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Chronic obstructive pulmonary disease self-management activation research trial (COPD–SMART): Results of recruitment and baseline patient characteristics

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ABSTRACT

Objective: To describe the recruitment methods, study participation rate, and baseline characteristics of a representative sample of outpatients with COPD eligible for pulmonary rehabilitation participating in a trial of a lifestyle behavioral intervention to increase physical activity.
Setting and design: A patient registry was developed for recruitment using an administrative database from primary care and specialty clinics of an academic medical center in northeast Texas for a parallel group randomized trial.
Results: The registry was comprised of 5582 patients and over the course of the 30 month recruitment period 325 patients were enrolled for an overall study participation rate of 35.1%. After a 6-week COPD self-management education period provided to all enrolled patients, 305 patients were randomized into either usual care (UC; n = 156) or the physical activity self-management intervention (PASM; n = 149). There were no clinically significant differences in demographics, clinical characteristics, or health status indicators between the randomized groups.
Conclusion: The results of this recruitment process demonstrate the successful use of a patient registry for enrolling a representative sample of outpatients eligible for pulmonary rehabilitation with COPD from primary and specialty care. Moreover, this approach to patient recruitment provides a model for future studies utilizing administrative databases and electronic health records.
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1. Introduction

COPD is a leading cause of disability and mortality worldwide, largely as a result of cigarette smoking and aging population [1,2]. While prevention through tobacco control has the greatest potential to decrease the burden of COPD, there remains an ongoing need for effective treatments. The goals of treatment are to manage symptoms and exacerbations, improve functional performance, improve quality of life, and decrease emergency care, hospitalizations, and mortality [3].

Abbreviations: COPD, chronic obstructive pulmonary disease; SMART, self-management activation research trial; UC, usual care; PASM, physical activity self-management; CRQ, Chronic Respiratory Questionnaire; 6MWD, six-minute walk distance; 6MWT, six-minute walk test; SD, standard deviation; ICD-9, International Classification of Diseases 9th revision; RAPA, Rapid Assessment of Physical Activity; GDS, Geriatric Depression Scale; CCI, Charlson co-morbidity index.

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Over the past two decades an increasing number of efficacious options for achieving these management goals have become available including pharmacological and non-pharmacological interventions [3]. However, effectiveness of these interventions in "real-world" clinical settings is often sub-optimal partly because of the limited external validity associated with clinical trials [4–6]. A major limitation to effectiveness is non-adherence to treatment that may result from factors at multiple levels including policy, community, delivery system, health care team, and patient [7]. To optimize adherence, multi-pronged approaches of patient support are needed in the clinical setting to assist patients in mastering a complex set of self-management behaviors [8,9].

Patient self-management includes adherence to medications, action plans for exacerbations, and lifestyle changes such as smoking cessation and increased physical activity [9]. While all of these behaviors affect patient outcomes, health behavior change is complex, which makes simultaneous change attempts for multiple behaviors difficult [10]. Moreover, sustained behavior change even for single behaviors often takes months and years of intermittent relapse and may never be permanent [11]. Due to these challenges, studies of self-management support interventions often focus on single behaviors such as exacerbation action plans and smoking cessation. Despite compelling evidence for the adverse effects of physical inactivity [12,13] and for the benefits of exercise rehabilitation programs [14,15] there have only been a few small-scale investigations of behavioral interventions to increase lifestyle physical activity among patients with COPD independent of pulmonary rehabilitation [16–20].

To address the limited evidence on interventions to increase physical activity among patients with COPD we designed and implemented the COPD self-management activation research trial (SMART) [21]. The goals of this paper are to: 1) describe the methods of patient recruitment, which were designed to optimize generalizability as recommended by the CONSORT (Consolidated Standards of Reporting Trials) statement [22], 2) estimate study participation rate [23], and 3) report baseline patient demographic and clinical characteristics after randomization.

2. Methods

Details of the rationale, design, intervention, measures, and statistical methods have been previously described [21]. In brief, this is a pragmatic, single-site, parallel group randomized trial. Patients with physician-diagnosed and spirometry confirmed COPD were actively recruited from primary and specialty care clinics of the University of Texas Health Science Center-Tyler (UTHSCT), an academic medical center with training programs limited to primary care in a large rural region of northeast Texas. Care for these patients was provided by a total of 49 health-care providers, which included family medicine faculty (n = 5), family medicine trainees (n = 28), internal medicine faculty (n = 5), physician assistants (n = 2), and pulmonary disease specialists (n = 9). The institution does not provide pulmonary rehabilitation services. The intervention was comprised of two components: 1) structured COPD self-management education, and 2) lifestyle physical activity behavioral intervention [21]. COPD self-management education was provided to all patients over 6 weeks using a workbook and was supported by weekly telephone calls from a trained health coach. After 6 weeks, patients were randomized to usual care (UC) or the physical activity self-management intervention (PASM). The PASM component lasted 20 weeks with outcomes evaluated at 6, 12, 18 months.

2.1. Recruitment

The target population was all outpatients with COPD who were eligible for pulmonary rehabilitation. To optimize external validity of the relationship between the study sample to the target population, recruitment and enrollment were conducted using criteria applied in the clinical setting for selection and referral of patients with COPD for pulmonary rehabilitation [21]. Specifically, criteria for exclusion of patients were largely limited to safety concerns or inability to participate in minimal physical activity rather than exclusion due motivation, recent exacerbations, or common co-morbid conditions. To meet enrollment goals two recruitment methods were used; a patient registry and provider referral.

2.1.1. Registry

The primary method of recruitment was a patient registry. An initial registry was developed from clinical administrative data for the time period 1/1/2004–11/3/2009. Patients >45 years of age with COPD were identified using ICD-9 diagnosis codes 491, 492, 493.2, and 496. This list of patients was randomly ordered by the data coordinating center and patients subsequently screened for eligibility as described below. A permuted block design was used for randomization in order to ensure that an equal number of subjects were randomized to each study arm within each block [21]. The patient registry was expanded in 2011 for the period 8/1/2009–11/17/2011.

A number of steps were taken by the principal investigator (DBC) and research coordinator (RR) before the registry was used for recruitment to ensure enrollment was efficient, met goals for representativeness of the sample, and adhered to Health Insurance Portability and Accountability Act (HIPAA) regulations. These steps included elimination of duplicate records, deceased patients, disqualifying spirometry, and records lacking an identifiable primary care or pulmonary physician. The protocol for development and use of the registry for recruitment of patients was approved by the UTHSCT institutional review board (IRB). All physicians provided written permission for the study team to contact their patients to determine interest in participating.

Clinical data from medical records were reviewed to determine potential eligibility. Potentially eligible patients were mailed informational materials about the study in groups of 30 to 500. The materials included a letter of introduction signed by their physician and principal investigator (DC) and other informational materials. Informational materials included a brochure explaining the study in more detail and how to begin the registration process using an automated computer assisted telephone (CAT) (TeleMinder™, Los Altos, CA) answering system. Research staff conducted follow-up telephone calls to all patients to determine further interest, screen for eligibility, and schedule an enrollment visit for final determination of eligibility.

The CAT system was used for several purposes including: 1) the enrollment process, 2) delivery of the intervention, and