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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

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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.

Keywords

Study design; aerobic exercise; smoking cessation; nicotine withdrawal symptoms; cigarette cravings; weight concerns

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 (CDC, 2008). Adults who smoke cigarettes often attempt to quit, with 40–45% of adults making at least one serious quit attempt each year (CDC, 2007; Shiffman, Brockwell, Pillitteri, & Gitchell, 2008). However, only 3–5% of adults are successfully quit one year after initiating their quit attempt (Hughes, Keely, & Naud, 2004). Although men are more likely to be smokers than women (21.6% vs. 16.5%; CDC, 2012), the gender gap in smoking rates has closed considerably over the past 50 years (CDC, 2007), and some studies show that women have more difficulty quitting and remaining abstinent (Cepeda-Benito, Reynoso, & Erath, 2004; Gritz et al., 1998; Ortner, Schindler, Kraigher, Mendelsohn, & Fischer, 2002; Piper et al., 2010; Ward, Klesges, Zbikowski, Bliss, & Garvey, 1997; Wetter et al., 1999; but see Fidler, Ferguson, Brown, Stapleton, & West, 2013; Killen, Fortmann, Varady, & Kraemer, 2002; Velicer, Redding, Sun, & Prochaska, 2007).

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 (Hill, 1981), which are common barriers for women attempting to quit smoking (USDHHS, 2001). 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 (Haasova et al., 2013; Roberts, Maddison, Simpson, Bullen, & Prapavessis, 2012; Taylor, Ussher, & Faulkner, 2007); however, only one (Marcus et al., 1999) of fifteen RCTs has been adequately powered to show that regular aerobic exercise is an effective long-term smoking cessation aid (Ussher, Taylor, & Faulkner, 2012).

One potential explanation for the discrepancy between laboratory and RCT outcomes is that compliance with exercise programs in previous RCTs has generally been poor and reliant on self-report (Ussher et al., 2012). 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 minutes after the exercise session (Daniel, Cropley, & Fife-Schaw, 2006; Taylor & Katomeri, 2007). Moreover, participants enrolled in laboratory studies are typically asked to abstain from smoking for 12–24 hour 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 (Bock, Marcus, King, Borrelli, & Roberts, 1999) or as an adjunct to nicotine replacement therapy (Harper, Fitzgeorge, Tritter, & Prapavessis, 2012; Williams et al., 2011). 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 (Bock et al., 1999; Williams et al., 2011).

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.

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 $N=164$; Figure 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) onsite 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 (Shiffman, Waters, & Hickcox, 2004), depressive symptoms (Rush et al., 2003), weight concerns (Borrelli & Mermelstein, 1998), and off-site physical activity behavior (Blair et al., 1985; Sallis et al., 1985). 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.

Rationale for Specific Design Aspects

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 (Fiore et al., 2008); and (b) the combination of exercise with 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.

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 (Brownson, Eyler, King, Brown, Shyu, & Sallis, 2000; Cox, Burke, Gorely, Beilin, & Puddey, 2003), is rarely medically contraindicated (ACSM, 2010), has a strong effect on reducing cravings (Haasova et al., 2013; Roberts, Maddison, Simpson, Bullen, & Prapavessis, 2012), 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.

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.

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 (Williams et al., 2010). 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

prevalence abstinence (48.3% vs. 23.3%; OR = 3.07, 95% CI: 0.89, 11.07). Moreover, attrition was low, with only 2/60 participants (including one unrelated fatality) not providing post-assessment data, and compliance to the programs was high, with participants attending a median of 86.4% and 95.5% of the thrice weekly exercise and contact control sessions, respectively (Williams et al., 2010).

Baseline Procedures

Recruitment and Screening

In QFH, healthy women (planned $N = 164$) are recruited from the community to participate in a 12-week smoking cessation program that includes brief smoking-cessation education at baseline, a quit day set for one week post-randomization, and ten weeks of the nicotine patch. Interested participants must complete a telephone- or internet-based screening questionnaire. Initial eligibility requires smoking five cigarettes/day for at least one year, moderate-to-vigorous intensity exercise < 60 min/week for the past three months, and consent from a personal physician. Exclusion criteria include medical contraindications for exercise, body mass index ≥ 40 , diastolic/systolic blood pressure $\geq 140/90$, resting heart rate ≥ 100 , pregnancy, current use of smokeless tobacco, ongoing smoking cessation treatment, and unwillingness to use the nicotine patch.

Orientation and Consent

All participants who are eligible following the initial screen are scheduled to attend an orientation session at our research center. The study is explained in detail and interested participants complete a consent form. To ensure eligibility, blood pressure, resting heart rate, and body mass index (weight [kg]/height [m²]) are assessed, and a CO sample is taken. Participants who consent to the study and are initially eligible are scheduled for the following additional baseline sessions.

One-Week Pre-Randomization Run-In Period

Following the orientation, participants are asked to attend three 60-min pre-treatment sessions during which they view educational films on health-related topics, such as general health, safety, headaches, emotional and mental well-being, and sleep, as well as information on specific medical conditions, such as arthritis, diabetes, and certain cancers. Films include minimal information on smoking cessation or exercise. The main purpose of these sessions is to acclimate participants to the nature of the wellness condition so that they understand what the program will consist of if they are randomized into that condition. A second purpose of these sessions is to identify and exclude (prior to randomization) participants who would be unlikely to adhere to the thrice weekly sessions over the 12-week program.

EMA Instructions

Participants who complete the one-week run-in period are scheduled the following week for an EMA instructions session at which they receive systematic training on use of the EMA program, supplemented by a graphical manual with practice examples. From the time that they leave the EMA instructions session, participants begin following the EMA protocol.

Baseline Fitness Test

After completing the EMA instruction session, participants are scheduled for their final baseline assessment session—a one-mile walk test to provide an indication of baseline fitness (Widrick, Ward, Ebbeling, Clemente, & Rippe, 1992).

Baseline Smoking Education and Randomization

Randomization sessions are completed early in the third week following orientation, at the beginning of week one of the 12-week smoking cessation program. At the randomization session, but prior to randomization, participants are weighed, report smoking status, and provide a CO sample. Participants must continue to meet eligibility criteria for smoking status and must meet a specified threshold response rate for EMA compliance (85%) to continue. All participants who remain eligible are then given brief smoking cessation education based on the CDC's "*You Can Quit Smoking*" consumer guide (Centers for Disease Control, 2009) that includes a manualized, five-step program (i.e., get ready, get support, learn new skills and behaviors, get medication and use it correctly, and be prepared for difficult situations). During the education session, participants are asked to set their quit day one week later (i.e., beginning of week two of the 12-week smoking cessation program). Participants are given their first box of nicotine patches and instructed to apply the first patch the morning of quit day. Immediately following the baseline education participants are randomized to either the exercise or wellness condition and asked to complete their first exercise/wellness session.

Experimental Conditions

Common Components

Both the exercise and wellness conditions require three on-site sessions per week over 12 weeks. The two conditions are identical except for the presence or absence of the exercise program (see below). Use of nicotine replacement therapy is in accordance with the current Clinical Practice Guidelines from the United States Department of Health and Human Services (Fiore et al., 2008). Participants are asked to use the patch beginning the first session of week 2 (quit day). At the beginning of weeks 3, 5, 7, and 9 participants are given additional two-week supplies of the nicotine patch. They are asked to discontinue patch use after 10 weeks (beginning of week 12) in order to obtain valid saliva cotinine assessment at the post-treatment assessment session.

Exercise Condition

Consistent with national guidelines (Haskell et al., 2007; Physical Activity Guidelines Advisory Committee, 2008), participants in the exercise condition attend three 50-minute exercise sessions (with three minutes of warm-up and three minutes of cool-down for a total of 56 minutes per session) per week for 12 weeks at our research center. Exercise training consists of brisk walking on a treadmill. Participants wear heart rate monitors and are instructed to exercise at moderate intensity (i.e., 64–76% heart rate maximum; American College of Sports Medicine, 2010). Heart rate is increased as necessary by increasing the speed and grade of the treadmill. Participants gradually progress to the target intensity and duration over the course of the first few sessions. Research staff limit their interactions with

research participants to safety monitoring and verification and documentation of exercise intensity.

Wellness Condition

The wellness condition is matched to the exercise condition for contact with research staff. All procedures are the same for the wellness condition, except health-related videos are watched while seated (and without heart rate monitoring) instead of while exercising.

Follow-up Procedures

Exercise Maintenance Program

After the end of the 12-week program, participants in the exercise condition receive a three-month membership to a local YMCA to facilitate continuation of their exercise program. Research staff arrange initial appointments between research participants and YMCA staff, but there is no further involvement from research staff once the initial appointment is arranged. For equity, participants in the wellness condition receive 3-month YMCA memberships at the end of the 9-month follow-up period.

Follow-up Assessments

All baseline assessments are repeated at the end of the 12-week program (i.e., post-treatment) and at 6, 9, and 12 months post-randomization.

Measures

Manipulation Check for Exercise Behavior

Exercise completed on-site as part of the 12-week program is directly observed by research staff. As a manipulation check, we will calculate the number of sessions attended, as well as the number of sessions in which mean heart rate was in the moderate intensity range (i.e., 64–76% heart rate maximum). We discourage any exercise outside of the on-site exercise sessions for participants in the exercise condition, and ask participants in the wellness condition not to begin a program of exercise (they are sedentary at baseline). Although additional exercise is discouraged, participants are asked to record any structured exercise completed during the course of the 12-week program in their electronic diaries (see below) and are assured that such reporting will not affect their continued eligibility for the study. For participants in the exercise condition, frequency of YMCA attendance is monitored via their swipe cards (with permission from participants). The 7-Day Physical Activity Recall structured interview (Sallis et al., 1985) is administered to assess exercise behavior at each follow-up assessment. Finally, the one-mile walk test (see above section on fitness testing) is conducted at each follow-up as an indication of exercise behavior during the follow-up period.

Smoking Behavior

Smoking status is assessed via self-report at each of the thrice weekly sessions during the 12-week program, and every three months during the 9-month follow-up period. Carbon monoxide level is also obtained at each assessment. Additionally, salivary cotinine analysis

is used at post-assessment and at each follow-up to confirm reports of 7-day point prevalence abstinence (PPA) at those timepoints. These assessments are used to compute a number of smoking cessation outcomes, including: (1) 7-day PPA (primary outcome); (2) initial abstinence (24-hour abstinence); (3) time to first lapse (first smoking event following initial abstinence); (4) time to relapse (smoking at least 5 cigarettes/day for 3 consecutive days); and (5) prolonged abstinence (reaching post-treatment without relapse following a two-week grace period after quit day).

Body Weight

Body weight is assessed at baseline, weekly during the 12-week program, and at each follow-up using a calibrated medical scale.

Questionnaires

At baseline, post-treatment, and each follow-up assessment, participants complete a packet of psychosocial questionnaires assessing stable and historical factors, including demographics (baseline only), history of physical activity (Sallis, Hovell, & Hofstetter, 1992) (baseline only) and nicotine dependence (Shiffman, Paty, Gwaltney, & Dang, 2004). Weight concerns (Borrelli & Mermelstein, 1998) and depressive symptoms (Rush et al., 2003) are assessed at baseline, weekly during the 12-week program, post-treatment, and each follow-up assessment.

EMA Procedures

EMA is used to assess exercise and smoking behavior during the 12-week program, as well as hypothesized mediators and other potential predictors of smoking cessation. The EMA protocol is adapted from prior use of EMA in the context of smoking cessation (Shiffman, 2009; Shiffman et al., 2002) and implemented on a handheld electronic device (HP iPAC 111) running software designed for this study. Participants begin following the EMA protocol one week prior to randomization and continue the protocol throughout the 12-week smoking cessation program. Participants are prompted by research staff at each on-site session regarding EMA-related questions or problems. EMA data are downloaded weekly. Research staff discuss with participants any anomalies in the data, and barriers to protocol adherence are addressed for participants falling below 85% compliance.

EMA Reports

The EMA protocol includes the following ten reports, representing a combination of event-based and time-based sampling (Shiffman, Stone, & Hufford, 2008). Event-based reports are initiated by participants at the onset of specific events, such as at the beginning of a quit attempt. Time-based reports are initiated by the EMA program at previously set times. The device prompts participants to complete time-based reports via alarm (beeping and/or flashing lights).

Event-based sampling reports

Wake-up report: Administered each day upon awakening.

Begin session report: Administered immediately prior to each on-site exercise/wellness session.

Smoke report: Administered immediately following a smoking episode (i.e., smoking as little as one puff) for participants whose current status is “not quit” (see below for description of smoking statuses).

Quit report: Administered at the beginning of a quit attempt. Although quit day is initially set for one-week post-randomization, participants can initiate a quit attempt at any time during the 12-weeks.

Slip report: Administered immediately following a smoking episode for participants whose current status is “quit”.

Bedtime report: Administered immediately prior to going to bed.

Time-based sampling reports

During session: Administered at 10, 28, and 46 minutes during each 50-min on-site exercise or wellness session (triggered from the begin session report).

End session report: Administered immediately following each on-site exercise or wellness session (triggered from begin session report).

Post-session report: Administered 45 min after completion of each on-site exercise or wellness session (triggered from the end session report).

Random report: Administered at random once within each three-hour block for which the e-diary is not in “sleep” or “suspend” mode (see below).

E-Diary Interface: Menu Options

General menu options—E-diaries display eight general menu options.

Wake-up: Initiates the wake-up report. If participants do not initiate a wake-up report, then non-redundant content from the wake-up report is added to the first random prompt of the day.

Begin session: Initiates a begin session report. Upon completion of a ‘begin session’ report, the only menu option available is “end session”.

End session: Initiates an end session report if the participant must end her session early. Otherwise, end session reports are prompted by alarm based on the time of the ‘begin session’ report.

Bedtime: Initiates a bedtime report.

Sleep mode: Initiates sleep mode, during which the participant will not receive any prompts. Upon entering sleep mode, participants must choose a time at which the device will sound an alarm and automatically exit sleep mode by returning to the main menu. Participants can also deliberately exit sleep mode at any time and return to the main menu.

Suspend: Initiates the suspend feature, during which the participant will not receive any prompts. Participants indicate the desired duration of the suspension, ranging from 30 minutes to 7 hours. Participants can deliberately exit suspend mode at any time and return to the main menu.

Demo: Initiates the demo feature, which consists of five sample questions.

Problem report: Initiates a problem report. This time stamps the time of problems participants encounter with the e-diary, so that researchers may later identify when in the data stream the problem occurred.

Additional menu options based on smoking status—Three additional menu options are available depending on participants' smoking status: either *quit* or *not quit*. All participants begin in *not quit* status, for which the following two menu options are also available (in addition to the general menu options):

Smoke: Initiates a smoke report.

Quit: Initiates a quit report.

After completion of a quit report, the participant's status changes to *quit* and the *smoke* and *quit* menu options are replaced with the *slip* menu option.

Slip: Initiates a slip report.

At the end of the slip report, participants may retain their *quit* status or change their status back to *not quit*. Smoking status is also assessed on the bedtime report.

EMA Content

EMA content is categorized into (a) smoking behavior, (b) hypothesized mediators, (c) manipulation checks, and (d) other potential predictors of smoking outcomes (Table 1).

Smoking behavior—In the context of smoke or slip reports (depending on smoking status), participants indicate a *smoking event* each time they smoke at least one puff. In order to capture any missed smoking events, all reports, with the exception of during and end session reports, ask participants to indicate any smoking events that have occurred since their last e-diary report. At each bedtime report, participants are asked to report the *number of cigarettes* they smoked during the course of the day. *Smoking status* is assessed in quit, slip, and bedtime reports.

Hypothesized mediators—Hypothesized mediators are assessed through multiple reports. *Core affect* is assessed with two items representing the valence (good/bad) and arousal (high/low) dimensions of the circumplex model (Russell, 1980). *Specific affective states* include single items for stressed, energized, relaxed, bored, calm, sad, irritable, happy, tired, frustrated/angry, and restless. Withdrawal symptoms (other than affect) include four items on *sleep quality*, and one item each for *concentration* and *hunger*. Current *cigarette cravings* and *weight concerns* are each assessed with a single item.

Manipulation checks—Participants are asked not to engage in off-site exercise; nonetheless, two items on the bedtime report assess volume and intensity of any *off-site exercise* performed during that day. A single item, administered in multiple reports, assesses current *nicotine patch use*.

Other potential predictors of smoking outcomes—Two items, administered in multiple reports, assess *motivation* to be smoke free and *expectancy* for becoming/staying smoke free. A single item is used to assess *hedonic response* to smoking at the time of a smoking event. Finally, two items on the bedtime report assess *anticipated hedonic response* to the next smoking event and *remembered hedonic response* to the most recent smoking event.

EMA Timeline

To reduce participant burden, the full EMA protocol is administered only for the first 7 weeks of the 12-week program. For the last 5 weeks a partial protocol is administered consisting of bedtime reports, and begin, during, and end session reports.

Participant Compliance and Retention

Because compliance with the exercise and wellness programs is essential to addressing the primary aims of the study, we provide monetary incentives for attending these sessions. Specifically, participants receive \$300 at the post-treatment assessment session for meeting the study goal of attending at least 33 of the 36 exercise/wellness sessions (three times per week over twelve weeks). The \$300 incentive is reduced by \$50 for every additional missed session, but not reduced below \$50, such that participants who attended up to 28 exercise/wellness sessions receive \$50 at the post-treatment assessment session. An additional \$75 is available for attendance at the three follow-up assessments (i.e., \$25 for each assessment), regardless of their previous attendance history.

High compliance is also necessary for valid examination of potential mechanisms. Thus, we provide up to \$218 in incentives for compliance with specific aspects of the EMA protocol (e.g., \$1 for completing each wake-up, bedtime, and random report).

The use of incentives for treatment and assessment compliance raises concerns regarding generalizability of the findings. However, because both conditions have incentives available to them and the incentives are not contingent on smoking status, generalizability is limited only to the extent that provision of incentives moderates the effects of exercise on smoking

cessation outcomes (i.e., the extent to which the differences between treatment conditions would be different in the absence of incentives).

Derivation of Sample Size

Our sample size is designed to have 80% power for testing the null hypothesis that the intention-to-treat effect is zero, versus the two-sided alternative. In our analysis and sample size calculations, we adopt the convention of treating all dropouts as treatment failures (smokers). This approach has empirical justification in studies of smoking cessation (Lichtenstein & Glasgow, 1992; West, Hajek, Stead, & Stapleton, 2005). Effect size estimates are based on results of the pilot study (i.e., OR = 3.07; Williams et al., 2010). While it is possible that effects may be stronger or weaker with a longer treatment program (12 weeks versus 8 weeks in the pilot study), we conservatively inflated the sample size estimate by 25% to account for a potential decrease in treatment effects resulting from the longer treatment. Thus, adopting a two-tailed alpha level of 0.05, a sample size of 82 participants per arm will be needed, for a total sample size of 164.

Planned Analyses

Primary Aim: Smoking Cessation Outcomes

We will examine the effects of treatment condition on the odds of being quit at end of the twelve-week program. Using logistic regression we will model the probability of 7-day PPA as a function of treatment assignment, as well as any baseline variables not balanced by randomization. These analyses will be repeated to examine the effects of treatment on prolonged abstinence. To examine the effects of treatment condition on smoking cessation during the nine-month follow-up period, we will use a repeated measures regression model implemented with generalized estimating equations (GEE's) with robust standard errors (Zeger & Liang, 1986). These adjusted standard errors account for repeated measurements within participant over time. Appropriate link functions will be used (*logit* link for binary outcomes and *identity* link for continuous outcomes). If needed, we will apply a normalizing transformation to the continuous response measures (such as taking the logarithm of physical fitness) before proceeding with the analysis. Models will also control for baseline variables that are not equally distributed across treatment conditions.

Secondary Aim: Treatment Mechanisms

The goal of this analysis is to examine the mechanisms through which the intervention impacts smoking cessation outcomes. This involves (a) examining associations between treatment assigned and each of the potential mechanisms and (b) examining the association between changes in the potential mechanisms and smoking outcomes over time. First, we will examine treatment effects on each of the potential mechanisms. Using a series of longitudinal regression models implemented with GEE's, we will regress the potential treatment mechanisms (e.g., withdrawal symptoms) over time on treatment assignment, while controlling for baseline values of the potential mechanism, quit status at the time the potential mechanism was assessed, and potential confounders, as determined by preliminary analyses (i.e., variables not balanced by randomization). We will then examine each of the potential mechanisms (e.g., withdrawal symptoms) as predictors of smoking cessation

outcomes. We will consider the smoking outcomes time to first lapse and time to the start of relapse during the 12-week program as smoking endpoints. This will allow us to focus on data that are reported *before* a participant returns to smoking, as weight concerns, cravings and withdrawal symptoms are expected to change significantly following relapse. Time to the start of relapse will be used by identifying a relapse, as defined by 5 cigarettes per day on 3 consecutive days, and then using the first cigarette smoked during the 3-day relapse process as the start of relapse.

Since our outcome is time to a defined event (i.e., time to first lapse, start of relapse), we will use survival analysis (Hosmer & Lemeshow, 1999) to model the risk of lapsing/relapsing over time. Survival analysis makes use of the full data set to inform an estimate of the risk of lapse/relapse. That is, each participant contributes two outcome variables to the model: T_i^* , time to first lapse/relapse and C_i , censoring time. For participants who lapse/relapse before the end of treatment, $T_i^* < C_i$; for those who don't lapse/relapse before end of treatment or who discontinue the study protocol before lapsing/relapsing, $T_i^* > C_i$. Thus, the model uses $T_i = \min(T_i^*, C_i)$ as the response for each participant. Using a Cox model (Cox, 1972), we can create the hazard function (which can be thought of as the number of lapses/relapses per patient-day of follow-up time) as a function of a baseline hazard rate $\lambda_0(t)$ and covariates $X(t)$. Note that the set $X(t)$ can include both time-variant and time-invariant covariates. For example, when examining weight concerns, we will include weight concerns data from the previous 7-day period in the model (entered as separate linear terms $X(t-7)$, $X(t-6)$, ..., $X(t-1)$). In addition we will include treatment assigned and other baseline variables that have been predictive in previous smoking cessation studies and are shown to vary across treatment condition (e.g., smoking self-efficacy), as well as a measure of *baseline* weight concerns.

Approaches to Missing Data

Analysis will be conducted on the intent to treat sample, and thus all participants randomized will be included in the analysis. Our primary and secondary aims are focused on the effect of randomization (treatment assigned) and not the effect of treatment received. We will however, test whether there are differences in compliance between treatment arms. We assume non-compliance will be ignorable but should that not be the case, analysis will be adjusted accordingly. For example, predictors of non-compliance will be identified (e.g., using logistic regression models in which the probability of non-compliance is regressed on key predictors) and then used as weights in the primary analyses

Limitations

The Quit for Health trial has a number of limitations most of which are a trade-off for the strong internal validity of the study. For example, because regular attendance at the exercise or wellness sessions and adherence to the EMA protocol is of primary importance, there may be a selection bias toward more motivated or tech-savvy participants. Likewise, we would not expect that the incentives provided to increase adherence to the exercise/wellness sessions would be replicated in a real-world intervention. However, because both conditions will have incentives available to them and the incentives are not contingent on smoking status, they will limit generalizability only to the extent that provision of incentives

moderates the effects of exercise on smoking cessation outcomes (i.e., the extent to which the differences between treatment conditions would be different in the absence of incentives). Moreover, the purpose of the Quit for Health trial is to provide a definitive test of the efficacy of moderate intensity exercise as an adjunct to standard smoking cessation treatment. If initial efficacy can be established, then further research will be warranted to test more disseminable moderate intensity exercise programs to establish effectiveness in real-world conditions (i.e., enhancing adherence to exercise programs in the absence of monetary incentives).

Two additional limitations are a function of study design decisions. First, we decided to set the quit date at week two—one week after beginning the exercise program. There has been debate in the literature regarding the feasibility of instituting an exercise or weight loss program at the same time as a smoking cessation attempt. Some authors have argued that there is strong evidence to support simultaneous behavior-change attempts (Spring et al., 2009; Spring, McFadden, Rademaker, & Hitsman, 2011), whereas others have argued that simultaneous behavior-change is less likely to be successful (Parsons, Lycett, & Aveyard, 2011; Parsons, Shraim, Inglis, Aveyard, & Hajek, 2009). Thus, the simultaneous behavior change required in the Quit for Health trial is a potential limitation.

Finally, the Quit for Health trial does not provide a test of exercise as a spontaneous *as-needed* tool to alleviate acute instances of craving. Instead, we are testing the effects of a program of *regular* exercise in an attempt to help regulate weight, mood, and craving during a quit-smoking attempt. Each approach has potential strengths and weaknesses. Use of exercise to alleviate acute cravings may not be feasible in certain settings and situations when cravings arise. Additionally, a consistent program of regular exercise has many health benefits—including weight management—that might not be achieved if smokers are only using exercise on an as-needed basis. On the other hand, use of exercise on an as-needed basis may be superior to structured regular exercise for preventing potential slips and ultimate relapse. The present study tests a program of consistent regular exercise under conditions in which the regular exercise is likely to be adhered to (i.e., is incented) and can be directly verified (something likely to be difficult to do when exercise is performed on an as-needed basis). We expect that this study will give us a good indication of the efficacy of regular exercise as a smoking cessation treatment adjunct. Future research will be needed to test the viability and efficacy of as-needed exercise approaches, as well as potential combination approaches.

Implications

The outcomes of QFH will serve as a stepping stone for further research and have immediate implications for national recommendations for smoking cessation. Specifically, if QFH shows moderate intensity exercise to be an *efficacious* treatment, then—based on the poor compliance rates in previous trials—more research will be warranted to increase compliance with exercise programs and thereby increase the *effectiveness* of aerobic exercise as a smoking cessation strategy. Additionally, regardless of its ultimate effectiveness among the broader population of women smokers, if QFH supports moderate intensity exercise as an efficacious smoking cessation treatment, then this will warrant its recommendation by

smoking cessation practitioners, since (a) certain individuals may successfully comply with exercise programs, (b) moderate intensity exercise has been shown to reduce cigarette withdrawal symptoms and cravings, and (c) unlike other treatment approaches (e.g., counseling, pharmacology), there will be little harm in recommending a program of regular exercise given its many positive side effects (deRuiter & Faulkner, 2006).

Finally, analysis of EMA data will allow us to answer questions about the temporal pattern of effects of the exercise treatment on hypothesized mechanisms. For example: (1) What is the strength, duration, and rate of dissipation of the effects of a single session of exercise on putative mechanisms? (2) Does the acute effects of a single session of exercise on withdrawal symptoms, cigarette cravings, or weight concerns change over an extended (e.g., 12-week) exercise treatment protocol? (3) Does the strength, duration, or rate of dissipation of the effects of a single exercise session on putative mechanisms determine latency to the next cigarette or exercise session? (4) Given the effects of exercise on cravings and withdrawal symptoms, what is the optimal dosing of exercise programs regarding frequency and duration? (5) Are the effects of exercise on putative mediators dependent on moderators, such as (a) baseline level of nicotine dependence (b) exercise history; (c) time of the exercise session; or (d) most recent level of craving prior to the exercise session? Answers to these questions will help resolve previous inconsistencies in the literature and thus have implications for the viability of exercise as a smoking cessation treatment.

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	Early-week	Mid-week	End-week
	Recruitment and Screening		
Orientation & consent		Orientation - Questionnaires - BP/HR/BMI (for eligibility) - Smoking report/CO (for eligibility) - Begin MD clearance process	
One-week pre-randomization run-in	View wellness video - No assessments	View wellness video - No assessments	View wellness video - No assessments
EMA Instructions and Baseline Fitness Test	EMA instructions - Must complete MD clearance & 3 run-in sessions to receive EMA device - Begin 1-week EMA baseline period		One mile walk - Fitness test
Treatment week 1	Randomization - Questionnaires - EMA review (for eligibility) - Smoking report/CO (for eligibility) - Weight - Baseline smoking education - Randomization to treatment condition - First exercise/wellness session	Exercise/wellness session - Smoking report/CO	Exercise/wellness session - Smoking report/CO
Treatment week 2	Exercise/wellness session - Questionnaires - Weight - Smoking report/CO - <i>Quit day</i> - <i>Begin NRT</i>	Exercise/wellness session - Smoking report/CO	Exercise/wellness session - Smoking report/CO
Treatment weeks 3-11	Exercise/wellness session - Questionnaires - Weight - Smoking report/CO	Exercise/wellness session - Smoking report/CO	Exercise/wellness session - Smoking report/CO
Treatment week 12	Exercise/wellness session - Questionnaires - Weight - Smoking report/CO - <i>End NRT</i>	Exercise/wellness session - Smoking report/CO	Exercise/wellness session - Smoking report/CO
Post-treatment assessment (3 months post-randomization)	Post-treatment assessment: - <i>End EMA protocol</i> - Questionnaires - Weight - Smoking report/CO/saliva cotinine - One-mile walk (fitness test)		
Initial follow-up period (from 3-6 months post-randomization)	- Exercise condition receives free YMCA memberships		
6 months post-randomization	6-month follow-up assessment: - Questionnaires - Weight - Smoking report/CO/saliva cotinine - One-mile walk (fitness test) - YMCA attendance via swipe card data (for exercise participants only)		
9 months post-randomization	9-month follow-up assessment: - Questionnaires - Weight - Smoking report/CO/saliva cotinine - One-mile walk (fitness test)		
12 months post-randomization	12-month follow-up assessment: - Questionnaires - Weight - Smoking report/CO/saliva cotinine - One-mile walk (fitness test)		

Figure 1.
Quit for Health Study Design

Table 1

Content of Ecological Momentary Assessment (EMA) Reports

Variable Category	Variable	EMA Report									
		Wake-up	Begin Session	During Session	End Session	Post Session	Smoke	Quit	Slip	Bedtime	Random
Smoking Behavior	Smoking Event	X	X			X	X	X	X	X	X
	Number of Cigs in Day									X	
	Smoking Status						X	X	X	X	
Hypothesized Mediators	Core Affect		X	X	X	X	X ^a	X	X ^a	X	X
	Specific Affective States		X		X	X	X ^b	X	X ^b	X	X
	Sleep Quality	X									
Concentration/Hunger	Concentration/Hunger		X		X	X	X ^b	X	X ^b	X	X
	Cigarette Cravings	X	X	X	X	X	X ^b	X	X ^b	X	X
	Weight Concerns		X		X	X	X ^b	X	X ^b	X	X
Manipulation Checks	Offsite Exercise									X	
	Nicotine Patch Use	X	X			X	X ^b	X	X ^b	X	X
Other Potential	Motivation/Expectancy	X	X		X	X	X	X	X	X	X
	Hedonic Response						X		X		
Predictors of Smoking Outcomes	Anticipated Hedonic Resp.									X	
	Remembered Hedonic Resp.									X	

^a Assessment refers the respondent to two time periods: (a) the present time and (b) immediately prior to the smoking event

^b Assessment refers the respondent to the time immediately prior to the smoking event