## Title

Randomized Controlled Trial of Health Coaching for Vulnerable Patients with Chronic Obstructive Pulmonary Disease.



## Journal

Annals of the American Thoracic Society, 15(10)

## ISSN

2329-6933

## Authors

Thom, David H
Willard-Grace, Rachel
Tsao, Stephanie
et al.

## Publication Date

2018-10-01

## DOI

10.1513/annalsats.201806-365oc

Peer reviewed

# Randomized Controlled Trial of Health Coaching for Vulnerable Patients with Chronic Obstructive Pulmonary Disease

David H. Thom[1], Rachel Willard-Grace[1], Stephanie Tsao[2], Danielle Hessler[1], Beatrice Huang[1], Denise DeVore[1], Chris Chirinos[1], Jessica Wolf[1], DorAnne Donesky[3], Chris Garvey[3,4], and George Su[5]

[1]Department of Family and Community Medicine, [4]Department of Physiological Nursing, and [5]Pulmonology, Critical Care, Allergy and Sleep Medicine Program, Department of Medicine, University of California, San Francisco, San Francisco, California; [2]San Francisco Department of Public Health, San Francisco, California; and [3]University of California San Francisco at Mount Zion Sleep Disorders Center, San Francisco, California

ORCID IDs: 0000-0002-8051-6757 (D.H.T.); 0000-0002-6425-681X (B.H.); 0000-0001-8526-2533 (C.G.); 0000-0001-7233-8981 (G.S.).

## Abstract

**Rationale:** Socioeconomically disadvantaged patients with chronic obstructive pulmonary disease (COPD) often face barriers to evidence-based care that are difficult to address in public care settings with limited resources.

**Objectives:** To determine the benefit of health coaching for patients with moderate to severe COPD relative to usual care.

**Methods:** We conducted a randomized controlled trial of 9 months of health coaching versus usual care for English- or Spanish-speaking patients at least 40 years of age with moderate to severe COPD. Primary outcomes were COPD-related quality of life and the dyspnea subscale of the Chronic Respiratory Disease Questionnaire. Secondary outcomes were self-efficacy for managing COPD, exercise capacity (6-min walk test), and number of COPD exacerbations. Additional outcomes were COPD symptoms, lung function (forced expiratory volume in 1 s percent predicted), smoking status, bed days owing to COPD, quality of care (Patient Assessment of Chronic Illness Care), COPD knowledge, and symptoms of depression (Patient Health Questionnaire). Outpatient visits, emergency department visits, and hospitalizations were assessed by review of medical records. Generalized linear modeling was used to adjust for baseline values and account for clustering by clinic.

**Results:** Of 192 patients enrolled, 158 (82%) completed 9 months of follow-up. There were no significant differences between study arms for the primary or secondary outcomes. At 9 months, patients in the coached group reported better quality of care (mean Patient Assessment of Chronic Illness Care score, 3.30 vs. 3.18; adjusted $P = 0.02$) and were less likely to report symptoms of moderate to severe depression (Patient Health Questionnaire score, $\geq 15$) than those in the usual care arm (6% vs. 20%; adjusted $P = 0.01$). During the study, patients in the coaching arm had 48% fewer hospitalizations related to COPD (0.27/patient/yr vs. 0.52/patient/yr), but this difference was not significant in the adjusted analysis.

**Conclusions:** These results help inform expectations regarding the limitations and benefits of health coaching for patients with COPD. They may be useful to health policy experts in assessing the potential value of reimbursement and incentives for health coaching–type activities for patients with chronic disease.

Clinical trial registered with www.clinicaltrials.gov (NCT02234284).

**Keywords:** self-management; motivational interviewing; quality of life; hospitalization; depression

(Received in original form June 2, 2018; accepted in final form June 28, 2018)

Supported by the Patient-Centered Outcomes Research Institute (PCORI AD-1306-03900). Data gathering and analysis were supported by National Institutes of Health (NIH)/National Center for Research Resources Colorado Clinical and Translational Science Institute grant UL1 RR025780 through use of REDCap (Research Electronic Data Capture) software. This article's contents are the authors' sole responsibility and do not necessarily represent official NIH views.

*Author Contributions*: Study concept and design: D.H.T., R.W.-G., D.H., and G.S.; study execution and data collection: all authors; data analysis: D.H.T., R.W.-G., and D.H.; drafting and revision of manuscript: D.H.T., R.W.-G., D.H.; and review and approval of the manuscript version for submission: all authors.

Correspondence and requests for reprints should be addressed to David H. Thom, M.D., Ph.D., Department of Family and Community Medicine, University of California, San Francisco, 1001 Potrero Avenue, Building 80, Ward 83, San Francisco, CA 94110. E-mail: david.thom@ucsf.edu.

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

Ann Am Thorac Soc Vol 15, No 10, pp 1159–1168, Oct 2018

DOI: 10.1513/AnnalsATS.201806-365OC
Internet address: www.atsjournals.org

Chronic obstructive pulmonary disease (COPD) is a common condition causing substantial morbidity and mortality (1). Evidence-based care can substantially reduce disease burden, improve quality of life, and prevent emergency visits and hospitalizations for disease exacerbations (2). Despite the widespread availability of internationally recognized recommendations for evidence-based care (3), more than one-third of patients with COPD do not receive the recommended care (4–6). These care gaps are even more pronounced for vulnerable low-income and minority patients (7) and likely contribute to disparities in COPD-related morbidity and mortality (8, 9).

Reasons for the gap between evidence-based and actual care include clinician, system, and patient factors. Primary care clinicians are often not aware of guideline recommendations (10) and lack the time necessary for the evaluation and tracking needed to deliver guideline-based care (2). System barriers include limited access to specialist consultation and lack of team support for management of patients with COPD. Patient barriers to better management include lack of knowledge, confidence, and personal support (9, 11, 12) and time and transportation barriers that make it difficult to attend classes or group support activities (13).

Although studies of integrated disease management programs for patients with COPD have shown benefit (14), such support programs are generally not sustainable in resource-limited federally qualified health centers (FQHCs) serving vulnerable low-income and minority patients. FQHCs generally do not have on-site access to pulmonary specialists, and most cannot afford to hire nurses or respiratory therapists to conduct patient education at the clinic level. Health coaching by unlicensed health workers trained as coaches could potentially provide similar benefits at lower cost. Health coaching has emerged as an effective model to improve management of other chronic conditions, particularly for low-income and vulnerable patients (15–23). Health coaching can potentially address several of the barriers to evidence-based care for patients with COPD, including limited access, poor coordination of care, distrust of and lack of engagement with the healthcare system (24), missed appointments, inadequate adherence to treatment (25), and poor patient–provider communication (26). Although a small number of randomized trials have evaluated a health coaching–based intervention for patients with COPD (27–33), none has evaluated the impact of health coaching by nonlicensed health workers for low-income and vulnerable patients with COPD in the primary care setting. We therefore conducted a randomized controlled trial comparing health coaching plus usual care with usual care alone for low-income and vulnerable patients with COPD.

## Methods

The Aides in Respiration Health Coaching for COPD (AIR) study was a randomized controlled trial of health coaching versus usual care for patients with moderate to severe COPD. A detailed description of the study protocol was previously published (34), and the protocol is available from www.clinicaltrials.gov. The study was approved by the University of California, San Francisco Committee on Human Research (14-12872). Informed consent was obtained from all study participants.

### Setting

The AIR study was conducted between November 12, 2014, and May 6, 2017, at seven urban public health primary care clinics in San Francisco designated as "FQHC look-alikes" by the Health Resources and Services Administration. Five clinics were in the community, and two were located at the county hospital medical campus.

### Participants

Patients were eligible for enrollment if they had been seen at least once in the past 12 months, were age 40 years or older, spoke Spanish or English, and had at least moderate COPD. A diagnosis of COPD was confirmed by the study pulmonologist (G.S.), blinded to allocation arm, on the basis of forced expiratory volume in 1 second ($FEV_1$)/forced vital capacity (FVC) ratio and other clinical criteria. A determination of having at least moderate COPD was made on the basis of meeting at least one of the following criteria: *1*) one or more hospital admissions, two or more emergency department (ED) visits, or prescription of oral steroids for a COPD exacerbation in the past 12 months; *2*) a current prescription of an anticholinergic or combination inhaled corticosteroid and long-acting β-agonist; *3*) ever having used home oxygen or meeting criteria for home oxygen; or *4*) ever having an $FEV_1$ less than 80% predicted.

### Recruitment, Enrollment, and Randomization

Potentially eligible patients were identified primarily through review of the electronic records from the previous 24 months for the seven clinics and the county hospital and ED. Patients with a COPD-related diagnosis (*International Classification of Diseases, Ninth Revision* [ICD-9], codes 491, 492, 496, 490 + 305.1, 493 + 305.1, 786 + 305.1; or ICD-10 codes J42, J43, J44, J40 + Z72, J45 + Z72, R06 + Z72) were assessed by review of electronic health record and their primary care provider (PCP) (Figure 1). A research assistant (RA) attempted to contact the patients not excluded to conduct additional eligibility screening. Eligible patients interested in the study met with the RA at their primary care clinic for informed consent provision and study enrollment. Patients were randomized individually, stratified by clinic, in permutated blocks of 10 for each clinic using the random number function in the Excel 2012 software program (Microsoft). Randomization by the individual, rather than by clinic, was chosen to enhance recruitment of clinics by being able to offer coaching for some patients at each participating clinic. After obtaining baseline measurements (survey, 6-min walk test, and spirometry if possible), the RA opened the next sequentially numbered envelope containing the study arm assignment.

### Health Coaching Training and Fidelity

We used the health coaching model developed at our institution to train unlicensed health workers to support patient self-management using commonly recognized patient-centered techniques such as motivational interviewing and action planning (34, 35). The two study health coaches were college graduates bilingual in Spanish and English without medical training or certification. Coaches received approximately 100 hours of training over 3 months. COPD-specific training was delivered by two pulmonary specialists and covered the physiology of

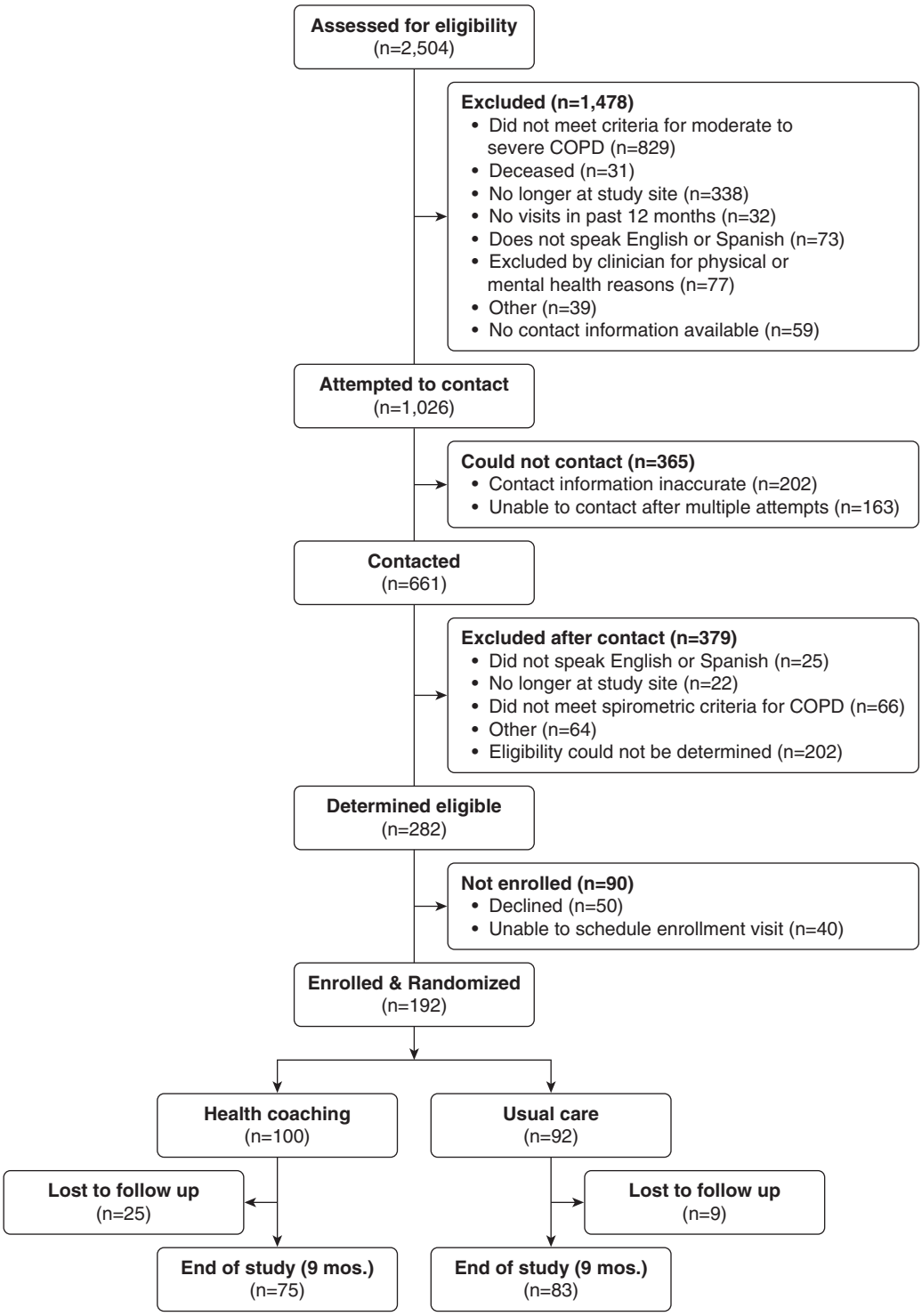


**Figure 1.** Consolidated Standards of Reporting Trials diagram. COPD = chronic obstructive pulmonary disease.

COPD; related comorbidities; Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines; and COPD management, including lifestyle changes. Upon completion of training, coaches were required to score at least 90% on three examinations assessing content knowledge and to demonstrate mastery of coaching skills through simulated role plays and observed health coaching sessions. The project manager observed health coaches, both immediately after training and periodically during the study, using a standardized checklist and providing immediate feedback to the coaches.

### Health Coaching Arm

Patients randomized to the health coaching arm received health coaching for 9 months. Each health coach worked with a total of 50 patients with a maximum caseload of 30 patients at any given time. Health coaches were expected to complete an initial visit within 2–3 weeks of enrollment; to meet in person with the patient at least three additional times over the course of the study; and to have a phone check-in call at least every 3 weeks, including within 2 weeks after each medical visit (minimum of 13 phone check-ins over 9 mo). In-person visits could be at the clinic, at the patient's home, or at a public location that afforded sufficient privacy. Additional contacts were guided by patient needs and preferences. Coaches were also expected to conduct at least one in-depth consultation with the study pulmonary nurse practitioner specialist and to attend medical visits between the patient and their PCP when possible. Health coaching focused on helping patients identify and achieve self-care goals for their COPD using techniques from motivational interviewing and adult learning models. Specific content included COPD education, action planning for exacerbations, teaching proper inhaler use, and facilitating consultation with a pulmonary nurse practitioner specialist. Further details are available in a previous paper (34).

### Usual Care Arm

Patients randomized to usual care continued to have visits with their PCP over the course of the 9-month period. They received any resources their provider and their clinic offered as part of standard care, including access to COPD educators, respiratory therapists, COPD education classes, pulmonary rehabilitation, smoking cessation classes, and pulmonary specialist referrals by the primary care clinician.

### Patient and Stakeholder Engagement

Study investigators and staff met with clinic leaders, clinicians, and staff at each clinic site during the planning and execution of the study. A study advisory board comprised of patients with COPD, clinicians, nurse educators, health coaches, and delivery system leaders met before the start of the study and every 6 months during the course of the study. In addition, the research team included a patient partner with COPD who participated in health coach training and health coach support during the study and attended monthly meetings of the core research team.

### Data and Safety Monitoring

A data and safety and monitoring board (DSMB) was established before recruitment. The DSMB consisted of a pulmonary nurse specialist, a primary care physician, and an epidemiologist. As directed by the DSMB, the research team reported ED visits and hospitalizations quarterly and participant deaths within 30 days over the course of the study.

### Data Collection

The study survey, spirometry, and exercise capacity testing were administered in person by an RA at baseline and again at 9 months. In addition, patients completed a brief telephone survey at 3 and 6 months, which measured COPD-related quality of life, number of days in bed for all or most of the day in the past 4 weeks owing to COPD (bed days), and smoking status. Medical records were reviewed for the presence of comorbid conditions (alcohol abuse, substance abuse, coronary artery disease, heart failure, diabetes, asthma, and obstructive sleep apnea). Patients received a gift card for completion of measures at baseline ($30), 3 and 6 months ($10), and 9 months ($60).

### Outcome Measures

The primary outcomes were overall COPD-related quality of life (mean item score, 1–7; minimal clinically important difference [MCID], 1.0) and dyspnea domain score (mean item score, 1–7; MCID, 0.5) measured by the short form of the Chronic Respiratory Disease Questionnaire (CRQ-SF) (36, 37), which has been validated in multiple studies (38, 39). Secondary outcomes were the number of COPD exacerbations (defined as worsening of respiratory symptoms resulting in prescription of an antibiotic and steroid medication, an ED visit, or a hospitalization) (29), exercise capacity measured using the standardized 6-minute walk test (40, 41), and self-efficacy for COPD management measured using a validated six-item scale (mean item score, 1–10) (42).

Additional prespecified outcomes were COPD symptoms and functional capacity (COPD Assessment Test total score, 0–40; MCID, 2.0) (43–45), lung function measured by spirometry as the percent predicted $FEV_1$, current smoking status defined as any self-reported cigarette use in the past 30 days, and number of bed days owing to respiratory problems in the past 4 weeks. Knowledge of COPD was measured as the percentage of correct responses to four questions developed for the present study. Patient-reported quality of care was measured using the Patient Assessment of Chronic Illness Care (mean item score, 1–8) (46, 47). ED visits and hospitalizations for COPD exacerbations and for other reasons were identified by review of participants' electronic medical records from the participating clinics and the county hospital, as well as from outside facilities for ED visits and hospitalizations identified by patients at baseline and over the course of the study. Records were reviewed by study co–principal investigators, a family physician (D.H.T.), and a pulmonologist (G.S.), blinded to study arm assignment. Symptoms of depression were assessed using the eight-item version of the Patient Health Questionnaire, with a score of 15 or greater indicating moderately severe depressive symptoms (48).

### Blinding

Blinding of patients and clinical teams was not feasible, owing to the nature of the intervention. Although RAs were trained to gather unbiased data, it was not possible to completely blind them to study arm, because we could not prevent patients from revealing that they worked with a health coach. Initial data analyses, including all prespecified outcomes, were conducted blinded to study arm.

### Sample Size

The target sample size of 190 patients provided approximately 80% power to detect an MCID of 0.5 in the CRQ-SF dyspnea domain score (37) and 22% for the number of COPD exacerbations (49) and a power greater than 90% for differences of 1.0 in the CRQ-SF total score (37) and of 50 m in the 6-minute walk test (50).

### Analysis

Baseline participant characteristics were compared between study arms and tested for significance using chi-square tests for categorical variables, *t* tests for normally distributed continuous variables, and appropriate nonparametric tests for nonnormally distributed continuous variables. Outcomes were compared by

group assignment (intention to treat) using generalized linear models with a normal distribution with identity link for continuous outcomes, Poisson distribution with log link for count outcomes, and binomial distribution with logit link for binary outcomes. Hypothesis tests were two sided, with *P* values less than 0.05 considered statistically significant. A robust standard error was used to account for clustering and accommodate missing data under the assumption that the outcomes are missing at random (51–55). In all models, baseline levels of the outcome were entered as a predictor and follow-up levels as the dependent variable. Event rates (exacerbations, outpatient visits, ED visits, and hospitalizations) are reported as events per person per year and adjusted for baseline rate and for clustering by participant because patients could have more than one event.

The following planned sensitivity analyses were conducted: *1*) repeating primary analyses with multiple imputation procedures; *2*) limiting intervention participants to those who received a prespecified minimal amount of the intervention, defined as at least seven health coach contacts, at least three of which were in person; and *3*) adjusting for season of enrollment, patient age, race, and sex as well as baseline variables that differed between study arms at $P < 0.10$. Heterogeneity of effects was examined for three prespecified subgroups: English versus Spanish as primary language, current smokers versus other, and GOLD category D COPD (high symptoms and high risk) versus other (3).

## Results

Recruitment and enrollment flow are shown in the Consolidated Standards of Reporting Trials diagram (Figure 1). Of 2,504 patients identified as potentially having COPD on the basis of codes used for visits in the past 2 years, 1,478 (59%) were excluded, most often because they did not meet criteria for at least moderate-severity COPD. An RA was able to contact 661 (64%) of the 1,026 remaining patients, 282 of whom were determined to be eligible. Ninety either explicitly declined enrollment or missed their enrollment appointment(s) and could not be successfully rescheduled; the remaining 192 patients were enrolled. Over 93% ($n = 179$) had COPD confirmed by an $FEV_1/FVC$ ratio less than 0.70; the remaining 13 were diagnosed on the basis of a combination of other criteria (e.g., $FEV_1/FVC$ ratio between 0.70 and 0.74 plus clinical history and highly suggestive of COPD) by the study pulmonologist. Outside hospitals responded to 91.5% of our requests for medical records.

Patients known to be eligible but not enrolled were significantly older than those enrolled (65.9 vs. 61.6 yr; $P < 0.001$), but they were similar on all other available measures. Attrition at 9-month follow-up was 9.8% in the usual care arm and 25% in the health coaching arm. There were no significant differences between study arms in baseline characteristics (including demographics and markers of disease severity) for patients who dropped out of the study. Baseline characteristics of participants and levels of outcome variables were similar between the study arms (Tables 1 and 2), with the exception of the number of hospitalizations for COPD in the previous 12 months, which was more than twice as high in the usual care group (0.34/person/yr vs. 0.13/person/yr), though this difference was not significant after adjustment for individual clustering.

Overall, 95% of patients in the coached arm had at least 3 contacts with a health coach, and 77% met the goal of 13 or more contacts (Table 3). Over 80% had five or more in-person visits, and 82% had at least one visit, with their PCP at which their health coach was present. Eighty-nine percent of patients received a consultation from the pulmonary nurse practitioner specialist, either in person (19%) or via presentation of the patient by the health coach (70%).

**Table 1.** Characteristics of participants at baseline

| Characteristic | All (*n* = 192) | Coaching Arm (*n* = 100) | Usual Care (*n* = 92) |
|---|---|---|---|
| Age, yr | 61.3 (7.6) | 60.7 (8.0) | 61.9 (7.2) |
| Demographic and medical | | | |
| Male sex | 126 (65.5%) | 67 (67.0%) | 59 (64.1%) |
| Less than high school education | 61 (31.9%) | 27 (27.0%) | 34 (37.4%) |
| Married or long-term relationship | 65 (34.0%) | 36 (36.0%) | 29 (31.9%) |
| Born outside United States | 34 (17.8%) | 13 (13.0%) | 21 (23.1%) |
| Spanish speaker | 18 (9.4%) | 7 (7.0%) | 11 (12.1%) |
| Employment status | | | |
| Works full/part time outside the home | 34 (17.8%) | 16 (16.0%) | 18 (19.8%) |
| Retired | 64 (33.5%) | 32 (32.0%) | 32 (35.2%) |
| On disability | 69 (36.1%) | 38 (38.0%) | 31 (34.1%) |
| Other (homemaker, unemployed) | 24 (12.6%) | 14 (14.0%) | 11 (12.0%) |
| Income <$10,000/yr | 84 (45.7%) | 44 (45.8%) | 40 (45.5%) |
| Race (detailed) | | | |
| White | 41 (21.4%) | 29 (29.0%) | 12 (13.0%) |
| African American | 109 (56.7%) | 53 (53.0%) | 56 (60.9%) |
| Asian | 7 (3.7%) | 2 (2.0%) | 5 (5.4%) |
| Native American | 4 (2.1%) | 2 (2.0%) | 2 (2.2%) |
| Pacific Islander | 3 (1.6%) | 1 (1.0%) | 2 (2.2%) |
| Other | 28 (14.6%) | 13 (13.0%) | 15 (16.3%) |
| Hispanic/Latino ethnicity | 32 (16.7%) | 13 (13.0%) | 19 (20.7%) |
| Less than full health literacy* | 71 (37.2%) | 39 (39.0%) | 32 (35.2%) |
| General health less than very good | 162 (84.4%) | 82 (83.0%) | 79 (85.9%) |
| Medicaid only | 108 (56.2%) | 59 (59.0%) | 49 (53.3%) |
| Lives alone | 91 (47.6%) | 49 (49.0%) | 42 (46.2%) |
| Housing insecurity or homelessness | 25 (13.0%) | 13 (13.0%) | 12 (13.0%) |
| Comorbid conditions | | | |
| Alcohol abuse | 33 (17.2%) | 17 (17.0%) | 16 (17.4%) |
| Substance abuse | 55 (28.7%) | 26 (26.0%) | 29 (31.5%) |
| Coronary artery disease | 17 (8.9%) | 8 (8.0%) | 9 (9.8%) |
| Heart failure | 23 (12.0%) | 13 (13.0%) | 10 (10.9%) |
| Diabetes | 44 (22.9%) | 19 (19.0%) | 25 (27.2%) |
| Asthma | 53 (27.6%) | 29 (29.0%) | 24 (26.1%) |
| Obstructive sleep apnea | 19 (9.9%) | 7 (7.0%) | 12 (13.0%) |

Note: Percentages may not add to 100%, owing to missing data. Data are presented as mean (standard deviation) or number (percent).
*Defined as needing someone help read medical information at least a little of the time (60).

**Table 2.** Baseline levels of outcome variables

| Outcome | Coaching Arm (*n* = 100) | Usual Care Arm (*n* = 92) |
|---|---|---|
| Primary | | |
| CRQ-SF total score | 4.24 (1.22) | 4.28 (1.23) |
| CRQ-SF dyspnea subscale score | 4.39 (1.46) | 4.63 (1.45) |
| Secondary | | |
| Incidence of exacerbations per person-year | 0.95 (1.57) | 0.92 (1.34) |
| Exercise capacity, m | 305.0 (83.1) | 292 (77.5) |
| Self-efficacy for managing COPD score | 6.36 (2.23) | 6.45 (2.11) |
| Others prespecified | | |
| COPD symptoms score | 20.6 (8.34) | 20.9 (7.41) |
| Lung function ($FEV_1$, % predicted) | 0.55 (0.19) | 0.60 (0.20) |
| Currently smoking | 54 (54.6%) | 45 (52.9%) |
| Bed days owing to COPD in past 4 wk | 2.75 (6.44) | 3.86 (6.86) |
| Knowledge of COPD score | 3.23 (0.83) | 3.07 (0.89) |
| Patient-reported quality of care score | 3.58 (0.98) | 3.29 (1.20) |
| Use 1 yr before enrollment per person-year | | |
| Outpatient visits | 6.62 (5.43) | 6.53 (4.08) |
| ED visits for not for COPD | 1.12 (2.52) | 0.62 (1.29) |
| ED visits for COPD | 0.54 (1.26) | 0.62 (1.19) |
| Hospitalizations not for COPD | 0.21 (0.57) | 0.18 (0.44) |
| Hospitalizations for COPD | 0.13 (0.39) | 0.34 (0.77) |
| Reported *post hoc* | | |
| Symptoms of moderate to severe depression | 13 (13.0%) | 17 (18.7%) |

*Definition of abbreviations*: COPD = chronic obstructive pulmonary disease; CRQ-SF = short form of the Chronic Respiratory Questionnaire; ED = emergency department; $FEV_1$ = forced expiratory volume over 1 second.
Data are presented as mean (standard deviation) or number (percent).

There were no significant differences between study arms for any of the primary outcomes or for the secondary outcomes with the exception of patient-reported quality of care (Table 4). Over the course of the 9-month study period, the incidence of all ED visits, both related and not related to COPD, was similar in the two study arms, as was the incidence of non-COPD hospitalizations. COPD-related hospitalizations were nearly twice as common for patients in the usual care arm (0.52 vs. 0.27 per person per yr), but this difference was not significant once adjusted for differences in the hospitalizations for COPD exacerbations in the 12 months before enrollment. At 9 months, usual care patients were over three times as likely to report symptoms of moderate or severe depression as were patients in the coached arm (19.5% vs. 5.6%; adjusted $P = 0.01$).

Table 5 shows outcomes tracked at 3, 6, and 9 months after enrollment. The proportion of current smokers declined somewhat more rapidly in the coached arm (Figure 2). Adjusting for baseline and clustering by site, this difference reached statistical significance at 3-month (adjusted difference, −37%; 95% confidence interval, −71% to −3.0%; $P = 0.02$) and 6-month follow-up (adjusted difference, −26%; 95% confidence interval, −52% to −1.0%; $P = 0.05$), but it was no longer significant at 9 months. There was a trend for smokers in the coached arm being more likely to receive a prescription for tobacco cessation medications over the course of the study, controlling for baseline level of tobacco cessation medications (adjusted $P = 0.07$).

The patterns of results reported above remained essentially unchanged when analyses were repeated using imputation of missing data, using per-protocol analysis, or after adjustment for additional baseline variables as described in the METHODS section. There were no significant differences in treatment effect between the prespecified subgroups.

**Table 3.** Intensity of health coaching (*n* = 100)

| Coaching Activity | Median (Interquartile Range) | Goal | Meeting Goal (*n* [%]) |
|---|---|---|---|
| All contacts | 24 (15–41) | ⩾13 | 77 (77.0) |
| In-person visits | 9 (6–14) | ⩾5 | 82 (82.0) |
| Medical visits with PCP | 2 (1–4) | ⩾1 | 82 (82.0) |
| Consultation with PNPS | N/A | 1 | 89 (89.0) |

*Definition of abbreviations*: N/A = not applicable; PCP = primary care provider; PNPS = pulmonary nurse practitioner specialist.

## Discussion

Despite the promise of health coaching as a means to address barriers to care for patients with COPD, we did not find any significant differences between study arms for any of the primary or secondary outcomes, with the exception of patient-reported quality of care, which was higher in the coaching arm. In *post hoc* analyses, we found a significant reduction in the proportion of patients with symptoms of moderate to severe depression in the health coaching group. The proportion of current smokers decreased substantially in both study arms from baseline to 9 months, with the drop occurring earlier in the health coaching group.

To place our results in the context of previous research, we identified seven studies that examined the impact of individual coaching for patient self-management support based on one or more models for patient-centered behavioral change (e.g., transtheoretical model with motivational interviewing [56, 57] or self-regulation theory [58]). Three of these studies also reported essentially negative overall results (27–30), though one showed a *post hoc* subgroup effect (29, 30). A fourth study, in which the intervention was delivered by a clinical pharmacist, resulted in significantly fewer hospital admissions, ED visits, and unscheduled primary care appointments for COPD, as well as better disease-specific quality of life (31). Two studies using a multidisciplinary team found significant improvement in patient

**Table 4.** Outcomes at 9 months, by study arm

| Outcomes | Coached | Usual Care | Difference | Adjusted* Difference | Adjusted* 95% CI | *P* Value |
|---|---|---|---|---|---|---|
| Primary | | | | | | |
| CRQ-SF total score | 4.58 (1.25) | 4.43 (1.28) | 0.15 | 0.14 | −0.15 to 0.43 | 0.35 |
| CRQ-SF dyspnea subscale score | 4.98 (1.39) | 4.78 (1.49) | 0.20 | 0.26 | −0.13 to 0.65 | 0.20 |
| Secondary | | | | | | |
| Incidence of exacerbations per person-year | 1.17 (1.87) | 1.44 (2.16) | −0.27 | −0.21 | −0.49 to 0.07 | 0.13 |
| Exercise capacity, m | 326 (68.3) | 311 (73.8) | 15.00 | 8.53 | −8.18 to 25.28 | 0.32 |
| Self-efficacy for managing COPD score | 6.84 (2.01) | 6.50 (2.00) | 0.34 | 0.30 | −0.23 to 0.83 | 0.27 |
| Others prespecified | | | | | | |
| COPD symptoms score | 19.1 (8.80) | 20.2 (9.25) | −1.10 | −0.83 | −2.78 to 1.12 | 0.40 |
| Lung function ($FEV_1$, % predicted) | 0.55 (0.20) | 0.59 (0.21) | −0.04 | 0.00 | −0.03 to 0.03 | 0.98 |
| Currently smoking | 29 (39.2%) | 34 (42.0%) | −2.8% | −11.5% | −33.3% to 10.2% | 0.30 |
| Bed days owing to COPD in past 4 wk | 2.15 (5.76) | 3.64 (8.81) | −1.49 | −0.73 | −2.07 to 0.62 | 0.29 |
| Knowledge of COPD score | 3.30 (0.75) | 3.18 (0.83) | 0.12 | | | |
| Patient-reported quality of care score | 3.91 (0.95) | 3.44 (1.17) | 0.47 | 0.38 | 0.07 to 0.68 | 0.02 |
| Use 1 yr before enrollment per person-year | | | | | | |
| Outpatient visits | 7.51 (5.64) | 6.83 (4.73) | 0.68 | 0.48 | −0.32 to 1.28 | 0.52 |
| ED visits for not for COPD | 0.98 (1.89) | 0.83 (2.33) | 0.15 | −0.08 | −0.56 to 0.40 | 0.80 |
| ED visits for COPD | 0.80 (1.63) | 0.89 (1.99) | −0.09 | −0.05 | −0.32 to 0.22 | 0.78 |
| Hospitalizations not for COPD | 0.16 (0.58) | 0.21 (0.81) | −0.05 | −0.08 | −0.20 to 0.04 | 0.37 |
| Hospitalizations for COPD | 0.27 (0.77) | 0.52 (1.25) | −0.25 | −0.13 | −0.32 to 0.06 | 0.35 |
| Reported *post hoc* | | | | | | |
| Symptoms of moderate to severe depression | 4 (5.6%) | 16 (19.5%) | −13.9% | −18.9% | −33.1% to −4.8% | 0.01 |

*Definition of abbreviations*: CI = confidence interval; COPD = chronic obstructive pulmonary disease; CRQ-SF = short form of the Chronic Respiratory Questionnaire; ED = emergency department; $FEV_1$ = forced expiratory volume over 1 second.
Data are presented as mean (standard deviation) or number (percent).
*Adjusted for baseline levels of variable and for clustering.

COPD-related quality of life and in patient assessment of their knowledge about COPD (32, 59). The seventh study found that health coaching over eight weekly sessions by a registered nurse or respiratory therapist after hospitalization for a COPD exacerbation resulted in significantly fewer hospital admissions for COPD, better COPD-related quality of life, and fewer COPD exacerbations (33).

The improvement in patient-reported quality of chronic illness care seen in our study may be due to the emphasis of health coaching on several aspects of care quality measured by the Patient Assessment of Chronic Illness Care, specifically goal setting, shared decision making, care planning, and follow-up between visits. None of the seven studies reported on quality care. We also found a significant decrease in the proportion of patients with symptoms of moderate to severe depression, in contrast to the one study that measured symptoms of depression (29), which found no difference between study arms.

Viewing the results from the AIR study in the context of previous studies of health coaching or similar interventions for patients with COPD suggests several implications. Although the

**Table 5.** Outcomes at baseline and at 3, 6, and 9 months, by study arm

| | Health Coaching (Mean [SD] or *n* [%]) | | | | Usual Care (Mean [SD] or *n* [%]) | | | |
|---|---|---|---|---|---|---|---|---|
| | Baseline | 3 Mo | 6 Mo | 9 Mo | Baseline | 3 Mo | 6 Mo | 9 Mo |
| CRQ-SF total score | 4.24 (1.22) | 4.42 (1.44) | 4.69 (1.38) | 4.58 (1.2) | 4.28 (1.23) | 4.41 (1.37) | 4.47 (1.34) | 4.43 (1.28) |
| CRQ-SF dyspnea score | 4.39 (1.46) | 4.62 (1.64) | 4.83 (1.66) | 4.98 (1.39) | 4.63 (1.45) | 5.00 (1.50) | 4.72 (1.60) | 4.78 (1.49) |
| Bed days owing to COPD in past 4 wk | 2.75 (6.44) | 4.82 (8.56) | 3.38 (6.52) | 2.15 (5.76) | 3.86 (6.86) | 3.44 (6.09) | 4.02 (6.39) | 3.64 (6.81) |
| Currently smoking | 54 (54.6%) | 28 (39.4%)* | 31 (40.3%)* | 29 (39.2%) | 45 (52.9%) | 34 (48.6%)* | 34 (48.6%)* | 34 (42.0%) |

*Definition of abbreviations*: COPD = chronic obstructive pulmonary disease; CRQ-SF = short form of the Chronic Respiratory Questionnaire; SD = standard deviation.
*Difference by study arm significant at $P < 0.05$.

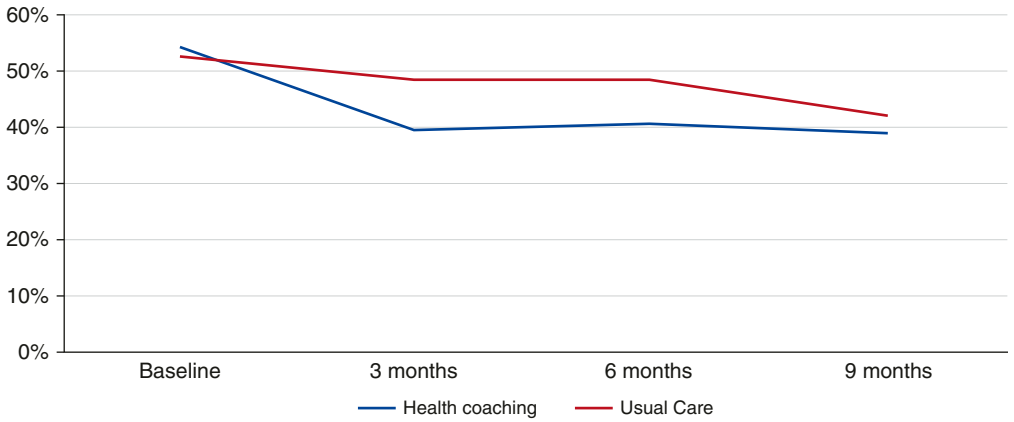


**Figure 2.** Percentage of patients currently smoking by self-report over the course of the study.

impact on disease-specific quality of life and dyspnea trended in favor of the health coaching group, the results suggest that any quality of life–related benefit of health coaching in our model is likely to be small. It is notable that all four previous studies showing a benefit used licensed health professionals, and two used a team rather than a single coach. In contrast, our study used a single unlicensed health worker as a health coach. These results suggest that healthcare professionals may be more effective at improving quality of life for patients with COPD than coaching provided by a single unlicensed health worker.

### Limitations

A potentially important limitation of our study design was that patients, rather than PCPs or clinics, were randomized. As a result, many PCPs had patients in both study arms, creating a potential "halo effect" whereby patients in the usual care group may have benefited from the presence of health coaching. For example, PCPs received recommendations to improve medication regimens in accordance with international guidelines, and this may have caused them to change their care of other patients with COPD. In addition, the differences in rates of smoking cessation should be interpreted with caution because the study did not include biochemical verification. We did not find any difference between study arms in the characteristics of patients who dropped out of the study, which is reassuring that the differential dropout rate did not bias our results. The higher dropout rate in the coached arm may be due in part to a higher participation burden in the coached group.

### Conclusions

After 9 months, patients in the coached group reported receiving higher quality of care and were less likely to report symptoms of moderate to severe depression, but they did not significantly differ from the usual care group for other outcomes. The nearly 50% lower incidence of hospitalizations for COPD in the coached group in the present study is encouraging, particularly given its potential impact on healthcare cost, but it was not significant when adjusted for baseline difference in this outcome. These results should be helpful to FQHCs that already use health coaching or that are interested in implementing a health coaching program at their clinic for patients with COPD, and they may be useful to health policy experts in assessing the potential value of reimbursement and incentives for health coaching–type activities for patients with chronic disease. A future study should examine if health coaching is more effective if delivered by a licensed professional. ■

**Author disclosures** are available with the text of this article at www.atsjournals.org.

**Acknowledgment:** The authors thank the clinicians, leaders, and staff at our clinic partners for their participation and active support of the AIR study: Maxine Hall Health Center, Silver Avenue Family Health Center, Southeast Health Center, Family Health Center, Richard H. Fine People's Clinic, Potrero Hill Health Center, and Castro-Mission Health Center. The authors also thank Eula Lewis, R.T., and the Community Spirometry Program at the Zuckerberg San Francisco General Hospital and Trauma Center for all the time and effort spent training our team and for sharing their wealth of knowledge. Members of the authors' study advisory board provided invaluable advice, insight, and new ideas that substantially improved the study. Specifically, the authors thank the patient representatives. The authors also thank other advisory board members Jennifer Coffey; Hali Hammer, M.D.; Camille Prado; Lydia Leung, M.D.; Rosaly Ferrer, R.N.; and health coach experts Adrianna Najmabadi, Amireh Ghorob, and Tom Bodenheimer, M.D. The authors owe a particular debt to Devon Low, our patient research partner, for his many insights and contributions to the AIR study.

### References

1 National Heart, Lung, and Blood Institute. Morbidity and mortality: 2012 chart book on cardiovascular, lung, and blood diseases. Bethesda, MD: National Institutes of Health [accessed 2018 May 26]. Available from: https://www.nhlbi.nih.gov/files/docs/research/2012_ChartBook_508.pdf.

2 Sadatsafavi M, Chen W, Tavakoli H, Rolf JD, Rousseau R, FitzGerald JM; Economic Burden of Asthma Study Group. Saving in medical costs by achieving guideline-based asthma symptom control: a population-based study. *Allergy* 2016;71:371–377.

3 Global Initiative for Chronic Obstructive Lung Disease (GOLD). GOLD 2017 global strategy for the diagnosis, management and prevention of COPD [accessed 2018 May 20]. Available from: http://goldcopd.org/gold-2017-global-strategy-diagnosis-management-prevention-copd/

4 Agency for Healthcare Research and Quality (AHRQ). National healthcare quality & disparities reports. Bethesda, MD: U.S. Department of Health and Human Services; 2011 [accessed 2018 May 26]. Available

from: https://www.ahrq.gov/research/findings/nhqrdr/index.html.
5 Kaufmann C, Markun S, Hasler S, Dalla Lana K, Rosemann T, Senn O, *et al*. Performance measures in the management of chronic obstructive pulmonary disease in primary care - a retrospective analysis. *Praxis (Bern 1994)* 2015;104:897–907.
6 Diette GB, Dalal AA, D'Souza AO, Lunacsek OE, Nagar SP. Treatment patterns of chronic obstructive pulmonary disease in employed adults in the United States. *Int J Chron Obstruct Pulmon Dis* 2015;10:415–422.
7 Gershon AS, Dolmage TE, Stephenson A, Jackson B. Chronic obstructive pulmonary disease and socioeconomic status: a systematic review. *COPD* 2012;9:216–226.
8 Eisner MD, Blanc PD, Omachi TA, Yelin EH, Sidney S, Katz PP, *et al*. Socioeconomic status, race and COPD health outcomes. *J Epidemiol Community Health* 2011;65:26–34.
9 Wong SS, Abdullah N, Abdullah A, Liew SM, Ching SM, Khoo EM, *et al*. Unmet needs of patients with chronic obstructive pulmonary disease (COPD): a qualitative study on patients and doctors. *BMC Fam Pract* 2014;15:67.
10 Barr RG, Celli BR, Martinez FJ, Ries AL, Rennard SI, Reilly JJ Jr, *et al*. Physician and patient perceptions in COPD: the COPD Resource Network needs assessment survey. *Am J Med* 2005;118:1415.e9–1415.e17.
11 George J, Kong DC, Thoman R, Stewart K. Factors associated with medication nonadherence in patients with COPD. *Chest* 2005;128:3198–3204.
12 Hillebregt CF, Vlonk AJ, Bruijnzeels MA, van Schayck OC, Chavannes NH. Barriers and facilitators influencing self-management among COPD patients: a mixed methods exploration in primary and affiliated specialist care. *Int J Chron Obstruct Pulmon Dis* 2016;12:123–133.
13 Sohanpal R, Seale C, Taylor SJ. Learning to manage COPD: a qualitative study of reasons for attending and not attending a COPD-specific self-management programme. *Chron Respir Dis* 2012;9:163–174.
14 Kruis AL, Smidt N, Assendelft WJ, Gussekloo J, Boland MR, Rutten-van Mölken M, *et al*. Integrated disease management interventions for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev* 2013;10:CD009437.
15 Bennett HD, Coleman EA, Parry C, Bodenheimer T, Chen EH. Health coaching for patients with chronic illness. *Fam Pract Manag* 2010;17:24–29.
16 Ruggiero L, Moadsiri A, Butler P, Oros SM, Berbaum ML, Whitman S, *et al*. Supporting diabetes self-care in underserved populations: a randomized pilot study using medical assistant coaches. *Diabetes Educ* 2010;36:127–131.
17 Thom DH, Ghorob A, Hessler D, De Vore D, Chen E, Bodenheimer TA. Impact of peer health coaching on glycemic control in low-income patients with diabetes: a randomized controlled trial. *Ann Fam Med* 2013;11:137–144.
18 Ivey SL, Tseng W, Kurtovich E, Lui B, Weir RC, Liu J, *et al*. Evaluating a culturally and linguistically competent health coach intervention for Chinese-American patients with diabetes. *Diabetes Spectr* 2012;25:93–102.
19 Turner BJ, Hollenbeak CS, Liang Y, Pandit K, Joseph S, Weiner MG. A randomized trial of peer coach and office staff support to reduce coronary heart disease risk in African-Americans with uncontrolled hypertension. *J Gen Intern Med* 2012;27:1258–1264.
20 Willard-Grace R, Chen EH, Hessler D, DeVore D, Prado C, Bodenheimer T, *et al*. Health coaching by medical assistants to improve control of diabetes, hypertension, and hyperlipidemia in low-income patients: a randomized controlled trial. *Ann Fam Med* 2015;13:130–138.
21 Palmer S, Tibbs I, Whybrow A. Health coaching to facilitate the promotion of healthy behaviour and achievement of health-related goals. *Int J Health Promot Educ* 2003;41:91–93.
22 Kivelä K, Elo S, Kyngäs H, Kääriäinen M. The effects of health coaching on adult patients with chronic diseases: a systematic review. *Patient Educ Couns* 2014;97:147–157.
23 Olsen JM, Nesbitt BJ. Health coaching to improve healthy lifestyle behaviors: an integrative review. *Am J Health Promot* 2010;25:e1–e12.
24 Dransfield MT, Bailey WC. COPD: racial disparities in susceptibility, treatment, and outcomes. *Clin Chest Med* 2006;27:463–471.
25 Wilper AP, Woolhandler S, Lasser KE, McCormick D, Bor DH, Himmelstein DU. A national study of chronic disease prevalence and access to care in uninsured U.S. adults. *Ann Intern Med* 2008;149:170–176.
26 Jackson K, Oelke ND, Besner J, Harrison A. Patient journey: implications for improving and integrating care for older adults with chronic obstructive pulmonary disease. *Can J Aging* 2012;31:223–233.
27 Bucknall CE, Miller G, Lloyd SM, Cleland J, McCluskey S, Cotton M, *et al*. Glasgow Supported Self-Management Trial (GSuST) for patients with moderate to severe COPD: randomised controlled trial. *BMJ* 2012;344:e1060.
28 Wood-Baker R, Reid D, Robinson A, Walters EH. Clinical trial of community nurse mentoring to improve self-management in patients with chronic obstructive pulmonary disease. *Int J Chron Obstruct Pulmon Dis* 2012;7:407–413.
29 Ashmore J, Russo R, Peoples J, Sloan J, Jackson BE, Bae S, *et al*. Chronic Obstructive Pulmonary Disease Self-Management Activation Research Trial (COPD-SMART): design and methods. *Contemp Clin Trials* 2013;35:77–86.
30 Coultas DB, Jackson BE, Russo R, Peoples J, Sloan J, Singh KP, *et al*. A lifestyle physical activity intervention for patients with chronic obstructive pulmonary disease: a randomized controlled trial. *Ann Am Thorac Soc* 2016;13:617–626.
31 Khdour MR, Kidney JC, Smyth BM, McElnay JC. Clinical pharmacy-led disease and medicine management programme for patients with COPD. *Br J Clin Pharmacol* 2009;68:588–598.
32 Efraimsson EO, Hillervik C, Ehrenberg A. Effects of COPD self-care management education at a nurse-led primary health care clinic. *Scand J Caring Sci* 2008;22:178–185.
33 Benzo R, Vickers K, Novotny PJ, Tucker S, Hoult J, Neuenfeldt P, *et al*. Health coaching and chronic obstructive pulmonary disease rehospitalization: a randomized study. *Am J Respir Crit Care Med* 2016;194:672–680.
34 Huang B, Willard-Grace R, De Vore D, Wolf J, Chirinos C, Tsao S, *et al*. Health coaching to improve self-management and quality of life for low income patients with chronic obstructive pulmonary disease (COPD): protocol for a randomized controlled trial. *BMC Pulm Med* 2017;17:90.
35 Willard-Grace R, DeVore D, Chen EH, Hessler D, Bodenheimer T, Thom DH. The effectiveness of medical assistant health coaching for low-income patients with uncontrolled diabetes, hypertension, and hyperlipidemia: protocol for a randomized controlled trial and baseline characteristics of the study population. *BMC Fam Pract* 2013;14:27.
36 Schünemann HJ, Goldstein R, Mador MJ, McKim D, Stahl E, Puhan M, *et al*. A randomised trial to evaluate the self-administered standardised chronic respiratory questionnaire. *Eur Respir J* 2005;25:31–40.
37 Schünemann HJ, Puhan M, Goldstein R, Jaeschke R, Guyatt GH. Measurement properties and interpretability of the Chronic Respiratory Disease Questionnaire (CRQ). *COPD* 2005;2:81–89.
38 Weldam SW, Schuurmans MJ, Liu R, Lammers JW. Evaluation of quality of life instruments for use in COPD care and research: a systematic review. *Int J Nurs Stud* 2013;50:688–707.
39 Davies N, Gibbons E, Fitzpatrick R. A structured review of patient-reported outcome measures for COPD: an update 2009. Oxford, UK: Patient-Reported Outcome Measurement Group, University of Oxford; 2009 [accessed 2018 May 20]. Available from: http://phi.uhce.ox.ac.uk/pdf/COPD2009_FINAL.pdf
40 ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. American Thoracic Society statement: guidelines for the six-minute walk test. *Am J Respir Crit Care Med* 2002;166:111–117.
41 Guyatt GH, Sullivan MJ, Thompson PJ, Fallen EL, Pugsley SO, Taylor DW, *et al*. The 6-minute walk: a new measure of exercise capacity in patients with chronic heart failure. *Can Med Assoc J* 1985;132:919–923.
42 Lorig KR, Ritter PL, Laurent DD, Plant K. Internet-based chronic disease self-management: a randomized trial. *Med Care* 2006;44:964–971.
43 Jones PW, Harding G, Berry P, Wiklund I, Chen WH, Kline Leidy N. Development and first validation of the COPD Assessment Test. *Eur Respir J* 2009;34:648–654.

44 Jones PW, Harding G, Wiklund I, Berry P, Tabberer M, Yu R, *et al*. Tests of the responsiveness of the COPD Assessment Test following acute exacerbation and pulmonary rehabilitation. *Chest* 2012;142:134–140.
45 Kon SS, Canavan JL, Jones SE, Nolan CM, Clark AL, Dickson MJ, *et al*. Minimum clinically important difference for the COPD Assessment Test: a prospective analysis. *Lancet Respir Med* 2014;2:195–203.
46 Glasgow RE, Wagner EH, Schaefer J, Mahoney LD, Reid RJ, Greene SM. Development and validation of the Patient Assessment of Chronic Illness Care (PACIC). *Med Care* 2005;43:436–444.
47 Gugiu PC, Coryn C, Clark R, Kuehn A. Development and evaluation of the short version of the Patient Assessment of Chronic Illness Care instrument. *Chronic Illn* 2009;5:268–276.
48 Kroenke K, Strine TW, Spitzer RL, Williams JB, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. *J Affect Disord* 2009;114:163–173.
49 Calverley PM. Minimal clinically important difference—exacerbations of COPD. *COPD* 2005;2:143–148.
50 Holland AE, Hill CJ, Rasekaba T, Lee A, Naughton MT, McDonald CF. Updating the minimal important difference for six-minute walk distance in patients with chronic obstructive pulmonary disease. *Arch Phys Med Rehabil* 2010;91:221–225.
51 Fairclough DL. Design and analysis of quality of life studies in clinical trials: interdisciplinary statistics. Boca Raton, FL: Chapman & Hall/CRC; 2002.
52 Little RJA, Rubin DB. Statistical analysis with missing data. New York: Wiley; 1987.
53 Kraemer HC, Wilson GT, Fairburn CG, Agras WS. Mediators and moderators of treatment effects in randomized clinical trials. *Arch Gen Psychiatry* 2002;59:877–883.
54 Raudenbush SW, Bryk AS. Hierarchical linear models: applications and data analysis methods. 2nd ed. Thousand Oaks, CA: Sage Publications; 2002.
55 Hedeker DR, Gibbons RD. Longitudinal data analysis. Hoboken, NJ: Wiley-Interscience; 2006.
56 Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. *Am J Health Promot* 1997;12:38–48.
57 Miller WR, Rose GS. Toward a theory of motivational interviewing. *Am Psychol* 2009;64:527–537.
58 Clark NM, Gong M, Kaciroti N. A model of self-regulation for control of chronic disease. *Health Educ Behav* 2001;28:769–782.
59 Steurer-Stey C, Dalla Lana K, Braun J, Ter Riet G, Puhan MA. Effects of the "Living Well with COPD" intervention in primary care: a comparative study. *Eur Respir J* 2018;51:1701375.
60 Chew LD, Griffin JM, Partin MR, Noorbaloochi S, Grill JP, Snyder A, *et al*. Validation of screening questions for limited health literacy in a large VA outpatient population. *J Gen Intern Med* 2008;23:561–566.