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Chronic obstructive pulmonary disease self-management activation research trial (COPD-SMART): Design and methods

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ABSTRACT

Background: Treatment of COPD requires multiple pharmacological and non-pharmacological intervention strategies. One target is physical inactivity because it leads to disability and contributes to poor physical and mental health. Unfortunately, less than 1% of eligible patients have access to gold-standard pulmonary rehabilitation.
Methods: A single-site parallel group randomized trial was designed to determine if a self-management lifestyle physical activity intervention would improve physical functioning and dyspnea. During the first six weeks after enrollment patients receive COPD self-management education delivered by a health coach using a workbook and weekly telephone calls. Patients are then randomized to usual care or the physical activity intervention. The 20 week physical activity intervention is delivered by the health coach using a workbook supported by alternating one-on-one telephone counseling and computer assisted telephone calls. Theoretical foundations include social cognitive theory and the transtheoretical model.
Results: Primary outcomes include change in Chronic Respiratory Questionnaire (CRQ) dyspnea domain and 6-minute walk distance measured at 6-, 12-, and 18-months after randomization. Secondary outcomes include other CRQ domains (fatigue, emotion, and mastery), SF-12, and health care utilization. Other measures include process outcomes and clinical characteristics.
Conclusions: This theory driven self-management lifestyle physical activity intervention is designed to reach patients unable to complete center-based pulmonary rehabilitation. Results will advance knowledge and methods for dissemination of a potentially cost-effective program for patients with COPD.

Abbreviations: ALED, Active Living Everyday; BODE index, [B]ody-mass index, degree of airflow [O]bstruction, [D]yspnea level, [E]xercise capacity; BMI, Body mass index; COPD, Chronic obstructive pulmonary disease; CRQ, Chronic Respiratory Questionnaire; CAT, Computer assisted telephone system; COPD-SMART, COPD self-management activation research trial; DCC, Data coordinating center; FEV1, Forced expiratory volume in one second; FVC, Forced vital capacity; GDS, Geriatric Depression Scale; GOLD, Global Initiative for Chronic Obstructive Lung Disease; JA, Jamile Ashmore; MCS, Mental health composite score; PASM, Physical activity self-management; PCS, Physical composite score; DBC, David B. Coultas; QALY, Quality adjusted life-years; RR, Rennie Russo; UTHSCT, University of Texas Health Science Center-Tyler; UC, Usual care

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1. Introduction and rationale

1.1. Burden of COPD

Chronic obstructive pulmonary disease (COPD) is a leading cause of morbidity, mortality, and economic burden worldwide [1]. The absolute number of years lost to disability attributed to COPD is higher than the years of life lost due to premature death [2]. The Institute of Medicine identified emphysema (i.e., COPD) among 15 “priority” conditions needing multiple intervention strategies to improve outcomes [3].

1.2. Gaps in evidence-based management

Because there is no cure, the goal of treating COPD is to improve or maintain patient quality-of-life and functional status. However, there remain large gaps in providing optimal care [4,5] despite improvements in pharmacological and non-pharmacological treatments [1]. These gaps appear to be the result of a complex array of factors at the community, health system, physician, and patient level of care [6]. Of these factors patients' beliefs, health literacy, coping skills, motivation, co-morbid conditions (e.g., depression), and access to care affect level of engagement in health-related behaviors, which in-turn affect outcomes. Therefore, a critical link for closing the gap and improving outcomes is to enhance self-management support for patients defined as "the systematic provision of education and supportive interventions by health care staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support" [7].

The evidence supporting self-management interventions has been examined in several recent reviews as part of stand-alone programs [8] and multi-component interventions [9,10]. Overall, there appears to be potential benefit. However, variation between the studies in content, methods of intervention, and outcomes prevent specific recommendations [8].

1.3. Rationale for targeting physical inactivity

A specific target for intervention through self-management support is physical inactivity, which is associated with disability due physical de-conditioning [11,12] and poor outcomes including systemic inflammation [13], lower quality of life [14], hospitalizations [15,16], and mortality [16,17]. Moreover, exercise rehabilitation among patients with COPD has been associated with improvements in dyspnea, physical and psychological functioning, quality of life, and marital adjustment [18,19]. However, few patients have access to pulmonary rehabilitation and less than 1% complete these programs [20].

1.4. COPD self-management activation research trial (COPD-SMART)

COPD-SMART was designed to examine the effectiveness of a home-based self-management intervention. The goal of the intervention is to improve patient functioning by enhancing COPD self-management and increase lifestyle physical activity among an underserved COPD population. Specific hypotheses include: 1) Patients with COPD who receive physical activity self-management (PASM) will have significant improvements in health status (Chronic Respiratory Questionnaire [CRQ]-dyspnea domain) and functional performance (6 minute walk distance) compared to usual care (UC). 2) The PASM program will be more cost-effective compared to UC.

2. Methods

2.1. Overview

This is a single-site randomized-controlled trial with parallel-group design comparing COPD self-management education plus UC to a self-management plus PASM intervention (Fig. 1). During the first six weeks after enrollment there is a run-in period when all patients are provided with COPD self-management education delivered by a trained health coach. Patients are then randomized to UC or PASM delivered over 20 weeks. Follow-up data are collected at 6, 12, and 18 months after randomization. The study was approved by the UTHSCT Institutional Review Board, and written informed consent was obtained prior to enrollment and data collection.

2.2. Recruitment setting, eligibility, and enrollment

Patients are recruited from clinics of the University of Texas Health Science Center-Tyler (UTHSCT), which is one of five health systems in an eight county region in east Texas. The predominantly rural region has an area of about 6139 square miles with a total population of 634,192 in 2009.

Patients ≥ 45 years of age with physician-diagnosed COPD are recruited from a registry ($n = 5582$), which is comprised of an administrative data base and provider referrals. The administrative database includes all patients seen at the clinics of UTHSCT with a coded COPD diagnosis (ICD-9 491, 492, 496) (Fig. 1). The goal is to randomly recruit a sample broadly representative of patients with COPD eligible for center-based pulmonary rehabilitation. Spirometry results and other exclusion criteria (Table 1) are reviewed in the medical record to determine initial eligibility. Potentially eligible patients are mailed a letter of invitation and contacted by telephone to schedule an enrollment visit. Final determination of eligibility is made at the enrollment visit. The registry will be continually sampled until the enrollment target is achieved (Fig. 1).

2.3. Randomization

A list of randomized unique patient identification numbers with group assignment was completed before patient enrollment by the data coordinating center (DCC) at the University of Alabama using a permuted block design. Blocked randomization ensures that an equal number of subjects are randomized to each study arm within each block, while randomly permuting blocks minimizes investigator bias by randomly determining the size of each block. Patients were sequentially assigned unique patient identification numbers at the time of enrollment but group assignment is provided only to the study coordinator (RR) and concealed from other study personnel and patients until after completion of the six-week COPD self-management component of the intervention described below.

2.4. Data collection

Data collection is conducted at UTHSCT during the enrollment visit and at 6, 12, and 18 months after randomization as well as monthly using automated telephone calls (Table 2). Baseline data collection is comprised of self-reported questionnaire items and physical measurements. The six month assessment is conducted to measure the short-term effects of the PASM intervention, and the 12- and 18-months assessments are intended to measure the intermediate and longer term maintenance of the intervention. In addition, automated telephone calls collect self-reported health care utilization (see Section 2.5.5). While data collection instruments are