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Designing trials of behavioral interventions to increase physical activity in patients with COPD: Insights from the chronic disease literature

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Summary
Objectives: There is increasing evidence that physical activity (PA) can affect health outcomes, particularly in chronic disease. While pharmacologic therapy and exercise training can improve exercise capacity, increasing PA requires behavior change. This review examined clinical trials testing the effectiveness of behavioral interventions to increase PA in adults with chronic disease to inform future research in COPD.
Methods: Embase and PubMed searches of studies published in English, 1995–2011. Inclusion criteria: Adults ≥45 years; COPD, diabetes, heart failure, obesity; exercise or PA endpoint; behavioral intervention described in sufficient detail to permit interpretation.
Results: 932 abstracts screened; 169 articles retrieved; 36 reviewed. Most were randomized trials (n = 32, 89%); 2 arms (n = 26, 72%), sample sizes 40–100 (n = 15, 42%); recruitment through clinical settings (n = 28, 78%); disease severity as primary eligibility criterion (n = 23, 64%); mean duration: 10 months (range: 1–84). Exercise intervention: aerobic activity, 30–60 min (n = 20, 56%), 3–5 times/week (n = 20, 56%). Behavioral intervention: Counseling (n = 19, 53%) with personal follow-up (n = 12, 33%). Control group: Exercise without behavioral intervention (n = 14, 39%) or usual care (n = 15, 42%). Significant effects were reported in 15 of 25 (60%) studies testing exercise capacity (6-minute walk, cycle, treadmill), 19 of 26 (73%) testing PA (pedometer, activity log, questionnaire), 11 of 22 (50%) measuring quality of life, and 8 of 13 (62%) capturing behavioral endpoints.

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Conclusions: This review provides insight into the range of designs, interventions, and outcome measures used in studies testing methods to improve PA in chronic disease with implications for designing trials in COPD.

Introduction

Chronic obstructive pulmonary disease (COPD) is a chronic respiratory disease characterized by a decline in lung function over time and accompanied by respiratory symptoms, primarily dyspnea, cough, and sputum production. Despite considerable advances in the management of the disease over the past 3 decades, COPD continues to be a growing cause of morbidity, mortality, and health-care costs worldwide [1,2]. Dyspnea is a major cause of reduced exercise capacity [3,4] and can lead to limitations in physical activity (PA) [5], i.e., movement resulting in elevated energy expenditure beyond basal levels, including standing or walking performed as part of one's daily activities.

It is widely recognized that a program of regular exercise can improve health, with increasing attention given to the effect of PA levels on health outcomes, particularly in people with chronic disease. Research suggests that higher levels of PA may prevent or delay the onset or progression of a range of chronic diseases and improve quality of life [6—10] and that sedentary behavior (low levels of PA) is an independent risk factor of poor health outcomes [11—13]. There is also evidence to suggest that PA levels in people with COPD are lower than healthy controls and patients with other chronic diseases [6,14] and that this inactivity may contribute to a downward spiral of deconditioning, increased dyspnea, exacerbations, declining lung function, and mortality [14—16]. Conversely, improving activity may improve health and well-being in people with COPD [17—20]. Although pharmacologic therapy and exercise training can improve the patient's capacity to increase activity, consistently and persistently increasing and maintaining PA requires a change in health behavior.

It has been proposed that interventions to change behavior are more effective when guided by an appropriate theoretical framework that fits the health problem of interest [21]. Four commonly-used theories of health behavior are the Health Belief Model (HBM) [22], Social Cognitive Theory (SCT) [23], Theory of Reasoned Action and Planned Behavior [24], and the Trans-theoretical (Stages of Change) Model (TTM) [25]. The HBM postulates that health behavior is predicted by one's belief or perceptibility of acquiring a disease and the approaches available to decrease the likelihood of occurrence [22]. SCT explains how individuals acquire and maintain specific behavioral patterns through observation [23]. The Theory of Reasoned Action and Planned Behavior proposes that a person's behavior is ultimately determined by their intent to perform the behavior, where intention is a function of attitudes and beliefs toward the behavior, the subjective norms, and perceived control behaviors [24]. Finally, the TTM conceptualizes a series of steps individuals move through in order to reach a specified behavior change. This model describes behavior change as a process in which intrinsic rewards or incentives are built to maintain positive health outcomes [25]. Across these theories, social support performs a vital role in understanding health behaviors and facilitating change, particularly in relationship to personal activity and exercise programs. Intervention studies informed by an underlying model or theoretical framework for understanding inactivity or a sedentary lifestyles and creating corresponding, targeted interventions to improve activity levels should be more likely to detect significant and meaningful treatment effects.

The purpose of this literature review was to examine clinical intervention studies testing behavioral interventions designed to increase PA in patients with chronic disease. Specifically, the intent was to identify key elements of studies that successfully improved activity levels, including sample selection and size, exercise and behavioral interventions, and outcome measures, to inform future studies in people with COPD.

Methods

A broad range of candidate articles were identified through Embase and PubMed using the following search terms: "physical activity", "motor activity", "exercise", "exercise prescription", "physical fitness", "sedentary lifestyle", "behavior modification", "health behavior", "health promotion", "behavioral intervention", "intervention studies", "program evaluation", and "clinical trial". The search was limited to empirical studies conducted in adults $\geq$45 years of age and published in English from 1995 to 2011. Abstracts were reviewed and selected for further evaluation if a behavioral intervention was tested in a sample of patients with COPD, diabetes, congestive heart failure or obesity, and exercise capacity, or PA was specified as a trial endpoint. The alternative chronic conditions were selected based on a common feature of inactivity with adverse health consequences and the potential for testing successful behavioral interventions in studies of patients with COPD. Although exercise capacity and PA are different health outcomes, with improvements in one not necessarily associated with improvements in the other, studies with either outcome were permitted to broaden the base of candidate exercise and behavioral interventions. Articles identified as potentially relevant were retrieved and reviewed, with papers excluded based on the following criteria: No outcome measure specified for PA or exercise capacity; limited description of the behavioral intervention, precluding further development or replication; or small sample size ($n \leq 10$). Because the focus was on interventions to increase PA outside of a rehabilitation program, rehabilitation trials were excluded.