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## Efficacy of Resistance Training as an Aid to Smoking Cessation: Rationale and Design of the Strength To Quit Study

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### Abstract

Despite recent declines in the rates of cigarette smoking, smoking remains prevalent among individuals with lower income, less education, and those with mental illness or HIV. Exercise is promoted as an aid to smoking cessation; however, the evidence for this recommendation is equivocal. To date, the majority of studies have only examined aerobic exercise; there is a poor understanding of the mechanisms of action; and there is an under-representation of male smokers. The goal of this trial is to produce new data that will help to address each of these gaps. A total of 206 male and female smokers will receive a brief smoking cessation education session prior to being randomized into a 12-week Resistance Training (RT) or Wellness Contact Control group. Both groups will have the option of using nicotine replacement therapy (NRT), and both will meet on-site twice per week during the 12-week program (24 total sessions). Follow-up assessments

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will occur at the end of the 12-weeks (3-month), and at a 6-month and 12-month (post-randomization) visit. Participants will not receive any additional smoking cessation treatment during follow-up; however, the RT group will receive a 9-month membership to a fitness center to encourage continued resistance training as a way to maintain cessation, and attendance will be tracked. The primary outcome is salivary-cotinine-verified 7-Day Point Prevalence Abstinence (PPA) at the 3-month assessment, and at the 6 and 12-month follow-ups. Secondary outcomes include effects of resistance training on nicotine withdrawal symptoms, indicators of mental health, and markers of disease risk.

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## Introduction

Each year, tobacco use kills nearly 6 million people and costs more than half a trillion dollars worldwide (WHO, 2013). In the United States (US), the primary method of tobacco use is cigarette smoking, and approximately 19.9% of men and 15.2% of women currently smoke (Schiller, Ward, & Freeman, 2013). These rates are known to differ by other demographic variables such as race, education, and income level (Schoenborn, Adams, Peregoy, 2013; CDC, 2012) and they differ by current health status. For example, the rate of cigarette smoking is estimated to be highest among persons living with human immunodeficiency virus (HIV; 59%–85%; Marshall et al., 2011; Tesoriero, Gieryic, Carrascal, & Lavigne, 2010) and those with a diagnosed mental illness (36.1%; CDC, 2013).

In the US, cigarette smoking and exposure to secondhand smoke is estimated to cause 480,000 deaths annually, or about one out of every five deaths (USDHHS, 2014; CDC, 2008). Lung cancer claims the most lives, followed by ischemic heart disease, and chronic obstructive pulmonary disease (COPD; CDC, 2008). In total, more deaths are caused by tobacco use in the US than by all deaths from illegal drug and alcohol use, HIV/AIDS, motor vehicle injuries, murders, and suicides combined (USDHHS, 2004). Fortunately, quitting smoking results in a number of short and long-term benefits. For example, the risk of developing heart disease drops by 50% within one year after quitting, and the risk for a stroke can fall to about the same as a nonsmoker's, 2–5 years after quitting (USDHHS, 2010). Other risks, such as cancer of the mouth or throat are cut in half five years after quitting, and the risk of dying from lung cancer drops by half 10 years after quitting (USDHHS, 2010). Smoking cessation can also improve mental health, as it is known to be associated with reduced depression, anxiety, and stress and improved mood and quality of life (Taylor, McNeill, Girling, Farley, Lindson-Hawley, & Aveyar, 2014).

Recent estimates indicate that the majority of US smokers would like to quit, with 45.8% having tried in the past year (Schoenborn, Adams, & Peregoy, 2013). Unfortunately, less than 5% of those who attempt to quit are able to maintain long-term abstinence (Rafful, García-Rodríguez, Wang, Secades-Villa, Martínez-Ortega, & Blanco, 2013), particularly greater than six months (Murthy & Subodh, 2010). There are several prescription and over-the-counter medications that have been shown to nearly double the success rate of smoking cessation when compared to a placebo (Herman & Sofuoglu, 2010); however, cost, access, and the perception of medication risk are well known barriers to use (Foulds et al., 2013). In addition, the weight gain associated with quitting can be problematic for both men and

women, as current evidence indicates that post-cessation weight gain can range from 4–10 kilograms (Aubin, Farley, Lycett, Lahmek, & Aveyard, 2012). Notably, the increases in body weight following smoking cessation may be attributed to a lower metabolic rate and increased amount of body fat (Kleppinger, Litt, Kenny, & Oncken, 2010; Pistelli, Aquilini, & Carrozzi, 2009). Such changes can significantly diminish the positive health effects of smoking cessation via associated reductions in glucose metabolism (Yeh, Duncan, Schmidt, Wang, & Brancati, 2010), lung function (Chinn et al., 2005), and increases in the risk of developing type 2 diabetes (Luo et al., 2013) and hypertension (Gratziou, 2009).

The U.S. Department of Health and Human Services currently advocates the use of exercise as an aid to quitting (USDHHS, 2008), as do researchers, tobacco treatment specialists and former smokers (Haasova et al., 2014; Everson, Taylor, & Ussher, 2010). However, the overall evidence for using exercise as an aid is equivocal. Specifically, a 2012 Cochrane review determined that larger, adequately powered, sufficiently intense interventions with equal contact control conditions are needed (Ussher, Taylor, & Faulkner, 2012). The authors identified a number of limitations of previous research that included a lack of testing potential mechanisms of action (e.g., reduction in nicotine withdrawal symptoms), a female-only sample, and a strict focus on using aerobic exercise. As such, newer, rigorous research is needed to elucidate the role exercise can play in aiding smoking cessation, particularly for male smokers and anyone who would prefer to engage in various different physical activity modalities. This could potentially enhance compliance and ultimately prevent relapse.

In a prior pilot study, we explored the feasibility of resistance training (i.e., weight training) as an aid to smoking cessation (Ciccolo et al., 2011). Briefly, 12 male and 13 female smokers received a 20-minute smoking cessation counseling session and Nicotine Replacement Therapy (NRT). Participants were then randomized into a two-session per week, 12-week resistance training or contact control program (i.e., 24 total sessions). At the end of treatment, carbon-monoxide (CO)-verified 7-day point prevalence abstinence (PPA) rates were 46% for the resistance training group and 17% for contact control (OR 4.3, 95% CI=0.7–27.8). Additionally, participants in the resistance training group had more favorable changes in body weight (Cohen's  $d = -0.7$ ) and body fat ( $d = -0.8$ ) when compared to the control.

The above pilot results warrant additional research, as the data suggest that resistance training could (1) be a potential aid for smoking cessation and (2) provide smokers with a method to reduce other health risks when trying to quit. More specifically, the potential mechanisms supporting resistance training as an aid for smoking cessation are that it could beneficially affect some of the most well known predictors of relapse, such as negative affect (Leventhal et al., 2013) and sleep disturbance (Hamidovic & de Wit, 2009), as well as barriers to quitting, such as weight gain (Pistelli, Aquilini, & Carrozzi, 2009). For example, studies have shown that resistance training can reduce many of the same negative affective states frequently reported during nicotine withdrawal, such as tension, anxiety, and depression (Arent, Landers, Matt, & Etnier, 2005; Singh, Stavrinou, Scarbek, Galambos, Liber, & Fiatarone-Singh, 2005). Other research has shown that there is a significant association between resistance training and increased quality of sleep (Yang, Ho, Chen & Chien, 2012); and the effects of resistance training on metabolism and body composition

have been rigorously tested and are well established (Strasser, Siebert, & Schobersberger, 2010). In addition to these potential positive effects, the health benefits gained from resistance training could also be particularly helpful for smokers, as resistance training has been shown to improve lung function (Singh, Jani, John, Singh, & Joseley, 2011), blood lipids (Kelley & Kelley, 2009), and blood glucose control (Strasser, Siebert, & Schobersberger, 2010). All of these factors are known indicators of disease risk that are also significantly associated with smoking (USDHHS, 2014).

As such, the purpose of this paper is to outline the rationale and design of *Strength To Quit*, a large, laboratory-based, randomized controlled trial (RCT) testing the use of resistance training as an aid to smoking cessation. *Strength To Quit* was specifically designed to examine the following three questions: (a) What is the efficacy of resistance training as an aid to smoking cessation for male and female smokers? (b) What are the psychological and physiological mechanisms of the effects of resistance training on smoking cessation? and (c) Does resistance training attenuate detrimental changes in markers of disease risk associated with quitting (e.g., body fat gain)?

## Study Methods

**Study Design**—*Strength To Quit* uses a 2-group design in which 206 participants will be randomized into 12-week Resistance Training (n=103) or Wellness Contact Control (n=103) conditions. A stratified block randomization procedure is used to achieve balance between the two groups on gender and intention to use the nicotine patch. All participants receive a brief smoking cessation education session prior to being randomized. Both groups meet on-site twice per week during the 12-week program (24 total sessions), and follow-up assessments occur at the end of the 12-weeks (3-month) and at a 6-month and 12-month (post-randomization) follow-up (See Figure 1). The primary outcome is salivary-cotinine-verified 7-Day PPA measured at each of the follow-up assessments.

**Participants and Eligibility**—Eligible participants are male and female smokers, age >18, who have a desire to quit smoking and have regularly smoked five or more cigarettes a day for at least the past 12 months. Potential participants are excluded if they currently engage in any combination of aerobic exercise or resistance training for >60 minutes/week or have over the past 3 months, currently use smokeless tobacco, are taking medication to quit smoking, or are participating in an ongoing smoking cessation treatment. Women who are pregnant or planning to become pregnant are excluded. Anyone with cardiovascular or pulmonary disease (e.g., coronary artery disease, emphysema), and anyone with orthopedic limitations that would prevent their ability to complete a full-body resistance training program are also excluded. Lastly, participants must be able to speak and read English, and have no plans to move out of the area within the next 12 months.

## Procedures

**Recruitment:** Advertisements for this study are posted in newspapers, at subway and bus stops, on the Internet (e.g., Craigslist), on bulletin boards in the local area (i.e., flyers), and on the radio. The bulk of advertisements are placed in a free metro newspaper that is

circulated throughout the New York City subway system, as it has a large readership that includes significant numbers of racial and ethnic minorities.

**Pre-Randomization Sessions:** Individuals who appear to be eligible at the phone screen are asked to attend three sessions prior to randomization. The first session is an orientation to provide additional information about the study and to obtain informed consent. The second and third sessions are used to collect survey data and conduct clinical assessments (See Figure 1). After completing the three pre-randomization sessions participants are eligible to be randomized and begin the 12-week program.

**Baseline Smoking Education and Randomization:** At the first session of the 12-week program, all participants receive a brief (20-minute) smoking cessation education session based on the Centers for Disease Control and Prevention's (CDC) "You Can Quit Smoking" consumer guide consisting of 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). Participants are asked to set their quit day one week from this education session. Immediately following the smoking education (i.e., at the same session), participants are randomized into either the Resistance Training or Wellness Contact Control condition. Specifically, participants open a sequentially numbered envelope, which reveals the group allocation. A blinded, off-site biostatistician previously determined the randomization sequence.

**Provision of the Nicotine Patch:** All participants are given the option of using nicotine replacement therapy during the trial. Use of the nicotine patch is in accordance with the current Clinical Practice Guidelines from the United States Department of Health and Human Services (Fiore et al., 2008). If a participant chooses to use nicotine patches, s/he is asked to use the patch at the beginning the first session of week 2 (quit day). Each week thereafter participants are given a two-week supply of the nicotine patches on an as-needed basis. Participants who smoke more than 10 cigarettes per day are instructed to use a 21 mg patch for six weeks (Weeks 2–7), tapered to a 14 mg patch for the next two weeks (Weeks 8–9), and a 7 mg patch for the final two weeks (Weeks 10–11). Participants who smoke between 5 and 10 cigarettes per day are instructed to begin with a 14 mg patch for six weeks (Weeks 2–7), which is tapered to a 7 mg patch for the next four weeks (Weeks 8–11). The 10 weeks of nicotine patch use and dose tapering protocol are consistent with clinical recommendations (Fiore et al., 2008). All participants 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.

### **Experimental Conditions**

**Resistance Training Program:** Participants in this study arm attend two, 45–60-minute, progressive resistance training sessions per week for 12 weeks. The program manipulates the key resistance training program variables of volume (repetitions/sets) and intensity (% of 1-repetition maximum; 1-RM), while maintaining a format of a 5-minute (aerobic) warm-up, 35–50 minutes of resistance training and a 5-minute cool-down (stretching). Specifically, participants are guided through a 10-exercise, full-body routine by study staff. For the first

2–3 weeks, participants complete 1–2 sets of each exercise at an intensity that elicits muscular fatigue within 10–15 repetitions (approximately 65%–75% of 1-RM). From weeks 4–12, participants complete 2–3 sets per exercise, and the weight is systematically increased to elicit muscular fatigue within 8–10 repetitions (75%–80% of 1-RM). The rest interval between sets is held constant across the 12 weeks at 30 seconds–1.5 minutes. This program is consistent with the American College of Sports Medicine’s Position Stand on Progression Models in Resistance Training (Ratamess, et al., 2009). Similar programs are known to produce increases in both muscular strength and aerobic fitness (Tanaka & Swensen, 1998).

**Wellness Contact Control Condition:** Participants in this study arm are required to attend the same number of sessions, for the same amount of time as those in the Resistance Training group. Each session includes a handout on pertinent healthy lifestyle topics for adults (e.g., human anatomy, sex and relationships), an informational video, and a practical component/demonstration. None of the sessions include information on smoking, smoking cessation or exercise. Participants are asked to not change their current exercise behavior during the 12-week intervention.

**Exercise Maintenance Program:** At the end of the 12-week program, participants in the Resistance Training group receive a 9-month membership to a local fitness center, and they receive an individualized, progressive resistance training plan, which is an extension of the routine completed during the intervention. This is meant to provide the participants with the knowledge and guidance needed to facilitate continued training during the follow-up period. Study staff arrange initial appointments between research participants and the fitness center, but there is no further involvement from research staff once the initial appointment is arranged. For equity, participants in the Wellness Contact Control also receive a 9-month fitness center membership after their 12-month follow-up visit (i.e., after they have completed the trial). Card swipe data detailing the time and date of each visit to the fitness center are collected in the Resistance Training group at the 6 and 12-month follow-ups.

**Incentives:** Compliance with the resistance training and wellness control programs is crucial to addressing the primary aims of the study (i.e., testing the efficacy of resistance training), therefore, monetary incentives are given to the participants as compensation for their time, effort and attendance. In both groups, participants are paid \$25 at week 4, \$50 at week 8, and \$75 at week 12, with a \$50 bonus for completing >22 sessions. In addition, all participants receive \$50 for attending each of the three follow-up assessments (3, 6, and 12 month), with a \$50 bonus for completing all three of the follow-up assessments. Incentives are not dependent on smoking status.

**Measures**—Participants complete a battery of assessments at baseline, weekly during the intervention, at the end of treatment (3-month), and at the 6 and 12-month follow-ups (see Figure 2).

**Primary Outcome:** The primary outcome is salivary-cotinine-verified 7-Day PPA at the 3-month assessment, and at the 6 and 12-month follow-ups. In addition, smoking status is assessed via self-report and measured objectively with a handheld breath carbon monoxide monitor at each of the two weekly sessions during the 12-week program, and at the 6 and



12-month follow-ups. Specifically, participants are asked whether or not “even a puff” was taken within the last 7 days, 24 hours, and the date of the last puff. This allows for an examination of the number of smoking cessation outcomes, including: (a) initial abstinence (24-hour abstinence); (b) time to first lapse (first smoking event following initial abstinence); (c) time to relapse (smoking at least 5 cigarettes/day for 3 consecutive days); (d) prolonged abstinence (reaching post-treatment without relapse following a two-week grace period after quit day); and (e) 7-day PPA. These outcome measures will be determined by self-report and confirmed by objective smoking assessments.

**Covariate: Nicotine Replacement:** Nicotine patch use is assessed at every session. Participants are asked if they used a nicotine patch since their last visit, how many, and if they have had any side effects. They are also asked if they have used any other supplemental nicotine (e.g., gum, lozenge), smoking cessation medications (e.g., varenicline, bupropion), or an electronic cigarette.

**Secondary Outcomes:** Secondary outcomes are divided into two major categories: (1) potential mechanisms of action; and (2) markers of disease risk associated (See Figure 2).

**Potential Mechanisms of Action Measures:** The potential mechanisms of action are measured at each session during the 12 weeks.

***Withdrawal Symptoms:*** Nicotine withdrawal symptoms are regularly reported as the major barrier to successful smoking cessation (Piasecki, 2006). To be consistent with other research in this area, the Mood and Physical Symptoms Scale (MPSS; West & Hajek, 2004) is used to measure nicotine withdrawal symptoms. The MPSS is a 7-item survey that shows good sensitivity to changes in craving and withdrawal symptoms over 24 hours abstinence, and compares well with other scales of nicotine withdrawal (West, Ussher, Evans, & Rashid, 2006).

***Cravings:*** Cigarette cravings and urges to smoke are reported by nearly all smokers following abstinence (Ussher, Beard, Abikoye, Hajek, & West, 2013). The Strength of Desire to Smoke (SoD), a single item measure (How strong are your smoking urges just now?), is used to assess cigarette craving. The SoD has been used in a number of previous studies testing the effects of aerobic exercise on cigarette craving with adequate reliability, validity and internal consistency (Taylor, Ussher, & Faulkner, 2007).

***Affect:*** Negative shift in affective valence is often experienced during nicotine withdrawal and is a consistent, independent predictor of relapse (Leventhal et al., 2013). There is currently a substantial amount of evidence detailing the acute benefits of resistance training on various mood states and well-being (Bibeau, Moore, Mitchell, Vargas-Tonsing, Bartholomew, 2010; Arent, Landers, Matt, & Etnier, 2005). As such, affective valence is acutely assessed; this is by using the single-item Feeling Scale. The scale ranges from -5 (very bad) to +5 (very good) with 0 (neutral) at the mid-point. The Feeling Scale has been used in research testing the effects of aerobic exercise on nicotine withdrawal with adequate reliability, validity and internal consistency (Taylor, Ussher, & Faulkner, 2007).

**Sleep:** Sleep is a primary symptom of nicotine withdrawal (Hamidovic & de Wit, 2009), and can interfere with the ability to quit smoking or maintain long-term abstinence (Riemerth, Kunze, & Groman, 2009). Chronic and acute resistance training has been shown to result in improved quality of sleep in individuals with and without sleep problems (Yang, Ho, Chen & Chien, 2012; Viana et al., 2012). Thus, participants' quality of sleep on the previous night is measured; this is by using the Leeds Sleep Evaluation Questionnaire (LSEQ), which has shown adequate consistency, reliability and validity in other research (Tarrasch, Laudon, & Zisapel, 2003).

**Markers of Disease Risk:** The markers of disease risk are measured by staff who are blind to the participant's condition. All assessments are taken at baseline and each follow-up.

**Body Weight and Composition:** Unlike the majority of studies on exercise and smoking cessation, both body weight and composition are monitored in this study. These assessments will identify any changes in fat mass that occur over the 12-month trial. Body weight is measured using a calibrated electronic scale (Cosmed, Inc., Concord, CA, USA). Body composition is determined using whole-body air displacement plethysmography (Bod Pod, Cosmed, Inc., Concord, CA, USA) with estimated thoracic gas volume according to the manufacturer's guidelines. Participants wear minimal clothing for each of these tests. The validity of air displacement plethysmography for male and female adults has been established (Baracos et al., 2012).

**Lung Function:** Smokers are at high-risk for developing impaired lung function (Nagelmann, Tonnov, Laks, Sepper, & Prikk, 2011). Resistance training can improve lung functioning (Singh, Jani, John, Singh, & Joseley, 2011) and is therefore monitored in this study. Lung function is assessed using a portable spirometer (Spirobank G Spirometer, Medical International Research, Inc., Waukesha, WI, USA). Forced expiratory volume in one second (FEV<sub>1</sub>) and forced vital capacity (FVC) is determined from three trials, and the values for FEV<sub>1</sub> and FVC are selected that fulfill the reproducibility and acceptability criteria in accordance with the American Thoracic Society criteria (Miller et al., 2005). Absolute values and percentages of predicted values of the lung function parameters will be used for analysis.

**Blood Sample:** Several studies have reported smokers to be at increased risk for developing insulin resistance (Luo et al., 2013) and dyslipidemia (Gepner, Piper, Johnson, Fiore, Baker, & Stein, 2011). Resistance training has been shown to result in statistically significant reductions in glycosylated hemoglobin (HbA1c), a marker of blood glucose control (Strasser, Siebert, & Schobersberger, 2010), and it may improve blood lipids (e.g., total cholesterol, triglycerides; Kelley & Kelley, 2009). As such, participants provide a sample of blood that is analyzed for HbA1c, total cholesterol, triglycerides, and high and low density lipoproteins. In addition, C-reactive protein (CRP) is measured, as it has been shown to be chronically elevated in smokers (Dietrich, Garcia, de Pablo, Schulze, & Hoffmann, 2007), and long-term elevations are consistently associated with an increased risk of coronary heart disease and stroke (Kaptoge et al., 2010). While research has shown that engaging in a resistance training program can lead to significant reductions in CRP concentrations



(Donges, Duffield, & Drinkwater, 2010), we are unaware of any published study that has investigated the relationships among CRP, resistance training and smoking.

**Physical Fitness:** Muscular strength (Ruiz et al., 2008) and aerobic capacity (Barry, Baruth, Beets, Durstine, Liu, & Blair, 2014) are well-known markers of disease risk and are predictors of mortality. The resistance training program used in this study is expected to impact both muscular strength and aerobic capacity (Tanaka & Swensen, 1998), thus, each is assessed. Muscular strength is measured using upper (chest press) and lower (leg extension) body exercises using the American College of Sports Medicine's (ACSM) protocol for 1-RM testing (ACSM, 2014). Aerobic capacity is assessed six-minute treadmill walk test (6MWT; Laskin et al., 2007). Both measures are regularly used to determine physical fitness in diseased and healthy populations, and both have acceptable validity and reliability (ACSM, 2013; Laskin et al., 2007).

**Mental Health Assessments:** Cigarette smokers are significantly more likely than non-smokers to report having a mental illness (SAMHSA, 2013), and smokers with a mental illness may be more likely to make a quit attempt (Morris, Burns, Waxmonsky, & Levinson, 2014). As such, the following assessments are taken at baseline and each follow-up.

**Anxiety:** Smokers are well known to have elevated levels of anxiety (Moylan, Jacka, Pasco, & Berk, 2012) and regular resistance training has been shown to reduce anxiety in a variety of populations (Herring, Jacob, Suveg, Dishman, & O'Connor, 2012; Hale & Raglin 2002). Trait anxiety is measured using the trait component of the State-Trait Anxiety Inventory (STAI; Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983). This 20-item scale measures items (e.g., I worry too much over something that really doesn't matter) on a 4-point scale from "Almost Never" to "Almost Always." The scale has shown adequate consistency, reliability and validity in a wealth of research (Spielberger, 1989).

**Depression:** Similar to anxiety, smokers are also known to have elevated levels of depression (Tjora, Hetland, Aarø, Wold, Wiium, & Overland, 2014) and reductions in depression have been reported after resistance training in clinical and non-clinical samples (Cooney et al., 2013; Singh, Stavrinou, Scarbek, Galambos, Liber, & Fiatarone-Singh, 2005). The 10-item Center for Epidemiologic Studies Depression Scale (CES-D) is used to measure depression symptoms over the past week (Björgvinsson, Kertz, Bigda-Peyton, McCoy, & Aderka, 2013). Items are rated on a 4-point scale from 0 (less than one day) to 4 (5–7 days). The scale has been validated (Björgvinsson, Kertz, Bigda-Peyton, McCoy, & Aderka, 2013) and used in other smoking cessation trials (e.g., Hennrikus et al., 2010).

**Potential Moderators:** Each of the following measures will be collected at baseline and tested as a potential moderator of the primary outcome.

**Demographics:** This questionnaire asks for information on the participant's age, gender, race, ethnicity, relationship status, family size, occupation, total household income and level of education.

**Nicotine Dependence:** The Fagerström Test for Nicotine Dependence (FTND) is used to measure nicotine dependence. The FTND is a 6-item measure with excellent reliability and validity in smoking research. It is considered the standard measure of nicotine dependence (Heatherton et al., 1991).

**Manipulation Check:** The resistance training completed on-site as part of the 12-week program is directly observed by research staff. Compliance to the program will be calculated as the number of sessions attended over the 12-weeks. Additional training outside of the on-site sessions is discouraged for the Resistance Training group, as is any exercise for the Wellness Control group. To monitor this throughout the trial, the past week Modifiable Activity Questionnaire (Pettee Gabriel, McClain, Schmid, Storti, Ainsworth, 2011) is administered at weeks 4, 8, 12, and at each follow-up assessment. In addition, for participants in the Resistance Training group, frequency of attendance at the fitness center during the follow-up period is monitored via their card swipe data; and any changes in fitness will be identified with the physical fitness tests.

## ANALYSIS

### Sample Size and Power Considerations

The 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 the analysis and sample size calculations, all dropouts will be coded as treatment failures (smokers). This approach has empirical justification in studies of smoking cessation (Lichtenstein & Glasgow, 1992). Sample size estimates for this trial were based on 6-month quit rates of 38% in the Resistance Training group versus 17% in the Contact Control (Ciccolo et al., 2011). While it is possible that effects may be stronger or weaker at the 12-month follow up (compared to those currently estimated from the 6-month follow-up in the pilot study), we do not anticipate significant differences from 6-month quit rates. Thus, using a multiplicity-adjusted two-tailed alpha level of 0.05/3 (1 outcome x 3 time points), a sample size of 103 participants per arm will be needed to have at least 80% power to detect between-group differences in objectively verified 7-day PPA at each of the follow-up times, for a total sample size of 206.

### Planned Analysis for Primary Outcomes

Using a longitudinal regression model implemented with Generalized Estimating Equations (GEEs; Zeger & Liang, 1986), with robust standard errors, the effect of treatment assignment on 7-day PPA will be tested. Specifically, the probability of being quit will be regressed on treatment assigned to, as well as any baseline variables that are not equally distributed across the two conditions. Furthermore, we will explore the effect of intention to use NRT and self-reported use on the estimated treatment effect by including each as a covariate in the model. Similar analyses will be conducted to examine the effects of treatment on prolonged abstinence.

## Planned Analysis for Secondary Outcomes

The treatment effects of resistance training on potential mechanisms of action will be tested using a series of longitudinal regression models implemented with GEEs (Zeger & Liang, 1986). The weekly measure of the mechanism (e.g., nicotine withdrawal symptoms) will be regressed on the treatment assignment, while controlling for baseline values of the mechanism, quit status at the time the mechanism was assessed, and potential confounders, as determined by preliminary analyses.

To examine potential mechanisms as predictors of smoking cessation outcomes, 7 day PPA, time to first lapse, and time to the start of relapse during the 12-week program will be considered as smoking endpoints. This will allow for a focus on quitting outcomes and on data that is reported before a participant returns to smoking. Time to the start of relapse requires first 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. When the outcome of interest is *time* to a defined event (i.e., first lapse, start of relapse), survival analysis (Hosmer & Lemeshow, 1999) will be used 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  $Ci$ , censoring time. For participants who lapse/relapse before the end of treatment,  $T^*i < Ci$ ; for those who do not lapse/relapse before end of treatment or who discontinue the study protocol before lapsing/relapsing,  $T^*i > Ci$ . Thus, the model uses  $Ti = \min \{ T^*i, Ci \}$  as the response for each participant. Using a Cox model (Cox, 1972; Therneau & Grambsch, 2000), we can write 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. Lastly, when the outcome of interest is 7-day PPA, logistic regression models will be used to regress the logit of the probability of 7-day PPA on withdrawal symptoms over time (for example), when controlling for treatment assignment and potential confounders of the association under consideration.

The effects of treatment on markers of disease risk will be tested at each time point (the 3, 6, and 12-month follow-ups) using a repeated measures regression model implemented with GEEs with robust standard errors. These adjusted standard errors will account for repeated measurements. Appropriate link functions will be used (e.g., identity link for continuous outcomes). If needed, a normalizing transformation to the continuous response measures (such as taking the logarithm of lung function) before proceeding with the analysis will be completed. Models will also control for baseline variables that are not equally distributed across treatment conditions. Lastly, the association between smoking outcomes and changes in markers of disease risk (i.e., from baseline to follow-up, 3, 6, and 12 months) will be examined using a longitudinal regression model implemented with GEEs with a logit link (which will estimate, for example, the effect of changes from baseline to time  $t$  in markers on the logit of 7-day PPA at time  $t$ , controlling for potential confounders).

Finally, using a similar set of analyses to those planned for the primary outcome, we will examine potential moderators of the treatment effect on smoking outcomes (7 day PPA and prolonged abstinence). Specifically, models will include the main effect of the potential moderator (gender for example), the main effect of treatment and the interaction between the two.

## LIMITATIONS

There are some limitations with the Strength To Quit trial that need to be acknowledged. First, the large incentives used to enhance compliance reduce the likelihood that the results from this study would easily translate into the community setting. However, because both conditions receive the same incentives and the incentives are not contingent on quitting, generalizability will be limited only to the extent that incentives moderate the effects of resistance training on smoking 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 Strength To Quit trial is to test the efficacy of resistance training as an aid for smoking cessation. If initial efficacy can be established, further research will be warranted, particularly studies that offer smokers a choice of different exercise programs that have been shown to be effective for aiding smoking cessation. Second, the mechanisms of action that are hypothesized to support sustained smoking abstinence during the follow-up period via continued resistance training (i.e., consistent reductions in negative affect, sleep disturbance, weight gain) are not monitored. As such, future studies should be designed in a way that would allow this data to be collected (e.g., using ecological momentary assessment) beyond the intervention period.

## DISCUSSION

To our knowledge, this is the first large-scale randomized controlled trial to test the use of resistance training as an aid to smoking cessation. This trial was designed to produce new data that will address some of the limitations of previous work on exercise and smoking cessation. For example, the vast majority of studies have used an aerobic-only exercise program, with the use of a female-only sample (Ussher, Taylor, & Faulkner, 2012). Furthermore, the hypothesized mechanisms of action (e.g., reduced negative affect, withdrawal symptoms) supporting a reduction in smoking with exercise have largely been studied outside the context of making a quit attempt (Roberts, Maddison, Simpson, Bullen, & Prapavessis, 2012; Taylor, Ussher, & Faulkner, 2007). As such, the results of this study will add to the literature base and inform current public health initiatives that promote the use of exercise as a method to achieve smoking cessation. Lastly, data from this study will reveal any effects resistance training may have on markers of disease risk in male and female smokers. While the beneficial health effects of resistance training are well known and accepted, the various effects resistance training may have on male and female smokers when trying to quit has not been rigorously examined.

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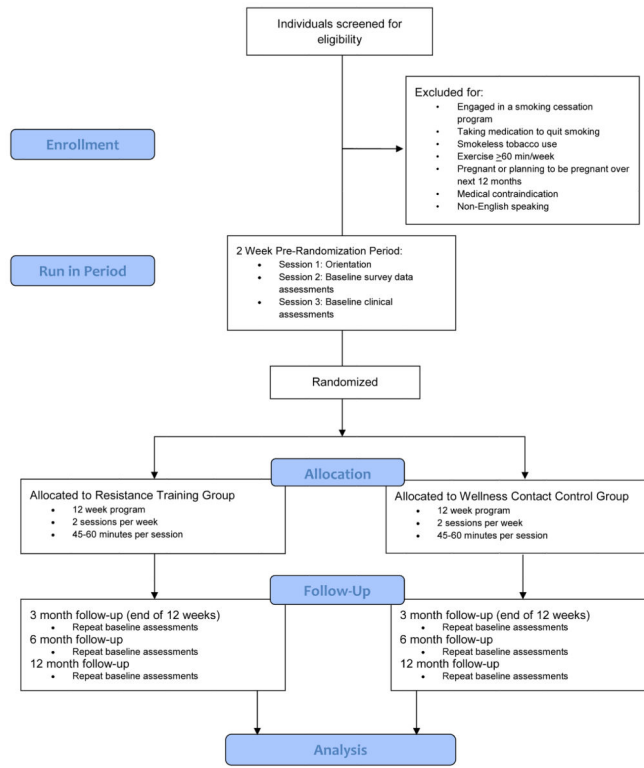


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### Highlights

- Tobacco use remains the leading worldwide preventable cause of death
- Smoking rates remain high among certain groups (e.g., those with mental illness)
- The research on the efficacy of exercise to enhance smoking cessation is equivocal
- The effects of resistance training in smokers have not been adequately tested



**Figure 1.**  
Study Design.

Assessment	Baseline	Weekly During Intervention	End of Intervention (3-Month)	6-Month Follow-up	12-Month Follow-up
<i>Smoking-Related Variables</i>					
Smoking History	√				
Smoking Status	√	√	√	√	√
Nicotine Patch Use		√	√	√	√
Salivary Cotinine			√	√	√
Carbon Monoxide	√	√	√	√	√
<i>Potential Mechanisms of Action Measures</i>					
Mood and Physical Symptoms Scale (MPSS)		√			
Strength of Desire to Smoke (SoD)		√			
Affect (Feeling Scale, Felt Arousal Scale)		√			
Leeds Sleep Evaluation Questionnaire		√			
<i>Markers of Disease Risk</i>					
Body Weight/Composition	√		√	√	√
Lung Function (FVC, FEV <sub>1</sub> )	√		√	√	√
Blood Lipids (total cholesterol, triglycerides, high and low density lipoproteins)	√		√	√	√
Glycosylated Hemoglobin (HbA1c)	√		√	√	√
C-reactive protein (CRP)	√		√	√	√
Muscular Strength	√		√	√	√
Aerobic Fitness	√		√	√	√
<i>Mental Health Assessments</i>					
State-Trait Anxiety Inventory (STAI)	√		√	√	√
Center for Epidemiologic Studies Depression Scale (CESD)	√		√	√	√
<i>Potential Moderators</i>					
Demographics	√				
Fagerström Test of Nicotine Dependence (FTND)	√		√	√	√

**Figure 2.**  
Schedule of Assessments.