Published in final edited form as:
Psychosom Med. 2014 October ; 76(8): 581–592. doi:10.1097/PSY.0000000000000101.

The Effects of a Telehealth Coping Skills Intervention on Outcomes in Chronic Obstructive Pulmonary Disease: Primary Results from the INSPIRE-II Study

James A. Blumenthal, PhD, **Charles F. Emery, PhD**, **Patrick J. Smith, PhD**, **Francis J. Keefe, PhD**, **Karen Welty-Wolf, MD**, **Stephanie Mabe, MS**, **Tereza Martinu, MD**, **Julie J. Johnson, PA-C**, **Michael A. Babyak, PhD**, **Virginia F. O'Hayer, PhD**, **Philip T. Diaz, MD**, **Michael Durheim, MD**, **Donald Baucom, PhD**, and **Scott M. Palmer, MD**
Department of Psychiatry and Behavioral Sciences (JAB, FJK, SM, JJJ, MAB, PJS, VFOH), the Department of Medicine (SMP, KW-W, TM, MD), Duke University Medical Center, Durham, NC, and the Durham Veteran's Administration Hospital (KW-W), the Department of Psychology, University of North Carolina, Chapel Hill, NC (DB), and the Department of Psychology (CFE) and the Department of Medicine (PTD), Ohio State University, Columbus, OH

Abstract

Objective—Chronic obstructive pulmonary disease (COPD) is associated with increased morbidity and mortality and reduced quality of life. Novel interventions are needed to improve outcomes in COPD patients. The present study assessed the effects of a telephone-based coping skills intervention on psychological and somatic quality of life and on the combined medical endpoint of COPD-related hospitalizations and all-cause mortality.

Methods—We conducted a dual-site, randomized clinical trial with assessments at baseline and after 16 weeks of treatment. The study population comprised 326 outpatients with COPD aged 38 to 81 years, randomized to Coping Skills training (CST) or to COPD Education (COPD-ED). Patients completed a battery of quality of life (QoL) instruments, pulmonary function tests, and functional measures and were followed for up to 4.4 years to assess medical outcomes.

Results—The CST group exhibited greater improvements in psychological QoL compared to controls (P = .001), including less depression (Cohen's d=0.22 [95%CI 0.08, 0.36]) and anxiety (d=0.17 [95%CI 0.02, 0.33]), and better overall mental health (d=0.17 [95%CI 0.03, 0.32]), emotional role functioning (d= 0.29 [95%CI 0.10, 0.48]), vitality (d= 0.27 [95%CI 0.11, 0.42]), and social functioning (d= 0.21 [95%CI 0.03, 0.38]). A significant baseline psychological QoL by Treatment group interaction revealed that CST with lower QoL at baseline achieved even greater improvements in psychological QoL compared to COPE-ED. CST participants also exhibited

Corresponding author: James A. Blumenthal, Ph.D., Department of Psychiatry and Behavioral Sciences, Box 3119, Duke University Medical Center, Durham, NC 27710 Tel: (919) 684-3828; Fax: (919) 684-8629; Blume003@mc.duke.edu.

Author contributions: Dr. Blumenthal had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analyses. *Study concept and design*: Blumenthal, Emery, Keefe, Baucom, Palmer; *Acquisition of data*: Blumenthal, Emery, Palmer, O'Hayer, Keefe, Smith, Johnson, Mabe, Welty-Wolf, Martinu, Diaz; *Analysis and interpretation of data*: Blumenthal, Babyak, Palmer, Durheim, Smith; *Drafting of the manuscript*: Blumenthal, Smith; *Critical revision of the manuscript for important intellectual content*: Babyak, Emery, Palmer, O'Hayer, Keefe, Baucom, Durheim, Martinu, Mabe, Welty-Wolf, Johnson; *Statistical analysis:* Smith, Babyak; *Administrative, technical and material support*: Blumenthal, Emery, Johnson, Mabe, Welty-Wolf, Smith; *Study supervision:* Blumenthal, Johnson, Emery, Keefe, O'Hayer.

greater improvements in Somatic QoL (P = .042), including greater improvements in pulmonary QoL (d= 0.13 [95%CI 0.01, 0.24]), less fatigue (d= 0.34 [95%CI 0.18, 0.50]), and less shortness of breath (d= 0.11 [95%CI −0.01, 0.23]) and greater improvement in distance walked on the 6 Minute Walk Test (d= 0.09 [95%CI 0.01, 0.16]). However, there was no significant difference in risk of time to COPD-related hospitalization or all-cause mortality between CST (34 events) and COPD-ED (32 events) (P= 0.430).

Conclusions—A telehealth coping skills training intervention produced clinically meaningful improvements in quality of life and functional capacity, but no overall improvement in risk of COPD-related hospitalization and all-cause mortality.

Trial Registration—clinicaltrials.gov Identifier NCT00736268

Keywords

COPD; stress; depression; coping skills; disease-management

Chronic Obstructive Pulmonary Disease (COPD) is widely recognized as a growing health problem in this country, affecting an estimated 15 million Americans.(1) COPD exacerbations are responsible for more than 800,000 hospital admissions in the United States each year, and there were 143,000 deaths attributed to COPD in 2011, making it the third leading cause of mortality in the United States.(2) Furthermore, acute exacerbations accelerate decline in lung function, reduce patients' quality of life (QoL), and increase health care use.(3) In recognition of the importance of QoL, the Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD) included an assessment of pulmonary symptoms in the revised disease severity assessment.(3)

Given the significant symptom burden and functional impairment associated with COPD, it is not surprising that studies have consistently documented the high prevalence of psychological distress among COPD patients compared to the general population.(4) This distress is apparent in the high rates of anxiety and depression observed in studies of COPD patients,(5–8) and has a profound adverse impact on QoL and physical functioning.(9–12) COPD patients with comorbid depression and anxiety report lower QoL,(11) and patients with greater physical symptoms also experience higher levels of psychological distress.(13) Increased levels of distress have been shown to be related to impaired functional capacity(14) over and above disease severity.(15) In fact, QoL is only weakly related to pulmonary function,(16) and there is evidence that higher levels of distress also may affect disease progression. (17) Despite the well-documented impact of psychological distress on the physical and emotional functioning of patients with COPD, these psychological symptoms commonly remain under-recognized and untreated.(18)

Improving patients' management of their disease has become increasingly recognized as being important in optimizing medical outcomes, and patient-centered outcomes are themselves now considered important therapeutic targets.(19) Disease self-management refers to patients' ability to manage their symptoms and to adopt health behaviors that enhance their QoL. In this manner, self-management requires patients' active engagement in managing their own health condition.(20, 21) Although a variety of strategies have been

used to promote self-management, most studies of COPD patients have relied primarily on educational approaches, with mixed results.(22) Telehealth interventions in COPD also have provided inconsistent results, with efforts directed primarily at improving medical management rather than at improving patients' ability to manage their own symptoms.(23, 24) Current clinical practice guidelines emphasize smoking cessation, education, pulmonary rehabilitation, nutrition, oxygen therapy, medications, and, surgery if necessary.(25, 26) However, few studies have focused on stress reduction or teaching patients strategies for coping more effectively with their illness.

The goal of the present study was to evaluate the efficacy of a telehealth coping skills training (CST) intervention for improving QoL and medical outcomes in COPD patients by helping them develop skills for coping more effectively with their disease. The CST intervention was initially developed for patients with end-stage lung disease awaiting lung transplantation. Results of our previous randomized clinical trial (RCT), known as the Investigational Study of Psychological Intervention in Recipients of Lung Transplant (INSPIRE) trial,(27) showed that CST improved psychological QoL, but did not improve somatic QoL or overall survival. In the present RCT, we modified the CST intervention and extended it to a broader population of COPD patients who are not transplant candidates. In recognition of the potential value of involving patient caregivers in the treatment program, (21) we included partners in the intervention whenever possible. Also, in order to potentially improve functional capacity and reduce somatic symptoms, we included a physical activity module to include in the CST intervention. Thus, INSPIRE-II sought to determine if a coping skills intervention, delivered over the telephone, compared to COPD education, would improve indices of psychological and somatic QoL and improve the combined medical outcome of all-cause mortality and COPD-hospitalizations in a relatively large sample of COPD outpatients.

METHODS

Eligibility and Trial Overview

A description of the rationale and methods of the INSPIRE-II trial has been published previously.(28) INSPIRE-II is a dual-site (Duke University Medical Center and Ohio State University), RCT of CST versus COPD education in patients diagnosed with COPD, with FEV_1 25–80% of predicted within 6 months of study enrollment; FEV_1/FVC <70%; and capacity to follow study procedures. Participants were required to have a caregiver or partner to participate unless they were unmarried or had no friends or family members; patients that had a caregiver who was unwilling to participate were ineligible. The protocol was approved by the respective Institutional Review Boards at Duke and Ohio State. All patients voluntarily provided written informed consent. Our first patient was randomized on January 5, 2009 and the last follow-up was completed May 30, 2013.

Assessment procedures

Patients completed an assessment battery tapping both psychosocial and somatic/physical QoL domains in the week before and the week following the 16-week telehealth intervention.

Psychological Quality of Life

Beck Depression Inventory II (BDI-II): (29) The 21-item BDI-II is a widely used measure of depression among medical patients and has been shown to have good one-week test-retest reliability (r = 0.93). BDI-II scores ≥ 14 are suggestive of clinically significant depression.

State-Trait Anxiety Inventory-State (STAI): (30) The 20-item STAI was used to assess levels of state anxiety. Test-retest reliability has been shown to be high, with 2-month reliabilities ranging from 0.65 to 0.75. (31) STAI scores ≥ 45 are suggestive of clinically elevated anxiety in medical patients.(32)

Short Form-36 Health Survey (SF-36): (33) The SF-36 measures psychological QoL in four domains: social functioning, role limitations due to emotional problems, vitality, and mental health. The SF-36 has excellent test-retest reliability with coefficients ranging from 0.73 to 0.96 over a two-week period.(34) Higher scores indicate better quality of life.

Somatic Quality of Life

Pulmonary Quality of Life Scale (PQLS): (35) The 25-item PQLS, was designed to assess health-related QoL among individuals with pulmonary disease. The PQLS has been shown to have high internal consistency (0.87) and correlates well with other indices of pulmonary QoL.(36) Higher scores indicate better somatic quality of life.

UCSD Shortness of Breath Questionnaire (SOBQ): (37) The 24-item SOBQ has been shown to have good reliability, with a test-retest reliability of 0.94, and is highly correlated with measures of pulmonary function and functional status.(37, 38) Lower scores indicate less shortness of breath.

Short Form-36 Health Survey (SF-36): The SF-36 is a self-report questionnaire that measures physical QoL in four domains: physical functioning, role limitations due to physical problems, pain, and general health perception. The SF-36 has been found to have excellent test-retest reliability with coefficients generally exceeding 0.85 over a two-week period. (34)

Brief Fatigue Inventory (BFI): (39) The BFI is a 9-item scale to assess fatigue. All items are rated on numeric scale from 0 to 10 with higher scores indicating greater fatigue. The BFI has excellent reliability, with a Cronbach's alpha of 0.96. Lower scores indicate less fatigue.

St. George's Respiratory Questionnaire (SGRQ): (40) The SGRQ is a 50-item scale that evaluates symptomatology (e.g., frequency of cough, sputum production, wheeze, breathlessness), activity (activities that cause or are affected by breathlessness), and impacts (on employment, need for medications, disruption of daily life). The SGRQ has been shown to have good reliability, with a Cronbach's alpha of ≥ 0.76.(41) Lower scores indicate better quality of life.

Pulmonary Function, Physical Activity, and Exercise Tolerance—Spirometry was performed in accordance with guidelines established by the American Thoracic Society. (42) Patients also completed a standard Six-Minute Walk test (6MWT)(43) to determine exercise tolerance by measuring the distance that patients were able to walk within a 6-minute time limit at a self-selected pace, with adequate oxygen to maintain saturations of 90% or greater. The Charlson Medical Comorbidity Index(44) was used to assess the cumulative burden of medical comorbidity. In addition, the Global Initiative for Chronic Obstructive Lung Disease (GOLD) system was used to classify patients into risk categories labeled A-D based on FEV_1 and self-reported respiratory symptomatology.(45, 46)

Staff performing each of these assessments was blinded to treatment condition.

Miscellaneous Questionnaires

Brief COPE: (47) The 28-item COPE was used to assesses dispositional coping and has been found to have good reliability, with indices generally exceeding 0.60.(48) For the purposes of this study, we identified 3 factors: Active coping, Disengagement, and Support Seeking.

Perceived Social Support Scale (PSSS): (49) The 12-item PSSS measures perceived support from family and friends and has good test-retest reliability, with coefficients exceeding 0.70. (50) Higher scores indicate greater perceived support.

CHAMPS Activities Questionnaire: (51) The CHAMPS is a self-report measure of physical activity that was used to quantify patients' typical activity level and to develop activity recommendations for the CST intervention. The CHAMPS has good test-retest reliability with coefficients for most indices exceeding 0.60. (52)

Marital Satisfaction Inventory: (53) For the subset of patients who had partners or caregivers, we administered the Affective Communication and Problem Solving subscales from the Marital Satisfaction Inventory, which has a test-retest reliability of 0.89. (54)

Caregiver Strain Index: (55) In recognition of the psychological impact of caregiving for patients with COPD,(56) caregivers completed the 13-Item Caregiver Strain Index, which assesses a variety of stressors commonly experienced by caregivers.(57) The Caregiver Strain Index has an internal reliability of 0.86. (55)

Medical Endpoints—Patients documented all medical encounters every 6 months. Medical records were reviewed by a physician assistant and a consensus conference of pulmonologists, blinded to treatment condition, adjudicated all medical events. The primary medical endpoint was defined as the combined endpoint of time to death from any cause or first COPD-related hospitalization.

Telehealth Interventions

Patients were randomized 1:1 either to Coping Skills Training (CST) or to COPD education (COPD-ED). Randomization was performed centrally by computer with conditional randomization (stratified by availability of a caregiver, FEV_1, gender, and current smoking

status) separately by site. Medications and other general aspects of COPD management were left to the discretion of participants' primary care providers and/or pulmonologists.

Coping Skills Training—CST provided instruction in cognitive-behavioral coping skills delivered to patients and partners over the telephone by clinical psychologists weekly for 12 weeks and biweekly for 1 month (14 sessions total over 16 weeks). The interventionists received training in the delivery of the CST intervention by experienced clinical psychologists (FJK, VO'H, JAB) who provided weekly supervision throughout the trial. Sessions were audiotaped and each audiorecording was reviewed using criteria for treatment fidelity (e.g., appropriate delivery of key session components, appropriate use of time in session) and therapist competence (e.g., use of interviewing skills, eliciting patient engagement, dealing with resistance) using procedures that we employed previously. (27) Each therapist was credentialed on pilot subjects for each of the 14 sessions prior to delivering the session to a study participant.

The CST protocol was manualized and included four components: 1) education about stress and pulmonary health; 2) training in a variety of coping skills (e.g., relaxation, problem-solving, cognitive restructuring); 3) promotion of physical activity (an individualized activity prescription based on FEV_1 values, Charlson Comorbidity Index Score, and baseline 6MWT performance, along with self-reported activities on the CHAMPS questionnaire was used to make personalized activity recommendations); and 4) maintenance and generalization. Caregivers participated fully in all sessions to facilitate communication between the patient and caregiver regarding the use of coping strategies to control symptoms and reduce distress, to prompt and reinforce patients' efforts to cope with COPD symptoms, and promote adherence to prescribed homework assignments. Each session was designed to last for 30 minutes.

COPD Education—Participants in COPD-ED received their usual care through their local physicians. Patients and their respective caregivers also received COPD education delivered via a series of 12 weekly and 2 biweekly telephone calls from a health educator (JJJ) with experience in the management of COPD. Each session began with a brief medical review of the prior week that provided patients (and caregivers) with an opportunity to discuss the patient's current treatment and symptoms. Each of the weekly educational discussions focused on a topic relevant for COPD management and included such topics as pulmonary physiology, medication usage, nutrition, and symptom management. The COPD-ED intervention was designed to provide attention, support, and relevant information about COPD, without providing instruction in specific coping strategies. Caregivers were encouraged to participate fully in all discussions.

Statistical analysis

Treatment effects on psychological and somatic QoL were evaluated using linear models with maximum likelihood estimation available in Muthen's Mplus software.(58) The latent variable *Psychological QoL* was comprised of scores on the BDI-II, STAI, SF-36 Mental Health, SF-36 Emotional Functioning, SF-36 Vitality, and SF-36 Social Functioning. The *Somatic QoL* latent variable was comprised of scores on the PQLS, SGRQ, BFI, SOBQ,

SF-36 Physical Role, SF-36 General Health, SF-36 Physical Functioning, and SF-36 Pain. Treatment group was the primary effect of interest, and age, gender, race, treatment site, oxygen utilization, FEV_1, and the corresponding baseline level of the outcome variable were included as adjustment covariables. If the latent variable model showed a significant treatment effect, follow-up analyses were conducted using the general linear model for each separate indicator of that latent variable. The primary models followed the intention-to-treat principle using the full information maximum likelihood method for managing missing data, available in Mplus.(59) Patients with and without an available caregiver were analyzed separately, but because the results were essentially the same, patients were combined in the reported analyses. Effect sizes for group differences were calculated using Cohen's *d*.(60)

We evaluated the effects of treatment on medical events with a logrank test for time to death or first hospitalization during the follow-up period. In this analysis, we used Cox regression, with the first clinical event coded as the event, and those participants with no events or who dropped out were censored at the time of last contact. We evaluated the extent to which models met assumptions, including additivity, linearity, and distribution of residuals. We found no evidence of significant violations of these assumptions.

RESULTS

Patient Characteristics

A total of 434 patients were initially considered eligible for the trial (Figure 1); 36 were classified as medically unstable, 30 were excluded because they were found not to have COPD by spirometric criteria, 24 declined to participate, 17 were excluded because their caregiver was unwilling to participate, and one was excluded because of advanced age, leaving 326 patients available for randomization: 162 patients were randomly assigned to CST and 164 were assigned to COPD-ED. Two hundred fifty-two individuals had a caregiver (77%); 63 participants from OSU had a caregiver (64%) and 189 participants from DUMC had a caregiver (83%); 74 patients without an identified caregiver were randomized and included in the analyses.

The mean age of the sample was 66.1 years and the majority of patients were Caucasian. The treatment groups were similar on background characteristics, including age, gender, ethnicity, and medical background variables including FEV_1 and performance on the 6MWT (Table 1).

Treatment Adherence

Attendance on CST phone calls ranged from one to 14 sessions. The median number of completed sessions was 14 (100%); for COPD-ED, the median number of completed sessions also was 14 (100%). For CST, sessions averaged 32.6 minutes (SD=4.7) with a median of 32.2 minutes. For COPD-ED, sessions averaged 10.8 minutes (SD=4.7) with a median of 9.9 minutes. Twenty-two participants (6.7%) dropped out during the course of the study (13 in CST and 9 in COPD-ED); three participants died during the intervention period, all of whom were in COPD-ED.

Psychological Quality of Life Outcomes

The pre- and post-treatment means for Psychological QoL are presented in Table 2 along with post-treatment group contrasts, adjusting for age, gender, race, FEV_1, oxygen use, treatment site, and the corresponding baseline level of the outcome variable. The CST group exhibited greater improvements in Psychological QoL compared to participants in COPD-ED (P = .001). Participants in the CST group exhibited less depression (d=0.22 [95%CI 0.08, 0.36]; P = .002) and anxiety (d=0.17 [95%CI 0.02, 0.33]; P= .030), and better overall mental health (d=0.17 [95%CI 0.03, 0.32]; P = .021), emotional role functioning (d= 0.29 [95%CI 0.10, 0.48]; P = .003), vitality (d= 0.27 [95%CI 0.11, 0.42]; P <.001), and social functioning (d= 0.21 [95%CI 0.03, 0.38]; P = .023).

Moderation—In addition to the overall treatment main effect for Psychological QoL, we also observed a significant baseline QoL by treatment group interaction (P = .037), indicating that there was a differential treatment response as a function of baseline levels of Psychological QoL. CST patients with lower Psychological QoL at baseline attained even greater improvements compared to COPD-ED patients (Figure 2). It is noteworthy, that the effect sizes for participants with low baseline QoL were moderate to high, suggesting clinically, as well as statistically, significant treatment group differences. For example, participants with baseline BDI-II scores ≥ 14 in CST showed greater reductions in depressive symptoms (M_{diff} = 4.6 [SE±1.1]) compared to COPD-ED controls (M_{diff} = 1.0 [SE=±1.2]) (d=0.46 [95%CI 0.14, 0.78], P = .006), whereas reductions in depressive symptoms were smaller among participants with BDI-II scores <14 (d = 0.22 [95%CI 0.00, 0.43], P = .048). Similarly, treatment effects were greater for individuals with clinically elevated anxiety (d = 0.66 [95%CI 0.13, 1.20], P = .019) compared to participants with STAI scores <45 (d=0.05 [95%CI −0.10, 0.21], P = 507). CST participants with baseline STAI scores ≥45 achieved a 10.6-point reduction (SE = ± 2.0) on the STAI compared to only a 3.1-point reduction (SE= ± 2.1) in COPD-ED patients with baseline STAI scores ≥45. The observed effects of treatment on psychological QoL were not moderated by age (P = .777), gender (P = .469), baseline FEV_1 (P = .833), or treatment site (P = .181).

Somatic Quality of Life Outcomes

Compared to COPE-ED, patients in CST exhibited greater improvements in Somatic QoL (P = .042). The pre- and post-treatment means and adjusted post-treatment group contrasts for Somatic QoL are presented in Table 3. Examination of separate somatic symptom measures revealed that participants in the CST group showed greater improvements in PQLS (d= 0.13 [95%CI 0.01, 0.24]; P = .040), less fatigue (d= 0.34 [95%CI 0.18, 0.50]; P < .0001), and less shortness of breath as measured by the St. George's Respiratory Questionnaire (d= 0.11 [95%CI −0.01, 0.23]; P= .068), but not the San Diego SOBQ (d= −0.01 [95%CI −0.12, 0.10];P = .859) compared to COPD-ED. There were no treatment group differences for SF-36 pain (d=0.01 [95%CI −0.16, 0.17];P= .947), SF-36 physical role (d= 0.10 [95%CI 0.08, 0.27]; P = .286), SF-36 general health (d= 0.09 [95%CI −0.05, 0.22]; P = .217), or SF-36 physical functioning (d= 0.07 [95%CI −0.05, 0.19]; P = .224). The observed treatment effects on Somatic QoL were not moderated by baseline somatic symptoms (P= .490), age (P = .388), gender (P = .176), baseline FEV_1 (P = .205), or treatment site (P = .130).

Pulmonary Function and Functional Status Outcomes

CST participants demonstrated greater improvement in distance walked on the 6MWT (d= 0.09 [95%CI 0.01, 0.16]; P = .030) compared to COPD-ED following treatment (Table 4). Participants in the CST group reported greater total activity (d= 0.19 [95%CI 0.00, 0.38]; P = .045) and total caloric expenditure (d= 0.21 [95%CI 0.03, 0.38] P = .022) on the CHAMPS compared to COPD-ED. There were no group differences with respect to changes in FEV_1 (d= 0.01 [95%CI −0.09, 0.12]; P = .796).

Additional Psychosocial Outcomes

The CST group also reported greater social support (M= 66.4 [95%CI 63.9, 69.0] vs. 63.2 [95%CI 60.6, 65.7]; P = .018) following treatment and, for those participants with a caregiver, greater improvements in communication as measured by the Marital Satisfaction Inventory Affective Communication (CST: M= 2.9 [95%CI 2.4, 3.3] vs. COPD-ED: 3.7 [95%CI 3.3, 4.1]; P = .011) and Problem Solving subscales (CST: M = 6.0 [95%CI 5.3, 6.6] vs. COPD-ED: 7.2 [95%CI 6.6, 7.8], P = .008) compared to patients in COPD-ED. Among caregivers, there were no treatment group differences in caregiver strain (CST: M= 5.4 [95%CI 4.5, 6.3] vs. COPD-ED: 5.1 [95%CI 4.3, 6.0]; P = .531).

Changes in Coping

In order to examine treatment effects on coping skills, we examined the impact of treatment on three latent coping variables, which were determined by maximum-likelihood factor analysis. A factor analysis yielded three coping latent variables, which we labeled *Active coping*, *Disengagement*, and *Support Seeking*. The Active coping (hereafter referred to as *Active*) was comprised of the Active, Planning, Acceptance, and Positive Reframing subscales from the COPE. The *Disengagement* latent variable was comprised of the Behavioral Disengagement, Blame, Denial, and Venting subscales. The *Support Seeking* latent variable was comprised of the Emotional Support Seeking, Instrumental Support Seeking, and Religion subscales. The loadings of the indicators for the coping variables ranged from .50 to .87 at both pre- and post-treatment assessments, with three minor exceptions (the Religion subscale loaded with the Support Seeking latent variable .37 before treatment and .32 after treatment and the Venting subscale loaded on the Disengagement latent variable at .44 before treatment. Although these loadings were not very strong, we allowed them to remain as indicators of their respective latent variables).

Examination of changes in coping styles revealed that the CST group showed greater improvements in the Active (P < .001) and Support Seeking latent variables (P = .005), but not on the Disengagement latent variable (P= .649). CST participants showed improvements in the Active (d = .30 [95%CI 0.21, 0.50], P = .003), Seeking Instrumental Support (d = 0.21 [95%CI 0.01, 0.41], P = .044), Seeking Emotional Support (d = 0.25 [95%CI 0.07, 0.43], P = .008), Acceptance (d = 0.33 [95%CI 0.13, 0.53], P = .002), Positive Reframing (d = 0.28 [95%CI 0.08, 0.47], P = .006), Distraction (d = 0.24 [95%CI 0.05, 0.44], P = .016), Blaming (d = 0.17 [95%CI −0.01, 0.34], P = .064) and Planning (d = 0.19 [95%CI −0.01, 0.38], P = .067) compared with COPE-ED participants (Table 5). In contrast, the groups did not differ in use of Religion (d = 0.02 [95%CI −0.11, 0.15], P = .726), Venting (d = 0.13 [95%CI −0.06, 0.31], P = .192), Denial (d = 0.06 [95%CI −0.14, 0.26], P = .529), Behavioral

Disengagement (d = 0.05 [95%CI −0.16, 0.25], P = .659), Substance Use (d = 0.04 [95%CI −0.13, 0.27], P = .656), or Humor (d = 0.08 [95%CI −0.12, 0.27], P = .451).

Mediational Analyses

We examined changes in coping style, as measured by the Brief COPE Inventory, as a potential mediator of the relationship of treatment group and Psychological QoL, while changes in 6MWT distance was considered as a potential mediator of treatment group and Somatic QoL. When the mediating paths (COPE latent variables) were included in the model, the direct effect of CST on Psychological QoL persisted (standardized coefficient = .12, P = .002); there was minimal evidence that the impact of CST on psychological QoL was mediated by improved by Active coping (P = .848), Disengagement (P = .617), or Support Seeking (P = .096).

In contrast, when the mediating path from CST to 6MWT to Somatic QoL was included in the model, the direct effect of CST on Somatic QoL was no longer significant (standardized coefficient = .07, P =.213), suggesting that the impact of CST on improved Somatic QoL was mediated by improvements in 6MWT (P = .032).

Survival and Medical Event Outcomes

Follow-up time varied from 0.4 to 4.4 years with a median follow-up time of 2.5 years (SD = 1.04 years). There were 11 deaths over the course of the study, 3 in CST and 8 in COPD-ED. For time-to-event analyses, there were 34 first events in CST group and 32 in the COPD-ED group. There was no difference between CST and COPD-ED in time to death or first COPD-related hospitalization (P = .430) (Figure 3).

DISCUSSION

COPD is a chronic and debilitating condition that affects millions of Americans and results in significant impairments in emotional well-being, physical functioning, and quality of life, as well as increased morbidity and mortality. Psychological distress negatively impacts quality of life, (9, 10) and functional capacity(14) and promotes disease progression (17) and risk for mortality in patients with COPD.(61) In an effort to improve QoL, reduce distress, and improve clinical outcomes, we conducted a dual-site, RCT to evaluate the effects of a partner-assisted telehealth coping skills training intervention in COPD patients. Although CST did not improve the combined medical endpoint of COPD-related hospitalization and all-cause mortality compared to COPD-ED, CST was associated with significant improvements in psychosocial QoL, including reduced depression and anxiety, greater vitality, improved social and emotional role functioning, and better overall mental health. For those participants with caregivers, patients in CST reported greater improvement in communication compared to patients in COPD-ED, which is considered important because COPD is known to adversely affect partner communication.(62, 63) CST participants also reported greater improvements in somatic QoL compared to COPD-ED, reporting less fatigue and shortness of breath and increased functional capacity as measured by the 6MWT and increased physical activity as measured by the CHAMPS. The CST intervention employed in INSPIRE II encouraged increased physical activity, which appeared to enhance

the effectiveness of CST in improving QoL. Indeed, regular exercise is a key component of pulmonary rehabilitation and has been shown to improve QoL and functional capacity in a number of studies.(64–67) Furthermore, mediational analyses revealed that improved functional capacity contributed to the improvements in somatic symptoms and somatic QoL achieved by CST participants.

The improvements in QoL for CST compared to COPD-ED were statistically significant; however, the effect sizes were relatively modest, and generally were in the range of d= 0.2 to 0.4. Because INSPIRE-II recruited COPD patients regardless of their initial level of distress and QoL at study entry, the effect sizes for the entire sample do not fully capture the clinical value of treatment. The baseline psychological QoL by treatment group interaction revealed that patients who entered the trial with diminished psychological QoL benefitted the most from CST. CST patients with greater distress at study entry achieved clinically, as well as statistically, significant improvements. For example, CST patients who obtained baseline BDI-II scores ≥14 had a 4.6-point reduction compared to only 1.0-points for patients in COPD-ED; the effect size was d= 0.46. Similarly, patients who obtained STAI scores ≥45 at study entry had a 10.6-point reduction if they were in CST compared to a 3.1-point reduction if they were in COPD-ED; the effect size was d= 0.66.

These improvements in anxiety and depression in our sample are especially noteworthy. Despite the high prevalence of depression in COPD,(68) less than half of depressed COPD patients are diagnosed and less than a third receive treatment.(18) In a review of treatments for depression in COPD patients, Fritzche et al.(69) noted that pharmacological and behavioral treatments in COPD patients were rare and inconsistent. Moreover, the small number of studies and poor methodologies contributed to heterogeneous results. In one of the better designed studies, Hynninen et al.(70) found CBT to improve depressive symptoms and Kunik et al.(71) reported that a single session of CBT reduced depressive symptoms in mildly depressed COPD patients. De Godoy and colleagues(72) reported that psychotherapy, when combined with pulmonary rehabilitation, showed improvements in anxiety, depression, QoL and functional capacity. Our findings demonstrate that a CST intervention also may be an effective treatment for patients with elevated depressive and anxiety symptoms who aren’t necessarily seeking psychiatric treatment for their distress.

Because there were many components to the CST intervention, it is not possible to determine which aspects of the program were most beneficial. In a cross sectional study, Scharloo et al.(73) studied 171 COPD outpatients in the Netherlands and found that illness representations, but not necessarily perceived control, were associated with improved QoL and suggested that interventions designed to discuss patients’ illness beliefs as well as helping patients develop behavioral skills to both manage their illness and cope more effectively with stress were likely to be most helpful. Although patients in CST improved their coping skills as evidenced by their higher scores on the Active and Support latent variables of the Brief COPE, mediational analyses provided little evidenced that improved coping was responsible for improved psychological QoL. The mechanisms responsible for the benefits of CST on psychological QoL remain uncertain.

There have been numerous reviews of telehealth interventions in COPD. McLean et al.(23) reviewed over 220 published reports consisting of 10 trials and 1004 patients. The interventions generally provided symptom management for COPD, without specific training in coping skills. Results indicated a reduction in emergency department visits and hospitalizations, but no reduction in mortality and no improvement in QoL compared to controls. In their review of home telemonitoring for COPD, Bolton and colleagues (24) identified only 2 randomized trials; however, methodological shortcomings, small sample sizes, and lack of detailed descriptions of the interventions led the authors to conclude that the benefits were inconclusive. Moreover, the interventions were geared to promote a response from health providers, presumably to reduce the risk of hospitalization by early intervention, rather than to teach patients skills to better manage their symptoms.

In a review of 6241 publications involving home telehealth, Polisena et al.(74) identified only nine original studies, including 858 COPD patients, of which four studies compared home telemonitoring with usual care and six RCTs compared telephone support with usual care. Only two RCTs were considered high quality. Clinical heterogeneity was present in many of the outcomes measured. Surprisingly, the mortality rates were greater in the telephone-support group compared with usual care (risk ratio = 1.21; 95% CI: 0.84 to 1.75), but telehealth interventions were similar or better than usual care for QoL and patient satisfaction outcomes. The interventions represented a mix of treatments and none specifically included training in coping skills.

In a review of educational programs for patients with COPD, Stoilkova, Janssen and Wouters (22) extracted 81 articles describing 67 educational interventions. In two-thirds of the studies, the topic of stress management was discussed. Most educational programs were delivered in an outpatient hospital setting, while a third were provided by telephone calls from nurses and less than 5% were delivered over the internet or using telehealth technology. The authors did not comment on which educational topics contributed to behavior change and optimal disease management, and did not compare the various modes by which education were delivered. The lack of consistency in results across studies was attributed to variations in study design, diversity in interventions and outcome measures, and important methodological flaws that characterized many studies.

Lemmens, Nieboer, and Jijsman(75) conducted a systematic review of multiple disease-management interventions in asthma and COPD. Thirty-six studies met their inclusion criteria, with studies often comparing an education-based intervention for patients and/or health professionals such as physicians or pharmacists in combination with case management to usual care. Because of the heterogeneity of patient groups and interventions, and the inconsistent pattern of results, it was difficult to draw any firm conclusions. No differences were noted between intervention and control groups on lung function or symptoms, although multiple interventions tended to be associated with greater improvements in QoL and reduced hospitalizations, but not in the number of emergency department visits.

A review by Niesink and colleagues (76) identified 10 education interventions, nine of which also included exercise training. Other elements of the programs included support,

relaxation training, smoking cessation, breathing retraining, recreational activities and occupational therapy. None specifically involved coping skills training, however. Five of the 10 studies showed positive effects on at least one of the measures of QoL compared to controls. However, it was noted that all of the trials were small (N<30 participants per group) and involved pulmonary rehabilitation, which has been shown to be effective in improving QoL regardless of whether it was part of integrated care.

Similarly, in a meta analysis of 23 RCTs of pulmonary rehabilitation, Lacasse (64) also showed improved QoL, irrespective of whether or not participants were part of integrated care. Several RCTs are especially relevant to the present study. Walters and colleagues(77) randomized 182 adults with COPD to a health mentoring intervention delivered by community nurses or to usual care and brief telephone calls. The health mentoring consisted of a series of 16 30-minute phone calls over 12 months that targeted smoking, nutrition, alcohol, physical activity, psychological well-being, and symptom management. Patients in the control group received their usual care and monthly phone calls from a research nurse. Results showed that disease self-management was improved relative to the control group, but there was no difference in QoL. However, only a completers analysis was performed, and the health mentoring group had a high rate of dropout and non-adherence, completing a median of only 9 of 16 phone calls.

In another RCT of 115 patients with either heart failure (HF) or COPD, Gellis and colleagues(78) reported that a multifaceted 3-month “tele-HEART” intervention improved QoL and reduced emergency department visits after 12 months relative to usual care. The telehealth monitoring system was provided to patients to improve their self-management of their disease and patients obtained counseling about the importance of daily monitoring of body weight, smoking cessation, behavioral activation, diet, medication adherence, problem solving strategies on managing their medication and monitoring symptoms that could reflect worsening HF. Results revealed that the telehealth intervention group reported greater improvements in general health and social functioning and reduced depressive symptoms compared to the usual care plus education group. Only 27 COPD patients were included in the study, however, and only a completers analysis was performed. Because COPD and HF patients were combined, it was not possible to determine the benefits of the intervention in the subgroup of COPD patients.

Emery and colleagues(79) randomized 79 COPD patients to 10 weeks of exercise, education and stress management; education and stress management; or to a wait list control group. Stress management and education did not improve depressive or anxiety symptoms or health QoL compared to usual care, but the addition of exercise to stress management resulted in greater benefits compared to either stress management without exercise or to wait list controls. The exercise intervention was highly intensive (4–5 hours/day), involving daily supervised exercise for 5 weeks followed by intensive exercise 3 days per week for an additional 5 weeks. Because exercise was not offered without stress management, however, it could not be determined if exercise alone would have produced these same benefits.

Limitations

By design, participants in the CST intervention spent on average 20 minutes longer on the telephone (30 min vs 10 min) compared to COPD-ED. Although we intended the COPD-ED condition to provide a brief, standardized program that would simulate real-world clinical practice, it is possible that the additional time on the telephone may have contributed to greater QoL benefits for the CST group. We also note that the patients in COPD-ED also showed improvements in psychological and somatic QoL, although not to the extent of CST on most measures. Education itself has been shown to be beneficial (80), and Gadoury et al. (81) reported that an education program that also included "skill-oriented" teaching, resulted in reduced hospitalizations over a 2-year follow-up period compared to standard care controls. In light of these data, it is possible that both groups in our study may have improved their QoL and may have had less healthcare utilization than they would have received usual care without any telehealth intervention. We did not monitor medication use throughout the trial, so that the extent to which medication use contributed to the results could not be determined. We also did not perform an economic analysis and the cost-effectiveness of the CST intervention was not assessed.

Our study design also did not permit determination of which components of the CST intervention may have been most effective. Exercise programs for COPD patients have been shown to improve QoL, and the extent to which our relatively simple prescription for increasing physical activity may have contributed significantly to the improvements in QoL could not be determined. Although the CST intervention reduced psychological distress, improved somatic symptoms and functional capacity, CST did not result in fewer deaths or COPD-related hospitalizations. The premise that improved psychological function would lead to better COPD-related medical outcomes remains unconfirmed at this time.

In summary, this relatively brief, manualized coping skills training program delivered over the telephone improved patients' psychological and somatic QoL. Although the intervention did not reduce all-cause mortality and COPD-related hospitalizations, the beneficial effects on quality of life and functional status, especially among those patients who were experiencing high levels of distress, should not be minimized. This intervention can be easily incorporated into the routine care of COPD patients for whom more traditional mental health services may not be readily available.

Acknowledgments

Duke University Medical Center: James A. Blumenthal, PhD (Principal Investigator); Scott M. Palmer, MD (Medical Director); Michael A. Babyak, PhD, Virginia Fenwick O'Hayer, PhD, Francis J. Keefe, PhD, Donald Baucom, PhD, Julie J. Johnson, PA-C, Kylie Stott, BA, Rachael Funk, BA, Meredith McAdams, BA, Meghan Cooper, BS, Carla Ducci, BA, Amelia Hoyle, BA Tamara Greene, BA, Tamara Somers, PhD, Todd Doyle, PhD, Aric Prather, PhD, Michael Coons, PhD, Marquisha Green, PhD, Sonia Marrone, PhD, Amy Goetzinger, PhD, Candace Patterson, PhD, Krista Ingle, PhD, Patrick Smith, PhD, Stephanie Mabe, MA, Karen Welty-Wolf, MD, Tereza Martinu, MD, Ohio State University: Charles F. Emery, PhD (Principal Investigator), Andrea K. Busby, PhD, Amy Buser, PhD, Philip T. Diaz, MD, James Duade, MA, Jessica Ebie, MS, Heidi Gehring, BA, Diana Gieske, MA, Christina Goodwin, MS, Victoria Lee, MS, Risa Long, BA, Robert Nichols, BA, Alison Panetta, MS

The authors also wish to thank the members of the INSPIRE Data and Safety Monitoring Board, Diane Catellier, PhD, Robert Carney, PhD, and Alan Hinderliter, MD for their guidance and advice throughout the trial.

This research was supported by Grant No. HL 065503 from the National Institutes of Health, Bethesda, Maryland

Abbreviations

ACE inhibitors	Angiotensin Converting Enzyme Inhibitors
ARBs	Angiotensin II Receptor Antagonists
BDI-II	Beck Depression Inventory-II
BFI	Brief Fatigue Inventory
CI	confidence interval
COPD	Chronic Obstructive Pulmonary Disease
CST	Coping Skills Training
CE	Caloric Expenditure
ED	Education
FEV_1	forced expiratory volume
GOLD	Global Initiative for Chronic Obstructive Pulmonary Disease
ICS	Inhaled Corticosteroids
INSPIRE	Investigational Study of Psychological Intervention in Recipients of Lung Transplant
IQR	Interquartile Range
LABA	Long Acting Beta Agonist
LAMA	Long Acting Muscarinic Antagonist
PQLS	Pulmonary Quality of Life Scale
QoL	Quality of Life
RCT	Randomized Clinical Trial
SABA	Short Acting Beta Agonist
SD	Standard Deviation
SF-36	Short Form-36 Health Survey
SGRQ	St. George Respiratory Questionnaire
SOBQ	UCSD Shortness of Breath Questionnaire
SSRI	Selective Serotonin Reuptake Inhibitor
STAI	Spielberger State-Trait Anxiety Inventory
6MWT	Six Minute Walk Test

References

1. Chronic obstructive pulmonary disease (COPD). World Health Organization; http://www.who.int/mediacentre/factsheets/fs315/en/
2. Hoyert, DXJ. National vital statistics reports: deaths: preliminary data for 2011. Centers for Disease Control and Prevention; 2012.

3. Vestbo J, Hurd SS, Agusti AG, Jones PW, Vogelmeier C, Anzueto A, Barnes PJ, Fabbri LM, Martinez FJ, Nishimura M, Stockley RA, Sin DD, Rodriguez-Roisin R. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: GOLD executive summary. Am J Respir Crit Care Med. 2013; 187:347–65. [PubMed: 22878278]

4. van Manen JG, Bindels PJ, Dekker FW, Ijzermans CJ, van der Zee JS, Schade E. Risk of depression in patients with chronic obstructive pulmonary disease and its determinants. Thorax. 2002; 57:412–6. [PubMed: 11978917]

5. Lacasse Y, Rousseau L, Maltais F. Prevalence of depressive symptoms and depression in patients with severe oxygen-dependent chronic obstructive pulmonary disease. Journal of Cardiopulmonary Rehabilitation. 2001; 21:80–6. [PubMed: 11314288]

6. Dowson CA, Town GI, Frampton C, Mulder RT. Psychopathology and illness beliefs influence COPD self-management. J Psychosom Res. 2004; 56:333–40. [PubMed: 15046971]

7. Hynninen KM, Breitve MH, Wiborg AB, Pallesen S, Nordhus IH. Psychological characteristics of patients with chronic obstructive pulmonary disease: a review. J Psychosom Res. 2005; 59:429–43. [PubMed: 16310027]

8. Porzelius J, Vest M, Nochomovitz M. Respiratory function, cognitions, and panic in chronic obstructive pulmonary patients. Behav Res Ther. 1992; 30:75–7. [PubMed: 1540118]

9. Anderson KL. The effect of chronic obstructive pulmonary disease on quality of life. Res Nurs Health. 1995; 18:547–56. [PubMed: 7480855]

10. Brenes GA. Anxiety and chronic obstructive pulmonary disease: prevalence, impact and treatment. Psychosomatic Med. 2003; 65:963–70.

11. Felker B, Katon W, Hedrick SC, Rasmussen J, McKnight K, McDonnell MB, Fihn SD. The association between depressive symptoms and health status in patients with chronic pulmonary disease. Gen Hosp Psychiatry. 2001; 23:56–61. [PubMed: 11313071]

12. Singer HK, Ruchinskas RA, Riley KC, Broshek DK, Barth JT. The psychological impact of end-stage lung disease. Chest. 2001; 120:1246–52. [PubMed: 11591568]

13. Small SP, Graydon JE. Perceived uncertainty, physical symptoms, and negative mood in hospitalized patients with chronic obstructive pulmonary disease. Heart Lung. 1992; 21:568–74. [PubMed: 1447004]

14. Kaptein AA, Brand PL, Dekker FW, Kerstjens HA, Postma DS, Sluiter HJ. The Dutch CNSLD Study Group. Quality-of-life in a long-term multicentre trial in chronic nonspecific lung disease: assessment at baseline. Eur Respir J. 1993; 6:1479–84. [PubMed: 8112442]

15. Kim HF, Kunik ME, Molinari VA, Hillman SL, Lalani S, Orengo CA, Petersen NJ, Nahas Z, Goodnight-White S. Functional impairment in COPD patients: the impact of anxiety and depression. Psychosomatics. 2000; 41:465–71. [PubMed: 11110109]

16. Domingo-Salvany A, Lamarca R, Ferrer M, Garcia-Aymerich J, Alonso J, Felez M, Khalaf A, Marrades RM, Monso E, Serra-Batlles L, Anto JM. Health-related quality of life and mortality in male patients with chronic obstructive pulmonary disease. Am J Resp Crit Care. 2002; 166:680–5.

17. Dahlen I, Janson C. Anxiety and depression are related to the outcome of emergency treatment in patients with obstructive pulmonary disease. Chest. 2002; 122:1633–7. [PubMed: 12426264]

18. Kunik ME, Roundy K, Veazey C, Souchek J, Richardson, Wray NP, Stanley MA. Surprisingly high prevalence of anxiety and depression in chronic breathing disorders. Chest. 2005; 127:1205–11. [PubMed: 15821196]

19. Schmier JK, Halpern MT, Higashi MK, Bakst A. The quality of life impact of acute exacerbations of chronic bronchitis (AECB): A literature review. Qual Life Res. 2005; 14:329–47. [PubMed: 15892423]

20. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. Patient Educ Couns. 2002; 48:177–87. [PubMed: 12401421]

21. Kaptein AA, Scharloo M, Fischer MJ, Snoei L, Hughes BM, Weinman J, Kaplan RM, Rabe KF. 50 years of psychological research on patients with COPD--road to ruin or highway to heaven? Respiratory medicine. 2009; 103:3–11. [Research Support, Non-U.S Gov't Review]. [PubMed: 18930645]

22. Stoilkova A, Janssen DJA, Wouters EFM. Educational programmes in COPD management interventions: A systematic review. Respiratory medicine. 2013; 107:1637–50. [PubMed: 24012387]

23. McLean S, Nurmatov U, Liu JLY, Pagliari C, Car J, Sheikh A. Telehealthcare for chronic obstructive pulmonary disease: Cochrane Review and meta-analysis. The British journal of general practice : the journal of the Royal College of General Practitioners. 2012; 62:e739–49. [PubMed: 23211177]

24. Bolton CE, Waters CS, Peirce S, Elwyn G, Epsrc, Allam O, Conley EC, Gray WA, Hardisty A, Maughan T, Owens D, Preece A, Rana O, Yousef Z. Team MRCGC. Insufficient evidence of benefit: a systematic review of home telemonitoring for COPD. J Eval Clin Pract. 2011; 17:1216–22. [PubMed: 20846317]

25. Celli BR, Macnee W, Members C. Standards for the diagnosis and treatment of patients with COPD: A summary of the ATS/ERS position paper (vol 23, pg 932, 2004). Eur Respir J. 2006; 27:242.

26. Siafakas NM, Vermeire P, Pride NB, Paoletti P, Gibson J, Howard P, Yernault JC, Decramer M, Higenbottam T, Postma DS, Rees J. Optimal Assessment and Management of Chronic Obstructive Pulmonary-Disease (Copd). Eur Respir J. 1995; 8:1398–420. [PubMed: 7489808]

27. Blumenthal JA, Babyak M, Keefe FJ, Davis RD, LaCaille RA, Carney RM, Freedland KE, Trulock E, Palmer SM. Telephone-based coping skills training for patients awaiting lung transplantation. JConsultClinPsychol. 2006; 74:535–44.

28. Blumenthal JA, Keefe FJ, Babyak MA, Fenwick CV, Johnson JM, Stott K, Funk RK, McAdams MJ, Palmer S, Martinu T, Baucom D, Diaz PT, Emery CF. Caregiver-assisted coping skills training for patients with COPD: background, design, and methodological issues for the INSPIRE-II study. Clin Trials. 2009; 6:172–84. [PubMed: 19342470]

29. Beck, AT.; Steer, RA.; Brown, GK. Beck Depression Inventory Manual. San Antonio, TX: The Psychological Corporation; 1996.

30. Spielberger, CE.; Gorsuch, RL. Manual for the state-trait anxiety inventory. Palo Alto, CA: Consulting Psychologists Press; 1970.

31. Spielberger, CD. State-Trait Anxiety Inventory: Bibliography. 2. Palo Alto, CA: Consulting Psychologists Press; 1989.

32. Bunevicius A, Staniute M, Brozaitiene J, Pop VJ, Neverauskas J, Bunevicius R. Screening for anxiety disorders in patients with coronary artery disease. Health Qual Life Outcomes. 2013; 11:37. [PubMed: 23497087]

33. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36), 1: conceptual framework and item selection. Med Care. 1992; 30:473–83. [PubMed: 1593914]

34. Brazier JE, Harper R, Jones NM, O'Cathain A, Thomas KJ, Usherwood T, Westlake L. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. BMJ. 1992; 305:160–4. [PubMed: 1285753]

35. Napolitano MA, Babyak MA, Palmer S, Tapson V, Davis RD, Blumenthal JA. Effects of a telephone-based psychosocial intervention for patients awaiting lung transplantation. Chest. 2002; 122:1176–84. [PubMed: 12377839]

36. Napolitano MA. Development of a pulmonary-specific quality of life scale (PQLS. Annals of Behavioral Medicine. 1999:21.

37. Eakin EG, Resnikoff PM, Prewitt LM, Ries AL, Kaplan RM. Validation of a new dyspnea measure: The UCSD shortness of breath questionaire. Chest. 1998; 113:619–62. [PubMed: 9515834]

38. Eakin EG, Sassi-Dambron DE, Ries AL, Kaplan RM. Reliability and validity of dyspnea measures in patients with obstructive lung disease. Int J Behav Med. 1995; 2:118–34. [PubMed: 16250781]

39. Mendoza TR, Wang SX, Cleland CS, Morrissey M, Johnson BA, Huber SL. The rapid assessment of fatigue severity in cancer patients: Use of the Brief Fatigue Inventory. Cancer. 1999; 85:1186–96. [PubMed: 10091805]

40. Jones PW, Quirk FH, Baveystock CM, Littlejohns P. A self-complete measure of health status for chronic airflow limitation. American Review of Respiratory Disease. 1992; 145:1321–7. [PubMed: 1595997]

41. Rutten-van Molken M, Roos B, Van Noord JA. An empirical comparison of the St George's Respiratory Questionnaire (SGRQ) and the Chronic Respiratory Disease Questionnaire (CRQ) in a clinical trial setting. Thorax. 1999; 54:995–1003. [PubMed: 10525558]
42. Pellegrino R, Viegi G, Brusasco V, Crapo RO, Burgos F, Casaburi R, Coates A, van der Grinten CP, Gustafsson P, Hankinson J, Jensen R, Johnson DC, MacIntyre N, McKay R, Miller MR, Navajas D, Pedersen OF, Wanger J. Interpretative strategies for lung function tests. Eur Respir J. 2005; 26:948–68. [PubMed: 16264058]
43. ATS statement: guidelines for the six-minute walk test. Am J Respir Crit Care Med. 2002; 166:111–7. [PubMed: 12091180]
44. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis. 1987; 40:373–83. [PubMed: 3558716]
45. Han MK, Muellerova H, Curran-Everett D, Dransfield MT, Washko GR, Regan EA, Bowler RP, Beaty TH, Hokanson JE, Lynch DA, Jones PW, Anzueto A, Martinez FJ, Crapo JD, Silverman EK, Make BJ. GOLD 2011 disease severity classification in COPDGene: a prospective cohort study. Lancet Respir Med. 2013; 1:43–50. [PubMed: 24321803]
46. Agusti A, Edwards LD, Celli B, Macnee W, Calverley PM, Mullerova H, Lomas DA, Wouters E, Bakke P, Rennard S, Crim C, Miller BE, Coxson HO, Yates JC, Tal-Singer R, Vestbo J. Characteristics, stability and outcomes of the 2011 GOLD COPD groups in the ECLIPSE cohort. Eur Respir J. 2013; 42:636–46. [PubMed: 23766334]
47. Carver CS. Assessing coping strategies: a theoretically based approach. Journal of personality and social psychology. 1989; 56:267–83. [PubMed: 2926629]
48. Carver CS. You want to measure coping but your protocol's too long: consider the brief COPE. Int J Behav Med. 1997; 4:92–100. [PubMed: 16250744]
49. Blumenthal JA, Burg M, Barefoot J, Williams R, Haney T, Zimet G. Social support, Type A behavior and coronary artery disease. Psychosomatic Med. 1987; 49:331–40.
50. Hughes JW, Tomlinson A, Blumenthal JA, Davidson J, Sketch MH, Watkins LL. Social support and religiosity as coping strategies for anxiety in hospitalized cardiac patients. Ann Behav Med. 2004; 28:179–85. [PubMed: 15576256]
51. Stewart AL, Mills KM, King AC, Haskell WL, Gillis D, Ritter PL. CHAMPS physical activity questionnaire for older adults: outcomes for interventions. Med Sci Sports Exerc. 2001; 33:1126–41. [PubMed: 11445760]
52. Hekler EB, Buman MP, Haskell WL, Conway TL, Cain KL, Sallis JF, Saelens BE, Frank LD, Kerr J, King AC. Reliability and validity of CHAMPS self-reported sedentary-to-vigorous intensity physical activity in older adults. J Phys Act Health. 2012; 9:225–36. [PubMed: 22368222]
53. Snyder, DK. Manual for the Marital Satisfaction Inventory. Los Angeles, CA: Western Psychological Services; 1997.
54. Snyder DK, Wills RM, Keiser TW. Empirical validation of the Marital Satisfaction Inventory: an actuarial approach. J Consult Clin Psychol. 1981; 49:262–8. [PubMed: 7217492]
55. Robinson B. Validation of a Caregiver Strain Index. Journal of Gerontology. 1983; 38:344–8. [PubMed: 6841931]
56. Grant M, Cavanagh A, Yorke J. The impact of caring for those with chronic obstructive pulmonary disease (COPD) on carers' psychological well-being: a narrative review. Int J Nurs Stud. 2012; 49:1459–71. [PubMed: 22386988]
57. Robinson B, Thurnber M. Taking care of aged parents: A family cycle transition. Gerontologist. 1979; 19:586–93. [PubMed: 527846]
58. Muthen, LKMB. Mplus user's guide. Los Angeles: 2001.
59. Arbuckle, JL. Full information estimation in the presence of incomplete data. In: Marcoulides, GASRE., editor. Advanced structural equation modeling: Issues and Techniques. Mahwah, NJ: Erlbaum; 1996. p. 243-77.
60. Cohen, J. Statistical power analysis for the behavioral sciences. 2. Hillsdale, NJ: Erlbaum; 1988.
61. Almagro P, Calbo E, Ochoa dE, Barreiro B, Quintana S, Heredia JL, Garau J. Mortality after hospitalization for COPD. Chest. 2002; 121:1441–8. [PubMed: 12006426]

62. Pinto RA, Holanda MA, Medeiros MM, Mota RM, Pereira ED. Assessment of the burden of caregiving for patients with chronic obstructive pulmonary disease. Respiratory medicine. 2007; 101:2402–8. [PubMed: 17624751]

63. Spence A, Hasson F, Waldron M, Kernohan G, McLaughlin D, Cochrane B, Watson B. Active carers: living with chronic obstructive pulmonary disease. International journal of palliative nursing. 2008; 14:368–72. [PubMed: 19023952]

64. Lacasse Y, Goldstein R, Lasserson TJ, Martin S. Pulmonary rehabilitation for chronic obstructive pulmonary disease. The Cochrane database of systematic reviews. 2006:CD003793. [Meta-Analysis Review]. [PubMed: 17054186]

65. Cote CG, Celli BR. Pulmonary rehabilitation and the BODE index in COPD. Eur Respir J. 2005; 26:630–6. [PubMed: 16204593]

66. Moser KM, Bokinsky GE, Savage RT, Archibald CJ, Hansen PR. Results of a comprehensive rehabilitation program. Physiologic and functional effects on patients with chronic obstructive pulmonary disease. Arch Intern Med. 1980; 140:1596–601. [PubMed: 6779723]

67. Couser JI Jr, Guthmann R, Hamadeh MA, Kane CS. Pulmonary rehabilitation improves exercise capacity in older elderly patients with COPD. Chest. 1995; 107:730–4. [PubMed: 7874945]

68. Schane RE, Woodruff PG, Dinno A, Covinsky KE, Walter LC. Prevalence and Risk Factors for Depressive Symptoms in Persons with Chronic Obstructive Pulmonary Disease. J Gen Intern Med. 2008; 23:1757–62. [PubMed: 18690488]

69. Fritzsche A, Clamor A, von Leupoldt A. Effects of medical and psychological treatment of depression in patients with COPD--a review. Respiratory medicine. 2011; 105:1422–33. [PubMed: 21680167]

70. Hynninen MJ, Bjerke N, Pallesen S, Bakke PS, Nordhus IH. A randomized controlled trial of cognitive behavioral therapy for anxiety and depression in COPD. Respiratory medicine. 2010; 104:986–94. [Randomized Controlled Trial]. [PubMed: 20346640]

71. Kunik ME, Braun U, Stanley MA, Wristers K, Molinari V, Stoebner D, Orengo CA. One session cognitive behavioural therapy for elderly patients with chronic obstructive pulmonary disease. PsycholMed. 2001; 31:717–23.

72. de Godoy DV, de Godoy RF. A randomized controlled trial of the effect of psychotherapy on anxiety and depression in chronic obstructive pulmonary disease. Arch Phys Med Rehabil. 2003; 84:1154–7. [PubMed: 12917854]

73. Scharloo M, Kaptein AA, Schlosser M, Pouwels H, Bel EH, Rabe KF, Wouters EFM. Illness perceptions and quality of life in patients with chronic obstructive pulmonary disease. J Asthma. 2007; 44:575–81. [PubMed: 17885862]

74. Polisena J, Tran K, Cimon K, Hutton B, McGill S, Palmer K, Scottt RE. Home telehealth for chronic obstructive pulmonary disease: a systematic review and meta-analysis. J Telemed Telecare. 2010; 16:120–7. [PubMed: 20197355]

75. Lemmens KMM, Nieboer AP, Huijsman R. A systematic review of integrated use of disease-management interventions in asthma and COPD. Respiratory medicine. 2009; 103:670–91. [PubMed: 19155168]

76. Niesink A, Trappenburg JCA, Oene GHDWV, Lammers JWJ, Verheij TJM, Schrijvers AJP. Systematic review of the effects of chronic disease management on quality-of-life in people with chronic obstructive pulmonary disease. Respiratory medicine. 2007; 101:2233–9. [PubMed: 17804213]

77. Walters J, Cameron-Tucker H, Wills K, Schuz N, Scott J, Robinson A, Nelson M, Turner P, Wood-Baker R, Walters EH. Effects of telephone health mentoring in community-recruited chronic obstructive pulmonary disease on self-management capacity, quality of life and psychological morbidity: a randomised controlled trial. Bmj Open. 2013; 3:e003097.

78. Gellis ZD, Kenaley B, McGinty J, Bardelli E, Davitt J, Ten Have T. Outcomes of a telehealth intervention for homebound older adults with heart or chronic respiratory failure: a randomized controlled trial. The Gerontologist. 2012; 52:541–52. [PubMed: 22241810]

79. Emery CF, Schein RL, Hauck ER, MacIntyre NR. Psychological and cognitive outcomes of a randomized trial of exercise among patients with chronic obstructive pulmonary disease. Health Psychol. 1998; 17:232–40. [PubMed: 9619472]

80. Worth H, Dhein Y. Does patient education modify behaviour in the management of COPD? Patient Educ Couns. 2004; 52:267–70. [PubMed: 14998596]

81. Gadoury MA, Schwartzman K, Rouleau M, Maltais F, Julien M, Beaupre A, Renzi P, Begin R, Nault D, Bourbeau J. Self-management reduces both short- and long-term hospitalisation in COPD. Eur Respir J. 2005; 26:853–7. [Multicenter Study Randomized Controlled Trial Research Support, Non-U.S Gov't]. [PubMed: 16264046]

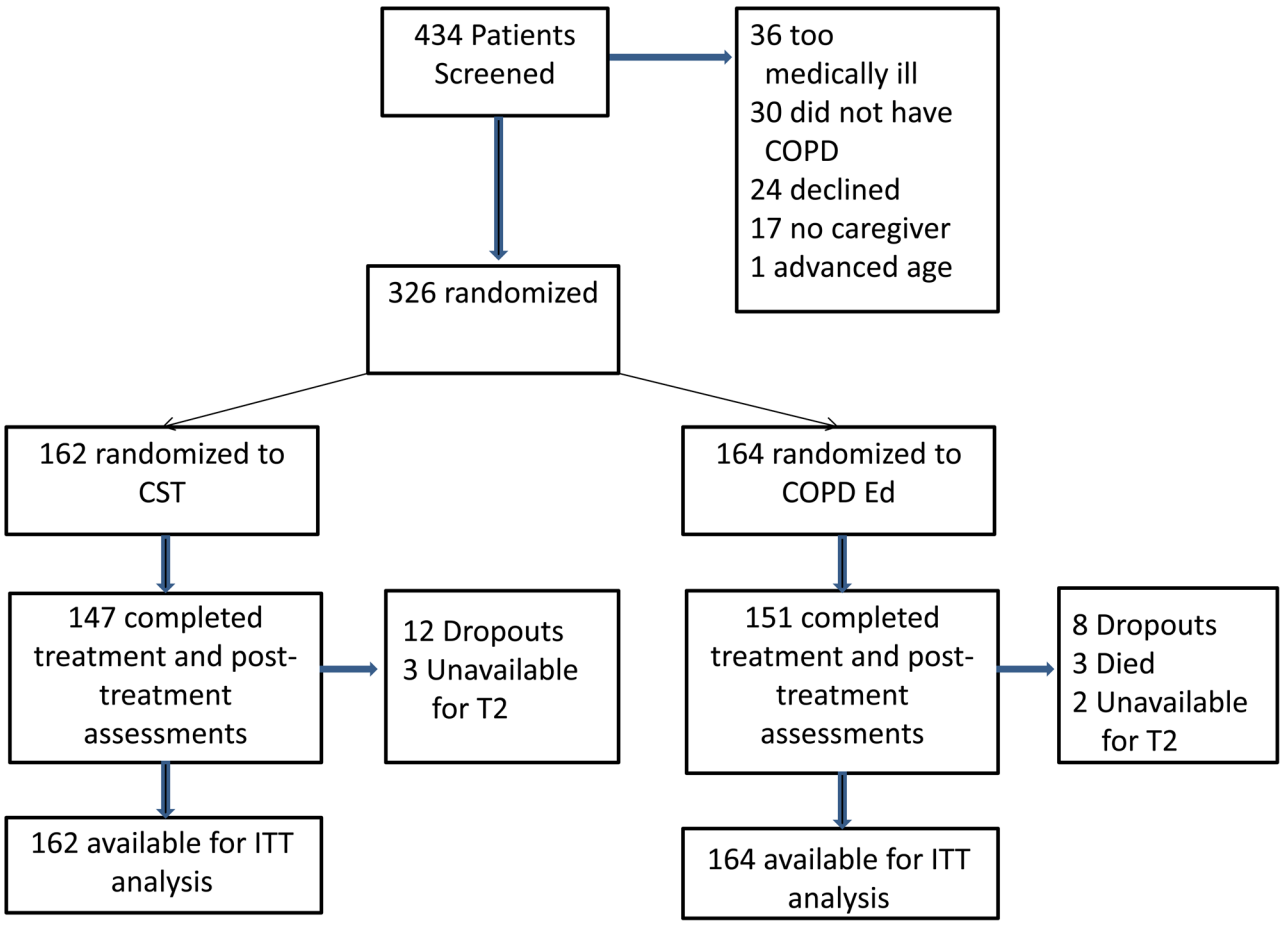

Figure 1.
Flow of participants from initial recruitment to end of treatment. ITT = intention-to-treat.

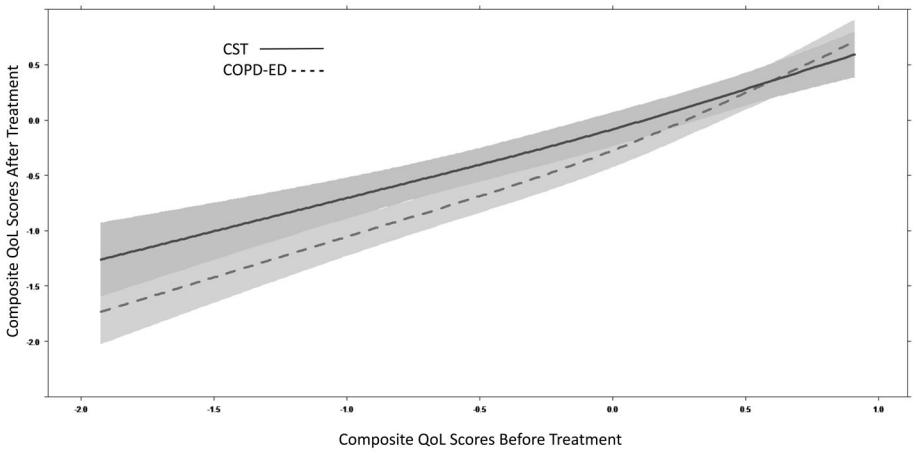

Figure 2.

Post-treatment Psychological Quality of Life (QoL) as a function of pre-randomization composite index of Psychological QoL.

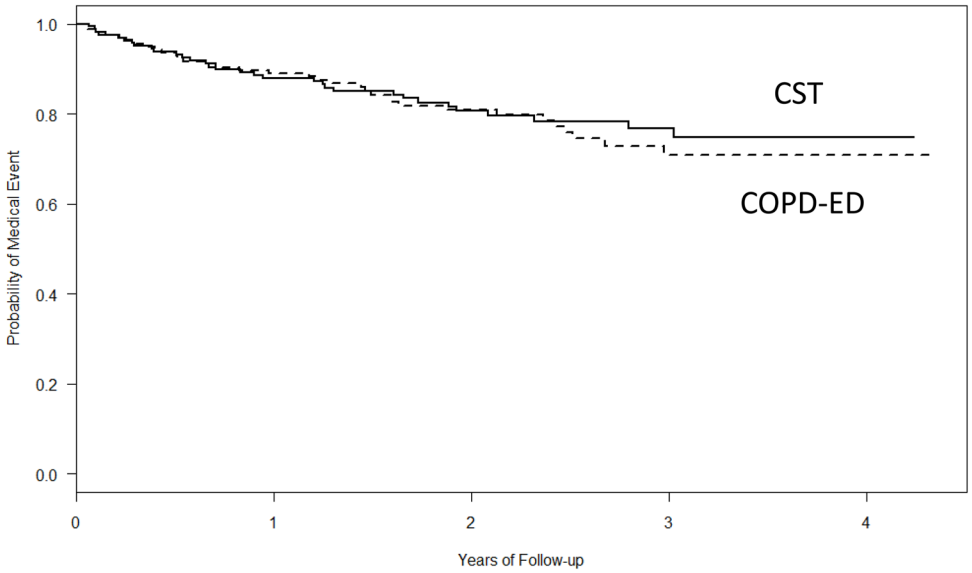

Figure 3.

Unadjusted Kaplan-Meier curves showing treatment and all-cause mortality or COPD-related hospitalizations. CST and COPD-ED participants did not differ in time to first medical event (P = .430).

Table 1

Baseline cohort characteristics by treatment group.

Variable	COPE-ED (N = 164)	CST (N= 162)	Full Cohort
Age, yrs, mean (SD)	66.6 (8.7)	65.6 (7.9)	66.1 (8.3)
Male N (%)	98 (60)	101 (62)	199 (61)
Caucasian, N (%)	144 (88)	141 (87)	285 (87)
Education ≥ HS, N (%)	137 (84)	143 (89)	280 (86)
Annual Income > $50K, N (%)	59 (36)	52 (32)	111 (34)
Married, N (%)	103 (63)	93 (58)	196 (60)
Caregiver Identified, N (%)	128 (78)	124 (77)	252 (77)
Charlson Index, median (IQR)	2.0 (3.0)	2.0 (2.0)	2.0 (2.0)
Smoking status, N (%)			
Never	7 (4)	6 (4)	13 (4)
Current	28 (17)	30 (19)	58 (18)
Former	129 (79)	124 (77)	253 (78)
Body Mass Index, kg/m^2, mean (SD)	28.6 (6.6)	29.1 (6.4)	28.9 (6.5)
FEV_1, Liters, mean (SD)	1.36 (0.62)	1.34 (0.61)	1.35 (0.62)
FEV_1, % predicted, mean (SD)	46.0 (16.8)	44.7 (16.7)	45.4 (16.8)
6MW Distance, meters, mean (SD)	353.1 (112)	356.7 (115)	354.9 (113)
Forced Vital Capacity (FVC)	2.71 (1.04)	2.71 (0.93)	2.71 (0.99)
FEV_1 / FVC	0.51 (0.14)	0.50 (0.15)	0.50 (0.15)
CHAMPS Physical Activity, mean (SD)			
Total Activity, hours/week	10.5 (9.3)	10.0 (9.0)	10.2 (9.2)
Moderate Activity, hours/week	5.4 (6.7)	4.9 (5.8)	5.1 (6.2)
Total Caloric expenditure/week	2807 (2667)	2827 (3048)	2816 (2859)
Supplemental Oxygen Usage, N (%)	62 (38)	57 (35)	119 (37)
Duration of COPD, N (%)			
< 1 year	26 (16)	24 (15)	50 (16)
1–4 years	59 (36)	43 (27)	102 (32)
5–8 years	35 (21)	44 (28)	79 (25)
9+ years	44 (27)	47 (30)	91 (28)
GOLD Classification, N (%)			

Variable	COPE-ED (N = 164)	CST (N= 162)	Full Cohort
A	16 (10)	13 (8)	29 (9)
B	44 (28)	49 (30)	93 (29)
C	8 (5)	7 (4)	15 (5)
D	92 (58)	92 (57)	184 (57)
History of Pulmonary Rehabilitation, N (%)	60 (38)	59 (37)	119 (37)
Medications			
Beta blockers, N (%)	34 (21)	46 (28)	80 (25)
ACE Inhibitors, N (%)	45 (27)	58 (36)	103 (32)
ARBs, N (%)	29 (18)	19 (12)	48 (15)
Aspirin, N (%)	66 (40)	72 (44)	138 (42)
Asthma Medications, N (%)	14 (9)	11 (7)	25 (8)
Other Antiplatelets, N (%)	12 (7)	10 (6)	22 (7)
Cholesterol-Lowering, N (%)	74 (45)	71 (44)	145 (45)
Nitrates, N (%)	6 (4)	5 (3)	11 (3)
LABA, N (%)	113 (69)	104 (64)	217 (67)
LAMA, N (%)	73 (45)	84 (52)	157 (48)
SABA, N (%)	123 (75)	116 (72)	239 (73)
SAA, N (%)	44 (27)	35 (22)	79 (24)
Inhaled Corticosteroids, N (%)	114 (70)	106 (65)	220 (67)
Psych Meds, N (%)	72 (44)	64 (40)	136 (42)
Anxiolytic, N (%)	34 (21)	27 (17)	61 (19)
Sleep, N (%)	10 (6)	10 (6)	20 (6)
SSRI, N (%)	31 (19)	32 (20)	63 (19)
Other Depression, N (%)	16 (10)	18 (11)	34 (10)
Diabetes, N (%)	21 (13)	22 (14)	43 (13)
Diuretic, N (%)	34 (21)	27 (17)	61 (19)

ACE inhibitors = Angiotensin Converting Enzyme Inhibitors, ARBs = Angiotensin II Reactor Antagonists, COPD = chronic obstructive pulmonary disease, FEV_1 = forced expiratory volume in 1 second, ICS = Inhaled Corticosteroids, IQR = interquartile range, LABA = Long Acting Beta Agonist, LAMA = Long Acting Muscarinic Antagonist, SAA = Short Acting Anticholinergic, SABA = Short Acting Beta Agonist, SD = standard deviation, SSRI = selective serotonin reuptake inhibitor.

* Due to incomplete data for some assessments, the total number of participants may not add up to 326 in all cases.

Table 2

Pre- and post-treatment raw and adjusted psychological QoL scores by treatment group.

	Before tx				After tx				Adjusted Post-tx			
	ED		CST		ED		CST		ED		CST	
	M	SD	M	SD	M	SD	M	SD	M	SE	M	SE
	Psychological Measures											
BD-II**	10.8	8.9	10.7	8.2	11.1	9.1	9.3	7.9	11.2	0.4	9.3	0.4
STAI*	34.1	11.0	33.9	11.3	33.8	11.7	31.8	10.5	33.8	0.6	31.8	0.6
SF-36 Mental Health*	73.9	18.4	74.3	18.8	73.4	19.9	77.1	16.9	73.6	1.0	76.9	1.0
SF-36 Role Emotional**	67.0	40.9	69.7	40.2	63.3	42.4	77.1	36.7	64.2	2.7	76.3	2.7
SF-36 Vitality**	46.8	21.7	46.1	20.8	46.1	22.3	51.4	19.4	46.2	1.1	51.8	1.1
SF-36 Social Functioning*	71.5	27.3	71.6	25.7	69.1	27.3	74.5	24.0	69.4	1.6	74.7	1.6

** = $P < .01$;

* $P < .05$ for differences between CST and COPD-ED participants at post-treatment adjusted for age, gender, race, treatment site, FEV_1, supplemental oxygen usage, treatment group, and the corresponding baseline level of the outcome; BDI-II = Beck Depression Inventory-II, STAI = Spielberger State Anxiety Inventory; SF-36 = Short Form-36 Health Survey

Table 3

Pre- and post-treatment raw and adjusted Physical QoL, Somatic Symptoms, and Pulmonary Function by treatment group.

	Before tx				After tx				Adjusted Post-tx			
	ED		CST		ED		CST		ED		CST	
	M	SD	M	SD	M	SD	M	SD	M	SE	M	SE
	Somatic Measures											
PQLS*	81.1	16.0	80.5	15.5	81.1	16.2	82.7	16.7	80.9	0.7	82.9	0.7
SOBQ	40.8	23.3	43.8	22.8	39.7	23.4	42.2	22.9	40.9	0.9	41.1	0.9
SF-36 Pain	66.2	25.6	66.2	24.0	66.9	24.9	66.9	24.9	67.0	1.4	66.9	1.5
SF-36 Role Physical	39.8	39.8	38.8	39.9	37.9	40.0	41.3	41.5	37.9	2.6	41.8	2.6
SF-36 General Health	43.8	22.4	40.9	21.1	43.1	23.7	42.5	21.7	41.9	1.1	43.8	1.1
SF-36 Physical Functioning	44.1	25.2	44.3	24.7	45.0	26.1	47.2	25.4	45.2	1.1	47.1	1.1
BFI**	30.3	21.0	30.2	21.2	34.5	21.5	27.8	18.8	34.6	1.2	27.8	1.2
SGRQ	44.3	17.9	46.3	17.2	42.8	18.9	42.9	17.6	44.0	0.8	42.0	0.8

** = $P < .01$;

* $P < .05$ for differences between CST and COPD-ED participants at post-treatment adjusted for age, gender, race, treatment site, FEV_1, supplemental oxygen usage, treatment group, and the corresponding baseline level of the outcome.

BFI = Brief Fatigue Inventory, PQLS = Pulmonary Quality of Life Scale, SGRQ = St. George Respiratory Questionnaire, SOBQ = Shortness of Breath Questionnaire; SF-36=Short Form-36 Health Survey.

Table 4

Pre- and post-treatment raw and adjusted measures of pulmonary function and functional status by treatment group.

	Before tx				After tx				Adjusted Post-tx			
	ED		CST		ED		CST		ED		CST	
	M	SD	M	SD	M	SD	M	SD	M	SE	M	SE
	Pulmonary Function and Functional Status											
Six-minute walk, meters*	353	112	357	115	349	124	363	117	351	3.4	361	3.4
FEV_1, %	46.0	16.8	44.7	16.7	46.8	17.9	46.0	18.3	46.4	0.7	46.6	0.7
FEV / FVC	0.51	0.14	0.50	0.15	0.51	0.15	0.49	0.15	0.51	.01	0.50	.01
Total Activity*	10.5	9.3	10.0	9.0	11.4	10.0	13.1	10.0	11.3	0.7	13.2	0.7
Moderate Activity	5.4	6.7	4.9	5.8	5.6	7.1	5.9	6.6	5.5	0.4	6.0	0.4
Total CE*	2807	2667	2827	3048	3076	3045	3624	3322	3113	212	3605	211

** = P < .01;

* P < .05 for differences between CST and COPD-ED participants at post-treatment adjusted for age, gender, race, treatment site, FEV_1, supplemental oxygen usage, treatment group, and the corresponding baseline level of the outcome.

CE = Caloric Expenditure, FEV_1 = forced expiratory volume, FVC = forced vital capacity.

Table 5

Pre- and post-treatment raw and adjusted measures of coping by treatment group.

	Before tx				After tx				Adjusted Post-tx			
	ED		CST		ED		CST		ED		CST	
	M	SD	M	SD	M	SD	M	SD	M	SE	M	SE
COPE Subscales												
	Active Coping											
Active**	5.8	1.7	5.8	1.7	5.8	1.7	6.4	1.4	5.8	0.12	6.3	0.13
Planning	5.9	1.6	5.4	1.7	5.6	1.9	5.9	1.6	5.6	0.12	5.9	0.12
Acceptance**	5.9	1.7	6.1	1.6	6.2	1.5	6.8	1.2	6.2	0.10	6.6	0.11
Positive Reframing**	5.2	1.8	5.5	1.8	5.2	1.8	5.9	1.8	5.3	0.13	5.8	0.13
	Support Seeking											
Seeking Instrumental Support*	4.3	1.8	4.5	1.9	4.6	1.8	5.0	1.9	4.6	0.13	4.9	0.13
Seeking Emotional Support**	5.0	2.0	4.9	1.9	5.2	1.9	5.7	2.0	5.1	0.13	5.6	0.13
Religion	5.3	2.2	5.2	2.2	5.4	2.1	5.3	2.2	5.3	0.10	5.4	0.10
	Behavioral Disengagement											
Venting	3.5	1.4	3.7	1.6	3.4	1.5	3.8	1.5	3.5	0.10	3.7	0.10
Denial	2.9	1.4	2.7	1.2	2.8	1.3	2.6	1.1	2.7	0.09	2.7	0.09
Behavioral Disengagement	2.7	1.2	2.7	1.1	2.6	1.2	2.6	1.1	2.6	0.08	2.6	0.08
Blaming	3.7	1.7	3.6	1.7	3.6	1.8	3.3	1.6	3.6	0.11	3.3	0.11
	Other											
Substance Use	2.3	1.0	2.4	1.0	2.4	1.1	2.4	1.1	2.4	0.06	2.4	0.06
Humor	3.5	1.8	3.8	1.9	3.3	1.6	3.4	1.7	3.5	0.12	3.3	0.12
Distraction*	4.9	1.7	4.9	1.9	4.8	1.8	5.3	1.9	4.9	0.13	5.3	0.13

** = P < .01;

* P < .05 for differences between CST and COPD-ED participants at post-treatment adjusted for age, gender, race, treatment site, FEV_1, supplemental oxygen usage, treatment group, and the corresponding baseline level of the outcome.

Improved Active coping (P < .001) and Support Seeking (P = .003) were both associated with improved Psychological QoL, whereas reduced disengagement was not (P = .688).