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Community-based physical activity as adjunctive smoking cessation treatment: Rationale, design, and baseline data for the Lifestyle Enhancement Program (LEAP) randomized controlled trial

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ABSTRACT

Despite advances in behavioral and pharmacological treatment for tobacco use and dependence, quit rates remain suboptimal. Increasing physical activity has shown some promise as a strategy for improving cessation outcomes. However, initial efficacy studies focused on intensive, highly structured exercise programs that may not be applicable to the general population of smokers. We describe the rationale and study design and report baseline participant characteristics from the Lifestyle Enhancement Program (LEAP), a two-group, randomized controlled trial. Adult smokers who engaged in low levels of leisure time physical activity were randomly assigned to treatment conditions consisting of an individualized physical activity intervention delivered by health fitness instructors in community-based exercise facilities or an equal contact wellness control. All participants received standard cognitive behavioral smoking cessation counseling combined with nicotine replacement therapy. The primary outcomes are seven-day point prevalence abstinence at seven weeks, six- and 12 months. Secondary outcomes include self-reported physical activity, dietary intake, body mass index, waist circumference, percent body fat, and nicotine withdrawal symptoms. Participants consist of 392 sedentary smokers (mean [standard deviation] age = 44.6 [10.2] = years; 62% female; 31% African American). Results reported here provide information regarding experiences recruiting smokers willing to change multiple health behaviors including smoking and physical activity.

1. Introduction

Despite notable reductions in cigarette use, 15% of the U.S. adult population continues to smoke [1]. Empirically-supported treatments are available but rarely exceed quit rates of 30–35% at one year [2,3]. Consequently, improving cessation strategies remains an important public health priority.

Some evidence suggests that physical activity and exercise may be beneficial to the quitting process. Physical activity refers to any movement of the body generated by skeletal muscles that leads to energy expenditure [4]. Exercise reflects a subcategory of physical activity that involves planned, structured, and repetitive activities that are engaged in for the specific purpose of improving or maintaining physical fitness [4]. Moderate-to vigorous-intensity physical activity or exercise is associated with several proximal outcomes that predict quitting success, including acute relief from nicotine withdrawal [5–12] and greater quitting self-efficacy [13,14]. Exercise also attenuates post-cessation weight gain [15], a common concern among smokers [16]. Most importantly, physical activity and exercise may enhance cessation. Four prior studies [17–20] demonstrated higher end-of-treatment cessation rates among smokers assigned to a physical activity or exercise intervention compared to control; however, only one study

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provided evidence that exercise improved long-term (12 month) abstinence [19].

Prior trials [8] were hampered by methodological limitations including small sample sizes [17,18,21–31], absence of men [17–19,25,27,29–36], and inadequate comparison groups. In addition, interventions often suffered from insufficient "dose" of activity, poor adherence to physical activity prescriptions, and lack of sustainable programming. Studies also varied substantially in both cessation treatment (e.g., number of treatment sessions and use of pharmacotherapy) and physical activity parameters (e.g., initiation relative to quit date, intensity, instructional format and location of the exercise) [10]. Thus, the potential for physical activity to enhance cessation, and the most effective approaches to promote physical activity in the context of a quit attempt, remain unclear.

In addition, many trials relied exclusively [18,19,22,25,26,34,37] or primarily [20,23,24,27,33] on highly structured, supervised exercise at research-based fitness facilities, typically targeting vigorous activities (e.g., stationary bicycling) in a group setting multiple times over several weeks. Although this has allowed for carefully-controlled evaluations of the efficacy of vigorous exercise for smoking cessation, it may not be an optimal strategy to maximize treatment effectiveness in community settings [38]. Additionally, trials generally have not encouraged participants to engage in short bouts of activity outside of supervised exercise sessions as a way to cope with withdrawal symptoms and urges to smoke, although this is likely to be helpful [9]. Programs have also not usually provided the resources or skills to optimally maintain long-term adherence to physical activity goals. Finally, access to exercise resources typically has been offered for a short duration and is terminated once the intervention is completed.

Given the potential to more effectively disseminate physical activity programming as an aid to smoking cessation in community settings [36,38], LEAP was designed to evaluate whether the efficacy of structured leisure-time moderate-intensity physical activity can be enhanced by using a more flexible treatment approach of longer duration (one year). The physical activity intervention included individual fitness instruction, cognitive-behavioral skills training, and delivery of the physical activity intervention in convenient and accessible community-based facilities (YMCAs). Physical activity programming was integrated as an adjunct to standard smoking cessation treatment (behavioral counseling and nicotine patch) and was compared to a wellness intervention that was matched on contact frequency. Here, we describe the methodological approach, recruitment flow, and baseline sample characteristics.

2. Methods

The trial was registered at www.ClinicalTrials.gov (Identifier NCT00403312). Protocols and consent documents were approved by The University of Memphis and The University of Tennessee Health Science Center Institutional Review Boards and reviewed by an independent Data and Safety Monitoring Board.

2.1. Design

The study is a two-group, randomized controlled trial comparing different adjuncts to standard smoking cessation treatment including a 1) physical activity intervention or 2) frequency matched wellness contacts. The primary outcome is seven-day point prevalence smoking cessation measured at the end of treatment (seven weeks) and both six- and 12 months. Secondary outcomes include changes in physical activity, dietary intake, body mass index (BMI), waist circumference, percent body fat, and nicotine withdrawal symptoms.

2.2. Study participants

Participants include adults 18–65 years of age who smoked at least five cigarettes per day for one or more years and were interested in quitting. To be eligible, individuals were required to be sedentary or engaging in only low levels of leisure-time physical activity for the past six months, defined as ≤ three days per week of 30 min of moderate-intensity leisure-time physical activity (equivalent to brisk walking) and ≤ one day per week of 30 min of vigorous-intensity leisure-time physical activity (equivalent to running), as measured by a brief, two-item screen that was created for the study. Prior to randomization, participants completed a medical screen to ensure they were healthy enough to engage in physical activity (described below). Eligibility and exclusion criteria are presented in Table 1. Smokers were excluded due to inability to understand consent procedures, contraindications to NRT use (known contraindication or sensitivity to nicotine replacement therapy, or currently pregnant, lactating, or intending to become pregnant, recent history of a cardiac event or procedure), history of a serious illness that might limit longevity or ability to participate in the study (e.g., significant renal disease, liver disease, cancer with life expectancy less than one year, or current substance abuse), and any of several health conditions that might be contraindications for initiating a physical activity program such as extremely elevated blood pressure, positive exercise tolerance test, uncontrolled arrhythmia or hyperthyroidism, symptomatic peripheral artery disease, 2nd or 3rd degree AV block on EKG, or congestive heart failure.

Table 1
Inclusion and exclusion criteria.

Inclusion criteria
1. Adult daily smoker (≥5 cigarettes per day for ≥ 1 year)
2. Sedentary or minimally active during leisure time (≤3 days per week of 30 min of moderate-intensity leisure time physical activity and ≤1 day per week of 30 min of vigorous-intensity leisure time physical activity) as determined by brief, two-item screen
Exclusion criteria
1. Inability to understand consent procedures
2. Known contraindication or sensitivity to nicotine replacement therapy
3. Currently pregnant, lactating, or intending to become pregnant
4. Blood pressure ≥160/95 mm Hg
5. History of myocardial infarction, stroke, unstable angina, coronary artery bypass grafting, or angioplasty/stent in the past 6 months
6. Symptomatic peripheral artery disease
7. History of congestive heart failure (NYHA Class III or IV)
8. EKG evidence of 2nd or 3rd degree AV block
9. Positive exercise tolerance test (ETT)
10. History of a serious illness that might limit longevity (e.g., significant renal or liver disease, cancer)
11. Current substance abuse or alcohol use of ≥21 drinks/week
12. Uncontrolled arrhythmia or hyperthyroidism

2.3. Recruitment and screening

Participants were recruited through several traditional strategies commonly used for community-based clinical trials [36]. These included paid advertisements and public service announcements in local newspapers and on radio and television, free university media including telephone "on hold" announcements and stories in employee newsletters, physician referral, and "word of mouth." Potential participants contacted the project office by telephone to receive information about the study. Individuals interested in participating completed a brief prescreen by telephone to determine whether they met basic study requirements based on self-reported age, smoking status, physical activity level, health status, plans to remain in the area for the next year, and current pregnancy or plans to attempt pregnancy. Recruitment was initiated in June of 2004 and continued until May of 2007. Enrollment was stopped at the point when there would not be sufficient time in the funding cycle to complete follow-up assessments. The top three sources for recruiting eligible randomized participants were newspaper ads (n = 134), television (n = 71), and word-of-mouth referrals (n = 71).

Those who passed the phone screen were scheduled for the first of