

YMCA Commit to Quit Randomized Trial Outcomes

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Background: Vigorous-intensity exercise has been shown to aid in smoking cessation, especially among women. In a previous trial, cognitive behavioral therapy (CBT) for smoking cessation plus regular vigorous aerobic exercise enhanced cessation rates, improved exercise capacity, and reduced weight gain compared to CBT plus equal contact time.

Purpose: This study examined the effectiveness of this program adapted for and implemented in the YMCAs.

Design: An RCT comparing CBT + Exercise (Exercise) to CBT + Contact Control (Control).

Setting/participants: Apparently healthy female smokers were recruited to four local YMCAs.

Intervention: YMCA staff members were trained to lead the manualized CBT smoking-cessation intervention and a standardized YMCA exercise program.

Main outcome measures: Seven-day point prevalence and continuous abstinence.

Results: Participants (330 women, mean age=44 years) were randomized to the Exercise ($n=166$) or Control ($n=164$) group. Results revealed no differences in 7-day point prevalence (29.5% vs 29.9%) nor continuous abstinence (13.9% vs 14.0%) between the Exercise and Control groups, respectively, at end of treatment or at the 3-, 6-, and 12-month follow-up. An examination of the relationship between exercise dose and quit status at end of treatment revealed that over 12 weeks, the odds of being quit (7-day point prevalence) grew by 4.5% for each additional aerobic exercise session (OR=1.05, 95% CI=1.01, 1.08) and by 7.7% for each additional resistance training session (OR=1.08, 95% CI=1.02, 1.14). Analyses were conducted between August 19, 2010, and December 16, 2011.

Conclusions: No differences were seen between groups in smoking outcomes. The association between greater exercise participation and higher odds of quitting within the exercise condition suggests that the lack of between-group differences might be a result of poor compliance with the exercise program.

Trial registration: This study is registered at clinicaltrials.gov NCT01615380.
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Background

Despite the well-known negative health consequences of smoking, 23.5% of men and 17.9% of women smoke cigarettes.¹ Although more men smoke, women may be less successful at quitting than men.² Intensive smoking-cessation programs may be needed to assist women who cannot quit with self-help or pharmacologic approaches.³ A major barrier to smoking cessation, especially among women, is postcessation weight gain.⁴ The average weight gain following cessation is 3–7 kg.^{5,6} Additional barriers to smoking cessation include the apparently greater physiologic and psycho-

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logical withdrawal symptoms experienced by women following smoking cessation.^{7,8} Such studies support other research showing that the negative affect experienced during abstinence can predict time to relapse.⁹

Exercise has been used as an adjunct to smoking-cessation treatment because it can reduce weight gain, negative affect, cigarette cravings, and withdrawal symptoms.¹⁰ In one of the first adequately powered RCTs, Marcus and colleagues^{11,12} conducted the Commit to Quit (CTQ) trial, which compared cognitive-behavioral therapy (CBT) for smoking cessation plus either (1) supervised vigorous-intensity aerobic exercise or (2) an equal staff contact control condition. Compared to the control condition, the *vigorous-intensity* aerobic exercise condition enhanced cessation rates and reduced weight gain and negative affect.^{11–13} For example, at the 3-month follow-up, 13.6% of the contact control group and 24.6% of the exercise condition group were abstinent for the last 7 days ($p=0.02$).¹¹ Although results from studies testing *moderate-intensity* aerobic exercise as a smoking-cessation treatment have been mixed,^{10,14} the efficacious vigorous-intensity exercise program remains a potentially disseminable intervention.

Dissemination of efficacious research studies in community settings is increasingly common in the scientific community. Many research teams have partnered with the YMCA, an ideal setting due to its nationwide presence and focus on general wellness, to test efficacious programs. For example, the Diabetes Prevention Program was translated into a real-world version and delivered in YMCAs.^{15,16} Researchers from the CTQ trial also partnered with a local YMCA to conduct a nonrandomized pilot study and found that participants considered the program feasible and acceptable.¹⁷ The goal of the current study was to test in an RCT the efficacy and effectiveness of CTQ, modified for delivery, in a community setting (see Appendix A for modification details, available online at www.ajpmonline.org).

Methods

This RCT compared two conditions: (1) CBT smoking cessation plus exercise (Exercise) and (2) CBT smoking cessation plus contact control (Control). It was conducted at two YMCAs in Rhode Island and two YMCAs in Southern Massachusetts. A block randomization procedure was used to assign participants to treatment arms, stratifying by site (YMCA location) and nicotine patch decision (intended to use the patch vs did not). Participants were randomly assigned to the Exercise or Control group every 4 weeks in a rolling admissions format. Data were collected from April 2007 through September 2010. The study protocol was approved by the IRBs of the Miriam Hospital and Brown University.

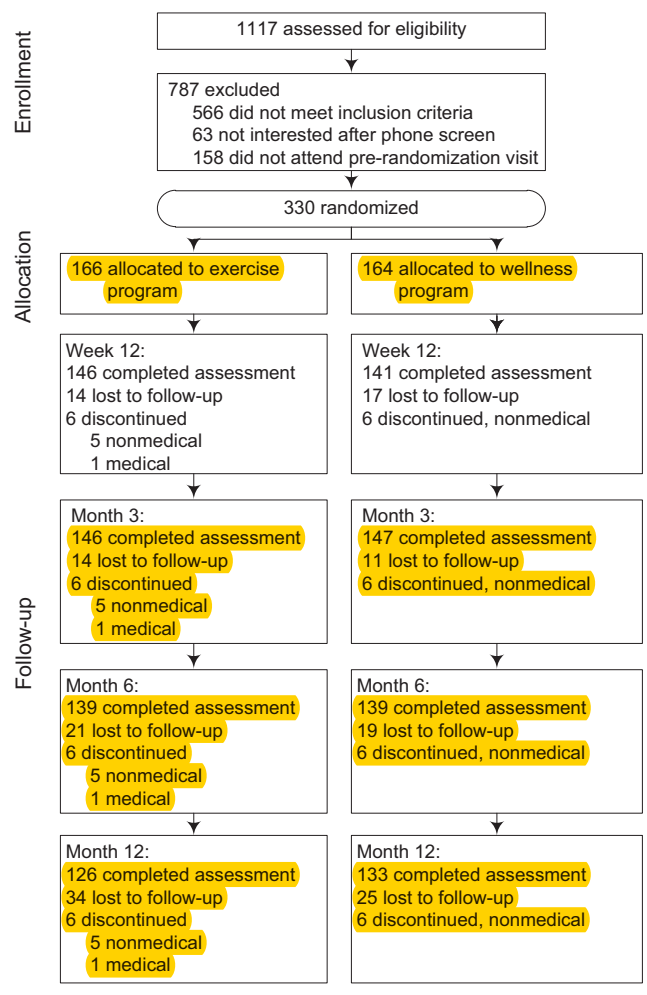


Figure 1. Participant study flow

Participants

Recruitment was conducted through newspaper and radio advertisements, Intranet postings in the researchers' hospital partner group, Internet postings, fliers at local businesses, YMCA-sponsored events, and local health fairs. Advertisements were placed in local minority newspapers and during ethnically targeted radio programming to attract a more diverse study sample. Eligibility telephone screens were conducted with interested individuals.

Inclusion criteria were aged 18–65 years; female; generally healthy; underactive (≤ 20 minutes of vigorous activity two times per week); and currently smoking ≥ 5 cigarettes per day. Health-related exclusion criteria included the following: diabetes mellitus, cardiovascular disease, uncontrolled hypertension, exercise-induced asthma, musculoskeletal problems that limit physical activity, and current or planned pregnancy. Other exclusion criteria included a schedule that would make adherence unlikely, current use of nicotine replacement therapy and/or participation in another smoking-cessation program, and self-reported consumption of > 3 alcoholic drinks per day on ≥ 5 days per week. Medical clearance was needed to participate in the study. See Figure 1 for the flow of participants through the trial.

Eligible women attended an orientation session at the YMCA of their choice, where they learned more about the study, provided

informed consent, and completed the baseline assessment. They were then randomly assigned to either the Exercise or Control condition. Appendix A (available online at www.ajpmonline.org) provides details regarding the difference between the original Commit to Quit Trial and the YMCA Commit to Quit.

YMCA Commit to Quit Program Components

Smoking-cessation program. All participants attended a weekly 60-minute, group-based smoking-cessation program. The sessions were led by trained YMCA staff members. Doctoral-level faculty from the study staff provided training and quality control for the YMCA staff members (Appendix B, available online at www.ajpmonline.org, provides details). The program consisted of a 12-week CBT program with content identical to that used in the previous CTQ trials^{11,18} but with modified timing to accommodate the rolling admissions format. Replacement sessions were not offered; research assistants called participants who missed a session to encourage them to attend the next session and mailed them the session materials.

All group facilitators participated in (1) baseline and quarterly training with doctoral-level licensed clinician researchers to cover research principles and the CTQ smoking-cessation curriculum; (2) baseline human subjects training; and (3) a YMCA Active Listening workshop. All smoking-cessation group sessions were audio-recorded, and 20% of recordings were audited to ensure adherence to the protocol and key counseling principles (Appendix B, available online at www.ajpmonline.org). Facilitators were not blind to condition; They attended weekly supervision sessions with a licensed clinical psychologist for treatment fidelity.

Exercise program. In addition to the smoking-cessation program, participants in the Exercise condition received a free 12-week membership to the YMCA and the YMCA Personal Fitness Program (PFP), a 12-week progressive aerobic and resistance training program led by YMCA personal trainers. Personal trainers met individually with participants for 40–60 minutes at Weeks 1, 4, 8, and 12. All participants were instructed to exercise at the YMCA three times per week, with at least 40 minutes of aerobic exercise per session, including a 5–10-minute warm-up and cool-down period. They were instructed to stay between 64% and 76% (moderate intensity) of their age-predicted maximal heart rate (HR_{max}) during Weeks 1–4 and between 77% and 85% (vigorous intensity) of their HR_{max} for Weeks 5–12.¹⁹

At Week 4, PFP trainers instructed participants to add 20–25 minutes of a full-body resistance training routine each week, following their aerobic exercise. Their goal was to complete at least one set of eight to ten repetitions for each of ten different machine-based resistance training exercises. Trainers reviewed participants' weekly logs and telephoned participants who did not record any exercise within the past 7 days. Participants received stage-matched manuals as well as weekly printed materials to reinforce the information presented by the trainers and to help increase motivation to exercise at Weeks 1, 4, 8, and 12.

Personal trainers at the YMCA followed study-developed guidelines and checklists during each of the four meetings. All personal trainers completed a basic research principles meeting highlighting the importance of delivering a standardized program for all participants. Study staff met weekly with the Fitness Director/Leader of each YMCA to discuss program progress (Appendix B, available online at www.ajpmonline.org).

Contact control. In addition to the smoking-cessation program, participants in the Contact group attended four wellness sessions that were led by trained research staff. Wellness session topics included general health and wellness, flu protection, nutrition, and stress reduction; they were modeled after the wellness sessions that were successfully used in the prior CTQ trial.^{11,12} The group-based wellness sessions were scheduled immediately before or after the smoking-cessation program sessions at Weeks 1, 4, 8, and 11. Researchers offered replacement wellness sessions before or after the next smoking-cessation group meeting for participants who missed smoking-cessation/wellness sessions.

Measures

Follow-up schedule and incentives. Primary outcome data were collected via in-person interviews at five time points: baseline; end of treatment (12 weeks from baseline); and then at 12, 24, and 52 weeks after end of treatment. Smoking status and carbon monoxide (CO) readings were taken weekly also at the smoking-cessation groups. Participants completed an in-depth survey packet and provided CO and saliva cotinine samples at the end of the 12-week program and at the 12-, 24-, and 52-week post-treatment follow-up points. Main outcome analyses are based on continuous abstinence from quit day through end of treatment, verified with saliva cotinine (cutoff = 10 mg/mL²⁰).

To decrease any possible barrier to weekly attendance at smoking-cessation groups, participants received a \$5 gas gift card for each session attended. To encourage follow-up attendance, participants received \$50 for each of the four follow-up assessments. On completion of the 52-week follow-up period, members of the Control arm received free 3-month YMCA memberships at one of the eight locations in the Greater Providence area.

Demographics. Participants reported their age, education level, race, ethnicity, occupation, household income, marital status, and number of children in the household.

Smoking status. To assess continuous abstinence and 7-day point prevalence abstinence (PPA), participants completed smoking status questions and provided CO samples at each weekly smoking-cessation group session. For the present study, participants were considered to have 7-day PPA if they had not had a puff in the last 7 days, had a CO level <10 ppm, and had a mean saliva cotinine value of <10 ng/mL. Further, a participant was considered to be continuously abstinent from quit day if she or he had 7-day PPA at Week 4 (1 week after quit day) and follow-up (Week 12; and 12, 24, and 52 weeks after treatment) and no disconfirming information in between. The Fagerström Test for Nicotine Dependence (FTND)²¹ was administered to gauge nicotine dependence levels at baseline; Week 12; and 12, 24, and 52 weeks after treatment.

Physical activity status. Self-reported physical activity was measured at baseline, end of treatment, and follow-up with the Paffenbarger Physical Activity Questionnaire,^{22,23} which measures leisure-time physical activity, and scores estimated kilocalories expended per week.

Aerobic fitness was measured on a random subsample ($n=135$) of the participants using the Rockport 1-mile treadmill walk test.²⁴ This validated test assesses the time taken to walk 1 mile and estimates maximal oxygen uptake (VO_{2max}). It has been used to measure changes in aerobic fitness in an adult population.²⁴ This specific walk test was selected primarily because of safety concerns

Table 1. Baseline demographics by treatment group, M (SD) or %, unless otherwise noted

	Exercise (n=166)	Contact control (n=164)	All (n=330)
Age (years)	44.07 (9.85)	42.98 (10.08)	43.52 (9.96)
Weight (lbs)	162.01 (33.20)	167.51 (39.04)	164.74 (36.27)
BMI	27.60 (5.43)	28.82 (6.16)	28.21 (5.83)
Education (at least some college)	63.64	66.46	65.05
Minority	22.29	23.17	22.73
Employed full-time	57.23	51.83	54.55
Married	37.95	34.76	36.36
Cigarettes/day	17.38 (7.98)	17.58 (6.25)	17.48 (7.16)
Carbon monoxide level	13.28 (7.98)	13.52 (8.18)	13.40 (8.30)
FTND	5.11 (2.29)	5.13 (2.09)	5.12 (2.12)
Kilocalories/week of exercise	720.21 (721.41)	584.02 (622.57)	652.96 (676.81)
VO ₂ mL/kg/minute (n=135)	27.10 (6.67)	25.11 (6.97)	25.11 (6.97)

Note: $p > 0.05$ for all between-group comparisons

FTND, Fagerstrom Test of Nicotine Dependence; VO₂ mL/kg/minute, maximal oxygen consumption, expressed in milliliters of oxygen per kilogram of body weight per minute

and to accommodate the wide range of physical fitness within the target population.

Participants in the exercise arm were asked to record each exercise session on a YMCA exercise log regularly used by the Personal Fitness Program and modified to suit the current study. The exercise log has two major sections, one for detailing aerobic exercise and one for detailing strength training.

Weight status. Body weight was measured weekly on a calibrated balance scale to evaluate weight changes among participants.

Data Analysis

The current trial was designed to randomize a total of 392 participants in order to have 80% power to test the null hypothesis that the intent-to-treat effect was equal to zero versus the one-sided alternative that exercise would have a positive benefit (with $\alpha = 0.05$). Effect size estimates for the power calculation were based on the continuous abstinence rates at end of treatment and at 3- and 12-month follow-up from the original Commit to Quit.^{11,12} An intent-to-treat approach was taken, such that all randomized participants were included in the analyses under the assumption that those with missing outcomes had returned to smoking.

Between-group comparisons of baseline characteristics were made using ANOVA and chi-square tests. Means and SDs are presented for continuous variables, and percentages are reported for categorical variables. Similarly, completers were compared to study dropouts with respect to baseline characteristics. Between-group differences in 7-day PPA and continuous abstinence were examined with one-sided chi-square tests.

Logistic regression models were used to examine the association between changes in the Paffenbarger (kilocalories of exercise/week) and smoking cessation at end of treatment. Similarly, logistic regression models were used to examine the dose effects of exercise on smoking cessation at end of treatment among those randomized

to the exercise arm. Between-group differences in weight gain over 12 weeks were assessed using ANOVA among completers only (i.e., were not imputed) as well as among participants who reported continuous abstinence throughout the treatment period. Finally, mean changes in fitness (treadmill time and estimated VO_{2max}) from baseline to 12 weeks were assessed with ANOVA. Analyses were conducted between August 19, 2010, and December 16, 2011.

Results

A total of 1117 women were screened by telephone for eligibility (Figure 1). Of these, 787 were ineligible and/or not interested in participating. The remaining 330 women were randomized at baseline to one of two treatment arms: Exercise ($n = 166$) or Control ($n = 164$). Demographic characteristics of the sample are presented in Table 1. No between-group differences were found on any baseline variables examined. In addition, there were no differences between study completers and dropouts with respect to baseline characteristics of the sample.

Adherence

Exercise participants attended an average of 60% of the 12 smoking-cessation sessions and 58% of the four personal trainer sessions at the YMCA. They logged an average of 295 minutes of aerobic activity (SD=361, range=0–1870); 9.7 aerobic exercise sessions (SD=10.13, range=0–41); and 4.2 strength training sessions at the YMCA over the 12 weeks of the study (SD=6.04, range=0–35). Control participants attended an average of 56% of the 12 smoking-cessation sessions and 76% of the four wellness sessions. Although the difference be-

tween arms with respect to smoking sessions attended was not significant ($p>0.05$), control participants attended more wellness sessions than exercise participants attended trainer sessions ($t=5.22$, $df=326$, $p<0.001$).

Of the 330 randomized to participate in the study, 287 women (87%) returned for the 12-week smoking-cessation session at which their treatment data were collected. Follow-up rates were as follows: 293 (89%) returned 12 weeks after treatment, 278 (84%) returned 24 weeks after treatment, and 259 (78.5%) returned 52 weeks after treatment. The dropout rates at each follow-up time between treatment arms and does not indicate any differential dropout during the study nor follow-up sessions (12, 24, and 52 weeks post-treatment).

Smoking Outcomes

Smoking outcomes are presented in Table 2. For the intent-to-treat analyses, at end of treatment (12 weeks), 29.5% of Exercise participants and 29.9% of control participants achieved 7-day PPA ($p>0.05$). No between-group differences with respect to 7-day PPA were found at any of the follow-up time points (12, 24, and 52 weeks post-treatment). Similarly, no between-group differences in continuous abstinence rates were found at 12 weeks (13.9% for Exercise vs 14.0% for Control, $p>0.05$) or follow-up (7.8 vs 8.5, $p>0.05$, at 12 weeks; 7.2 vs 5.5, $p>0.05$, at 24 weeks; 6.6 vs 3.7, $p>0.05$, at 52 weeks). Among those who returned to follow-up, no differences were found in 7-day PPA or continuous abstinence at any time point. Satisfaction data are shown in Appendix C (available online at www.ajpmonline.org).

Exercise Outcomes

Aggregated across treatment arms, increases in kilocalories of exercise over 12 weeks were associated with greater odds of 7-day PPA at end of treatment (12 weeks), $p=0.03$. Specifically, a 300-kcal increase in 7-day Paffenbarger score from baseline to Week 12 was associated with a 9% increase in the odds of 7-day PPA at end of treatment (OR=1.09, 95% CI=1.01, 1.17). Further, exercise participants reported higher mean increases in kilocalories of exercise over 12 weeks (457, SD =1017) than control participants (189, SD=800), $t=2.65$, $df=328$, $p=0.01$.

Moreover, results indicated an association between amount of exercise completed (total sessions of aerobic activity, total resistance training sessions, and total minutes of reported aerobic activity) and 7-day PPA at 12 weeks among Exercise participants. Specifically, the odds of 7-day PPA at 12 weeks increased by 4.5% for every one-session increase in aerobic activity (OR=1.05, 95% CI=1.01, 1.08); 7.7% for every one-session increase in resistance training (OR=1.08, 95% CI=1.02, 1.14);

Table 2. 7-day PPA and continuous abstinence rates by treatment group, %

	Exercise	Contact control
7-DAY PPA		
12 weeks		
ITT sample	29.52	29.88
Completers-only	33.56	34.75
12 weeks post-treatment		
ITT sample	21.08	21.95
Completers-only	23.97	24.49
24 weeks post-treatment		
ITT sample	21.69	20.12
Completers-only	25.90	23.74
52 weeks post-treatment		
ITT sample	18.67	15.85
Completers-Only	24.60	19.55
CONTINUOUS ABSTINENCE		
12 weeks		
ITT sample	13.86	14.02
Completers-only	15.75	16.31
12 weeks post-treatment		
ITT sample	7.83	8.54
Completers-only	8.90	9.52
24 weeks post-treatment		
ITT sample	7.23	5.49
Completers-only	8.63	6.47
52 weeks post-treatment		
ITT sample	6.63	3.66
Completers-only	8.73	4.51

Note: $p>0.05$ for all between-group comparisons
ITT, intention to treat; PPA, point prevalence abstinence

and 3.6% for every 30-minute increase in aerobic activity (OR=1.04, 95% CI=1.01, 1.06) over 12 weeks.

Weight Gain

On average, participants gained 2.9 pounds (SD = 9.2) over 12 weeks, with no between-group difference ($p=0.60$).

Fitness Changes

On average, Exercise participants increased their estimated VO_{2max} by 2.2 mL/kg/minute (SD=2.6) over 12 weeks, which was more than Control participants, who increased by 0.86 mL/kg/minute (SD=2.8), $F=5.48$,

$p=0.02$. In addition, a random subsample of exercise participants improved their 1-mile treadmill walk time more than did a random subsample of control participants (-1.71 minutes, $SD=2.44$ vs -0.60 minutes, $SD=1.87$), $F=5.77$, $p=0.02$, over 12 weeks.

Discussion

Unlike in the original Commit to Quit trial,^{11,12} between-group differences were not found in 7-day PPA nor continuous abstinence rates at end of treatment or any of the follow-up assessments. At 12 weeks, both groups achieved a 7-day PPA just less than 30%; at 52 weeks post-treatment, 19% of the Exercise and 17% of the Control group achieved 7-day PPA (Table 2).

To understand the lack of treatment differences, a manipulation check on exercise was performed by examining changes in physical fitness and self-reported physical activity between the two groups from baseline to end of treatment. Fitness test results from a random subsample of participants revealed significant increases in estimated VO_{2max} in the Exercise group only. Exercise group participants also reported more physical activity than controls at 12 weeks. Dose effects of exercise were examined across both study arms and within the exercise arm. Across the two arms, a 300-kcal/week (roughly equivalent to 60 minutes of moderate-intensity activity, estimated by Paffenbarger score) increase in energy expenditure from baseline to 12 weeks was associated with a 9% increase in the odds of a 7-day quit. Similarly, as sessions of aerobic exercise and resistance training increased, so too did the odds of being quit for 7 days.

The dose–response findings in the current study suggest that exercise may have a beneficial impact on quit status. However, the lack of between-group differences precludes the interpretation that exercise outperformed a contact control group. A number of interpretations for the lack of between-group treatment differences in smoking status are possible. For example, exercise may favorably affect smoking cessation, as demonstrated by the dose–response findings, but the poor compliance among many participants in the exercise condition (24 minutes/week completed rather than the prescribed 90 minutes/week) eliminated a between-group exercise effect.

Another possible explanation is that participants performed more moderate- than vigorous-intensity activity, despite the vigorous exercise prescription. Although vigorous-intensity exercise has favorably affected smoking cessation,^{11,12} findings for moderate-intensity exercise have been mixed.¹⁰ Participants' exercise logs suggested that they largely engaged in moderate- rather than vigorous-intensity exercise; thus, lower-than-recommended intensity may have further compounded

the less-than-recommended duration and frequency problem previously identified.

Further, an exercise contamination effect may have occurred, in that those in the control group might have increased their physical activity during the study for a variety of study-related reasons, such as their weekly exposure to a YMCA, at which the smoking-cessation group met, or their enrollment in an exercise-based smoking-cessation study. This contamination may have mitigated the effect of exercise in the Exercise group. Indeed, the mean uptake of exercise by control-group participants, nearly 200 additional kilocalories from baseline to 12 weeks, rivaled that of the Exercise group's mean increase from baseline of approximately 460 kcal.

Further, a dose-effect of exercise across the two arms was apparent, such that regardless of group assignment, every 300-kcal increase of activity in a 7-day period corresponded to a 9% increased chance of 7-day PPA at Week 12. Finally, despite a sound theoretic prediction, exercise may not actually be an effective smoking-cessation adjunct; rather, individual characteristics, such as overall motivation, may explain the apparent dosing effects of exercise (e.g., those who are more motivated to exercise are also more motivated to quit smoking).

Limitations

A number of limitations in the current study should be noted. One limitation was the impact of the relatively low attendance to the smoking-cessation sessions on the completeness of the data; 30%–50% of participants did not attend the weekly smoking-cessation groups. This is in contrast to the original trial where participants attended approximately 70% of the smoking-cessation sessions. However, at the 12-week point where end-of-treatment data were collected, a \$50 incentive for completion of the data was offered and the attendance rate increased dramatically to 87%, as compared to participation rates that were between 65% and 69% at 12 weeks in the original trial.

Although the incentive for end-of-treatment and follow-up data may have aided data collection, these incentives limit the external validity and generalizability of the study. Another limitation of this study was its reliance on self-reported exercise data (i.e., YMCA logs and Paffenbarger questionnaire). Self-reported exercise data notoriously overestimate actual physical activity levels, and supplementary objective measures of physical activity would have strengthened the conclusions reached.

The present study's strong external validity may have undermined its internal validity. This was a real-world test of a program with demonstrated efficacy in a previous, tightly controlled study. It was translated from a medical research setting into the community, making it more accessible to participants. In addition, YMCA staff members were

trained to lead both the smoking-cessation and exercise programs, increasing the generalizability and sustainability of the programs but perhaps reducing internal validity because of a possible decrease in fidelity of the original CTQ study.

Conclusion

The association between greater exercise participation and higher odds of quitting among exercise participants suggests that the lack of treatment effects might be a result of poor compliance with the exercise program. However, although the dose effects found in the exercise arm are encouraging, they do not establish causality between exercise uptake and smoking cessation, and alternative (i.e., third-variable) explanations cannot be discounted. The YMCA could be an excellent vehicle to reach many women trying to quit smoking. Thus, additional studies focused on increasing vigorous-intensity exercise compliance should be conducted in the YMCA setting.

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Appendix

Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.amepre.2012.05.025>.