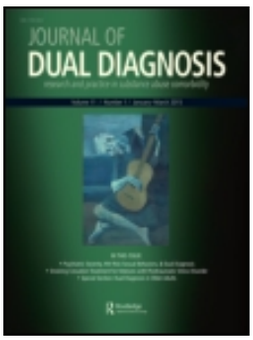

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Exercise and Counseling for Smoking Cessation in Smokers With Depressive Symptoms: A Randomized Controlled Pilot Trial

Paquito Bernard, PhD,[1,2] Gregory Ninot, Pr,[1] Fabienne Cyprien, Dr,[3] Philippe Courtet, Pr,[4,5] Sebastien Guillaume, Pr,[4,5] Vera Georgescu, PhD,[6] Marie-Christine Picot, Pr,[6] Adrian Taylor, Pr,[7] and Xavier Quantin, Pr[1,2]

Objective: Despite various strategies to help smokers with depressive disorders to quit, the smoking relapse rate remains high. The purpose of this pilot study was to estimate the effects of adding an exercise and counseling intervention to standard smoking cessation treatment for smokers with depressive disorders. We hypothesized that the exercise and counseling intervention would lead to improved abstinence, reduced depressive symptoms, and increased physical activity. **Methods:** Seventy smokers with current depressive disorders were randomly assigned to standard smoking cessation treatment plus exercise and counseling ($n = 35$) or standard treatment plus a time-to-contact control intervention on health education ($n = 35$). Both programs involved 10 sessions over 8 weeks. The primary outcome was continuous abstinence since the quit date and was measured at week 8 (end of the intervention) and again at 12-, 24-, and 52-week follow-ups. **Results:** Nearly 60% of participants were female ($n = 41$), 38 (52.3%) were single, 37 (52.9%) had education beyond high school, and 32 (45.7%) met criteria for major depressive disorder or dysthymia. Participants in the two treatment conditions differed at baseline only in marital status ($\chi^2 = 4.28$, $df = 1$, $p = .04$); and smoking abstinence self-efficacy, $t(66) = -2.04$, $p = .04$). The dropout rate did not differ significantly between groups and participants attended 82% and 75% of the intervention and control sessions, respectively. Intention-to-treat analysis showed that, at 12 weeks after the beginning of the intervention, continuous abstinence did not vary significantly between the intervention and control groups: 48.5% versus 28.5%, respectively, $OR_{adj} = 0.40$, 95% CI [0.12–1.29], $p = .12$. There were no group differences in depressive symptoms, but the intervention group did outperform the control group on the 6-minute walking test ($M_{int} = 624.84$, $SD = 8.17$, vs. $M_{con} = 594.13$, $SD = 8.96$, $p = .015$) and perceived physical control ($M_{int} = 2.84$, $SD = 0.16$, vs. $M_{con} = 2.27$, $SD = 0.18$, $p = .028$). The sample was not large enough to ensure adequate statistical power. **Conclusions:** This finding, while preliminary, suggests that an exercise and counseling intervention may yield better results than health education in improving smoking abstinence. This study is registered at www.clinincaltrials.gov under # NCT01401569. (*Journal of Dual Diagnosis*, 11:205–216, 2015)

Keywords *exercise, counseling, smoking cessation, depression, physical activity, sedentary, behavioral change techniques*

Cigarette consumption is the leading cause of death in the world (Hatsukami, Stead, & Gupta, 2008). The benefits of smoking cessation are numerous and include increased longevity and decreased morbidity (Mathers & Loncar, 2006). However, smokers with current depressive disorders (e.g., major depressive disorders, dysthymia, subthreshold depressive symptoms) are generally excluded from clinical trials (Smith, Mazure, & McKee, 2014; Strat, Rehm, & Foll, 2011). The prevalence of tobacco dependence among adults with current major depressive disorder or dysthymia varies between 27% and 60% (Borrelli, 2010; Husky, Mazure, Paliwal, & McKee, 2008; Khaled et al., 2012), and 28% of them are categorized as heavy smokers (> 24 cigarettes per day; McClave et al., 2009). In parallel, past major depressive disorder and severity of depressive symptoms are not associated with the motiva-

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tion to quit (Acton, Prochaska, Kaplan, Small, & Hall, 2001; Prochaska et al., 2004).

Despite the development of various strategies to help smokers with current depressive disorders to quit, the smoking relapse rate remains high. Longitudinal investigations have found that current major depressive disorder, dysthymia (Weinberger, Pilver, Desai, Mazure, & McKee, 2012, 2013), or pre-treatment subthreshold depressive symptoms (Berlin & Covey, 2006; Niaura, Shadel, Goldstein, Abrams, & Brown, 2001) are associated with lower rates of smoking cessation and higher likelihood of smoking relapse over a long-term period.

The US Department of Health and Human Services guideline for treating tobacco dependence underlines the need to develop specific smoking cessation interventions (Fiore et al., 2008). Recently, two meta-analyses have explored the effectiveness of smoking cessation treatments in individuals with depression (Gierisch, Bastian, Calhoun, McDuffie, & Williams, 2011; Van der Meer, Willemsen, Smit, & Cuijpers, 2013). The first study suggested that the combination of behavioral counseling with nicotine replacement therapy or nicotine partial agonists is associated with positive short-term results (Gierisch et al., 2011). The second study concluded that adding a mood management component to a standard smoking cessation program increased cessation rates (Van der Meer et al., 2013). However, these treatments do not seem to be sufficient to obtain significant long-term abstinence rates, and few trials have exclusively enrolled smokers with current depressive disorders. Among other potential treatments, physical exercise needs to be considered for smokers with depressive disorders (Bernard et al., 2013).

Indeed, the use of exercise interventions for smoking cessation or antidepressive treatments has garnered increased interest. A systematic review described the significant impact of exercise on the reduction of tobacco withdrawal symptoms (Ussher, Taylor, & Faulkner, 2014). Additionally, two meta-analyses reported a significant decrease in craving following exercise sessions (Haasova et al., 2013; Roberts, Maddison, Simpson, Bullen, & Prapavessis, 2012). Nevertheless, in spite of considerable research (up to 20 randomized controlled trials), the positive impact of exercise on relapse has not been clearly demonstrated. Moreover, remarkably, the effects of exercise on smoking abstinence among smokers with current depressive disorders have not been studied (Ussher et al., 2014). The above studies suffered from several limitations, including inadequate length of exercise training, program brevity, and lack of formal cessation treatment. On the other hand, the antidepressant effect of exercise was well-identified in numerous meta-analyses. In those studies, the effect sizes were moderate to large (ranging from 0.5 to 1.1; Ekkekakis, 2015; Cooney et al., 2013; Rethorst, Wipfli, & Landers, 2009).

It has been suggested that smoking and physical activity are interrelated behaviors (deRuiter, Cairney, Leatherdale, & Faulkner, 2014). Interventions targeting other health behavior (e.g., weight management) during smoking cessation demonstrated a higher abstinence rate in the short term (Spring et al., 2009). Higher levels of pre-cessation physical activity are associated with a lower risk of long-term relapse, specifically in smokers with current depressive disorders (Bernard et al., 2012; Bernard, Ninot, & Quantin, 2015). Finally, a pilot study also suggested that counseling sessions focusing on physical activity should be offered during smoking cessation (Vickers et al., 2009). The authors recommended the development of a more intensive intervention, which would include counseling and supervised exercise (Bernard et al., 2013; Vickers et al., 2009) specifically targeted to these smokers.

Our study was designed with the following three objectives. First, we aimed to estimate the short-term effects of an exercise and counseling intervention in continuous abstinence rates prior to a larger and longer study. Second, we wanted to examine the effects of the exercise and counseling intervention on physical activity and sedentary behavior at the end of the intervention and over time. Third, we planned to study the effects of an exercise and counseling intervention on smoking-related variables, anxiety, depression, quality of life, and physical fitness.

METHODS

Study Design

We designed a randomized controlled pilot trial with two parallel arms to examine whether adding exercise and counseling to a smoking cessation program could increase the rate of smoking abstinence in smokers with current depressive disorders. The participants in the comparison condition received standard smoking cessation treatment (i.e., initial individual session and prescription of nicotine replacement therapy or varenicline) and a health education intervention, matched for overall contact time. The selection, inclusion, and treatment of participants, as well as the collection of data, were performed at Montpellier University Hospital in France. The protocol was approved by all local institutional review boards and was accepted by the Independent Ethics Committee of Montpellier. It was also registered at ClinicalTrials.gov (number NCT01401569).

Setting and Sample

Participants were recruited over a 17-month period (between October 2010 and May 2012) via news releases and advertisements in local print and electronic media. The advertisements briefly described the study (i.e., "8-week study to compare health education with exercise and counseling in smoking cessation program including pharmacological treatment") and did not mention depressive symptoms. Potential participants called a research assistant who briefly introduced the study, explained the screening procedure and further assessed patients' eligibility (i.e., nicotine dependence, level of depres-

sion, physical activity). Eligible participants were invited to a first visit during which their eligibility was confirmed. Eligible and consenting participants were then asked to read and sign the informed consent form. The participants were blinded to the study's specific goals or hypotheses; they were only told that the investigators were attempting to determine which intervention would be the most effective.

Potential participants were included if they (a) scored 8 or higher on the Depression subscale of the Hospital Anxiety and Depression Scale (HADS; Roberge et al., 2013) and 4 or higher on the Fagerström Test for Nicotine Dependence (FTND); (b) had not engaged in physical activity regularly (at least 20 minutes per day on fewer than 3 days per week) and were able to exercise at 60% maximum heart rate (upon physician approval); and (c) were not currently receiving smoking cessation pharmacotherapy. All selected participants provided written informed consent.

Potential participants were excluded if they (a) were unable to complete self-administered questionnaires in French; (b) had a diagnosis of psychosis, bipolar disorder, or substance dependence (other than nicotine, as assessed with the Mini International Neuropsychiatric Interview [MINI]); (c) had a medical contraindication to exercise; (d) were taking mood stabilizers and antipsychotics; or (e) were pregnant.

Intervention

In an initial individual session with a medical doctor, all participants were encouraged to stop smoking and selected a quit date within the 2 weeks. The session included brief counseling (see details in Supplementary File 1) and a 12-week prescription for nicotine replacement therapy or varenicline. The pharmacological treatment was implemented upon patient approval only. In accordance with the current Clinical Practice Guidelines of the French Health Products Safety Agency (Le Foll, Melihan-Cheinin, Rostoker, & Lagrue, 2005), nicotine replacement therapy dosage was adjusted to the level of expired carbon monoxide and patches and gum were associated. Participants who received varenicline treatment started at 0.5 mg daily for 3 days, then 0.5 mg twice daily for 4 days, and 1 mg twice daily thereafter. Participants were not excluded from the study based on refusal to comply with the drug recommendations, because this study primarily assessed the adjunct intervention and aimed to adhere to conditions found in actual, real-world practice.

Both interventions consisted of a 10-session, 8-week group program, with biweekly meetings for weeks 1 and 2 and weekly meetings for weeks 3 through 8. The two conditions provided equal clinician contact time (75 minutes per session). Attendance was taken for each session; anyone who failed to attend a session was telephoned by a staff member, encouraged to continue, and scheduled for a make-up session (maximum 2 sessions).

Exercise and Counseling

The smokers assigned to the exercise intervention were invited to attend a supervised group exercise program, focused on addiction, which included counseling sessions. Participants were expected to attend two supervised exercise sessions and two counseling sessions weekly in the first 2 weeks. In weeks 3 through 8, they were required to attend one supervised exercise session and one counseling session weekly, plus one home-based, unsupervised exercise session (see Supplementary File 1). Supervised exercise and counseling sessions were performed consecutively.

The supervised exercise sessions consisted of a 5-minute warm-up, followed by 30 minutes of aerobic activity (stationary cycle ergometer) and a 5-minute cool-down period including stretching. The intensity of the training ranged from 60% to 85% maximum heart rate. To assist participants in exercising at the appropriate intensity level, we recommended an equivalent perceived exertion level of 4 out of 10 (Borg, 1998). The sessions were supervised by a qualified adapted physical activity professional who checked and documented the heart rates of participants. The home exercise sessions consisted of 40 minutes of aerobic exercise (i.e., walking, cycling, or running). The intensity level of the training for these sessions ranged from 6 to 8 on a breathlessness visual analogue scale. A paper reminder was given to participants, which described the home exercise sessions they were expected to do.

The counseling sessions focused alternatively on physical activity and smoking cessation. They were conducted by a qualified physical activity expert, who coached the group for a period of 40 minutes. The counseling goals were (a) to increase one's level of physical activity in the long term, (a) to use short bouts of exercise in response to negative affect and craving, (c) to develop skills for managing withdrawal symptoms, and (d) to develop skills for becoming and remaining an ex-smoker. The content of the counseling sessions included a set of behavioral change techniques, as labeled in the smoking cessation and physical activity taxonomies (Michie, Ashford et al., 2011; Michie, Hyder, Walia, & West, 2011). These techniques are described in detail in Supplementary file 1.

Health Education Control

The participants assigned to the health education control condition (i.e., contact time) received information on a variety of health prevention topics including sleep hygiene, nutrition, stress, and health screening tests for cancer prevention. Lectures, handouts, films, and discussions addressed health and lifestyle issues.

The counseling and health education sessions were delivered by a PhD-level postdoctoral fellow in health psychology with 1 year of post-degree experience. The counselor followed written treatment procedures in both conditions (available on request from first author). Fidelity checks were not made. The

supervised exercise sessions were conducted by two master's-level adapted physical activity specialists who ran 25% and 75% of the sessions, respectively.

Outcomes

Primary Outcome

The primary outcome of this study was continuous abstinence since the quit date and was assessed at week 8 (end of the intervention) and at 12-, 24-, and 52-week follow-ups. The subjects were considered to be continuously abstinent if they had not smoked after the quit day, as confirmed by a carbon monoxide concentration of 10 parts per million or less (with the Micro 4 Smokerlyzer; Hughes et al., 2003).

Secondary Outcomes

Anxiety and depression were assessed with the HADS (Roberge et al., 2013). Three smoking-related variables were measured using a self-assessment questionnaire: smoking abstinence self-efficacy (Smoking Self-Efficacy Questionnaire [SSQ-12]; Etter, Bergman, Humair, & Perneger, 2000), cigarette craving (Tobacco Craving Questionnaire; Berlin, Singleton, & Heishman, 2010), and nicotine dependence (FTND; Heatherton, Kozlowski, Frecker, & Fagerström, 1991). Physical activity was assessed using both subjective and objective instruments. Objective physical activity data was collected using a 2-axis accelerometer (SenseWear Pro Armband; Hill, Dolmage, Woon, Goldstein, & Brooks, 2010). We asked patients to wear the armband for 7 consecutive days (daytime only) before and after the program. Self-reported physical activity was assessed using the International Physical Activity Questionnaire–Short Form, a widely accepted measure that classifies physical activity levels into three categories (low, moderate, and high) based on scoring algorithms (Gauthier, Lariviere, & Young, 2009; Craig et al., 2003). For our analytic purposes, we considered that participants in the high physical activity category met current recommendations for health-enhancing behavior and created a dichotomous variable to reflect this (i.e., meeting high physical activity levels or not; Sjöström, Oja, Hagströmer, Smith, & Bauman, 2006). Sedentary behavior information was collected using the accelerometer. The participants also completed the Alcohol Use Disorders Identification Test (AUDIT; Gache et al., 2005), the Short Form Health Survey (Gandek et al., 1998), and the Physical Self-Perception Profile (Ninot, Delignières, & Fortes, 2000). To assess the physical fitness of the subjects, a trained research assistant administered the 6-Minute Walk Test (6MWT) following the international guidelines (American Thoracic Society, 2002).

All the measures included in the self-reported questionnaires had previously been validated in French. Attendance was taken for each session. Table 1 outlines the data collection protocol, including the nature of the variables measured and the time when they were assessed. Supplementary File 2 presents the details of our questionnaires, assessment tools, and data monitoring.

TABLE 1
Summary of Assessments

	First Visit	End of Intervention	12-Week Visit	24-Week Visit	52-Week Visit
Demographic data	■				
MINI 5.0	■				
SF-12	■	■	■		
AUDIT	■				
Smoking					
Consumption	■	■	■	■	■
Abstinence	■	■	■	■	■
Expired CO	■	■	■	■	■
Fagerström	■				
PSPP	■	■			
SSQ-12	■	■			
TCQ-12	■	■			
Mood					
HADS-D	■	■	■	■	■
HADS-A	■	■	■	■	■
Physical activity					
Accelerometer	■	■			
IPAQ-SF	■	■	■	■	■
Physical Fitness					
Weight (kg)	■	■	■	■	■
6MWT	■	■			

Note. MINI 5.0 = Mini International Neuropsychiatric Interview; CO = carbon monoxide; HADS-D = Hospital Anxiety Depression Scale–Depression subscale; HADS-A = Hospital Anxiety Depression Scale–Anxiety subscale; IPAQ-SF = International Physical Activity Questionnaire–Short Form; 6MWT = 6-Minute Walk Test; SF-12 = Short Form Health Survey 12; PSPP = Physical Self-Perception Profile; SSQ-12 = Smoking Self-Efficacy Questionnaire; TCQ-12 = Tobacco Craving Questionnaire; AUDIT = Alcohol Use Disorders Identification Test.

Baseline Variables

Age, sex, employment status, primary occupation, level of education, marital status, pharmacological treatments, and household income level data were collected during the initial (baseline) visit. Smoking variables were also assessed at baseline and included age at smoking initiation, age at smoking daily, history of dependence, number of quit attempts, cannabis consumption, and number of cigarettes smoked daily. A trained research assistant evaluated possible psychiatric disorders and antecedents using a validated and reliable diagnostic structured interview covering 17 disorders and based on *DSM-IV* criteria (assessed with the MINI; Lecrubier et al., 1997).

Randomization

Following their baseline assessment, the participants were randomized using TENALEA, an online randomization service (TENALEA, 2010). The randomization was not stratified on depression level, antidepressant treatment, or any other variable.

Statistical analyses

Sample Size

The assumed difference in quit rates at 12 weeks between the two treatment groups was 30%. With a power of 80%, under a two-sided hypothesis and assuming a dropout rate of 15%, sample size calculations indicated that 96 participants (48 per group) were required to detect a difference at a 5% level of significance. The sample size was computed using "proc power" of SAS software.

Data Analysis

An analysis of demographic and baseline characteristics was performed using all randomized subjects. Patient characteristics were also compared between groups. Quantitative variables were compared between groups using *t*-tests for Gaussian variables (according to the Shapiro-Wilk test) and Mann-Whitney tests otherwise. Qualitative variables were either compared using Chi-square tests or Fisher's exact test when the conditions of validity for the Chi-square test were not met. An analysis of demographic and baseline characteristics was performed using all randomized subjects. For smoking abstinence, we conducted intention-to-treat analyses. We used logistic regression and odds ratios with 95% confidence intervals to examine relationships between condition and abstinence on each visit. Included covariates were gender, AUDIT score, SSQ-12 score, HADS-D score, marital status, antidepressant treatment, and history of major depressive disorder, all of which are commonly linked to poor cessation outcomes for smokers with current depressive disorders (Bernard et al., 2012, 2013; Gierisch et al., 2011).

For secondary outcomes, changes since baseline on continuous variables were evaluated with an analysis of covariance (ANCOVA), using a term for treatment and the baseline variable as a covariate. For other secondary outcomes, all the data collected were used (from the inclusion visit to all the follow-up visits). Mixed-effects model analysis was used to assess the overall treatment effect, with participants as random effects and time and group assignment as a fixed effect. Random intercept and slopes were investigated. The Restricted maximum likelihood estimation method was used for the mixed-effects model. All descriptive, logistic regression, ANCOVA and mixed-effects regression model analyses were conducted using SAS Version 9.2.

RESULTS

Participants

As shown in Figure 1, 476 candidates were assessed for eligibility; 143 of them were eligible, and 70 were randomized. The number of participants did not reach the required total of 96 for adequate statistical power. Our recruitment process proved more difficult and time-consuming than anticipated. Available funding for this study did not allow an extension of the recruitment period.

The demographic and clinical characteristics of our sample are presented in Table 2. Forty-one participants (58.6%) were female, 38 (52.3%) were single, and 37 (52.9%) had education beyond high school. Thirty-eight participants (54.3%) had sub-threshold depressive symptoms and 32 (45.7%) met diagnostic criteria for major depressive disorder or dysthymia. At baseline, participants in the two treatment conditions differed in marital status ($\chi^2 = 4.28$, df $= 1$, p $= .04$) and smoking abstinence self-efficacy level; t(66) $= -2.04$, p $= .04$. However, there were no other differences on demographic or smoking characteristics between treatment conditions. The dropout rate did not vary significantly between the intervention (7 out of 35, 20%) and control (13 out of 35, 37.1%) groups; $\chi^2(1) = 1.75$, $p = .18$.

Adherence to the Intervention

At week 8, no statistical difference was found in adherence to group sessions, with 82% (8.2 of 10) attendance in the exercise and counseling intervention and 75% (7.5 of 10) in the control intervention; $Z = -1.44$, $p = .14$. However, participants in the exercise intervention self-reported adhering to only 63% (3.7 of 6) of the home-based exercise sessions. Length of smoking cessation medication treatment did not differ significantly between groups. For exercise and control intervention subjects, respectively, the mean length of the nicotine replacement therapy was 105.5 days ($SD = 64.3$) and 102.0 days ($SD = 53.5$), and that of the varenicline treatment was 91.7 days ($SD = 42.6$) and 89.8 days ($SD = 67.0$).

Smoking Abstinence

Primary Outcome

Twelve weeks after the beginning of the intervention, 48.5% (17/35) of the exercise participants and 28.5% (10/35) of the control participants had remained continually abstinent from smoking; $\chi^2(7) = 2.95$, $p = .08$. While this difference was

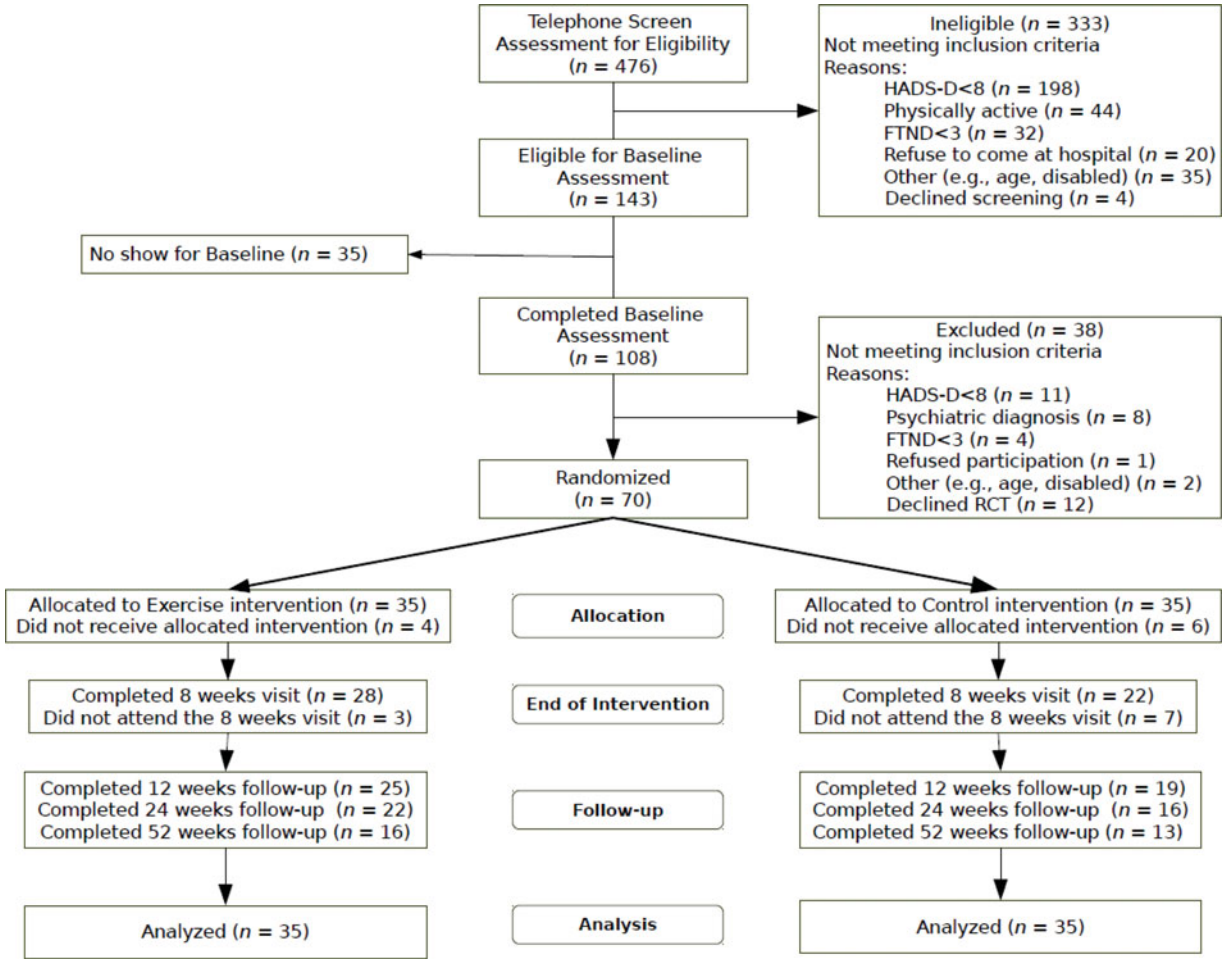

FIGURE 1 Consolidated Standards of Reporting Trials (CONSORT) flowchart of study participant inclusion, randomization, intervention and follow-up analyses. *Note*. HADS-D = Hospital Anxiety Depression Scale–Depression subscale, FTND = Fagerström Test for Nicotine Dependence; RCT = randomized controlled trial.

not statistically significant, the trend was in the expected direction, with intervention subjects showing lower continuous abstinence rates than control participants (this was true at all assessment points). Logistic regression analyses also did not reveal any significant difference between the two intervention groups (see Table 3).

Secondary Outcomes

After adjusting for baseline scores, participants' walk test distance differed significantly between the two conditions at week 8, with intervention participants walking farther (M = 624.8 m, SD = 8.17) than controls (M = 594.1 m, SD = 8.9); $F(1, 43) = 6.38$, $p = .015$, partial $\eta^2 = 0.13$. The only other variable that differed significantly between groups at any assessment point was perceived physical control at week 8; $F(1, 43) = 5.16$, $p = .028$, partial $\eta^2 = 0.10$. Results for all the secondary outcomes are presented in Table 4.

DISCUSSION

This study suggests that, given good adherence, the exercise and counseling intervention may result in higher continuous abstinence rates, compared to an equal contact health education group. Due to the fact that the size of our sample was not large enough to ensure adequate statistical power, we cannot draw decisive conclusions.

There are some important differences and similarities between our findings and those of prior randomized controlled trials. First, on the 24- and 52-week follow-up visits, smoking abstinence rates were slightly higher in our sample than those observed in randomized controlled trials using an adjunct "behavioral" treatment (e.g., psychosocial mood management), including for smokers with depressive disorders.

TABLE 2
Baseline Demographic and Clinical Characteristics of the Sample ($N = 70$)

Characteristics	Exercise and Counseling ($n = 35$)	Control ($n = 35$)	Statistic, p-level
	M (SD)	*M (SD)*	
Age	48.5 (10.9)	48.4 (10.0)	
Age at smoking initiation	18.9 (5.1)	17.6 (3.1)	
Weight (kg)	72.2 (16.9)	64.7 (13.9)	$Z = 1.02, p = .20$
BMI	24.9 (5.1)	24.3 (5.1)	
Cigarettes per day	21.9 (8.5)	21 (9.3)	$Z = 0.75, p = .45$
Nicotine dependence (FTND)	6.3 (1.5)	6.4 (1.8)	$Z = -0.07, p = .94$
Expired CO level (ppm)	30.3 (17.1)	28.1 (12.3)	$Z = 0.16, p = .87$
Prior quit attempts	1.8 (1.2)	1.8 (1.5)	$Z = .17, p = .85$
Longest time without cigarette	596.4 (997.9)	330.8 (482.4)	$Z = -.78, p = .43$
HADS-D score	10.7 (3.1)	10.2 (2.7)	$Z = 0.16, p = .87$
HADS-A score	11.7 (3.7)	11.4 (4.1)	$t = 0.32, p = .74$
AUDIT score	7.2 (6.5)	6.9 (6.2)	$Z = -0.25, p = .80$
TCQ-12 score	42.7 (11.8)	41.0 (11.0)	$t = 0.6, p = .54$
SSQ-12 score	28.4 (9.9)	33.1 (9.0)	$t = -2.04, p = .04$
PSPP score			
Global self-concept	2.9 (0.9)	3.0 (0.9)	$t = -0.47, p = .64$
Physical self-worth	2.4 (1.1)	2.4 (0.9)	$Z = 0.31, p = .76$
Perceived physical condition	2.0 (1.0)	2.0 (1.4)	$Z = 0.44, p = .83$
Sport competence	2.1 (1.2)	2.0 (0.9)	$Z = 0.57, p = .99$
Perceived strength	2.4 (1.1)	2.4 (1.1)	$Z = 0.59, p = .99$
SF-12	78.8 (9.7)	78.1 (73.5)	$t = -0.79, p = .43$
MVPA time	864.4 (719.4)	1057.5 (911.9)	$Z = 1.06, p = .29$
Sedentary time	7228.6 (3165.6)	8509.3 (3460.5)	$Z = 1.20, p = .23$
6MWT distance	580.2 (84.5)	573.9 (69.1)	$t = 0.31, p = .76$
	n (%)	*n* (%)	
Gender			$\chi^2(1) = 2.88, p = .09$
Female	17 (48.6)	24 (68.6)	
Male	18 (51.4)	11 (31.4)	
Marital status			$\chi^2(1) = 4.28, p = .04$
Single	15 (42.8)	23 (67.6)	
Married/partnered	20 (57.1)	11 (32.5)	
Education			$\chi^2(1) = 0.52, p = .47$
High school	15 (42.8)	18 (51.4)	
College or higher	20 (57.1)	17 (48.5)	
Smoking cessation medication			
Nicotine Replacement Therapy	17 (48.5)	19 (54.2)	$\chi^2(1) = 0.23, p = .63$
Varenicline	18 (51.4)	15 (42.8)	$\chi^2(1) = 0.51, p = .47$
Current Axis I diagnoses			
Major depressive disorder	3 (8.5)	2 (5.7)	Fisher, p = .61
Dysthymia	15 (42.8)	12 (34.2)	$\chi^2(1) = 0.54, p = .46$
Substance abuse	4 (11.4)	2 (5.7)	Fisher, $p = .49$
Panic disorder without agoraphobia	2 (5.7)	2 (5.7)	Fisher, $p = 1$
Lifetime Axis I diagnoses			
Major depressive disorder	27 (77.1)	30 (85.7)	$\chi^2(1) = 0.85, p = .35$
Hypomanic episode	4 (11.4)	4 (11.4)	Fisher, $p = 1$
Current antidepressant	26 (74.2)	24 (68.5)	$\chi^2(1) = 0.28, p = .59$
Current anxiolytic	10 (28.5)	7 (20.0)	$\chi^2(1) = 0.70, p = .40$
IPAQ-SF	3 (8.8)	6 (18.1)	Fisher, $p = .30$

Note. CO = carbon monoxide; FTND = Fagerström Test for Nicotine Dependence; HADS-D = Hospital Anxiety Depression Scale–Depression subscale; HADS-A = Hospital Anxiety Depression Scale–Anxiety subscale, AUDIT = Alcohol Use Disorders Identification Test; TCQ 12 = Tobacco Craving Questionnaire, SSQ-12 = Smoking Self-Efficacy Questionnaire, PSPP = Physical Self-Perception Profile, SF-12 = Short Form Health Survey 12, IPAQ-SF = International Physical Activity Questionnaire–Short Form, MVPA = Moderate Vigorous Physical Activity; 6MWT = 6-Minute Walk Test; BMI = body mass index.

In those randomized controlled trials, abstinence rates were 14% (MacPherson et al., 2010), 13% (Hall et al., 2006), and 23% (Cincirpini et al., 2010) at approximately 24 weeks and 0% (MacPherson et al., 2010), 14% (Hall et al., 2006), and 11% (Cincirpini et al., 2010) at approximately 52 weeks post-intervention, while our intervention group obtained 34% and 20%, respectively. MacPherson et al. (2010) and Hall et al. (2006) used 7-day point prevalence abstinence criteria; Cin-

TABLE 3
Continuous Abstinence Rates by Treatment Condition on Intention-To-Treat Basis

	Exercise ($n = 35$)	Control ($n = 35$)	$\chi^2(1)$	Adjusted OR[a] [95% CI]	Likelihood ratio test $\chi^2(7)$
End of intervention (week 8)	20 (57.1%)	13 (37.1%)	2.81, $p = .09$	0.40 [0.12–1.29], $p = .12$	13.3, $p = .10$
12-week visit	17 (48.6%)	10 (28.6%)	2.95, $p = .08$	0.40 [0.13–1.27], $p = .12$	7.3, $p = .38$
24-week visit	12 (34.3%)	8 (22.9%)	1.12, $p = .28$	0.62 [0.18–2.06], $p = .43$	4.7, $p = .69$
52-week visit	7 (20%)	4 (11.4%)	0.97, $p = .32$	0.58 [0.13–2.63], $p = .48$	4.4, $p = .72$

Note. OR = odds ratio; CI = confidence interval.
[a]Adjusted for baseline characteristics: gender, Alcohol Use Disorders Identification Test score, Smoking Self-Efficacy Questionnaire 12 score, Hospital Anxiety and Depression Scale–Depression subscale score, marital status, antidepressant treatment, and history of major depressive disorders.

ciripini et al. (2010) used continuous abstinence criteria. This difference may be also explained by an important interventional "dose" (i.e., 10 sessions, 75 minutes). Indeed, behavioral interventions comprising at least four sessions are associated with higher abstinence in the long term (Stead & Lancaster, 2012). The continuous abstinence rates of our study's exercise intervention participants were also higher than those of subjects in randomized controlled trials focusing on supervised exercise interventions in a smoking cessation context. For example, the moderate-intensity and vigorous-intensity exercise trials yielded 1% and 12% abstinence rates at 52 weeks (Marcus et al., 2005, 1999), respectively.

Second, although exercise is a well-identified strategy to reduce the severity of depression (Bernard et al., 2013), our findings showed no difference in depression level between the exercise and control groups at the end of the intervention or in the long term. Previous randomized controlled trials did not identify a significant association between abstinence status and post-intervention depression score among smokers with current depressive disorders (Brown et al., 2007; Hall et al., 2006; Hall, Muñoz, & Reus, 1994). This result could be explained by insufficient duration exercise intervention (i.e., 8 weeks). Indeed, Rethorst et al. (2009) suggest that 10- to 16-week exercise interventions are more effective to decrease depression levels. Alternatively, most participants received antidepressant treatment (74% and 68%), and medication side effects may have lessened the effects of the exercise intervention (Bernard & Carayol, 2015).

Third, contrary to our expectations, objectively measured moderate to vigorous physical activity and sedentary behavior did not change after the intervention, despite the development of physical activity skills through home exercise and counseling sessions. This result is in line with those of a previous randomized controlled trial, which provided customized support to modify the physical activity behavior of adults with depressive disorders without obtaining any significant lifestyle change over a short-term period (Chalder et al., 2012).

Fourth, the participants in the exercise and counseling intervention walked a significantly longer distance (6MWT) at week 8 than at baseline. Therefore, we infer that exercise sessions did increase the physical fitness of participants. This result is corroborated by a significant increase in the perceived physical condition of participants in the exercise intervention and counseling group. However, no significant weight loss was identified. This finding does not support the result of a previous randomized controlled trial, which showed significant weight loss (2.4 kg) at the end of its exercise intervention (3 sessions per week of vigorous intensity exercise over 8 weeks; Marcus et al., 1999).

Finally, our recruiting and retention rates were poor. Among 143 eligible patients, 35 were absent for baseline session assessment. It is possible that our participants (i.e., smokers with current depressive disorders) had trouble engaging in part because of their depressive symptoms and in part because the intervention (i.e., exercise and counseling) may have seemed particularly daunting. Several strategies could prove useful in optimizing recruiting and retention in future studies, including monetary incentives, adapted contents of study advertisements, and better communication with primary care providers (Thompson et al., 2015). Williams et al. (2014) suggest providing increased monetary incentives for attending exercise/control sessions and each follow-up assessment and decreased amounts for missing sessions. To recruit participants with current depressive disorders for an exercise clinical trial, McPherson et al. (2014) suggest that contents of advertisements and messages displaying the study need to be specifically targeted. For instance, the exercise intervention description may need to emphasize that it is realistic, easy to do, and fun. Furthermore, mental health clinicians do not often address smoking during patient interviews because they perceive lack of patient interest in smoking cessation (Brown et al., 2015). We used advertising across many sources (i.e., via hospital websites, local radio stations, posters). We also placed an advertisement in a specific publication for local family physicians because most adults with depressive disorders present initially to primary care rather than specialty care settings (Kovess-Masfety et al., 2007). Primary care clinicians may be more reluctant to provide smoking cessation treatment to patients with depressive disorders (Prochaska, 2011). Therefore, further information and availability of communication tools for primary care providers should improve the recruiting rate in future studies.

This trial is the first to assess the effects of a group-supervised exercise and counseling intervention versus an

TABLE 4
Treatment Conditions and Secondary Outcomes

	Baseline ($N = 70$)	8 weeks ($n = 50$)	12 weeks ($n = 44$)	24 weeks ($n = 38$)	52 weeks ($n = 29$)
	(*n*/total)	(*n*/total)	(*n*/total)	(*n*/total)	(*n*/total)
IPAQ-SF[1]					
Exercise	3/35 (8.6%)	10/28 (35.7%)	9/25 (36%)	5/22 (22.7%)	6/16 (37.5%)
Control	6/35 (17.1%)	6/22 (27.3%)	3/19 (15.8%)	3/16 (18.8%)	3/13 (23.1%)
	M (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)
Cigarettes per day					
Exercise	21.9 (8.53)	2.3 (5.4)	2.28 (5.1)	2.8 (6.0)	4.3 (7.9)
Control	21.0 (9.36)	3.3 (7.5)	3.1 (7.0)	2.4 (5.7)	2.9 (5.7)
Expired CO (ppm)					
Exercise	30.3 (17.1)	8.3 (11.7)	7.4 (8.9)	9.9 (13.1)	17.6 (16.2)
Control	28.1 (12.3)	11.4 (14.1)	13.2 (17.3)	13.8 (16.0)	15.6 (10.8)
Weight (kg)					
Exercise	72.2 (16.9)	70.2 (15.4)	71.3 (14.7)	72.9 (14.9)	76.5 (13.9)
Control	67.4 (13.9)	68.6 (13.2)	71.4 (13.3)	72.8 (14.7)	71.5 (14.7)
HADS-A					
Exercise	11.73 (3.73)	8.19 (3.28)	8.54 (4.61)	9.05 (3.87)	7.25 (3.66)
Control	11.42 (4.13)	7.77 (3.08)	7.94 (3.24)	8.73 (4.14)	7.84 (2.94)
HADS-D					
Exercise	10.74 (3.13)	5.92 (4.41)	5.25 (4.87)	6.50 (4.96)	3.87 (2.89)
Control	10.28 (2.71)	5.36 (3.38)	5.63 (3.51)	6.66 (4.56)	4.83 (3.78)
SF-12					
Exercise	78.87 (9.78)	87.50 (8.14)	87.52 (8.92)		
Control	80.49 (6.90)	86.47 (6.88)	85.93 (6.87)		
SSQ-12					
Exercise	28.43 (9.96)	44.57 (2.27)			
Control	33.15 (8.82)	46.64 (2.37)			
TCQ-12					
Exercise	42.7 (11.8)	24.66 (1.69)			
Control	41.0(11.0)	24.67 (1.80)			
Accelerometer[b] (Log MVPA min)					
Exercise	6.46 (0.79)	6.50 (0.12)[a]			
Control	6.69 (0.70)	6.54 (0.16)[a]			
Sedentary (min)					
Exercise	4563.6 (1279.3)	3718 (1271)[a]			
Control	5257.9 (1565.9)	4365 (1518)[a]			
6MWT (meter)					
Exercise	580.2 (84.5)	624.84 (8.17)[a 2]			
Control	573.9 (69.1)	594.13 (8.96)[a]			
PSPP					
GSC	2.09 (0.9)	3.45 (0.14)[a]			
Exercise	3.0 (0.9)	3.50 (0.15)[a]			
Control					
PSW					
Exercise	2.4 (1.1)	3.37 (0.19)[a]			
Control	2.4 (0.9)	2.87 (0.21)[a]			
PPC					
Exercise	2.9 (1.11)	2.84 (0.16)[a 3]			
Control	2.2 (0.9)	2.27 (0.18)[a]			
SC					
Exercise	2.1 (1.2)	3.56 (0.17)[a]			
Control	2.0 (0.9)	3.53 (0.18)[a]			
PS					
Exercise	2.5 (1.1)	2.53 (0.15)[a]			
Control	2.2 (0.9)	2.80 (0.16)[a]			

Note. CO = carbon monoxide; HADS-D = Hospital Anxiety Depression Scale–Depression subscale; HADS-A = Hospital Anxiety Depression Scale–Anxiety subscale; NRT = Nicotine Replacement Therapy; TCQ 12 = Tobacco Craving Questionnaire; SSQ-12 = Smoking Self-Efficacy Questionnaire; PSPP = Physical Self-Perception Profile; GCS = global self-concept; PSW = physical self-worth; PPC = perceived physical condition; PS = perceived strength; SC = sport competence; SF-12 = Short-Form Health Survey 12; IPAQ-SF = International Physical Activity Questionnaire–Short Form; log MVPA = logarithms of moderate vigorous physical activity; 6MWT = 6-Minute Walk Test.

[1]Participants categorized as high in physical activity based on the IPAQ-SF scoring algorithm.

[2]$M_{\text{diff}} = 30.7$ ($SD = 12.1$); $F(1, 43) = 6.38$, $p = .015$, partial $\eta^2 = 0.13$.

[3]$M_{\text{diff}} = .57$ ($SD = .24$); $F(1, 43) = 5.16$, $p = .028$, partial $\eta^2 = 0.10$.

[a]Adjusted means.

[b]Data were available on 50% of the trial participants from both randomized groups who had at least 5 days with > 10 hours of usable accelerometer data.

equal contact health education group among smokers with current depressive disorders. Our sample included smokers with a range of depression symptoms (including major depressive disorder, dysthymia, and sub-threshold depressive symptoms). To our knowledge, few smoking cessation trials have specifically included smokers with current depressive disorders or major depressive disorder (Bernard et al., 2013). The adherence rate was satisfactory, especially in view of the fact that participants did not receive any compensation. Nonetheless, there are several limitations to this study. First, the enrollment rate was lower than initially anticipated, leading to a significant reduction in statistical power. Second, participants' expectations regarding the treatment program were not controlled, although written information about the trial included a brief description of both interventions. It is possible that some of the participants assigned to the control condition wished to participate in the exercise intervention and therefore performed exercise sessions at home (i.e., contamination effect). Third, the absence of treatment fidelity checks is a serious limit that may compromise the external validity of our study (Leeuw, Goossens, de Vet, & Vlaeyen, 2009). Fourth, the demands of the study's assessments (e.g., accelerometer) and the time constraints they placed upon the participants may have contributed to the non-participation and dropout rates. Consequently, the participants who remained in the study were likely a more motivated group of individuals who did not fully and generally represent adults with depressive disorders.

Therefore, we continue to posit that exercise and counseling interventions may have stronger positive effects upon smoking abstinence than health education. However, since we performed our final analyses on a sample that was smaller than originally anticipated, we prefer to remain cautious in our conclusion. Additional research is necessary to identify effective, customized strategies to recruit smokers with current depressive disorders. Future studies should attempt to replicate our results with higher statistical power and to identify optimal exercise modalities (e.g., intensity, beginning after quit date) and behavioral change techniques for smokers with current depressive disorders.

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