

The effects of exercise and nicotine replacement therapy on smoking rates in women

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Abstract

Purpose: To examine the individual effects of supervised and intensive exercise as well as the combined effects of exercise and nicotine replacement therapy (NRT) on (a) smoking cessation and reduction rates and (b) psychological and physiological processes during withdrawal.

Methods: One-hundred and forty-two inactive female smokers were randomised into the following four groups: exercise+nicotine patch; exercise+no nicotine patch; cognitive behavior therapy (CBT)+nicotine patch and CBT+no nicotine patch. Smoking abstinence (verified by saliva cotinine and expired carbon monoxide), cessation self-efficacy, and physical fitness and body weight were assessed at baseline (week 1), quit date (week 6), program termination (week 12), and 3- and 12-month follow-up.

Results: There were significant differences in a 7-day point prevalence but not continuous abstinence rates between treatment groups across targeted end points. Consistently higher cessation rates were seen when NRT was added to both treatment programs. Compared with CBT participants, exercise participants had significantly increased functional exercise capacity and had gained significantly less weight during program end points but these differences did not hold at a 12-month follow-up. Compared with exercise participants, CBT participants felt greater cessation efficacy and reported greater knowledge, coping and support resources across all end points.

Conclusions: Exercise combined with NRT facilitates smoking cessation, improves functional exercise capacity, and delays weight gain in women smokers. We recommend that physicians and health care professionals recommend exercise and NRT together for highly motivated women interested in quitting smoking.

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Keywords: Smoking cessation; Exercise; Intervention; Weight control

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1. Introduction

Smoking is the leading cause of preventable death in the world, with an estimated 4.9 million tobacco related deaths per year (World Health Organisation, 2002, 2003). Although smoking prevalence rates have declined in developed nations over the past 20 years (World Health Organisation, 2002, 2003), most smokers find it difficult to abstain, and there is a high recidivism rate among individuals who do attempt to abandon their habit (Law & Tang, 1995). Research has indicated that inability to quit and/or relapse may be due, in part, to failures in coping with the physiological and psychological correlates of smoking withdrawal (Katz & Singh, 1986; Piasecki et al., 2000). These correlates include anxiety and tension, general fatigue, weight gain and sleep disturbances as well as other mental and physical problems (Hatsukami, Hughes, Pickens, & Suilis, 1984; Murray & Lawrence, 1984; Shiffman, 1979).

Exercise may have the potential to moderate some of the negative consequences of smoking withdrawal. An expanded body of literature suggests that aerobic exercise has positive effects on physical functioning, psychological states and mental processes (Martinsen & Stephens, 1994). Furthermore, many of the variables influenced by regular exercise are the same ones that are negatively affected by smoking withdrawal. There is little doubt, for example, that regular exercise is an essential component of weight control programs (DiPietro, 1995). Weight gain is a fear often reported by potential quitters and a cause of relapse among quitters (Levine, Perkins, & Marcus, 2001). Exercise has also been shown to relieve the symptoms of depression (Craft & Landers, 1998), anxiety (Petruzzello, Landers, Hatfield, Kubitz, & Salazar, 1991), and psychosocial stress (Crews & Landers, 1987). There is further evidence that sleep patterns (Kubitz, Landers, Petruzzello, & Han, 1996) as well as cognitive functioning (Tomprowski & Ellis, 1986) may be improved by certain types of exercise. Exercise has also been shown to positively influence coping ability (Steptoe, Edwards, Moses, & Matthews, 1989) and self-esteem (McAuley, Milhalko, & Bane, 1997), two factors that may protect against smoking relapse (Derby, Lasater, Vaas, Gonzalez, & Carlton, 1994; King, Marcus, Pinto, Emmon, & Abrams, 1996).

These findings, taken in concert, suggest that aerobic exercise could benefit individuals who wish to stop smoking. Marcus et al. have conducted a number of studies (Bock, Marcus, King, Borrelli, & Roberts, 1999; Marcus et al., 1999; Marcus, Albrecht, Niaura, Abrams, & Thompson, 1991; Marcus et al., 2003) examining this issue and in general reported encouraging results. In their seminal paper, Marcus et al. (1999) randomised 281 sedentary female smokers to either a 12-week cognitive behavior smoking cessation program (CBT) with vigorous exercise (experimental group) or to the same program with equal staff contact (control group). Abstinence from smoking was based on self-report that were verified by saliva cotinine level measured at end of treatment, and 3 and 12 months post-treatment. Results showed that compared with the control group, the exercise group (a) achieved significantly higher levels of continuous abstinence at all three time periods and (b) gained significantly less weight at the end of treatment. Using an identical protocol Marcus et al. (2003) found less encouraging results for moderate levels of physical activity. Specifically, notable differences in smoking abstinence across groups were seen at 3-months post-treatment but not at the end of treatment or 12 months. In general, other studies have reported similar abstinence results (Martin, Kalfas, & Patten, 1997) as well as similar withdrawal, craving, and weight gain findings (Kawachi et al., 1996; Ussher, Nunziata, Cropley, & West, 2001).

Although the studies by Marcus and colleagues offer evidence to suggest that supervised, vigorous intensity exercise (60–85% of heart rate reserve) may be a useful aid to smoking cessation, there is a dearth of empirical evidence that has documented the marginal benefit of adding pharmacological agents, such as nicotine replacement therapy (NRT), to exercise programs. To our knowledge the work of Ussher,

West, McEwen, Taylor, and Steptoe (2003) is the only published study that has addressed this issue. They found that adding brief exercise counselling to a 6-week smoking cessation program which included NRT did not increase abstinence or reduce weight gain, however self-reported exercise levels were raised and there were some beneficial effects on psychological symptoms during smoking withdrawal. Unfortunately, comparing their findings to the work of Marcus and colleagues is difficult because of differences in respective exercise programs used.

There also is a dearth of evidence documenting the stand-alone effectiveness of exercise on smoking abstinence and reduction. Previous trials have focused on the additive effects of exercise in combination with a traditional behaviourally-based smoking cessation program. However, most smokers attempt to quit without enrolling in such support programs. Hence, in a recent review, Taylor and Ussher (2005) recommended that a trial is needed to examine the effects of exercise alone on rates of smoking abstinence. Perhaps exercise does not need to be integrated into existing behavioral smoking cessation and NRT programs for it to be a useful aid to smoking cessation. From a theoretical stand-point, exercise on its own may have the potential to influence psychological and physiological processes that are important for smoking cessation and smoking reduction to occur. From a practice stand-point, exercise is a cost-effective strategy that may be more attractive than other smoking cessation strategies for certain women (i.e., those that are concerned about weight gain). For instance, smokers trying to quit may be more receptive to initiating an active lifestyle than smokers in general (King et al., 1996).

Hence, the main aim of the present study was to examine the individual effects of exercise and the combined effects of exercise and NRT against the individual effects of CBT and the combined effects of CBT and NRT on (a) smoking cessation and reduction rates and (b) psychological and physiological processes during withdrawal. We decided that there was no need to focus on an NRT alone condition as its independent effects are well established (Silagy, Mant, Fowler, & Lancaster, 2000).

2. Methods

2.1. Participants

One-hundred and forty-two inactive women (engaged in less than 30 min of moderate to vigorous exercise twice per week for the past 6 months), between 18 and 62 years who had smoked in excess of 10 cigarettes per day for the last 3 years were recruited from local newspaper advertisements. Those with medical and psychological problems or who were on medications that would make compliance with exercise difficult were excluded from the present study.

2.2. Research design and general procedure (Fig. 1)

2.2.1. Preliminary session and pre-quit smoking—phase I (weeks 1–6)

Interested participants attended an orientation meeting at the host institution where the purpose of the project and the methodology were described. An indication of each person's willingness to participate was obtained at this time, and they were asked to sign a form of disclosure and informed consent. Background data (i.e., age, body weight, height, number of years spent smoking, percentage of family and friends who smoke, smoking dependence, and exercise habits) were recorded. Participants required a written consent from their family physician to participate in the project. Using a computer generated

program, participants were then randomly assigned to either a supervised exercise program (EX) or a supervised cognitive behavioral smoking cessation program (CBT). All participants followed their respective programs separately for a 6-week period with a targeted goal of trying to quit at the end of this phase (Fig. 1).

2.2.2. Post quit smoking—phase II (weeks 7–12)

At the end of the phase I (6 weeks), all participants attempted to stop smoking. Participants from both conditions (i.e., EX and CBT) were then further randomised into two treatment conditions: those who received nicotine replacement therapy (NRT patches) and those who did not. This randomisation procedure created four conditions: EX + nicotine patch; EX + no nicotine patch; CBT + nicotine patch and CBT + no nicotine patch. All participants continued to follow their respective CBT and EX programs for a 6-week period with a targeted goal of trying to remain abstinent.

2.2.3. Follow-up smoking—phase III and IV (3 and 12 months)

Participants were contacted 3 and 12 months after the completion of their respective programs to provide smoking data. The study's host institution's human subject ethics committee approved all procedures.

2.3. Treatment

2.3.1. Exercise program

Participants in the EX took part in three 45-minute supervised exercise sessions each week for 12 weeks. The three weekly sessions consisted of closely supervised exercise on a cycle ergometer, treadmill, and rower, with the majority of each session spent on the cycle ergometer. Participants were instructed to exercise to a training intensity of 60–75% of their estimated maximum heart rate reserve as determined by the initial fitness test results (Gore, Booth, Bauman, & Owen, 1999). All exercise data were recorded.

2.3.2. Smoking cessation program

Participants in the CBT were required to take part in three, 45-minute supervised group education sessions per week for 12 weeks. The CBT focused on traditional topics such as self-monitoring and

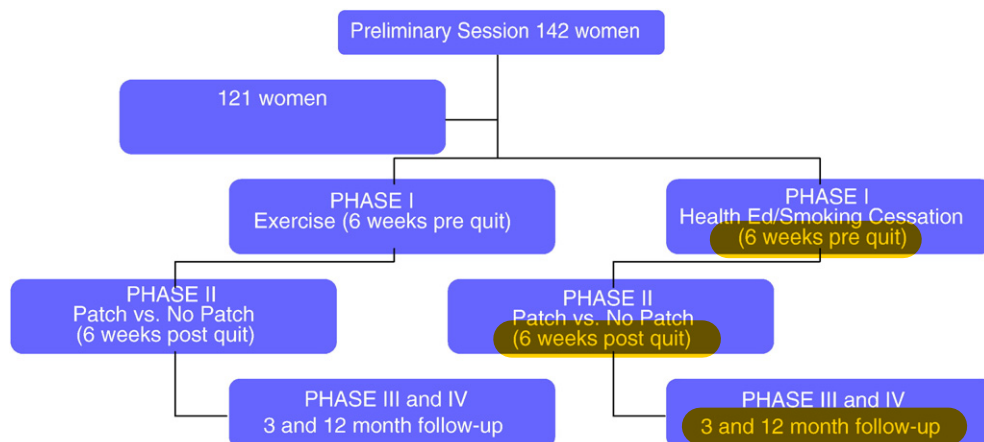


Fig. 1. Participant flow and study design.

copied with cravings and high-risk situations as well as highly relevant cessation issues for women such as concerns about weight gain during abstinence (Pirie et al., 1992; Pirie, Murray, & Luepker, 1991), the link between smoking and stress (Abrams et al., 1987), and the need for social support (Lichtenstein, Glasgow, & Abrams, 1986). In addition, health education topics important to women were covered (e.g., healthy eating, prevention of cardiovascular disease, mood management and managing work and family (Marcus et al., 1999). The frequency and duration of the sessions ensured identical contact time was provided to both groups, thereby allowing the researchers to distinguish the specific effect of exercise from the non-specific effect of receiving more treatment. Participants were instructed not to adopt a program of regular vigorous exercise until the treatment portion of the study was completed.

2.3.3. Nicotine replacement therapy

Nicotine replacement therapy (NRT) has been shown to be a more effective aid to smoking cessation than physician encouragement and advice as well as individual and group behavior modification techniques (Silagy, Lancaster, Stead, Mant, & Fowler, 2003). Compared to other forms of NRT, transdermal nicotine patches are as effective for increasing smoking abstinence and tend to be related with higher compliance rates (Hajek et al., 1999). In the present study, those who received patches followed the Nicabate 10-week program which contained 3 steps. The patches were designed to supply one's body with controlled amounts of nicotine which decrease as one progresses from step 1 (21 mg—once daily for 6 weeks) to step 2 (14 mg—once daily for 2 weeks) to step 3 (7 mg—once daily for 2 weeks).

2.4. Measures

2.4.1. Smoking behavior

Self-report on the number of cigarettes smoked daily was collected each week during both pre-quit I and post-quit II phases (weeks 1–12), and at phase III (week 18) and phase IV (week 52) follow-up months, respectively. These self-report measures were biochemically validated by correlations with expired air carbon monoxide (CO) levels using a Bedfont Smokerlyzer (Ussher et al., 2003) as well saliva cotinine values (Marcus et al., 1999). Carbon monoxide monitors within hours of smoking whereas cotinine monitors within days of smoking (Murray, Connell, Lauger, & Voelker, 1993). The main outcome measure was smoking abstinence which was assessed in two ways: 7-day point prevalence abstinence (e.g., PPA—7 consecutive days of not smoking during post-quit phase II) and continuous abstinence from quit day to end of treatment (6 weeks post-quit) and 3 and 12 months after treatment (18 and 52 weeks post-quit), respectively. To be considered abstinent, participants needed to have CO cut-off levels less than 10 ppm and cotinine cut-off levels less than 10 ng/mL (Marcus et al., 1999).

A secondary analysis was to examine rates of smoking reduction. For some women smoking reduction is a more realistic goal than complete abstinence. The number of cigarettes participants smoked over the 12-month trial was used to assess rates of reduction. Research has shown that when biochemical indices of smoking are used the accuracy of reporting improves (Glynn, Gruder, & Jegersky, 1986). In addition, Murray et al. (1993) provide evidence from the Lung Health Study that self-report smoking bias does not appear to be an issue that would result in seriously misleading findings in smoking cessation studies such as the present one. Finally, Palmer, Graham, Taylor, and Tattersson (2002) provide a convincing argument that the number of cigarettes might be preferred to “tobacco exposure” in intervention studies because they are more proximal and changeable.

2.4.2. Psychological variables

Psychological variables that were collected at the end of phase I (week 6), phase II (week 12), and phase IV (week 52) included 17 purpose-built items to assess four components (i.e., social attraction—4 items, social support—5 items, acquired knowledge—5 items and coping skills—3 items) of the cognitive behavior therapy (CBT) program. All responses were provided on a 7-point scale anchored by the extremes *definitely* and *definitely not*. Example items representing the four components include: “I have formed some good friendships with some of the women in this program”—social attraction; “The other women in the program provide me a great deal of support”—social support; “I have gained some useful knowledge about how to quit smoking from this program”—acquired knowledge; and “I have a range of strategies to deal with the difficult times during the quit period”—coping skills. Adequate coefficients alpha were obtained for all scales across all end points (α range was .84–.86).

In addition, the Cessation Self-Efficacy Questionnaire (CSEQ—DiClement, 1981) was used to assess participants’ confidence in their ability to avoid smoking in a variety of situations. Confidence to avoid smoking has been correlated with number of cigarettes smoked per day, difficulty in maintaining abstinence, and weeks of successful abstinence (DiClement, 1981). Cessation self-efficacy was assessed during the 12-week program (i.e., baseline, end of phase I, and end of phase II), and at both 3- and 12-month follow-up periods (i.e., end of phase III and IV). Adequate coefficients alpha were obtained for the scale across all end points (α range was .87–.96).

2.4.3. Physiological variables

All participants undertook a modified physical work capacity (PWC) 75% estimate of aerobic power test (Gore et al., 1999). To determine fitness level changes, all participants were tested at baseline (week 1) and end of phase I (week 6), the end of phase II (week 12), and again at the end of phase IV (week 52). Gender-specific issues—such as concerns about weight gain (Pirie et al., 1991)—are relevant to smoking cessation programs for women. Hence, body weight was recorded throughout the 12-week program and at 3 and 12 months follow-up. Body weight was recorded on an electronic scale (Sauter Balance No. 3) after participants had removed their shoes and any heavy clothing.

2.5. Data analysis

The trial was designed to randomise and have at the end of the 12-month follow-up 80 subjects (20 in each of the four conditions). An initial sample of 142 subjects was projected to provide a power of 80% ($\alpha=.05$) and to detect a large effect size (i.e., standard deviation=.80) or 30% difference between treatment conditions on the primary variable of interest—smoking abstinence (Cohen, 1992). Analyses were conducted by intent to treat which was based on the 121 participants who started the program. This decision was based on several considerations. One, we were more concerned with the potential benefits in participants who received treatment (efficacy) rather than the pragmatic estimate of the benefit of the change in treatment (effectiveness). Glasgow, Strycker, Eakin, Boles, and Whitlock (1999) argued that efficacy-based research is needed before health promotion interventions can be implemented into public health policy. Two, it is unlikely that the exclusion of participants who did not start the allocated intervention will lead to bias. For example, exercise as an aid for smoking cessation can be effective only if the participant receives the treatment; it is unlikely that the allocation to an exercise or non-exercise group could affect this (Hollis & Campbell, 1999). Three, participants were randomised in the NRT condition only after they started their respective CBT and exercise programs.

All reported p values are two-tailed tests. Repeated measures ANOVA and chi-square χ^2 tests were used to analyse differences in smoking as well as both psychological (i.e., cessation self-efficacy) and physiological (i.e., weight) indices between treatment conditions. These analyses were performed on all participants as well as for those who achieved abstinence. For smoking abstinence data, participants failing to attend a treatment or follow-up session where an appointment could not be made within 48 h were recorded as having relapsed. For all other data, missing values were replaced using linear trend estimation techniques using SPSS 12.0.1, as recommended by Tabachnick and Fidell (2001). A χ^2 test was used to determine whether there were differential attrition rates between treatment groups at the end of phases I and II as well as after 3 and 12 months follow-up.

3. Results

3.1. Participants

A total of 445 women responded to advertisements placed in national and local newspaper advertisements. These participants were screened by telephone to determine initial eligibility. Two hundred and fifty participants attended an information night and were further screened using the stage of exercise readiness questionnaire (Marcus, Rakowski, & Rossi, 1992). Of these, 20 participants were deemed ineligible (17 due to a health condition or acute injury, 2 due to the high level of regular aerobic training, 1 due to anticipated long-term travel during the study period), while 88 participants chose not to participate. The remaining 142 participants were randomised into the CBT or EX (see Fig. 1). Twenty-one of those 142 women dropped out within the preliminary session leaving 121 who started the program. Baseline data across treatment groups show no notable differences in demographics or initial smoking and exercise characteristics (see Table 1).

Table 1
Baseline characteristics of study groups

Characteristics	Cognitive behavior therapy		Exercise group		p^a
	No.	Mean (SD)	No.	Mean (SD)	
Age (y)	66	38.2 (10.9)	76	37.9 (12.4)	0.87
Weight (kg)	66	68.9 (15.3)	76	71.1 (16.5)	0.41
Height, cm	66	163.7 (6.4)	76	164.7 (10.9)	0.51
Body mass index (kg/m ²)	66	25.7 (5.7)	76	26.7 (8.9)	0.46
Smoking rate ^b	65	1.7 (0.7)	75	1.7 (0.6)	0.83
Smoking (y)	66	21.0 (10.0)	74	20.2 (11.1)	0.65
Carbon monoxide level (ppm)	66	17.3 (10.4)	75	15.5 (7.0)	0.23
Estimated VO ₂ max, (mL kg ⁻¹ min ⁻¹)	66	29.8 (6.1)	76	28.9 (6.9)	0.43
75% PWC	66	85.5 (20.9)	76	85.7 (21.2)	0.96
Stage of exercise ^c	64	2.7 (1.2)	75	2.5 (1.0)	0.40
Percentage of family and friends who smoke (%)	66	39.3 (26.1)	74	35.8 (24.0)	0.42

^a For differences between groups.

^b Where 0 = “less than 6”, 1 = “6–15” cigarettes/day, 2 = “16–25” and 3 = “26–35” cigarettes/day.

^c Where 1 = pre-contemplation, 2 = contemplation phase, 3 = preparation phase, 4 = action and 5 = maintenance.

3.2. Adherence to treatment

Cognitive behavior therapy (CBT) group participants attended an average of 62.8% of their smoking cessation sessions whereas the exercise group (EX) participants attended an average of 62.4% of their training sessions. There was no differential loss to end of treatment and 3-month follow-up between groups. Of the 121 who started the program, 77.4% and 79.2% of the CBT participants and 70.6% and 73.5% of the EX participants returned at the end of treatment and 3-month follow-up, respectively ($p = .40$; $p = .47$). At the 12-month follow-up, 77.4% of the CBT and 60.3% of the EX participants returned ($p = .05$).

At the 3-month follow-up, 61.6% of the CBT participants and 63.7% of the EX participants reported that they had complied with wearing the transdermal nicotine patch. There was no significant difference in compliance between the EX and CBT participants ($p = .81$).

3.3. Manipulation check

The present study involved two manipulations: (a) an increase in physical fitness through participation in the exercise program and (b) an increase in knowledge, coping skills and social support and group attraction through participation in the CBT program. As can be seen in Fig. 2, notable differences in the expected direction were seen in fitness between treatment groups at 6 weeks ($p < .09$) and 12 weeks ($p < .01$), respectively. The EX group significantly increased their physical fitness during the 12-week training program, however this gain was lost at 12 months follow-up. In contrast, there was no significant fitness improvement for those in the CBT program.

As can be seen in Fig. 3a, b, and c, the CBT participants scored significantly higher than their exercise counterparts on all four psychological variables related to the CBT program during weeks 6 and 12, respectively (all p values less than .001). These group differences were maintained for three out of the four variables at 12-month follow-up (p values less than .001). Overall these data, taken together, provide evidence that participants derived psychological benefits from this treatment.

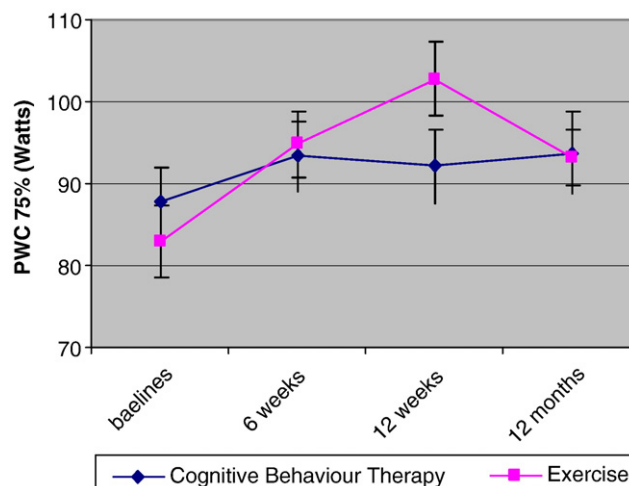


Fig. 2. Mean fitness scores by treatment groups.

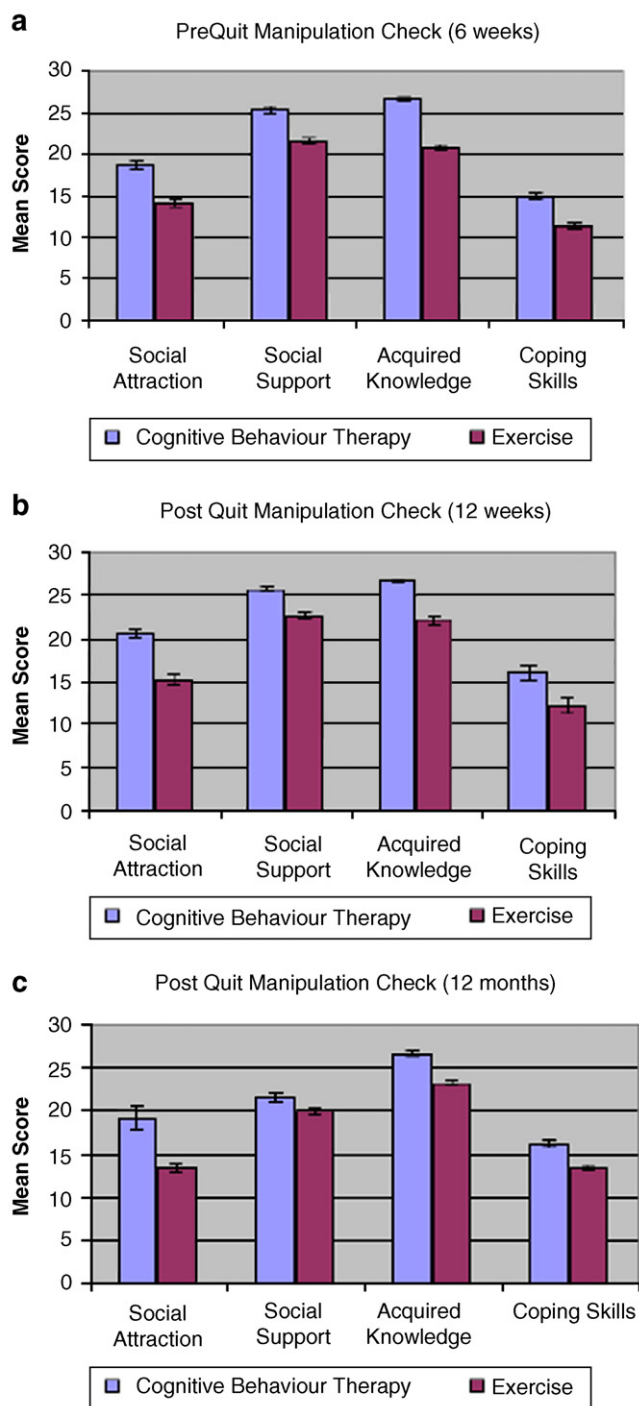


Fig. 3. (a) Mean CBT manipulation check scores by treatment groups at 6 weeks pre-quit. (b) Mean CBT manipulation check scores by treatment groups at 6 weeks post-quit. (c) Mean CBT manipulation check scores by treatment groups at 12 months post-quit.

Table 2

Seven-day point prevalence abstinence and continual abstinence by group ($N=121$)

	Time after quit day, week	No. (%)				<i>p</i>
		Cognitive Behavior therapy group		Exercise group		
		No patch (<i>n</i> =27)	Patch (<i>n</i> =26)	No patch (<i>n</i> =35)	Patch (<i>n</i> =33)	
<i>7-day point prevalence abstinence</i>						
End of treatment	6	19 (70)	21 (81) ^a	18 (51) ^b	28 (85)	0.01
Follow-up	18	13 (48)	13 (50)	14 (40)	19 (58)	0.55
	52	12 (44) ^c	11 (42) ^d	6 (17)	12 (36) ^e	0.08
<i>Continual abstinence</i>						
End of treatment	6	16 (59)	20 (77)	17 (49)	23 (70)	0.11
Follow-up	18	9 (33)	7 (27)	7 (20)	13 (39)	0.34
	52	4 (15)	4 (15)	3 (9)	9 (27)	0.22

^a Significantly different to exercise, no patch group, $p=0.02$.^b Significantly different to exercise, patch group, $p=0.01$.^c Significantly different to exercise, no patch group, $p=0.02$.^d Significantly different to exercise, no patch group, $p=0.03$.^e Significantly different to exercise, no patch group, $p=0.02$.

3.4. Smoking outcome

Seven-day (PPA) and continuous abstinence data by the four treatment conditions are presented in Table 2. Following 12 weeks of treatment (6 weeks post-quit), there were significant differences across groups for 7-day PPA. Both treatment groups with patches had significantly more abstainers than the exercise group with no patches. Between treatment conditions, no significant differences in 7-day PPA were found at 3-month follow-up (18 weeks post-quit), but a significant trend was noted between treatment conditions at 12-month follow-up (52 weeks post-quit). Both treatment groups with patches as well as the CBT group with no patches had significantly more abstainers than the EX group with no patches.

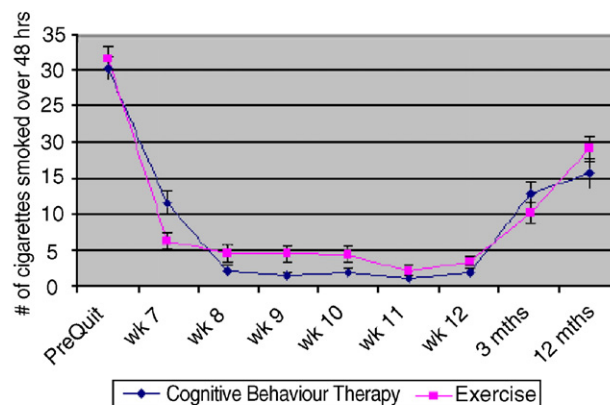


Fig. 4. Mean number of cigarettes smoked over 48 h by treatment groups (pre-quit period averaged over 6 weeks).

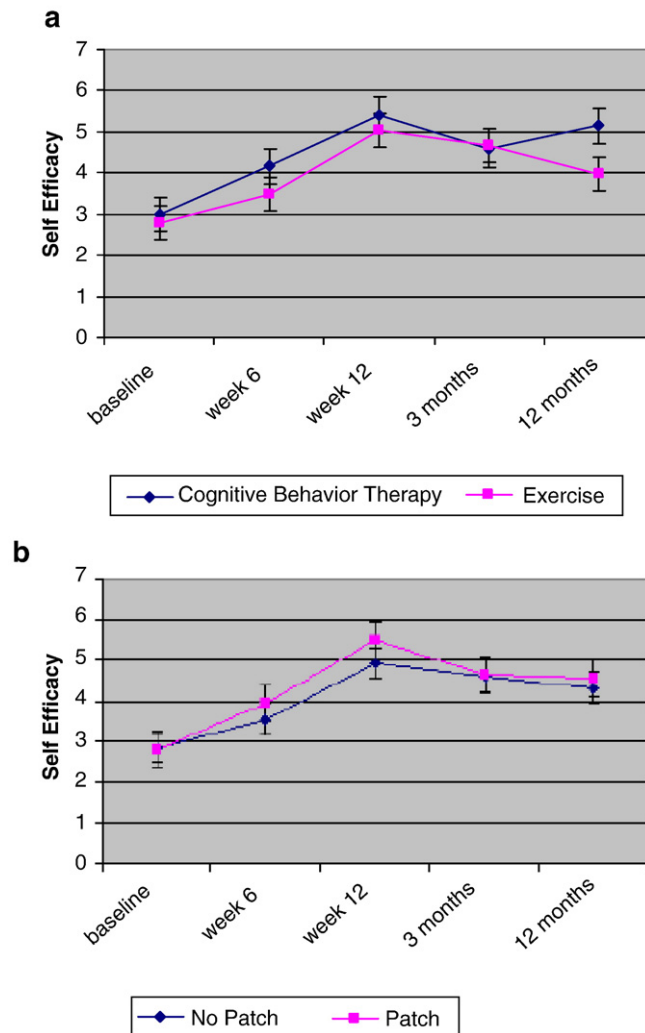


Fig. 5. (a) Mean self-efficacy scores by treatment groups. (b) Mean self-efficacy scores by patch/no patch condition.

For continuous abstinence, no significant differences between conditions were noted at the three post-quit time periods. To explore this issue further, participants who received a patch were compared to those who did not receive a patch, irrespective of CBT or exercise treatment. Results showed that at 12 weeks (6 weeks post-quit), 72.9% of those who received patches compared to 53.2% of those who did not receive patches were likely to be continuously abstinent ($p = .03$). At 3-month follow-up (18 weeks post-quit) and 12-month follow-up (52 weeks post-quit), 33.9% and 22.0% of those who received patches compared to 25.8% and 11.3% of those who did not receive patches remained continuously abstinent, respectively ($p = .33$; $p = .11$).

The number of cigarettes smoked during the 12-week program and at 3- and 12-month follow-ups is illustrated in Fig. 4. As expected, the results showed a significant time effect ($p = .01$) where both CBT and EX groups significantly reduced the mean number of cigarettes smoked from the pre-quit period (31.0) to

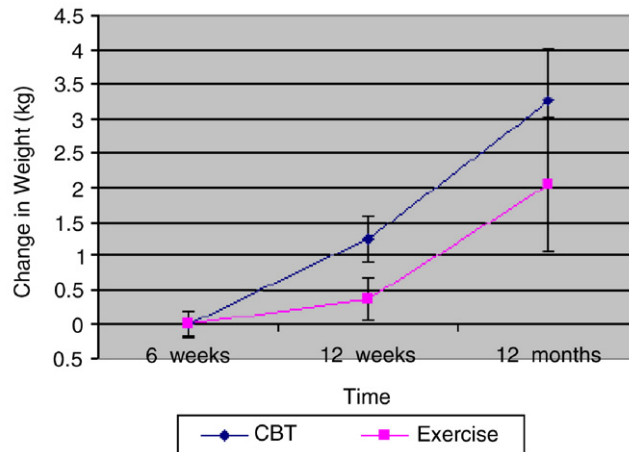


Fig. 6. Mean change in weight between treatment groups.

the end of treatment (6 weeks post-quit) (3.8). At 3 and 12 months follow-up, however, there was a notable rebound effect where the mean number of cigarettes smoked increased to 11.3 and 17.5, respectively. There was also a time by group interaction effect ($p=.01$) whereby the CBT group reported significantly fewer cigarettes compared to the EX group during weeks 7 through 10 and week 12. No time by patch effect or time by group by patch effect was observed (both p values $>.76$). The correlation between the number of cigarettes and (a) CO ranged between 0.60 and 0.81 and (b) cotinine ranged between 0.51 and 0.78.

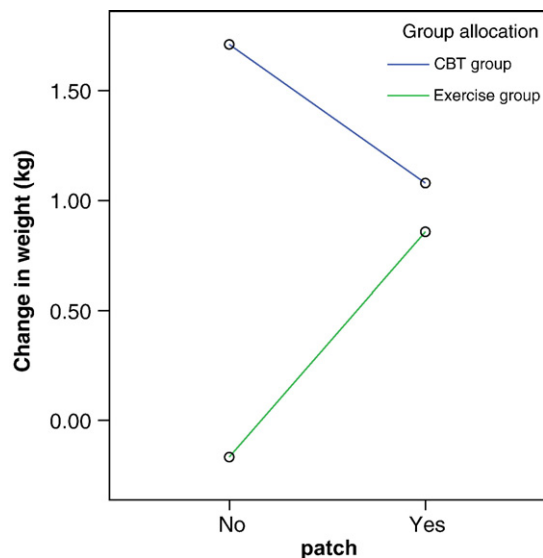


Fig. 7. Mean change in weight between treatment groups by patch/no patch condition.

3.5. Cessation self-efficacy

For all participants, a 2 (treatment group) by 2 (patch versus no patch) repeated measures ANOVA, using cessation self-efficacy scores as the dependent measure, revealed a significant time effect ($p=.01$) as well as significant time by group effect ($p=.01$) and time by patch trend ($p=.09$) (see Fig. 5a and b). No three-way interaction effect was observed ($p>.11$). In general, cessation self-efficacy increased throughout the 12-week intervention period and then tapered off throughout follow-up. Notable differences between treatment groups were seen at 6 weeks, 12 weeks and 12 months with the CBT participants reporting significantly higher efficacy scores than the exercise participants (all p values less than .01). Notable differences between patch conditions were also seen at 6 weeks and 12 weeks where those who received a patch felt more confident about quitting than those who did not receive a patch (p values less than .05).

For 7-day PPA at week 12 (6 weeks post-quit), a 2 (treatment group) by 2 (patch versus no patch) ANOVA showed a patch effect only ($p=.05$). Those who received a patch reported significantly higher cessation efficacy (5.65), than those who did not receive a patch (5.12). For continuous abstinence at week 12 (6 weeks post-quit), an ANOVA showed a patch effect that was similar to what was shown for 7-day PPA.

3.6. Weight gain

Fig. 6 shows the average change in weight (kg) by treatment groups for all participants. As can be seen, a linear increase in weight gain occurs in both groups throughout the treatment and at 12 months follow-up. The EX participants at week 12 (end of treatment), however show significantly less weight gain compared to their CBT counterparts ($p<.01$).

With respect to abstainers, a 2 (treatment group) by 2 (patch versus no patch) ANOVA revealed an interaction trend for 7-day PPA ($p=.08$) at 6 weeks post-quit (see Fig. 7). Specifically, no differences in weight gain are evident between treatment groups when participants received a patch. When participants did not receive a patch, however, those in the CBT group gained significantly more weight than those in the EX group. For continuous abstinence at 6 weeks post-quit, there was a treatment by patch trend effect ($p=.08$). These data paralleled the 7-day PPA at 6 weeks (see Fig. 7).

4. Discussion

This study shows that adding NRT as part of a vigorous and supervised exercise program leads to substantial rates of both 7-day PPA and continuous abstinence in female smokers. Although no statistically significant differences were seen in continuous abstinence between the four treatment conditions the size of the effect actually observed (a 12% absolute increase in exercise and NRT seen at 12 months) in our opinion, is clinically meaningful, but the study did not have sufficient power to detect an absolute difference of less than 30% between groups. The chance of detecting a significant difference in abstinence rates between exercise and CBT groups also was reduced by the differential loss at 12-month follow-up. The exercise group had lower attendance rates at the quit day visit relative to the CBT. While we cannot be certain that the observed differences were not caused by chance alone, the consistently higher cessation rate in the exercise and NRT group for both 7-day PPA and continuous abstinence supports the conclusion that

the combined effect of exercise and NRT is a real finding. Our data suggest that exercise plus NRT is equally effective as an aid to smoking cessation as the tried and tested combination of CBT plus NRT. Our data also suggest that both EX and CBT are less effective without NRT.

Further evidence supporting our findings can be seen when we compared our abstinence data with other exercise smoking cessation interventions. For instance, [Ussher et al. \(2003\)](#) combined exercise and NRT into an existing smoking cessation program and reported continuous abstinence rates of 39% at 6 weeks post-quit whereas continuous abstinence rates reported at that time for our study was 70%. As expected abstinence rates in our study declined in both treatment groups over the following year. Consistent with the literature these abstinence rates are approximately doubled that reported by [Marcus et al. \(1999\)](#) and are clearly superior to other interventions such as personal advice and encouragement, supplementary material and behavior modification techniques ([Law & Tang, 1995](#)). The present cessation program is the first to combine an intensive and supervised exercise program with pharmacological agents such as NRT. Despite these positive findings, it is worth noting from our abstinence data that exercise without NRT was the least effective treatment. It suggests that exercise and NRT have marked additive effects on abstinence rates. Larger studies are warranted to substantiate the individual and joint effects of exercise and NRT on smoking abstinence.

It seems that different mechanisms were operating to explain the effectiveness of the two treatment programs that added NRT. For instance, those who received the patch felt more efficacious about quitting than those not receiving the patch during the last 6 weeks of the treatment program. Also, the CBT group reported significantly higher efficacy scores throughout the program and at 12 months compared to their EX group counterparts. In addition, compared to the exercise participants, the CBT participants reported significantly higher cessation knowledge, coping and support scores at all measured end points. These data, taken together, suggest that CBT as an adjunct to NRT facilitates smoking cessation primarily through psychological mechanisms (i.e., improves cessation self-efficacy and enhances cessation knowledge, coping and support).

On the other hand there was significantly less weight gain for EX at the end of the 12 weeks of treatment compared to their CBT counterparts. Although not significant, these group differences were evident at 12 months follow-up (see [Fig. 6](#)). Results from [Fig. 6](#) suggest that weight gain was delayed but not prevented by exercise in this trial. Interestingly, the modest increase in weight gain for exercise participants at 12 months coincided with the decrease in their 12-month physical fitness. This suggests that many exercise participants were unable to take part in enough physical activity to assist with weight maintenance. For those who were abstinent (both 7-day PPA and continuous) at 6 weeks post-quit, there was significantly less weight gain for exercise participants who were not using NRT than CBT participants who were not using NRT (see [Fig. 7](#)). Specifically, following 6 weeks of abstinence the CBT participants gained more than 2.0 kg body weight than the EX participants. This finding is consistent with that of [Marcus et al. \(1999\)](#) who observed a 2.4 kg difference in weight between exercise and control groups. Interestingly, [Fig. 7](#) also shows no differences between treatment groups when participants use NRT and that modest weight gains occur (<1.2 kg) for both of these treatment groups. This result is in line with previous work which has shown that NRT attenuates post-cessation weight gain ([Jorenby et al., 1996](#)).

Although the relationship between weight gain concerns and successful quitting is not straightforward (cf. [Jeffery, Henrikus, Lando, Murray, & Liu, 2000](#)), concerns about weight gain after cessation attempts are prevalent among females ([Levine et al., 2001](#); [Pirie et al., 1991](#)). Incorporating weight control interventions during cessation, however, has been unsuccessful in preventing weight gain ([Taylor &](#)

Ussher, 2005). Overall, our weight gain data support the tenet that vigorous and supervised exercise is effective in preventing weight gain during the period participants take part in the exercise intervention.

There are several fruitful avenues worth exploring in exercise and smoking. For instance, is there a minimum level of exercise that is required to produce significant increases in abstinence? Comparing exercise of different doses (i.e., high versus moderate) on tobacco abstinence and withdrawal is recommended. Less vigorous exercise is likely to have greater appeal, better adherence, and is more in line with current physical activity guidelines. Conversely, less vigorous exercise will likely be insufficient to aid weight maintenance. As previously mentioned, the work by Marcus et al. (2003) reported less encouraging data for moderate levels of exercise in aiding smoking cessation.

In addition, future research should determine whether inexpensive home-based exercise programs can maintain physical activity after program termination in order to support the goals for long-term weight maintenance and continued smoking cessation. In practice, long-term supervised and structured vigorous exercise regimes are beyond the scope of most smoking cessation services. Also, from our data, it seems that an important next step would be to assess the efficacy of a program that combines all three sets of treatment; CBT, Ex and NRT. Finally, the beneficial effect of exercise in male smokers has yet to be proven.

In closing, within the limitations of the present trial, it can be concluded that exercise combined with NRT facilitates smoking cessation, improves exercise capacity, and delays weight gain in women smokers. We recommend that physicians and health care professionals recommend exercise and NRT together for highly motivated women interested in quitting smoking.

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