

**Exercise as a Smoking Cessation Treatment for Women:  
A Randomized Controlled Trial**

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### Abstract

Cigarette smoking remains the leading behavioral risk factor for chronic disease and premature mortality. This RCT tested the efficacy of moderate intensity aerobic exercise as an adjunctive smoking cessation treatment among women. Participants ( $N=105$ ; age=42.5, SD=11.2) received brief smoking cessation counseling and 10 weeks of nicotine replacement therapy and were randomized to 12 weeks of moderate intensity exercise (Exercise;  $n=53$ ) or 12 weeks of health education (Control;  $n=52$ ). Longitudinal models, with Generalized Estimating Equations, showed no differences between Exercise and Control in cotinine-verified 7-day point prevalence abstinence (Wald=1.96,  $p=0.10$ ) or continuous abstinence (Wald=1.45,  $p=0.23$ ) at 12-weeks (post-treatment) or 6-, 9-, or 12-month follow-up, controlling for differences in baseline nicotine dependence. There was no effect of exercise on smoking cessation. The present study adds to the literature suggesting null effects of exercise a smoking cessation adjunctive treatment despite promising findings in short-term laboratory based studies.

**Keywords:** Exercise, physical activity, smoking cessation, nicotine replacement, women

Cigarette smoking is the leading preventable cause of morbidity and mortality in the United States, accounting for approximately 480,000 premature deaths and economic costs of \$107 billion per year in lost productivity and up to 14% of healthcare costs (Warren et al., 2014). Adults who smoke cigarettes often attempt to quit, with 53-69% making at least one serious quit attempt each year; however, only 5-7% of adults are successfully quit one year after initiating their quit attempt (Babb et al., 2017). Although men are more likely to be smokers than women (20.6% vs. 12.8%; Creamer et al., 2019), the gender gap in smoking rates has closed considerably over the past 50 years (Warren et al., 2014), and some studies show that women have more difficulty quitting and remaining abstinent (for a review see Smith et al., 2016).

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 (Ussher et al., 2019), which are common barriers for women attempting to quit smoking (Beebe & Bush, 2015; Clark et al., 2006; Faulkner et al., 2018; Rodriguez-Cano et al., 2017). Research findings have, however, been mixed. Experimental laboratory-based studies have consistently shown that a single session of aerobic exercise has a favorable impact on cravings and withdrawal symptoms in temporarily abstinent smokers (Haasova et al., 2013, 2014; Roberts et al., 2012; Taylor et al., 2007). However, a recent meta-analysis of 24 randomized controlled trials (RCTs) found no evidence that adding exercise to standard smoking cessation treatment (e.g., nicotine replacement therapy [NRT]) improves abstinence compared to treatment alone (Ussher et al., 2019).

One potential explanation for the discrepancy between laboratory and RCT outcomes is that compliance with exercise programs in RCTs has generally been poor and reliant on self-report (Ussher et al., 2019). As a result, the efficacy of exercise as a smoking cessation treatment

adjunct 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 the exercise programs.

While two prior RCTs (included in the meta-analysis (Ussher et al., 2019)) provide some evidence that vigorous intensity exercise may—when compliance is adequate—be an efficacious smoking cessation treatment (Marcus et al., 1999; Smits et al., 2016), there are a number of reasons why moderate intensity exercise may be preferred as a potential smoking cessation treatment. Moderate intensity brisk walking is the most preferred form of exercise for women (Brownson et al., 2000), is rarely medically contraindicated (American College of Sports Medicine et al., 2018), has a similar strong effect of reducing cravings as vigorous intensity PA in controlled laboratory studies (Haasova et al., 2013; Roberts et al., 2012; Taylor et al., 2007), and does not require expensive equipment. For these reasons, moderate intensity brisk walking, relative to vigorous intensity exercise, has a greater chance of public health impact if it proves to be an efficacious adjunct to smoking cessation treatment.

The present paper reports the findings from Quit for Health (Q4H), an RCT comparing 12 weeks of regular moderate intensity aerobic exercise to contact control as adjunct to 10 weeks of nicotine replacement therapy (NRT) among previously inactive female smokers (NCT01522274). To disentangle efficacy of versus compliance with the exercise treatment, exercise sessions were completed on site and directly observed, with monetary incentives provided for attendance at both Exercise and Control sessions irrespective of quit status. We hypothesized that women randomized to the Exercise condition would have higher rates of smoking cessation at end-of-treatment and at six, nine, and 12-month follow-ups.

## Methods

Adult female smokers were recruited via community fliers, newspaper, and internet. Eligibility criteria included a desire to quit smoking, current smoking  $\geq$  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 included medical contraindications for exercise, body mass index  $\geq$  40, diastolic/systolic blood pressure  $\geq$  140/90, resting heart rate  $\geq$  100, pregnancy, current use of smokeless tobacco, ongoing smoking cessation treatment, and unwillingness to use the nicotine patch.

Eligible participants provided written informed consent and were randomly assigned in a 1:1 ratio to a 12-week program of either; (a) moderate intensity exercise (Exercise), or (b) 12 weeks of a video-based wellness program that controlled for contact time and participant burden (Control). Randomization was based on a permuted block randomization procedure generated in R by the study statistician, with small random-sized blocks (ranging in size from 2-6). The randomization schedule was used to create sequentially numbered envelopes in which treatment allocation was listed on a card within the envelope. The envelopes were made by the study statistician and given to the study staff, which allowed staff to remain blind to treatment assignment.

A total sample size of 164 (82 participants per condition) was determined based on effect size estimates from a pilot study (D. M. Williams et al., 2010), a two-tailed alpha level of 0.05, and a conservative inflation in sample size of 25%. However, due to ongoing budget cuts throughout the study, recruitment was discontinued after 105 participants were randomized, which was a sufficient sample to obtain adequate power (.73), assuming expected effect sizes.

All treatment sessions were conducted from January 2012 to July 2017 at a university in New England where IRB approval was obtained. A CONSORT checklist is presented in Appendix A and a detailed description of the study design and procedures has been published elsewhere (David M. Williams et al., 2014).

### **Treatment Components**

Conditions were matched for contact time and burden. Participants in both conditions were required to attend three on-site sessions/week over 12 weeks and asked not to engage in offsite exercise. Both conditions were provided with brief smoking cessation counseling at baseline by a bachelor's level research assistant (CDC, 2009) and provided 10 weeks of NRT, beginning on the scheduled quit day (first session of week 2—one week post-randomization) through the end of week 11, with dose tailored to each participant's current smoking level. This schedule allowed for a one-week period with no NRT prior to saliva sampling at the end of week 12.

To achieve the national guidelines of 150 min/week of moderate intensity PA (USDHHS, 2018), participants randomized to the Exercise condition were prescribed three 50-min exercise sessions (three minutes of warm-up and three minutes of cool-down for a total of 56 min per session) per week for 12 weeks. Exercise consisted of brisk walking on a treadmill during which heart rate monitors were worn and participants were instructed to stay within their moderate intensity range (i.e., 64-76% heart rate maximum (American College of Sports Medicine, 2010)). Heart rate was increased as necessary by increasing the speed and grade of the treadmill. Participants gradually progressed to the target intensity and duration over the course of the first few sessions. Interactions with research staff were limited to safety monitoring and verification and documentation of exercise intensity. To minimize differences between the Exercise and

Control conditions, participants in the Exercise condition watched the same health-related videos as the Control condition, while exercising, on monitors mounted to each treadmill. Following the 12-week treatment period (including structured on-site exercise program), participants in the Exercise condition received a three-month membership to the local YMCA to provide assistance with transitioning their exercise outside of the laboratory setting.

Participants randomized to the Control condition completed the same procedures as exercise participants except the health-related videos were viewed while seated instead of while exercising. Control participants received three-month YMCA memberships upon completion of the 12-month study.

### **Participant Incentives**

Because compliance with the Exercise and Control programs was essential to addressing the primary aims of the study, we provided monetary incentives for attending sessions. Specifically, participants received \$300 at the post-treatment assessment session for meeting the study goal of attending at least 33 of the 36 Exercise/Control sessions (three times per week over twelve weeks), with a three-session forgiveness for illness, vacation, etc. The \$300 incentive was reduced by \$50 for every additional missed session, but not reduced below \$50 regardless of attendance rate. An additional \$75 was provided for attendance at the 6-, 9-, and 12-month follow-up assessments (i.e., \$25 for each assessment), regardless of previous attendance.

### **Measures**

Assessments were conducted continuously over the 12-week treatment and at 6-, 9-, and 12-month follow-up assessments. Baseline assessments included demographic information (e.g., age, education, race, ethnicity, household income, employment status, partner status), height and weight to calculate body mass index (BMI), nicotine dependence (Shiffman et al., 2004),

smoking rate and level of physical activity via the 7-day Physical Activity Recall (Sallis et al., 1985).

Because exercise was supervised, attendance at the thrice weekly in-person sessions was used as the primary manipulation check. We also examined number of sessions with mean HR within the target HR range, as well as change in cardiorespiratory fitness from baseline to post-treatment using the one-mile walk test (Widrick et al., 1992). Although offsite exercise was discouraged during the treatment period, it was assessed, via ecological momentary assessment (EMA), to control for possible dosage inconsistencies within the Exercise condition as well as contamination in the Control condition.

Self-reported smoking status (24-hour quit; yes/no), verified by exhaled carbon monoxide (CO) < 10 ppm, and smoking rate (cigarettes/day since last assessment) were collected three times/week for 12 weeks and at each of the follow-up visits (6, 9, and 12 months post-randomization). The primary outcome was self-reported 7-day PPA at 12 weeks post-randomization (end-of-treatment [post-treatment]) and follow-ups, as verified by saliva cotinine < 15 mg/ml, as well as absence of smoking at any of the thrice weekly sessions in the 7 days prior to the post-treatment assessment. Participants demonstrating 7-day PPA at post-treatment were also considered continuously abstinent (secondary outcome) at post-treatment if there were no disconfirming instances of CO-verified quit status during the 12-week treatment beginning at the start of week four, thus allowing for a two-week grace-period following quit day. Continuous abstinence at each follow-up required continuous abstinence at post-treatment and up to the last follow-up for which PPA was demonstrated. Smoking assessments were conducted by a research assistant who was aware of treatment assignment; however, this was not considered to increase risk of bias given use of biochemical validation of smoking status (see (Ussher et al., 2019), p.



7). Additional questionnaires (i.e., weight concerns (Borrelli & Mermelstein, 1998) and depressive symptoms (Rush et al., 2003)) and EMA assessed potential mediators of treatment outcomes and are not reported here.

### **Analyses**

Between-group differences in baseline characteristics and program attendance were explored using parametric (Analysis of Variance [ANOVA]), and non-parametric (Chi-squared) tests as appropriate. A series of generalized linear models were used to examine between group differences in changes in cardiorespiratory fitness from baseline to end-of-treatment. A longitudinal mixed-effects model with subject specific intercept was used to examine between group differences in exercise performed outside of treatment across 12 weeks.

Next, using a series of longitudinal models implemented with Generalized Estimating Equations (GEEs) with robust standard errors, we tested the effect of randomization on binary smoking outcomes (7PPA and continuous abstinence). Data were clustered within participant over time, and standard errors were adjusted accordingly. Specifically, smoking status at each post-quit-date assessment through 12-month follow-up, was regressed on condition, time, and time\*condition adjusting for baseline smoking rate and potential confounders that were not balanced between conditions at baseline, and including a subject-specific intercept to adjust for repeated measures of the outcome within participant.

All analyses were conducted on the Intent to Treat (ITT) sample. Models used likelihood-based approaches to estimation and thus made use of all available data without directly imputing missing data. Results were compared to the conservative assumption that missing equals smoking (in the case of binary outcomes) and did not differ substantially from the Maximum

Likelihood Estimation. All analyses were run using SAS 9.3 and R and significance value was set at  $\alpha=0.05$  a priori.

## Results

The overall sample consisted of 105 participants randomized to Exercise ( $n=52$ ) vs. Control ( $n=53$ ). Participant recruitment, enrollment, and retention are presented in the CONSORT diagram (Figure 1). A full description of the study sample is in Table 1. Participants were 42.5 years of age on average ( $SD=11.2$ ), predominantly non-Hispanic white (93%) with 50% reporting a college-level education. Participants smoked an average of 17.0 ( $SD=7.7$ ) cig/day at baseline. Mean standardized nicotine dependence was -0.3 ( $SD=1.0$ ) at baseline, with significantly higher scores in Exercise vs. Control ( $p=.004$ ). There were no between-group differences at baseline on demographic characteristics, BMI, smoking rate, level of physical activity, cardiorespiratory fitness, or depressive symptoms.

Table 2 provides unadjusted values for attendance, compliance with exercise prescriptions, exercise behavior outside of treatment, and changes in cardio-respiratory fitness. On average, Exercise participants attended 26.9 ( $SD=9.8$ ) sessions over the treatment period compared to 28.9 ( $SD=8.5$ ) in Controls with no difference between groups ( $p=.28$ ). Attendance data were skewed, with 67% of participants attending the program goal of 33 of 36 sessions and 77.1% attending at least 25 sessions, thus showing high compliance for the majority of participants. Moreover, among Exercise participants, an average of 88.3% of exercise sessions were within the prescribed heart rate range and there was a significant increase from baseline to end-of-treatment in cardiorespiratory fitness ( $VO_2$  max;  $p<.001$ ), which was significantly greater than the change in fitness observed in controls (observed between-group difference in pre-post change,  $p=.004$ ). NRT use did not differ between conditions ( $F=.97$ ,  $p=.33$ ), with participants

reporting wearing a nicotine patch at a median of 14.5 sessions over 12 weeks, with a range of 0-32. Finally, participants in the Exercise condition reported an average of 6.7 min/day (SD=14.1) of exercise outside of the lab (median=0.71, range: 0-83.3) vs. 3.8 min/day (SD=6.7) among Control participants (median=.3, range: 0-31.9), with no significant between group differences ( $p=.17$ ).

Unadjusted smoking cessation outcomes are presented in Table 3. Contrary to hypotheses, adjusted longitudinal models did not suggest significant between-group differences in smoking cessation at post-treatment, or at 6-, 9-, or 12-month follow-ups (7-day PPA, Wald=1.96,  $p=.10$ ; continuous abstinence, Wald=1.45,  $p=.23$ ).

### **Discussion**

The goal of this study was to provide a rigorous test of the efficacy of moderate intensity aerobic exercise as a smoking cessation treatment adjunct (combined with NRT) among women. The impetus for the present trial was that previous RCTs testing the efficacy of moderate intensity exercise as a smoking cessation treatment adjunct have typically used a home-based approach, resulting in exercise compliance that has been unverified and often inadequate (Ussher et al., 2019). In contrast, in two prior RCTs that were among the few to exhibit significant effects of exercise on smoking cessation outcomes, exercise was supervised and thus directly observed and compliance was adequate; however, in these trials exercise was of vigorous intensity (Marcus et al., 1999; Smits et al., 2016). In the present trial we sought to combine the rigor of direct observation of exercise with the use of moderate intensity exercise, which, relative to vigorous intensity exercise, may have a greater chance of public health impact if proven to be an efficacious adjunct to smoking cessation treatment.

Compliance with the exercise program was directly observed and incentivized to avoid the confound between treatment compliance and treatment effects that has plagued prior studies (Ussher et al., 2019). Compliance was adequate, with approximately 85% of sessions attended across treatment conditions and 88% of completed exercise session within the prescribed moderate intensity range. Physical activity completed outside the laboratory sessions was discouraged but assessed on a daily basis and was minimal and did not differ between conditions. Smoking cessation was objectively assessed with CO and saliva cotinine. Thus, findings from the study provide a largely unbiased estimate of the efficacy of moderate intensity aerobic exercise as a smoking cessation treatment for women.

After controlling for nicotine dependence, which was significantly higher at baseline among Exercise participants, there was no effect of treatment condition on 7-Day PPA or continuous abstinence at the 12-week post-treatment or at 6-, 9-, or 12-month post-randomization follow-ups. Thus, moderate intensity exercise was not supported as an efficacious smoking cessation treatment adjunct even when compliance with the exercise program was verified and adequate. These findings are largely consistent with the null aggregate findings from the meta-analysis of previous RCTs (Ussher et al., 2019).

However, the findings from the present RCT are at odds with consistently promising findings from laboratory studies. Methodological differences between laboratory studies and the present field-based clinical trial may account for the discrepancy in findings. In laboratory studies, participants are often asked to abstain from smoking for 12-24 hours prior to the exercise manipulation. This results in a baseline level of cravings that a session of PA may serve to alleviate. However, in the present trial, participants were given NRT, which likely served to reduce cravings and thus attenuate the effects of PA on cravings. Additionally, while most prior

laboratory studies include only a single session of PA (versus control), the PA program in the present RCT continued for 12 weeks during which time cravings and other withdrawal symptoms may have subsided, thus again attenuating the effects of PA.

It should be noted that analyses for the present study were slightly underpowered by typical standards (i.e., .73 in the present trial versus a standard of .80 (Cohen, 1988)). However, lack of between-group differences in mean quit rates at each time point (Table 3) suggest that the non-significant findings cannot be reasonably attributed to a lack of power. Additionally, the participant sample for the present study was predominantly non-Hispanic white and thus further research is needed with more diverse participant samples.

In conclusion, this study added to the literature suggesting that over the course of a sustained (6-12 weeks) smoking cessation program, moderate intensity exercise is unlikely to be an efficacious adjunct to standard smoking cessation treatment (i.e., NRT and brief counseling) among women. However, given the many laboratory studies suggesting that aerobic exercise can have a short-term effect on cigarette cravings (Haasova et al., 2013, 2014; Roberts et al., 2012; Taylor et al., 2007), there is still the potential that it can be of some benefit in the context of smoking cessation programs. For example, future research should examine the additional value and potential synergistic effects of incorporating aerobic exercise as one of multiple strategies to alleviate short-term cravings in the context of a more comprehensive treatment package. This could potentially be achieved in the context of a multifactorial micro-randomized trial (Collins et al., 2014) in which exercise is examined as one independent variable in combination with other smoking cessation treatment components.

Likewise, the present findings, while suggesting that aerobic exercise may not be an efficacious smoking cessation treatment on its own or as an adjunct to NRT, do not nullify the

prior laboratory results suggesting that it can potentially a valuable clinical tool for alleviating short-term cigarette cravings.

**Table 1. Baseline Characteristics by Study Condition**

	<b>Exercise (n=52)</b>	<b>Control (n =53)</b>
	<b>Mean (Standard Deviation)</b>	
Age	42.9 (10.8)	42.5 (11.4)
BMI	27.9 (5.4)	27.6 (5.0)
Nicotine dependence (overall)*	-0.1 (1.0)	-0.6 (.9)
Smoking rate (cig/day)	17.4 (8.4)	16.3 (6.2)
Min/week MVPA	17.1 (68.6)	8.7 (26.6)
	<b>Frequency (%)</b>	
Education, N=104 <sup>a</sup>		
<HS grad	4 (7.8%)	5 (9.4%)
HS grad	3 (5.9%)	7 (13.2%)
Some college	15 (29.4%)	16 (30.2%)
College grad	19 (37.3%)	19 (35.8%)
Post-college grad	10 (19.6%)	6 (11.3%)
Race		
American Indian/Alaska	1 (1.9%)	0
Black	5 (9.6%)	5 (9.4%)
White	44 (84.6%)	42 (79.2%)
Other	2 (3.8%)	6 (11.3%)
Ethnicity		
Hispanic	4 (7.7%)	4 (7.5%)
Household Income		
<10k	7 (13.5%)	10 (18.9%)
10k-19,999	8 (15.4%)	8 (15.1%)
20k-29,999	10 (19.2%)	7 (13.2%)
30k-39,999	6 (11.5%)	2 (3.8%)
40k-50k	5 (9.6%)	12 (22.6%)
>50k	10 (19.2%)	11 (20.8%)
Don't know	4 (7.7%)	3 (5.7%)
Refused	2 (3.8%)	0
Employment		
Unemployed	19 (36.5%)	20 (37.7%)
Employed	32 (61.5%)	33 (62.3%)
Refused	1 (1.9%)	0
Partner Status		
Single	20 (38.5%)	23 (43.4%)
Married/Partnered	15 (28.8%)	17 (32.1%)
Widowed	0	2 (3.8%)
Separated/Divorced	17 (32.7%)	10 (18.9%)
Refused	0	1 (1.9%)

<sup>a</sup> One participant did not report education level.

\*Exercise participants had higher average baseline nicotine dependence than Control participants,  $p < .05$ . MVPA= Moderate-vigorous physical activity; BMI= Body mass index

**Table 2. Treatment Compliance by Study Condition**

	<b>Exercise (n=52)</b>	<b>Control (n =53)</b>
	<b>Mean (Standard Deviation)</b>	
Total sessions attended	26.9 (9.8)	28.9 (8.5)
% exercise sessions within prescribed HR range	88.3 (18.0)	N/A
Average min/day of exercise outside the lab	6.7 (14.1)	3.8 (6.7)
Fitness		
VO <sub>2</sub> max baseline	26.7 (8.0)	26.6 (7.7)
VO <sub>2</sub> max Post	29.2 (7.7)	26.6 (7.2)

Note. No between-group differences on any of these variables ( $p>.05$ ).

VO<sub>2</sub> max= Maximum volume of oxygen consumption, an indicator of cardiorespiratory fitness

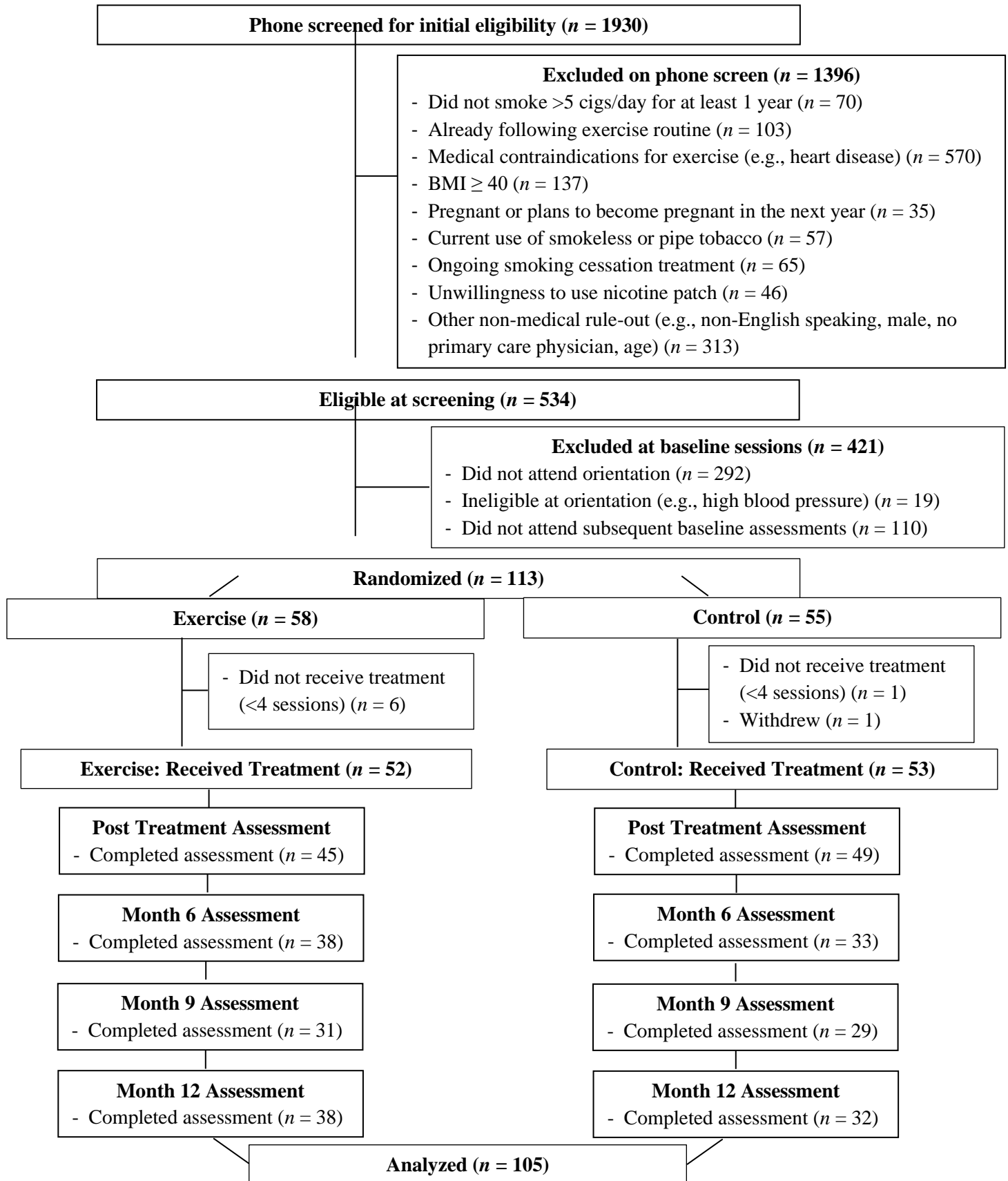


**Table 3. Unadjusted Smoking Outcomes by Study Group**

	<b>Exercise (<i>n</i>=52)</b>	<b>Control (<i>n</i> =53)</b>
Verified 7-day PPA		
Post treatment	25.0%	39.6%
6M	15.4%	17.0%
9M	13.5%	11.3%
12M	17.3%	22.6%
Continuous abstinence		
Post treatment	13.5%	17.0%
6M	7.7%	3.8%
9M	7.7%	0%
12M	5.8%	0%

Note. Denominator for reported percentages is the total number of participants in Exercise (*n*=52) and Control (*n*=53) conditions, rather than the number attending each follow-up session. Thus, for purposes of presenting unadjusted smoking outcomes, participants who missed a follow-up session were assumed to be smoking. See text for adjusted results controlling for baseline differences in nicotine dependence and using likelihood-based approaches to missing data. PPA= Point prevalence abstinence.

Figure 1. Flow of participants through the study.



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