



Overcoming limitations in previous research on exercise as a smoking cessation treatment: Rationale and design of the “Quit for Health” trial

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ABSTRACT

Aerobic exercise has been proposed as a stand-alone or adjunct smoking cessation treatment, but findings have been mixed. Laboratory studies have shown that individual exercise sessions lead to decreases in withdrawal symptoms and cigarette cravings, but findings are limited by lack of follow-up and artificial settings. On the other hand, smoking cessation treatment RCTs have generally failed to show positive effects of exercise on smoking cessation, but have been plagued by poor and/or unverified compliance with exercise programs. This paper describes the rationale and design for Quit for Health (QFH)—an RCT designed to determine the efficacy of aerobic exercise as an adjunct smoking cessation treatment among women. To overcome limitations of previous research, compliance with the exercise (and wellness contact control) program is incentivized and directly observed, and ecological momentary assessment is used to examine change over time in withdrawal symptoms and cigarette cravings in participants' natural environments.

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1. Background

Cigarette smoking is the leading, preventable cause of morbidity and mortality in the United States, accounting for approximately 443,000 premature deaths and economic costs of \$193 billion per year [5]. Adults who smoke cigarettes often attempt to quit, with 40–45% of adults making at least one serious quit attempt each year [7,34]. However, only 3–5% of adults are successfully quit one year after initiating their quit attempt [20]. Although men are more likely to be smokers than women (21.6% vs. 16.5%; [6]), the gender gap in smoking rates

has closed considerably over the past 50 years [7], and some studies show that women have more difficulty quitting and remaining abstinent ([9,15,24,28,45,47]; but see [13,21,44]).

Aerobic exercise has been proposed as a stand-alone or adjunct smoking cessation treatment because of its potential to reduce withdrawal symptoms, cigarette cravings, and concerns about weight gain [52], which are common barriers for women attempting to quit smoking [42]. Research findings have, however, been mixed. Laboratory studies have consistently shown that a single session of aerobic exercise has a favorable impact on cravings and withdrawal symptoms [16,29,41]; however, only one [23] of fifteen RCTs has been adequately powered to show that regular aerobic exercise is an effective long-term smoking cessation aid [43].

One potential explanation for the discrepancy between laboratory and RCT outcomes is that compliance with exercise

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programs in previous RCTs has generally been poor and reliant on self-report [43]. As a result, the efficacy of exercise as a smoking cessation treatment aid has been confounded with participants' compliance with the exercise program. Given the positive findings of laboratory studies, it remains possible that exercise is an efficacious smoking cessation treatment if there is adequate compliance with exercise programs.

Alternatively, it is possible that exercise-induced changes in withdrawal symptoms and cravings that have been demonstrated in laboratory studies may be too short-lived to produce meaningful effects on smoking behavior. For example, the effects of exercise on reductions in craving or smoking latency typically have not been assessed beyond 30–60 min after the exercise session [11,40]. Moreover, participants enrolled in laboratory studies are typically asked to abstain from smoking for 12–24 h prior to the study, but are not actively attempting to quit smoking. These weaknesses of laboratory studies have been addressed to some extent by secondary analyses from exercise treatment studies in which acute effects of exercise have been shown to reduce cravings and withdrawal symptoms among women who are attempting to quit smoking using exercise as a monotherapy [3] or as an adjunct to nicotine replacement therapy [17,49]. However, two of the latter studies also showed that the effects of exercise on cravings and withdrawal symptoms dissipated by the time of the next assessment—i.e., one to seven days later [3,49].

Thus, with respect to the literature on exercise as a treatment for smoking cessation, at least two questions remain unanswered. Is regular aerobic exercise a viable treatment adjunct for women attempting to quit smoking? And, what is the intensity, duration, and trajectory of the effect of exercise on relief from cravings and withdrawal symptoms? The purpose of the present paper is to discuss the rationale, design, and potential implications of the Quit for Health study (QFH)—an ongoing RCT that addresses outstanding questions regarding exercise as a smoking cessation treatment among women.

2. Overview of the “Quit for Health” study

The primary aim of QFH is to determine the *efficacy* of aerobic exercise as an adjunct smoking cessation treatment by maximizing and directly observing compliance with the exercise program. The secondary aim is to gain a better understanding of the temporal patterns of change in putative treatment mechanisms (e.g., withdrawal symptoms and craving) through frequent assessment of these variables in participants' natural environments. To achieve these aims, QFH compares regular moderate intensity aerobic exercise (referred to hereafter as *exercise*) versus wellness contact control (referred to hereafter as *wellness*) as adjuncts to the nicotine patch among previously inactive female smokers (planned $N = 164$; Fig. 1). Both conditions include 10 weeks of the nicotine patch and require three 50-min on-site sessions per week over 12 weeks. Participants in the exercise condition perform 50 min of supervised moderate intensity treadmill walking at each session, while watching health-related videos. Participants in the wellness condition watch the same health-related videos while seated. Assessments are administered at baseline, post-treatment (month 3), and months 6, 9,

and 12 and include (a) on-site self-reported smoking confirmed by breath carbon monoxide (CO) and saliva cotinine; (b) treadmill walk test to assess physical fitness; (c) body weight; and (d) questionnaires for nicotine dependence [37], depressive symptoms [30], weight concerns [4], and off-site physical activity behavior [2,31]. Additionally, ecological momentary assessment (EMA) is used to examine the pattern of changes in withdrawal symptoms and cigarette cravings in real time in participants' natural environments during the 12-week treatment program.

3. Rationale for specific design aspects

3.1. Use of nicotine replacement therapy as the base smoking cessation treatment

We considered delivering a more intensive smoking cessation treatment for all participants, such as cognitive behavioral therapy (CBT). However, we decided to provide only brief smoking cessation education plus the nicotine patch for two reasons: (a) the nicotine patch has been designated as an effective treatment in the AHRQ guidelines [14]; and (b) the combination of exercise with the nicotine patch is a potentially more disseminable intervention (if shown to be initially efficacious) than the use of more intensive and expensive interventions, such as CBT.

3.2. Use of moderate intensity brisk walking as the mode of exercise

Moderate intensity brisk walking is used because it is the most preferred form of exercise for women [53], is rarely medically contraindicated [1], has a strong effect on reducing cravings [16,29], and does not require expensive equipment. For these reasons, moderate intensity brisk walking has a greater chance of public health impact if it proves to be an efficacious adjunct to smoking cessation treatment.

3.3. Use of supervised on-site exercise instead of home-based exercise

We considered a home-based exercise program that would have fewer barriers to participation than the on-site, supervised program. However, we thought it essential to verify compliance with the exercise protocol to optimally test our primary aim. While some sacrifice of external validity is expected as a result of these procedures, we believe that this sacrifice is necessary in order to increase the internal validity of the study, which is most relevant to our primary aim.

4. Pilot study

A pilot study was conducted to test the feasibility of the research methods, demonstrate proof-of-concept, and obtain an effect-size estimate [50]. Sixty healthy, previously sedentary female smokers were randomly assigned to an eight-week program consisting of brief baseline education and the nicotine patch plus either 150 min/week of supervised moderate intensity exercise or a wellness contact control. At end of treatment, participants in the exercise condition had greater rates of CO-confirmed 7-day point

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