the RCP and for HCP Plus Peer arm participants the number of get-together events attended (maximum number per participant is eight) and the number of phone interactions with the BREATHE Pal (unlimited number allowed per participant). We predefined adherence in the HCP Plus Peer arm as having at least four peer interactions, either by attending a get-together or having a phone conversation.

We conducted exploratory subgroup analyses of the difference in treatment effect between the arms in subgroups of patients with characteristics that might affect the primary outcome, including enrollment site (HCGH vs. JHBMC), recruitment setting (inpatient vs. outpatient), sex, age, oxygen use, past hospitalizations, living alone, and having a diagnosis of congestive heart failure (CHF). These subgroup effects were estimated by including a three-way interaction between the subgroup variable, the study arm variable, and the 6-month time variable within the linear mixed random effects model. We tested for differences in treatment effect between subgroups by a hypothesis test of the three-way interaction in this model. We estimated the subgroup treatment effects using linear combinations of the pertinent coefficients from the model. Analysis was performed in Stata/SE15.1. Statistical significance was inferred for $P < 0.05$ (two-sided).

Results

Figure 1 depicts participant recruitment, enrollment, and follow-up. Of 1,464 screened for participation, 1,061 were eligible and 292 were enrolled. Participants'

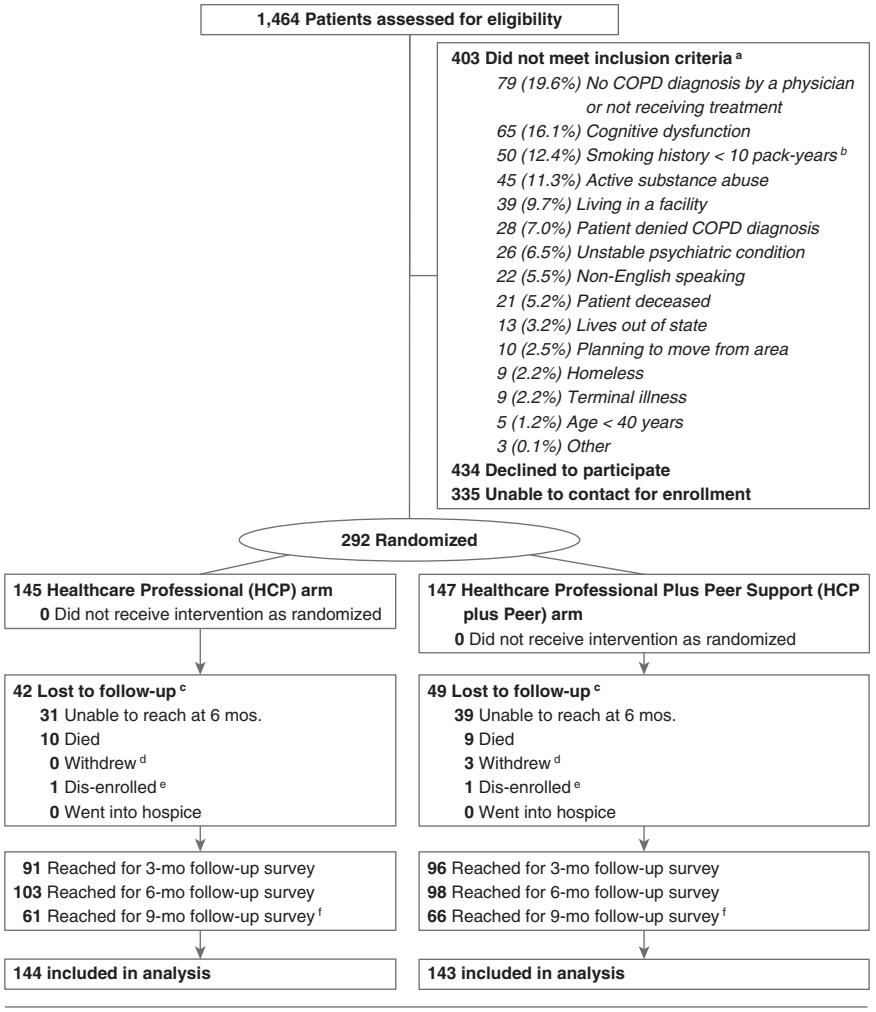

Figure 1. Recruitment, randomization, and retention of participants. [a]Participants may have had more than one reason for being ineligible. [b]As of July of 2018, this exclusion criterion was no longer applicable for prospective patient participants. [c]Study primary endpoint was at 6 months. All participants' vital statuses were tracked until 9 months after enrollment, however. Deaths at 9 months were 15 and 13 for healthcare professional (HCP) and HCP Plus Peer arms, respectively. [d]"Withdrew" indicates participant requested to be removed from the study. [e]"Dis-enrolled" indicates participant was removed from the study for administrative reasons (for example, participant died before receiving any interventions). [f]The number of participants who were candidates for the 9-month survey was 229 (not all were candidates, as the study ended before they reached the 9-month postenrollment time point). COPD = chronic obstructive pulmonary disease.

baseline characteristics were similar across the study arms except for the percentage of current smokers (27.9% in the HCP Plus Peer arm compared with 21.4% in the HCP arm) and the percentage of patients with CHF (42.9% in the HCP Plus Peer arm compared with 26.9% in the HCP arm) (Table 1). No data were missing for baseline covariates. The mean (standard deviation [SD]) participant age was 67.7 (9.4) years, and the majority were White (70.9%) and female (61.3%). Thirty-one participants (21.4%) in the HCP arm and 39 participants (26.5%) in the HCP Plus Peer arm could not be reached for the 6-month follow-up interview. The baseline characteristics of participants surveyed at 6 months compared with those who had missing data (not reached) showed significant differences in continuous oxygen treatment (21.8% among those observed, 40.3% among those missing) and current smoking status (20.9% among those observed, 36.1% among those missing). We found similar differences for these two variables within each study arm. No other significant differences were found (*see* Table E1 in the data supplement). Acute care events data were collected on all study participants. There were 10 deaths (6.9%) in the HCP arm and 9 deaths (6.1%) in the HCP Plus Peer arm.

Primary Outcome

Effect on HRQOL at 6 months. Mean (SD) baseline SGRQ total score was 55.85 (17.66) in the HCP Plus Peer arm compared with 55.17 (20.45) in the HCP arm. The mean change in SGRQ score at 6 months from baseline was −0.52 points in the HCP Plus Peer arm and −1.78 in the HCP arm (unadjusted difference of 1.26 points; 95% confidence interval [CI], −5.44 to 7.96; $P = 0.591$). A negative change in SGRQ scores indicates improved HRQoL. After adjustment for baseline scores, site, and setting, there was no significant difference between the treatment arms (adjusted difference of 1.46 points; 95% CI, −2.47 to 5.38; $P = 0.467$). No significant difference was found after additional adjustment for baseline patient characteristics. (Table 2)

Secondary Outcomes

Effect on HRQOL at 9 months. There was no significant difference between the treatment arms in the change in SGRQ scores from baseline to 9 months (Table E2).

Effect on COPD-related and All-Cause Acute Care Events

Data on acute care events were available for all enrolled participants. The mean number of COPD-related events per participant at 3 months was 0.27 (SD, 0.56) in the HCP Plus Peer arm compared with 0.41 (SD, 0.83) in the HCP arm. At 6 months it was 0.62 (SD, 1.06) in the HCP Plus Peer arm compared with 0.79 (SD, 1.64) in the HCP arm. Table 3 depicts COPD-related and all-cause event rates and incidence rate ratios (IRRs) comparing the study arms at 3, 6, and 9 months after enrollment. In fully adjusted models, participants randomized to the HCP Plus Peer arm had a lower number of COPD-related acute care events than the

Table 1. Participant baseline characteristics

Baseline Characteristics	Total (*N* = 292)	Study Arm	
		HCP Plus Peer (*n* = 147)	HCP (*n* = 145)
No. of patient participants*			
Enrolled from HCGH inpatient	67 (22.9)	33 (224)	34 (23.4)
Enrolled from HCGH outpatient	55 (18.8)	29 (197)	26 (17.9)
Enrolled from JHBMC inpatient	122 (41.8)	62 (422)	60 (41.4)
Enrolled from JHBMC outpatient	48 (16.4)	23 (156)	25 (17.2)
Age, yr, mean (SD)	67.7 (9.4)	679 (93)	67.4 (9.5)
Race			
White	207 (70.9)	106 (721)	101 (69.7)
African American	76 (26.0)	34 (231)	42 (29.0)
Other	9 (3.1)	7 (48)	2 (1.4)
Sex			
Female	179 (61.3)	85 (578)	94 (64.8)
Male	113 (38.7)	62 (422)	51 (35.2)
Education			
Eighth grade or less	16 (5.5)	8 (54)	8 (5.5)
Some high school	41 (14.0)	23 (156)	18 (12.4)
High school graduate or GED	86 (29.5)	52 (354)	34 (23.4)
Some college and above	149 (51.0)	64 (435)	85 (58.6)
Income (*n* = 286)†			
⩽$20,000	116 (39.7)	56 (381)	60 (41.4)
$20,001–$40,000	63 (21.6)	36 (245)	27 (18.6)
>$40,001	107 (36.6)	52 (354)	55 (37.9)
Continuous oxygen treatment	77 (26.4)	37 (252)	40 (27.6)
Currently smoking	72 (24.7)	41 (279)	31 (21.4)
Living alone	85 (29.1)	45 (306)	40 (27.6)
St. George's Respiratory Questionnaire, mean (SD)			
Total score	55.6 (19.0)	563 (180)	55.0 (20.0)
Symptoms score	59.5 (20.4)	587 (202)	60.4 (20.6)
Activity score	72.6 (22.5)	741 (209)	71.0 (23.9)
Impacts score	44.8 (21.6)	453 (206)	44.3 (22.6)
Breathlessness grade 3 and 4‡	173 (59.2)	87 (592)	86 (59.3)
Charlson Comorbidity Index, mean (SD)	2.6 (1.8)	27 (18)	2.6 (1.9)
Congestive heart failure	102 (34.9)	63 (429)	39 (26.9)
Self-reported health status§, mean (SD)			
Physical	3.7 (0.9)	37 (09)	3.7 (1.0)
Emotional	2.8 (1.1)	29 (12)	2.8 (1.0)
Has participated in pulmonary rehabilitation	72 (24.7)	38 (259)	34 (23.4)
Extremely confident filling out medical forms‖	175 (59.9)	88 (599)	87 (60.0)

Definition of abbreviations: GED = Graduate Equivalency Degree; HCGH = Howard County General Hospital; HCP = healthcare professional; JHBMC = Johns Hopkins Bayview Medical Center; mMRC = Modified Medical Research Council; SD = standard deviation.
Data are presented as *n* (%) unless otherwise noted.
*Randomization is stratified by enrollment site and setting. Participants are enrolled from HCGH inpatient, HCGH outpatient, JHBMC inpatient, and JHBMC outpatient.
†Six patients declined to provide information on income.
‡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."
§Self-reported health status: 1 = excellent; 2 = very good; 3 = good; 4 = fair; 5 = poor.
‖Reflects adequate health literacy.

HCP arm, with an estimated IRR at 3 months of 0.68 (95% CI, 0.50–0.93; $P = 0.016$) and at 6 months of 0.84 (95% CI, 0.71–0.99; $P = 0.04$). There was no significant difference in the rate of COPD-related events between the study arms at 9 months. In addition, there were no significant differences in all-cause events at the 3-, 6-, or 9-month time points.

Post Hoc Analyses

We conducted supplementary analysis for events at 1 month after enrollment. There was a significant and larger difference in the rates of COPD-related events (IRR, 0.46; 95% CI, 0.30–0.70; $P < 0.001$) and all-cause events (IRR, 0.65; 95% CI, 0.51–0.83; $P = 0.001$) between the study arms at the 1-month time point (Table 3).

An exploratory subgroup analysis revealed a significant study arm and site interaction in the total SGRQ score at 6 months, with an estimated adjusted difference between treatment arms of −1.94 (95% CI, −2.18 to −1.70) at HCGH and 4.61 (95% CI, 2.82 to 6.41) at JHBMC (Table E3). No other significant interactions were found.

Table 2. Mean change in health-related quality of life as measured by total score on St. George's Respiratory Questionnaire from baseline to 6 months after enrollment

	HCP Plus Peer Arm	HCP Arm	*P* Value
Total SGRQ score at baseline, mean (SD)	55.85 (17.66)	55.17 (20.45)	—
Total SGRQ score at 6 mo after enrollment, mean (SD)	55.33 (23.82)	53.39 (25.86)	—
Difference from baseline, mean (SD), HCP Plus Peer $n = 107$; HCP $n = 113$	−0.52 (18.32)	−1.78 (19.66)	—
Unadjusted raw difference between arms (95% CI)	1.26 (−5.44 to 7.96)		0.591
Difference between arms (95% CI), adjusted for baseline score and site/setting.* Mixed random effects model sample size: total no. of participants analyzed = 292;† n for participant timepoint observations = 667	1.46 (−2.47 to 5.38)		0.467
Adjusted difference between arms (95% CI), full model.‡ Mixed random effects model sample size: total no. of participants analyzed = 285;§ n for participant timepoint observations = 654	1.82 (−1.76 to 5.40)		0.319

Definition of abbreviations: CI = confidence interval; HCP = healthcare professional; SD = standard deviation; SGRQ = St. George's Respiratory Questionnaire.
Randomization is stratified by enrollment site and setting. Standard errors for all analyses clustered at the site/setting level. Normality of residuals is good. SGRQ score scale from 0 to 100, with higher scores indicating a worse quality of life.
*Mixed effects linear model adjusted for baseline SGRQ domain scores, and site and setting fixed effects.
†HCP Plus Peer support, $n = 147$; HCP $n = 145$.
‡Mixed effects linear model adjusted for age, sex, continuous oxygen use, ever hospitalized in the previous year, Charlson Comorbidity Index, congestive heart failure diagnosis, annual income, education, smoking status, self-reported general and emotional health, postenrollment disposition, baseline SGRQ domain scores, and site and setting fixed effects.
§HCP Plus Peer support, $n = 143$; HCP, $n = 142$.

Intervention Delivery and Outcomes by Adherence Group

Table E4 describes intervention delivery by study arm, site, and setting. More than 99% of participants had an initial RCP session. In the HCP Plus Peer arm, the average number of peer support interactions (attending a get-together or having a phone conversation with a BREATHE Pal) was 4.4 per participant. Using the prespecified adherence definition, 67 (48.9%) participants in the HCP Plus Peer arm adhered to treatment,

Table 3. Incidence of COPD-related and all-cause acute care events (hospitalizations and emergency department visits) across the study arms at 1, 3, 6, and 9 months

Measure	Cumulative Incidence Rate (95% CI)		IRR (95% CI) Adjusted for Site and Setting*	*P* Value	IRR (95% CI) Full Set of Adjustors†	*P* Value
	HCP Plus Peer	HCP				
COPD-related events						
At 1 mo‡	0.08 (0.03–0.13)	0.22 (0.08–0.35)	0.39 (0.30–0.51)	<0.001	0.46 (0.30–0.70)	<0.001
At 3 mo§	0.27 (0.15–0.38)	0.41 (0.16–0.67)	0.67 (0.42–1.08)	0.098	0.68 (0.50–0.93)	0.016
At 6 mo‖	0.62 (0.34–0.90)	0.79 (0.30–1.29)	0.82 (0.58–1.16)	0.261	0.83 (0.70–0.98)	0.028
At 9 mo¶	1.02 (0.45–1.60)	1.06 (0.22–1.90)	1.03 (0.71–1.49)	0.869	1.08 (0.84–1.39)	0.532
All-cause events						
At 1 mo‡	0.17 (0.07–0.28)	0.30 (0.12–0.48)	0.58 (0.52–0.65)	<0.001	0.65 (0.51–0.83)	0.001
At 3 mo§	0.53 (0.30–0.76)	0.70 (0.30–1.10)	0.78 (0.52–1.18)	0.236	0.86 (0.65–1.14)	0.294
At 6 mo‖	1.07 (0.58–1.55)	1.32 (0.52–2.12)	0.86 (0.64–1.15)	0.306	0.96 (0.84–1.09)	0.488
At 9 mo¶	1.65 (0.82–2.48)	1.78 (0.47–3.09)	1.00 (0.71–1.43)	0.978	1.12 (0.98–1.28)	0.090

Definition of abbreviations: CI = confidence interval; COPD = chronic obstructive pulmonary disease; HCP = healthcare professional; IRR = incidence rate ratio.
Randomization is stratified by enrollment site and setting. Standard errors for all analyses clustered at the site/setting level. Normality of residuals is good. Cumulative incidence rates and IRRs were estimated using a negative binomial regression. The incidence rates are the mean number of events during the time period (from enrollment to 1 mo, 3 mo, etc.). The IRRs are the ratios of the incidence rate between the HCP Plus Peer group and the HCP group. Patients who have passed away or withdrawn from the study are excluded from analysis starting from the time at which they died or decided to withdraw from the study.
*Model 1: Negative binomial model adjusted for site and setting fixed effects.
†Model 2: Negative binomial model adjusted for age, sex, continuous oxygen use, ever hospitalized in the previous year, Charlson Comorbidity Index, diagnosis of congestive heart failure, annual income, education, smoking status, and site and setting fixed effects. Six patients declined to provide information on income and were excluded from the analysis.
‡Study sample at 1 month for model 1 = 290 (HCP = 144; HCP Plus Peer = 146) and model 2 = 284 (HCP = 141; HCP Plus Peer = 143).
§Study sample at 3 months for model 1 = 282 (HCP = 140; HCP Plus Peer = 142) and model 2 = 276 (HCP = 137; HCP Plus Peer = 139).
‖Study sample at 6 months for model 1 = 272 (HCP = 135; HCP Plus Peer = 137) and model 2 = 266 (HCP = 132; HCP Plus Peer = 134).
¶Study sample at 9 months for model 1 = 259 (HCP = 120; HCP Plus Peer = 130) and model 2 = 253 (HCP = 126; HCP Plus Peer = 127).

Table 4. Participant outcomes at 6 months in the healthcare professional and healthcare professional plus peer arms by adherence to intervention

	HCP	HCP Plus Peer	
		Adequate Adherence to Intervention	Low Adherence to Intervention
Health-related quality of life			
No. of participants*	113	58	49
SGRQ total score baseline, mean (SD)	55.17 (20.45)	55.37 (17.56)	56.42 (17.94)
SGRQ total score at 6 mo, mean (SD)	53.39 (25.86)	52.04 (19.44)	59.23 (27.86)
Mean change in score (95% CI) at 6 mo	−1.78 (−5.41 to1.84)	−3.33 (−6.5 to −0.17)	2.80 (−3.71 to 9.3)
Acute care events			
No. of participants	145	79	68
Mean number (95% CI) of all-cause acute care events per participant in the 6 mo after enrollment	1.37 (0.85 to 1.88)	0.96 (0.65 to 1.26)	1.32 (0.9 to 1.73)
Mean number (95% CI) of COPD-related acute care events per participant in the 6 mo after enrollment	0.83 (0.56 to 1.09)	0.57 (0.36 to 0.77)	0.72 (0.44 to 0.99)

Definition of abbreviations: CI = confidence interval; COPD = chronic obstructive pulmonary disease; HCP = healthcare professional; SD = standard deviation; SGRQ = St. George's Respiratory Questionnaire.
Intervention adherence is defined as having had at least four interactions with the peer program by either attending a get-together or having a phone interaction with a BREATHE Pal.
*Analyses based on living participants reached for the 6-month survey for measurement of SGRQ.

with the lowest adherence among those enrolled in the JHBMC inpatient setting, particularly for attending group events. Of note is that JHBMC inpatients were sicker and had lower education and income levels (Table E5). Reported reasons for not attending events included being too sick to attend, lack of transportation, and having other more important medical problems at the time. Comparison of the baseline characteristics among HCP Plus Peer arm participants by adherence group (Table E6) showed more participants with low income and education levels and higher comorbidities in the low-adherence group. Table 4 shows study outcomes by adherence group. Within the HCP Plus Peer arm, participants in the adequate adherence group had an improvement in HRQoL, whereas those with low adherence had reduced HRQoL (mean differences in SGRQ scores at 6 months of −3.33 and 2.80, respectively). Participants in the adequate adherence group also had a better HRQoL than those in the HCP arm. Acute care events were also lower among participants who adhered to the HCP Plus Peer intervention than those who had low adherence and those in the HCP arm. This pattern held for all-cause and COPD-related events.

Adverse Events

No adverse events were attributed to the study interventions.

Discussion

In this study, we evaluated whether providing peer support together with HCP support to help patients with COPD self-management resulted in added benefits compared with relying only on HCP support. Most study participants were recruited during a hospitalization. Although we found no significant differences in HRQoL between the participants who were randomized to the HCP support arm and those randomized to receive dual support (HCP Plus Peer), the participants in the dual-support arm had substantially fewer COPD-related acute care events during the 6-month intervention period. The study findings are consistent with prior studies on COPD SMS interventions showing reductions in COPD-related acute care use and marginal effects on HRQoL (37–40). In a pooled analysis of 10 COPD SMS RCTs with 1,413 patients, Zwerink and colleagues reported a mean difference in SGRQ total score of −3.51 (−5.37 to −1.65) in intervention compared with control groups, which is less than the MCID of four points (15). Similar findings of limited effects on HRQoL were reported in a recent systematic review on integrated disease management for COPD (41). Unlike HRQoL, COPD-related acute care use is an outcome that may be directly affected by the actions that a patient takes at the time when they feel short of breath and is likely sensitive to changes in patients' behaviors at those specific times. Patients' behaviors in these situations range from attempting to self-manage at home, calling the outpatient provider, going to an acute care facility, or calling 911. During the peer get-togethers and phone calls, the topics of coping with COPD and how to manage the times when they feel short of breath with breathing techniques and rescue inhaler use were discussed, together with an action plan for what to do when experiencing symptoms of a COPD flare-up. Changes in patient actions at those times could directly lead to reducing COPD-related acute care use.

The reductions in acute care events occurred during the intervention period and were not seen at 9 months, suggesting that a longer intervention duration may be needed. This is consistent with other behavioral intervention studies for COPD, CHF, and other conditions reporting more improvements with longer intervention durations (39, 42, 43).

SMS interventions for patients with COPD have largely relied on HCPs for intervention delivery (15, 38–41). Few studies have demonstrated feasibility of peer-delivered COPD self-management interventions and shown evidence of acceptability to patients and increased self-efficacy (44, 45). Peer support has been shown to improve outcomes among patients with diabetes, mental health, and addiction problems (46–50), and payment

mechanisms now exist to pay for peer support services (51, 52). To our knowledge, this is the first RCT that compares the effect of self-management programs with and without peer support among patients with COPD. In this study, "expert patients" served as peer supporters, providing support over a 6-month period to help participants self-manage COPD and minimize its impact on their life. The HCP provided a 1-hour session on COPD self-management to participants in both study groups. This abbreviated version of HCP support, compared with other HCP-delivered SMS interventions, may be why there was no change in HRQoL in either group. In this study, we used systematic proactive approaches for recruitment and enrolled participants during their inpatient stays. The participants represent a broad population of patients at various stages of readiness for receiving peer support and engaging in COPD self-management. This has likely affected adherence to planned interventions and limited our ability to show intervention effectiveness based on intent-to-treat analysis. In an exploratory analysis comparing outcomes based on intervention adherence, the participants who had adequate adherence to the HCP Plus Peer interventions had improved quality of life and lower COPD-related and all-cause acute care use than those with low adherence and those who were randomized to the HCP arm. Although this finding is subject to selection bias, because participants self-selected whether to adhere to the intervention, it does point to the benefits of peer support, particularly for a subset of participants who are interested and ready to receive it. Further research is needed to test peer support interventions that are tailored to patient readiness and degree of motivation.

This trial was done in real-life settings, and although participants were encouraged to participate in all interventions, they were not required to do so. Intervention adherence was particularly low among participants enrolled at the JHBMC inpatient setting, despite intensive outreach efforts. The JHBMC inpatient participants (about 40% of study participants) had lower income and less education, more severe COPD, more comorbidities, and worse self-reported physical and emotional health status. These participants likely met more barriers to participation. Although the peer program helped address modifiable barriers, such as transportation challenges, other barriers, such as being too sick at the time of a get-together or having more important life problems than COPD during the study period, remained. Further research is needed to test additional support interventions for patients facing socioeconomic and health challenges.

Finally, the coronavirus disease (COVID-19) pandemic has resulted in increased use and familiarity with online platforms. This paves the way for testing technology-assisted peer support interventions, which can offer unique advantages regarding scalability and reach to patients who are more severely ill, have transportation challenges, or live in rural areas.

Limitations

This study has several limitations. The study was conducted within one health system, and the majority of participants were recruited during a hospitalization; thus, its findings may not be generalizable to all patients with COPD. The participants were enrolled based on physician diagnosis of COPD, making it possible that some participants may not have had COPD. The assessment of treatment effects was limited by reduced adherence to peer support activities. Finally, for those participants whom we were not able to reach at 6 months after enrollment, we could not measure their quality of life but could still measure all their acute care events.

Conclusions

In this RCT, we compared effectiveness of providing peer support together with HCP support to that of HCP support alone for helping patients self-manage COPD. Providing peer support did not result in further improvement in HRQoL; however, it did result in considerably fewer COPD-related acute care events during the 6-month intervention period. ■

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References

1 Adeloye D, Chua S, Lee C, Basquill C, Papana A, Theodoratou E, *et al.*; Global Health Epidemiology Reference Group (GHERG). Global and regional estimates of COPD prevalence: Systematic review and meta-analysis. *J Glob Health* 2015;5:020415.

2 Wheaton AG, Cunningham TJ, Ford ES, Croft JB; Centers for Disease Control and Prevention. Employment and activity limitations among adults with chronic obstructive pulmonary disease—United States, 2013. *JMMWR Morb Mortality Wkly Rep* 2015;64:289–295.

3 Biener AI, Decker SL, Rohde F. Prevalence and treatment of chronic obstructive pulmonary disease (COPD) in the United States. *JAMA* 2019;322:602.

4 Jones R. Too little, too late–the patients' perspective on education for COPD. *Chron Respir Dis* 2007;4:189–190.

5 Rodgers S, Dyas J, Molyneux AW, Ward MJ, Revill SM. Evaluation of the information needs of patients with chronic obstructive pulmonary disease following pulmonary rehabilitation: a focus group study. *Chron Respir Dis* 2007;4:195–203.

6 Stellefson M, Tennant B, Chaney JD. A critical review of effects of COPD self-management education on self-efficacy. *ISRN Public Health* 2012; 2012:152047.

7 Press VG, Arora VM, Shah LM, Lewis SL, Charbeneau J, Naureckas ET, *et al.* Teaching the use of respiratory inhalers to hospitalized patients with asthma or COPD: a randomized trial. *J Gen Intern Med* 2012;27: 1317–1325.

8 Melani AS, Bonavia M, Cilenti V, Cinti C, Lodi M, Martucci P, *et al.*; Gruppo Educazionale Associazione Italiana Pneumologi Ospedalieri. Inhaler mishandling remains common in real life and is associated with reduced disease control. *Respir Med* 2011;105:930–938.

9 Kessler R, Ståhl E, Vogelmeier C, Haughney J, Trudeau E, Löfdahl CG, *et al.* Patient understanding, detection, and experience of COPD exacerbations: an observational, interview-based study. *Chest* 2006; 130:133–142.

10 Hernandez P, Balter M, Bourbeau J, Hodder R. Living with chronic obstructive pulmonary disease: a survey of patients' knowledge and attitudes. *Respir Med* 2009;103:1004–1012.

11 COPD Foundation releases groundbreaking COPE survey results: low patient awareness about COPD exacerbations poses barrier to effective management. Business Wire 2014 Jun 17 [accessed 2021 Nov 4]. Available from: https://www.businesswire.com/news/home/20140617005140/en/COPD-Foundation-Releases-Groundbreaking-COPE-Survey-Results.

12 Menezes AM, Landis SH, Han MK, Muellerova H, Aisanov Z, van der Molen T, *et al.* Continuing to confront COPD international surveys: comparison of patient and physician perceptions about COPD risk and management. *Int J Chron Obstruct Pulmon Dis* 2015;10:159–172.

13 Krishnan JA, Gussin HA, Prieto-Centurion V, Sullivan JL, Zaidi F, Thomashow BM. Integrating COPD into patient-centered hospital readmissions reduction programs. *Chronic Obstr Pulm Dis (Miami)* 2015;2:70–80.

14 Han MK, Martinez CH, Au DH, Bourbeau J, Boyd CM, Branson R, *et al.* Meeting the challenge of COPD care delivery in the USA: a multiprovider perspective. *Lancet Respir Med* 2016;4:473–526.

15 Zwerink M, Brusse-Keizer M, van der Valk PD, Zielhuis GA, Monninkhof EM, van der Palen J, *et al.* Self management for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev* 2014;2014:CD002990.

16 Bourbeau J, van der Palen J. Promoting effective self-management programmes to improve COPD. *Eur Respir J* 2009;33:461–463.

17 Vestbo J, Hurd SS, Agustí AG, Jones PW, Vogelmeier C, Anzueto A, *et al.* Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: GOLD executive summary. *Am J Respir Crit Care Med* 2013;187:347–365.

18 Pearson ML, Mattke S, Shaw R, Ridgely MS, Wiseman SH. Patient self-management support programs: an evaluation. Final Contract Report (Prepared by RAND Health under contract no. 282-00-0005). Rockville, MD: Agency for Healthcare Research and Quality. AHRQ Publication No. 08-0011.

19 Taylor SJ, Sohanpal R, Bremner SA, Devine A, McDaid D, Fernández JL, *et al.* Self-management support for moderate-to-severe chronic obstructive pulmonary disease: a pilot randomised controlled trial. *Br J Gen Pract* 2012;62:e687–e695.

20 Campos MA, Alazemi S, Zhang G, Wanner A, Sandhaus RA. Effects of a disease management program in individuals with alpha-1 antitrypsin deficiency. *COPD* 2009;6:31–40.

21 Lorig KR, Ritter P, Stewart AL, Sobel DS, Brown BW Jr, Bandura A, *et al.* Chronic disease self-management program: 2-year health status and health care utilization outcomes. *Med Care* 2001;39:1217–1223.

22 Clark NM, Becker MH, Janz NK, Lorig K, Rakowski W, Anderson L. Self-management of chronic disease by older adults: a review and questions for research. *J Aging Health* 1991;3:3–27.

23 Lorig KR, Sobel DS, Stewart AL, Brown BW Jr, Bandura A, Ritter P, *et al.* Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: a randomized trial. *Med Care* 1999;37:5–14.

24 Tang TS, Ayala GX, Cherrington A, Rana G. A review of volunteer-based peer support interventions in diabetes. *Diabetes Spectr* 2011;24:85–98.

25 Fisher EB, Boothroyd RI, Coufal MM, Baumann LC, Mbanya JC, Rotheram-Borus MJ, *et al.* Peer support for self-management of diabetes improved outcomes in international settings. *Health Aff (Millwood)* 2012;31:130–139.

26 Long JA, Jahnle EC, Richardson DM, Loewenstein G, Volpp KG. Peer mentoring and financial incentives to improve glucose control in African American veterans: a randomized trial. *Ann Intern Med* 2012;156:416–424.

27 Parent N, Fortin F. A randomized, controlled trial of vicarious experience through peer support for male first-time cardiac surgery patients: impact on anxiety, self-efficacy expectation, and self-reported activity. *Heart Lung* 2000;29:389–400.

28 Fisher EB, Coufal MM, Parada H, Robinette JB, Tang PY, Urlaub DM, *et al.* Peer support in health care and prevention: cultural, organizational, and dissemination issues. *Annu Rev Public Health* 2014;35:363–383.

29 Crawford S, Bath N. Peer support models for people with a history of injecting drug use undertaking assessment and treatment for hepatitis C virus infection. *Clin Infect Dis* 2013;57:S75–S79.

30 Halding AG, Wahl A, Heggdal K. 'Belonging': patients' experiences of social relationships during pulmonary rehabilitation. *Disabil Rehabil* 2010;32:1272–1280.

31 Philis-Tsimikas A, Fortmann A, Lleva-Ocana L, Walker C, Gallo LC. Peer-led diabetes education programs in high-risk Mexican Americans improve glycemic control compared with standard approaches: a Project Dulce promotora randomized trial. *Diabetes Care* 2011;34:1926–1931.

32 Bandura A, Adams NE, Beyer J. Cognitive processes mediating behavioral change. *J Pers Soc Psychol* 1977;35:125–139.

33 Aboumatar H, Naqibuddin M, Neiman J, Saunders J, Kim S, Chaudhry H, *et al.* 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. *Contemp Clin Trials* 2020;94:106023.

34 Maryland Health Services Cost Review Commission. Clinical public use data requests [accessed 2022 May 25]. Available from: https://hscrc.maryland.gov/Pages/hsp-data-request.aspx.

35 Chesapeake Regional Information System for Our Patients. Research and quality improvement - improve outcomes and enhance the patient experience [accessed 2022 May 25]. Available from: https://www.crisphealth.org/resources/research-and-quality-improvement/#crisp-research-initiative.

36 Jones PW, Quirk FH, Baveystock CM. The St George's Respiratory Questionnaire. *Respir Med* 1991;85:25–37.

37 Effing T, Monninkhof EM, van der Valk PD, van der Palen J, van Herwaarden CL, Partidge MR, *et al.* Self-management education for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev* 2007;4:CD002990.

38 Tan JY, Chen JX, Liu XL, Zhang Q, Zhang M, Mei LJ, *et al.* A meta-analysis on the impact of disease-specific education programs on health outcomes for patients with chronic obstructive pulmonary disease. *Geriatr Nurs* 2012;33:280–296.

39 Jonkman NH, Westland H, Trappenburg JC, Groenwold RH, Bischoff EW, Bourbeau J, *et al.* Characteristics of effective self-management interventions in patients with COPD: individual patient data meta-analysis. *Eur Respir J* 2016;48:55–68.

40 Lenferink A, Brusse-Keizer M, van der Valk PD, Frith PA, Zwerink M, Monninkhof EM, *et al.* Self-management interventions including action plans for exacerbations versus usual care in patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev* 2017;8:CD011682.

41 Poot CC, Meijer E, Kruis AL, Smidt N, Chavannes NH, Honkoop PJ. Integrated disease management interventions for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev* 2021;9:CD009437.

42 Fjeldsoe B, Neuhaus M, Winkler E, Eakin E. Systematic review of maintenance of behavior change following physical activity and dietary interventions. *Health Psychol* 2011;30:99–109.

43 Göhler A, Januzzi JL, Worrell SS, Osterziel KJ, Gazelle GS, Dietz R, *et al.* A systematic meta-analysis of the efficacy and heterogeneity of disease management programs in congestive heart failure. *J Card Fail* 2006;12:554–567.

44 White P, Gilworth G, Lewin S, Hogg L, Tuffnell R, Taylor SJC, *et al.* Improving uptake and completion of pulmonary rehabilitation in COPD with lay health workers: feasibility of a clinical trial. *Int J Chron Obstruct Pulmon Dis* 2019;14:631–643.

45 Yao X, Wang X, Yuan J, Huang Z, Wu D, Xu H. Benefits conferred by peer-support nursing intervention to pulmonary function and quality of life in nonsmoking patients with COPD. *Can Respir J* 2021;2021:7450979.

46 Davidson L, Chinman M, Sells D, Rowe M. Peer support among adults with serious mental illness: a report from the field. *Schizophr Bull* 2006;32:443–450.

47 Chinman M, George P, Dougherty RH, Daniels AS, Ghose SS, Swift A, *et al.* Peer support services for individuals with serious mental illnesses: assessing the evidence. *Psychiatr Serv* 2014;65: 429–441.
48 Latkin CA, Sherman S, Knowlton A. HIV prevention among drug users: outcome of a network-oriented peer outreach intervention. *Health Psychol* 2003;22:332–339.
49 Dennis CL, Hodnett E, Kenton L, Weston J, Zupancic J, Stewart DE, *et al.* Effect of peer support on prevention of postnatal depression among high risk women: multisite randomised controlled trial. *BMJ* 2009;338:a3064.
50 Brady TJ, Murphy L, O'Colmain BJ, Beauchesne D, Daniels B, Greenberg M, *et al.* A meta-analysis of health status, health behaviors, and health care utilization outcomes of the Chronic Disease Self-Management Program. *Prev Chronic Dis* 2013;10:120112.
51 Davidson L, Bellamy C, Guy K, Miller R. Peer support among persons with severe mental illnesses: a review of evidence and experience. *World Psychiatry* 2012;11:123–128.
52 Substance Abuse and Mental Health Services Administration. Person- and family-centered care and peer support [accessed 2022 May 25]. Available from: https://www.samhsa.gov/section-223/care-coordination/person-family-centered.