The challenges of translating an efficacious smoking cessation program, Commit to Quit, to the community setting of YMCAs

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Cite this as: *TBM* 2013;3:47–58
doi: 10.1007/s13142-012-0181-0

Abstract

Commit to Quit (CTQ), a program that utilized vigorous intensity exercise as an adjunct to a cognitive-behavioral smoking cessation program, was shown to be effective for female smokers (Marcus et al., *Prev Med* 26(4):586–597, 1997; Marcus et al., *Arch Intern Med* 159(11):1229–1234, 1999). Adapting effective programs, such as CTQ, to community settings could lead to a large public health impact as the program could substantially increase its reach. This case study chronicles the steps taken by researchers to translate CTQ from the medical to the community setting of YMCAs (CTQY). Use of aspects of Diffusion Theory [3] such as identifying a champion of the program and attending to the characteristics of an innovation to enhance program adoption are discussed. Details regarding attending to the tensions between internal and external validity as the program was adapted to the community setting are also outlined. The challenges of conducting community trials are discussed.

Keywords

Translation, Smoking cessation, Physical activity, Community setting, Diffusion Theory

Although women smoke at lower rates than men (17.9 % vs. 23.5 %) [4], women are less able to quit and stay quit [5]. One of the reasons quitting may be more difficult for women than men is that postcessation weight gain is considered to be a bigger barrier to smoking cessation among women [6]. Programs that address weight gain may be especially helpful for women trying to quit smoking. Exercise has been used as an adjunct to smoking cessation treatment because it can reduce weight gain, negative effect, cigarette craving, and withdrawal symptoms [7].

The purpose of this case study is to describe the process we undertook in translating an efficacious program developed for the research setting that uses exercise as an adjunct to a cognitive-behavioral smoking cessation therapy and adapting it for the community setting for delivery through the YMCA. The translation process was guided by

Implications

Practice: Translation of efficacious laboratory-based interventions into the community setting can be difficult and may require trade-offs and compromises. Even with careful planning, it should not be assumed that interventions shown to be efficacious in a laboratory setting will be efficacious in the community setting.

Policy: No policy implications can be drawn at this time.

Research: Cumulative science, specific to behavioral interventions, is needed to contribute to generalized knowledge about translating interventions shown to be effective in laboratory settings.

Diffusion Theory [3] and input from YMCA management and staff. We will discuss the challenges encountered in conducting an effectiveness trial in the community where there is a need to balance internal validity (which is characteristic of research setting efficacy trials) while also promoting external validity to ensure that the program was feasible and has the potential to be sustainable in the community setting.

BUILDING ON THE PREVIOUS TRIALS: COMMIT TO QUIT THE ORIGINAL AND PILOT

CTQ original

CTQ Design Format and Outcomes [1, 2]

The original Commit to Quit (CTQ) was a randomized, controlled clinical trial (RCT) designed as an efficacy study conducted in a medical research setting. Participants were screened for eligibility, assessed at baseline, and randomized to either group-based cognitive-behavioral smoking cessation plus exercise (Exercise) or the same smoking cessation program plus contact control (Control).

The smoking cessation program was led by Ph.D.-level psychologists. Participants who missed a session received a replacement session led by one of their group leaders. Exercise participants were overseen by trained exercise research staff to use treadmills, stationary cycles, and other standard gym equipment. All participants completed a graded maximal fitness test at baseline and were given a prescription of thrice weekly exercise. They were encouraged to start slowly and to increase exercise intensity over time to reach a vigorous intensity of 60–85 % functional capacity. Control group participants attended health and wellness lectures, discussions, and movies about a variety of topics, excluding physical activity. These sessions were scheduled thrice weekly to ensure equal contact time between the two study arms.

CTQ results

Results for this trial are as follows (Table 1). Attendance to the smoking cessation session was 72 % for the Control group and 70 % for the Exercise group. Participants in the exercise arm attended 67 % of the possible 36 prescribed, supervised exercise sessions. Participants randomized to Exercise had significantly higher cessation rates for 7-day point prevalence (Exercise=31 % and Control=22 %, $p=0.09$) and continuous abstinence (Exercise=19 % and Control=10 %, $p=0.03$), and reduced weight gain and negative affect compared to Controls [1, 2, 8]. The percentage of people who began treatment and attended the end-of-treatment sessions was 69 % for Exercise and 65 % for the Control groups.

CTQ YMCA pilot (CTQY-p)

CTQ: A one group design pilot of CTQ in the YMCA [9] After establishing the efficacy of vigorous exercise as an adjunct to CBT for smoking cessation, we conducted a pilot program to determine how best to test this program in a community setting. We partnered with the YMCA as it is well positioned for

potential dissemination [9]. Since according to Diffusion Theory [3], identifying champions is a key aspect to successful adoption of a program, our first step was to meet with key YMCA leaders who identified a specific YMCA that was considered to be a model YMCA in their network. We then conducted a one-group study (Exercise arm from CTQ) in that YMCA (CTQY-p) [9]. The Diffusion Theory [3] states that in order to adopt a new innovation, a program needs to be: (1) *compatible* with existing structures (the YMCA in our case), (2) not overly *complex*, (3) display a *relative advantage* to other programs, (4) be perceived as *trialable* (the degree to which an innovation/program may be tried on an experimental basis before deciding to adopt it), and (5) be *observable* to others (the degree to which the results of an innovation/program are visible to others) [3, 9]. We used these five characteristics to guide our program adaptation, as we believed it would better position our program for dissemination in the future.

Whenever possible, we incorporated these five innovation characteristics into our program (CTQ-p) so that it would be seen as a good fit for the YMCAs and for smokers interested in the program. In addition, we tried to determine how best to balance *internal validity* and *external validity* while in a community setting. Table 2 presents the rationale for the various adaptations that were taken in moving from the research facilities to the YMCA setting. The study entry procedures were adapted. Rather than having a series of baseline visits as had been the case with the original CTQ, which tends to increase internal validity, we sought to be compatible with YMCA practices and adopted the Informational Session model. This is most similar to the normal practice at YMCAs. In CTQ-p, one brief Informational Session was used in which we: (1) described the study to interested smokers, (2) conducted a shortened self-administered eligibility screener, (3) consented eligible participants, and (4) had participants complete a streamlined packet of study questionnaires. The CTQY-p trial minimized participant burden for the research components of the

Table 1 | Outcomes from the three CTQ trials

	CTQ [1, 2]		CTQY-p [9]	CTQY [10]	
	Exercise N=134	Control N=147	Exercise N=43	Exercise N=166	Control N=164
Quit status ^a					
7-Day PPA	30.6 %	21.8 %	7.0 %	29.52 %	29.88 %
Continuous abstinence	19.4 %*	10.2 %*	2.3 %	13.86 %	14.02 %
End-of-treatment follow-up rates	68.7 %	64.6 %	58.1 %	81.9 %	82.9 %
Attendance at smoking cessation session	69.6 %	72.2 %	49.0 %	60.0 %	56.0 %
Adherence to exercise prescription	67.3 %	n/a	n/a	26.9 %	n/a

^a Analysis was conducted on the intent-to-treat sample, missing=smoking

^b Exercise prescription was to attend lab-based exercise sessions 3 times/week

^c Exercise prescription was to do 3 aerobic exercise sessions/week at the YMCA

* $p<0.05$ for between-group difference

Table 2 | Rationale and changes made among the CTQ trials

	CTQ [1, 2]	CTQ-p [9]	Rationale for changes from CTQ to CTQ-p	CTQY [10]	Rationale for changes from CTQ and CTQ-p to CTQY
1 Design	<ul style="list-style-type: none"> • RCT: 2 groups, CBT + exercise vs.CBT + contact control 	<ul style="list-style-type: none"> • 1 group: CBT + exercise 	<ul style="list-style-type: none"> • An initial demonstration of feasibility and acceptability in the YMCA setting 	<ul style="list-style-type: none"> • RCT: 2groups, CBT + exercise vs.CBT + contact control 	<ul style="list-style-type: none"> • A return to the research question of isolating the effects of vigorous activity on smoking status
2 Setting	<ul style="list-style-type: none"> • Research hospital facilities 	<ul style="list-style-type: none"> • A local YMCA 	<ul style="list-style-type: none"> • Increase <i>external validity</i> 	<ul style="list-style-type: none"> • 4 local YMCAs 	<ul style="list-style-type: none"> • Maintaining emphasis on increasing <i>external validity</i>
3 Study entry procedures	<ul style="list-style-type: none"> • Eligibility criteria were extensive 	<ul style="list-style-type: none"> • Eligibility criteria were minimal 	<ul style="list-style-type: none"> • A <i>champion</i> was identified who recommended the YMCA and agreed that it was <i>compatible</i> with the Y's desire to increase wellness programming 	<ul style="list-style-type: none"> • Eligibility criteria list > CTQY-p but<CTQ 	<ul style="list-style-type: none"> • Continued to work with the same champion from YMCA headquarters who guided and assisted with identifying additional YMCAs
	<ul style="list-style-type: none"> • Eligibility phone screens conducted 	<ul style="list-style-type: none"> • Eligibility screen conducted as part of an informational session at the YMCA 	<ul style="list-style-type: none"> • Increase <i>external validity</i> by decreasing stringency of entry criteria and by reducing the participant burden of multiple contacts prior to randomization 	<ul style="list-style-type: none"> • Eligibility phone screen 	<ul style="list-style-type: none"> • Increase <i>internal validity</i> from CTQ-p
	<ul style="list-style-type: none"> • 2 baseline assessment visits at research facility 	<ul style="list-style-type: none"> • Same info. session as above also contained all assessments 		<ul style="list-style-type: none"> • 1 baseline visit 	<ul style="list-style-type: none"> • Tried to <i>maintain compatibility</i> with YMCA programs while ensuring participant safety
	<ul style="list-style-type: none"> • MD consent required for all 	<ul style="list-style-type: none"> • No MD consent required for those cleared by PAR-Q 		<ul style="list-style-type: none"> • MD consent required for all 	
4 Incentives	<ul style="list-style-type: none"> • Participants were asked to provide \$100 deposit before participating, which was refunded in increments upon completion of the follow-up assessments 	<ul style="list-style-type: none"> • 3-month YMCA membership was only incentive 	<ul style="list-style-type: none"> • Increase <i>external validity</i> by not compensating for an assessment visit 	<ul style="list-style-type: none"> • 3-month YMCA membership 	<ul style="list-style-type: none"> • Increase <i>internal validity</i>. After CTQ-p attendance rates of 49 % of the smoking sessions and 58 % for the follow-ups (Table 1), incentives were added for both to increase participation. Without increasing chances of receiving a dose of treatment and follow-up, data it would not have been possible to evaluate the effectiveness of the program in the YMCAs
	<ul style="list-style-type: none"> • Not compensated for assessments 			<ul style="list-style-type: none"> • Participants received \$5 gas cards at each CBT session attended 	

Table 2 (continued)

	CTQ [1, 2]	CTQ-p [9]	Rationale for changes from CTQ to CTQ-p	CTQY [10]	Rationale for changes from CTQ and CTQ-p to CTQY
				<ul style="list-style-type: none"> Participants received \$50 for completion of end of treatment, 3-, 6-, and 12-month follow-up assessments Those randomized to contact received a 3-month YMCA membership after completion of the 12-month follow-up 	
5	Retention protocols <ul style="list-style-type: none"> Intensive: reminder calls for assessments, full length make-up sessions in-person for smoking, exercise, and wellness program 	<ul style="list-style-type: none"> Low to moderate, no reminder calls for assessments, brief make-up sessions by telephone for smoking sessions, make-up trainer sessions 	<ul style="list-style-type: none"> Increase <i>external validity</i> 	<ul style="list-style-type: none"> Low, reminder calls for assessments, no in-person nor telephone make-up sessions for smoking sessions, make-ups in-person for trainer and wellness sessions 	<ul style="list-style-type: none"> Further increase <i>external validity</i> by not having make up sessions for the smoking cessation
			<ul style="list-style-type: none"> In order to make the program more <i>compatible</i> with YMCA practices where there generally is little time to conduct reminders nor make-up sessions 		<ul style="list-style-type: none"> Further increase <i>compatibility</i> with Y practices
6	Smoking cessation leaders <ul style="list-style-type: none"> PhD level researchers 	<ul style="list-style-type: none"> PhD level researchers 	<ul style="list-style-type: none"> Maintain <i>internal validity</i> by retaining PhD led groups 	<ul style="list-style-type: none"> Researchers trained YMCA staff 	<ul style="list-style-type: none"> Increase <i>external validity</i> by moving to YMCA-led smoking cessation groups
	<ul style="list-style-type: none"> A YMCA staff was present and trained with PhD leader but never led the program alone 			<ul style="list-style-type: none"> YMCA staff observed a 12-week group, then co-lead a group with a researcher and then co-lead the program with trained YMCA facilitator 	<ul style="list-style-type: none"> Enhance <i>compatibility</i> of the program by having the program YMCA-led
				<ul style="list-style-type: none"> YMCA staff trained and supervised by researchers 	
7	Exercise program leaders <ul style="list-style-type: none"> Research trainers present at every exercise session 	<ul style="list-style-type: none"> YMCA trainers met with participants 4 times over 12 weeks 	<ul style="list-style-type: none"> Increase <i>compatibility</i> by using the YMCA program already in place and as intended to be delivered by the YMCA staff 	<ul style="list-style-type: none"> YMCA trainers met with participants 4 times over 12 weeks 	<ul style="list-style-type: none"> After some concern that the participation in exercise was low in CTQ-p and it was not clear what was covered in each trainer session, we attempted to increase <i>internal validity</i> of our primary manipulation
		<ul style="list-style-type: none"> Little contact with 		<ul style="list-style-type: none"> Researchers worked with trainers 	

Table 2 (continued)

CTQ [1, 2]		CTQ-p [9]	Rationale for changes from CTQ to CTQ-p	CTQY [10]	Rationale for changes from CTQ and CTQ-p to CTQY	
		researchers		to schedule the 1st training session before participant began exercise program		
				<ul style="list-style-type: none">Weekly contact between trainers and researchers		
				<ul style="list-style-type: none">Trainers filled out a researcher-created goal sheet every session with participant		
				<ul style="list-style-type: none">Trainer met participant after smoking group to schedule training sessions		
8	Exercise program	<ul style="list-style-type: none">At research facility	<ul style="list-style-type: none">YMCA personal fitness program	<ul style="list-style-type: none">Increase <i>compatibility</i>	<ul style="list-style-type: none">Tried to increase the <i>internal validity</i> from CTQ-p while still retaining as much <i>compatibility</i> and <i>external validity</i> with existing YMCA programs	
		<ul style="list-style-type: none">Supervised vigorous intensity activity	<ul style="list-style-type: none">Unsupervised moderate to vigorous intensity exercise	<ul style="list-style-type: none">Increase <i>external validity</i>	<ul style="list-style-type: none">Met with YMCA trainer 4 times over 12 weeks in program to learn use of equipment and receive coaching	
		<ul style="list-style-type: none">No resistance training	<ul style="list-style-type: none">Resistance training was introduced around week 4 in program as part of the Y program	<ul style="list-style-type: none">Resistance training was introduced around week 4 in program as part of the Y program		
				<ul style="list-style-type: none">Kept an exercise log	<ul style="list-style-type: none">Participants who missed a YMCA trainer session were called by YMCA trainer and rescheduled for a replacement session	
					<ul style="list-style-type: none">Little oversight of YMCA trainers for training and implementation	
9	Exercise prescription	<ul style="list-style-type: none">Vigorous intensity	<ul style="list-style-type: none">Vigorous intensity	<ul style="list-style-type: none">Attempt to retain <i>internal validity</i>	<ul style="list-style-type: none">Attempt to work within findings from CTQ-p that participants were self-reporting moderate intensity in their logs so a progressive program was developed to work towards vigorous intensity	
		<ul style="list-style-type: none">60–85 % functional capacity, 5 min warm up	<ul style="list-style-type: none">60–85 % of age predicted maximum heart rate	<ul style="list-style-type: none">64–76 % of their age-predicted maximal heart rate (HRmax) during		

Table 2 (continued)

	CTQ [1, 2]	CTQ-p [9]	Rationale for changes from CTQ to CTQ-p	CTQY [10]	Rationale for changes from CTQ and CTQ-p to CTQY
				weeks 1–4; 77–85 % of their HRmax for weeks 5–12	
	<ul style="list-style-type: none"> Supervised, 3×/week 30–40 min aerobic activity, 5 min cool down 	<ul style="list-style-type: none"> Self-directed, 3 days/week, 30–40 min per session 			
				<ul style="list-style-type: none"> Self-directed, 3×/week for 30–40 min aerobic activity, 5–10 min cool down; full body resistance training (20–25 min) 	<ul style="list-style-type: none"> Self-directed sessions retained <i>compatibility</i> with the YMCA program
10	Wellness program (contact control condition)	<ul style="list-style-type: none"> 36 sessions 	<ul style="list-style-type: none"> None, no control group 	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> Increase <i>external validity</i> by making a program that could be delivered in multiple YMCAs
	<ul style="list-style-type: none"> 3×/week for 30–45 min 			<ul style="list-style-type: none"> Met with research staff 4 times over 12 weeks to receive and discuss wellness handouts 	
	<ul style="list-style-type: none"> 12 weeks of wellness lectures by research staff and experts, handouts, films, and discussion 			<ul style="list-style-type: none"> Sessions were held directly before or after the smoking cessation groups 	
	<ul style="list-style-type: none"> Participants who missed a session were called by research staff and scheduled for a replacement session 			<ul style="list-style-type: none"> Participants who missed a wellness session could attend their missed session after their next smoking cessation group 	

program to maximize its similarity to other YMCA offerings (i.e., compatible and not too complex).

Another difference between CTQ and CTQ-p was that we did not give participants incentives for participation in the assessment sessions. Instead, we provided either a 3-month membership to YMCA nonmembers or paid for 3 months of a YMCA membership for the existing members. This adaptation was an attempt to increase *external validity* in that multiple assessment sessions are not a typical YMCA practice. Similarly, we did little to enhance study attendance to sessions or the assessments, again trying to enhance compatibility with the YMCA operations.

To further enhance *compatibility*, we trained YMCA staff members to co-lead the CBT groups along with the Ph.D.-level researcher. Since YMCA staff members are very busy with little time to focus on enhancing member attendance to ensure adequate doses of treatment, researchers conducted brief make-up sessions by phone with participants who missed a CBT session, rather than an in-person make-up session (used in CTQ) that YMCA staff members would not be able to replicate in the future. To optimize *compatibility* and minimize *complexity* for the exercise program, the existing YMCA Personal Fitness Program (PFP) was used. In that program, participants met with a YMCA personal trainer in weeks 1, 4, 8, and 12 of the program to learn aerobic and resistance training (RT) exercises. The recommendation was for participants to exercise 3 days/week for 30–40 min/session at 60–85 % of their age-predicted maximum heart rate. Exercise was not directly supervised as had been the case in the original CTQ trial. We also did not collect adequate data on attendance to the prescribed exercise sessions so that it was difficult to determine the dose of exercise received both in terms of frequency of sessions and intensity of the exercise.

CTQ-p results

Results indicated that by the end of the 12-week program, 7 % of participants were abstinent from smoking (7-day point prevalence) and the program received high satisfaction ratings from the completers [9]. Participants also showed a significant increase in weekly kilocalories of energy expended from 530.3 kcal at baseline to 1,256.4 kcals at the end of treatment ($p < .001$) [9]. In addition, the percentage of individuals who attended the end-of-treatment assessment session was lower than the CTQ Original trial by almost 10 %. In this trial, attendance to the smoking cessation session was more than 20 % lower than in the original trial at 49 %. This preliminary trial indicated high participant satisfaction and led us to conduct a randomized trial in YMCAs. However, it was also clear that additional changes were needed to increase the internal validity of the study by improving atten-

dance to the smoking cessation, exercise, and assessment sessions.

CTQ YMCA (CTQY): the randomized trial [10]

The goal of this effectiveness trial was to test the CTQ program in the community setting of the YMCA. This case study describes the adaptations that were made to do so. The adaptations were made in an attempt to maintain fidelity to the original program (i.e., *internal validity*) and address poor rates of adherence in the pilot, while at the same time, develop a program that was practical and flexible enough to be adopted and sustained by YMCAs (i.e., *external validity* and generalizability). We continued to use components of the Diffusion Theory [3], such as identifying and working with champions of the program and incorporating the five characteristics of an innovation to guide our decisions and protocols. Table 2 highlights differences between the original CTQ [1, 2], the CTQY-p pilot [9], and the CTQY trial [10].

The research design

As in the CTQ trial [1, 2], this was an RCT comparing two conditions: (1) CBT smoking cessation plus exercise (Exercise) and (2) CBT smoking cessation plus contact control (Control).

Study entry procedures

To balance the lack of eligibility criteria for most YMCA programs with the desire to reduce confounds (e.g., eliminating individuals already enrolled in other quit-smoking programs), eligibility criteria were less stringent than the original CTQ. However, we did increase the eligibility criteria from CTQ-p so that they were more similar to the original efficacy study. We did this to increase *comparability* between the efficacy trial and this effectiveness trial. We went from a telephone screener in CTQ to an in-person screening session in CTQ-p, back to a telephone screen in CTQY. Due to the large sample size ($N=330$) and multiple YMCAs needed for CTQY, we returned to our previous model of phone screening to increase efficiency. Upon receiving medical clearance, participants were scheduled to attend an Informational Session, which was similar to the CTQ-p session minus the eligibility screening (components described above) at the YMCA of their choice. In this way, we streamlined the process while trying to maintain internal validity.

Incentives

In the CTQ trial, participants paid a \$100 deposit upfront, which they received back in increments as they completed assessments. In CTQ-p, participants received a free YMCA membership but were not incented in any other way. As can be seen in Table 1,

the attendance rates to the smoking groups and assessment session dropped dramatically between CTQ and CTQ-p. We were concerned that we would not be able to conduct an adequate test of the intervention if the attendance rates mirrored those from CTQ-p. Thus, for CTQY, we implemented an incentive system to increase participation in the smoking cessation and assessment sessions that is more typical of efficacy studies in lab settings. Incentives were intended to increase internal validity albeit at the risk of reducing generalizability (Table 2). Incentives included a 3-month YMCA membership, \$5 gas cards given at the Informational Session and at each smoking cessation session, and \$50 for completion of end of treatment, 3-, 6-, and 12-month follow-up assessments. It is important to note that the price of gas increased dramatically at the beginning of the trial to nearly \$5/gallon so that this incentive was added to reduce the transportation cost burden on participants. Those randomized to Control received their 3-month YMCA membership after completion of the 12-month follow-up. Again, this level of incentivizing was higher than the previous trials but was considered important to attract and retain participants at a higher rate than had occurred in the pilot trial (Table 1) so that we could test the efficacy of the intervention.

Changes to the smoking cessation program

As in our prior trials, all participants attended a group-based smoking cessation program. One major difference from CTQ was that the CTQY smoking cessation and exercise programs were delivered by YMCA staff rather than research staff. In the CTQ-p, we had trained a YMCA staff member to co-lead the smoking groups with a Ph.D.-level researcher. In the CTQY “train-the-trainer” model, we sought to test CTQY in a real-world scenario with two YMCA staff members co-leading the smoking cessation sessions (Table 2) without a Ph.D. researcher present. This represents a potential loss to *internal validity* while enhancing *compatibility* and generalizability.

Other changes to the program design were a result of adapting to the busy and dynamic location of YMCAs. YMCA staff do not have dedicated time to carry out many of the strategies used to improve research intervention adherence and compliance such as reminder calls, make-up sessions, and sending repeated mailings and birthday cards. To promote *compatibility* with YMCA practice and reduce *complexity*, we minimized research staff contact with participants outside of scheduled sessions at the YMCAs. Specifically, we did not call participants with reminders to attend sessions prior to the groups nor to conduct make-up sessions, rather participants were mailed the print materials for any missed sessions (Table 3).

Changes to the exercise program

The location and content of the exercise program have varied across the three trials. Unlike CTQ, the exercise program for CTQY was conducted at the YMCAs. As in CTQY-p, participants in the exercise condition received the YMCA PFP. The PFP requires participants to meet with a YMCA personal trainer four times over 12 weeks to receive instruction on how to progress through an exercise program using goal setting techniques based on social cognitive theory (Table 3). For this study, YMCA personal trainers had individual 40–60-min meetings with participants at weeks 1, 4, 8, and 12. The original intention of the study was to have participants attend the YMCA PFP program in each YMCA location. However, after participant feedback from the CTQY pilot as well as meetings with all of the PFP directors in the different YMCAs, we realized that the program was delivered differently in different YMCA sites and by different trainers within each site. Thus, study investigators met with the Fitness Director/Leader and his/her staff at each YMCA prior to starting the study and introduced a training program for PFP leaders. The aim of this training was to enhance *internal validity* of the delivery of the exercise program, both across and within sites by developing a consistent, standardized approach to program delivery. We trained YMCA PFP trainers in study guidelines and provided a checklist to follow at each meeting with participants. Training included the protection of human subjects, the importance of consistency in research practices, the trainer's role in the study and in program delivery. Dr. Ciccolo (co-investigator), or the Project Director also held weekly telephone meetings with the Fitness Director/Leader of each YMCA to discuss program progress. Thus, we were unable to conform to *compatibility* as we would have liked to do in order to retain our ability to make the comparisons between the two treatment arms in the study and separate out the effects of exercise on smoking cessation outcomes.

In a big departure from the CTQ trial, where participants exercised in the research facility with a researcher present at all times, participants in CTQY were instructed to exercise at the YMCA three times per week, at the times and days most convenient for them (Table 2). This approach was used to promote *compatibility* with how exercise is typically performed in a YMCA and how the PFP program was designed to be run: it was never designed to be direct supervision of all exercise sessions. For apparently healthy participants, the goal was to transition from moderate intensity aerobic exercise during the first 4 weeks to vigorous intensity aerobic exercise for the remaining 8 weeks. Participants were instructed to exercise within a heart rate range corresponding to the 64–76 % of age-predicted maximal heart rate (HRmax) during weeks 1–4 and a heart rate range corresponding to 77–85 % of their HRmax for weeks 5–12. All

Table 3 | Personal fitness program content by session and week in the study

Session number	Week in the study	Content
Session 1	Week 1	Introduction to aerobic exercise <ul style="list-style-type: none"> • Monitoring heart rate • Using machines (i.e., treadmill and upright bicycle) • Using YMCA exercise log
Session 2	Week 4	Review of participant progress <ul style="list-style-type: none"> • Provide feedback on progress • Address questions Introduce resistance training <ul style="list-style-type: none"> • Demonstrate exercises • Guidance on choosing proper weight
Session 3	Week 8	Review of participant progress <ul style="list-style-type: none"> • Provide feedback on progress • Address questions
Session 4	Week 12	Review of participant progress <ul style="list-style-type: none"> • Provide feedback on progress • Address questions • Discuss barriers encountered and goals achieved • Discussed strategies to continue exercise beyond program

participants were given guidance on how to steadily increase the amount of aerobic exercise completed. The goal of the program was to complete at least 40 min of aerobic exercise per session, including a 5–10-min. cool down period. Beginning in week 4, participants were also instructed to complete a full body (i.e., every major muscle group) RT routine following aerobic exercise. The RT consisted of a series of ten different machine exercises (e.g., leg press and chest press). Participants were instructed to complete at least one set of eight to ten repetitions of each exercise. Personal trainers provided guidance on how to choose a weight that would achieve muscular fatigue by the 10th repetition, with a goal of completing all ten exercises in 20–25 min.

Changes to the wellness program (Control)

The wellness program in the CTQ trial consisted of 36 sessions over 12 weeks to equate contact time between study arms (Table 2). These sessions were led by research staff and consisted of lectures by experts from the hospital and research community, discussions, and movies. This format did not seem compatible or sustainable due to the *complexity* of delivering this program in a YMCA setting, where the study would be delivered in across multiple YMCAs. Thus, for CTQY, we equated for contact time between conditions by conducting four wellness sessions over 12 weeks to match the four PFP sessions. Topics included general health and wellness, reproductive issues, and nutrition. Sessions were group-based and were scheduled prior to and immediately following smoking program sessions at weeks 1, 4, 8, and 11. Participants who missed a wellness session attended replacement sessions following the next smoking session attended. As with the PFP sessions, research staff completed checklists at the end of each session to rate adherence to the protocol, and a co-investigator met regularly with

research staff to ensure consistent delivery of the wellness sessions.

Measures

Compared to the original CTQ trial, measures were streamlined for CTQY but were more extensive than they had been in CTQ-p. To stay within the acceptable limits of an Informational Session being offered at the YMCA, the questionnaire packet was designed to take 20–30 min to complete. Table 4 outlines the measurements and assessment schedule from baseline to 12-month follow-up. During each smoking cessation session, participants provided carbon monoxide samples and answered smoking status questions to measure continuous abstinence and 7-day point prevalence. At the end of the 12-week program and at 3-, 6-, and 12-month follow up, participants in both conditions completed the full survey packet, minus the demographics questionnaire, and provided carbon monoxide and saliva cotinine samples. A consumer satisfaction questionnaire was completed at week 12.

CTQY results

Findings from CTQY indicated that there were no between groups differences in smoking cessation rates at the end of treatment (Table 1). To determine if there might have been a dose-response relationship for exercise, we examined the association between number of aerobic and RT sessions and smoking cessation rates. Results indicated there was a positive association between number of sessions attended (treatment received) and the odds of being quit. The percent of individuals who attended the end-of-treatment follow-up was higher than in both CTQ-p and CTQ at approximately 82 %. In CTQY, attendance to smoking cessation sessions was more than 10 % lower than in CTQ, but almost 10 %

Table 4 | Measurement schedule

Measure	Baseline	During smoking Tx	End-of-Tx	3-Month follow-up	6-Month follow-up	12-Month follow-up
Demographics	x					
Smoking status						
• Smoking rate, 24 h, 7 days, and continuous abstinence	x	x	x	x	x	x
• Carbon monoxide [11]	x	x	x	x	x	x
• Cotinine by saliva sample [11]			x	x	x	x
• Withdrawal symptoms, Minnesota Nicotine Withdrawal Scale [12, 13]	x	x	x	x	x	x
• Situational relapse circumstances [14] nicotine dependence [15]	x		x	x	x	x
Physical activity status						
• Leisure time physical activity [16]	x		x	x	x	x
• Aerobic fitness, Rockport One-Mi Walk Test on subset [17]	x		x			
• YMCA log for aerobic and resistance training completed at the YMCA (exercise group only)		x				
Weight status						
• Weight	x		x	x	x	x
• Weight history and fear of postcessation weight gain, Smoking Situations Questionnaire [18]	x		x	x	x	x
Psychosocial measures						
• Smoking self-efficacy [19] and stage of change [20]	x		x	x	x	x
• Depressive symptoms, Center for Epidemiological Depression Scale [21]	x		x	x	x	x
• Anxiety symptoms, Taylor Manifest Anxiety Scale (TMAS) [22, 23]	x		x	x	x	x
• Consumer satisfaction			x			

higher than in CTQ-p (Table 1). However, the adherence to the exercise prescription was 40 % lower in CTQY than CTQ.

DISCUSSION

This trial can be conceived as an effectiveness trial, where the efficacy of the CTQ program needed to be tested in the community setting. The tensions between conducting a study high in internal validity as is the norm in efficacy trials and one that is high in external validity as is the norm in effectiveness or dissemination trials are evident when conducting an RCT in a community setting. We used the Diffusion Theory [3] whenever possible to guide us in our attempts to make sound decisions so that we could rigorously test our program while adjusting our protocols and program to promote compatibility with YMCA practices and program offerings.

In CTQY, we did not find a between-group difference in smoking cessation status [10] as had been true in the original trial [2]. Some of the efforts to increase external validity and to make the program compatible with the YMCA setting might have contributed to this finding. In particular, the rate of participation in exercise was only 27 % in CTQY compared to 67 % in the original CTQ trial

(Table 1). By not including rigorous efficacy trial protocols for attendance to exercise and follow-up for missed sessions by the YMCA exercise trainers, we risked not truly performing an exercise manipulation as was intended with the design. The dose-response findings, in which there are improvements in smoking cessation rates as exercise participation rates increased, suggests that there may have been greater between-group differences if the adherence to the exercise prescription had been higher [10]. We did see an increase in smoking cessation session attendance compared to CTQ-p, but it was still lower than the attendance had been in the lab setting (CTQ). This difference does not explain the lack of between-group findings, as it was not statistically between the two groups, but it does point to the difficulty of intervention adherence in real-world settings. It also suggests that our gas card incentive may have helped enhance participation in CTQY. The end-of-treatment follow-up rate was higher in CTQY than any previous trial, indicating our assessment incentive was effective. Thus, while many of the aspects can be directly compared between CTQY and CTQ, some of the changes that were made to accommodate the setting might have impacted our outcomes.

We also faced unexpected challenges in this study. The content and delivery of the PFP varied greatly across and within YMCA sites, and the sudden rise in gas prices coinciding with the start of CTQY presented an unexpected challenge. In response, we increased incentives to offset travel costs (gas card), at the risk of reducing external validity. We also developed more rigorous training and supervision protocols for the smoking cessation leaders and personal trainers than we originally anticipated so that we could promote consistency and standardization across and within sites. All of these tensions were due to the need to retain as much internal validity as possible in an RCT conducted in community sites.

The Diffusion Theory [3] suggestion of identifying and working with an individual from the community who would champion the program was tremendously important to the success of the program. This individual was the Wellness Director at the YMCA headquarters level. She was able to help us identify YMCAs for the trial, facilitated the initial meetings with the Personal Fitness Directors in each YMCA, and identified YMCA staff to be trained to become the smoking cessation leaders. She was also able to help us problem solve systems issues such as payments of membership and staff and was able to promote accountability across the sites throughout the duration of the trial.

We also were mindful of the five characteristics of an innovation that increase adoption so that we could test a program that could be adopted by the YMCAs. If we were to conduct all of the typical internal validity practices found in efficacy trials, we would have risked testing programs that could not be replicated by YMCA staff. For example, if we had used our research co-investigators who were Ph.D.-level psychologists to conduct the smoking cessation groups or the Ph.D.- and Masters-level researchers to conduct an exercise program, we would not know if the program was feasible in the YMCA setting absent of the researchers' presence. Similarly, we refrained from multiple reminder calls and make-up sessions to remain compatible with community programming practices.

Of the five characteristics of an innovation proposed by Rogers [3], we found that promoting *compatibility* of our programs and protocols with YMCA practices and reducing *complexity* from standard efficacy trial research practices were the two characteristics that made the most sense to incorporate. The other three characteristics, *relative advantage*, *trialability*, and *observability*, seemed less applicable to a research study of a health behavior change program. These characteristics are more applicable to the adoption of new technology such as the iPad where potential adopters can research the *relative advantage* of the iPad to other similar technologies in advance of its purchase, can try it and return it if they don't like it, and they can observe and be observed using the device, which

might elevate their standing among peers. With a health promotion program, it is less clear how to evaluate the *relative advantage* of a quit smoking program before entering the trial; it cannot be returned and it is less obviously *observable*.

The recommendations from this trial are to determine the goals of your study and then balance issues of *internal* and *external validity* based on a theoretical rationale and the data that is available to you. In this trial, data regarding attendance rates in our pilots as well as information gathered from the study sites led us to employ standardization practices across the sites but fell short of having researchers lead the smoking cessation and exercise sessions. As a result, we know that the program was deemed satisfactory by participants [10] but lacked statistically significant between-group differences. If the goal of this study had been to determine if it was feasible to implement the program in the YMCAs on a larger scale, the answer would have been affirmative. To date, this program has not been adopted by the YMCAs. One key reason for this most likely includes not establishing a mechanism for ongoing training and supervision of the YMCA leaders, two functions provided by the research team during the trial. Perhaps in future effectiveness and dissemination trials, a plan for sustained training needs to be put in place from the beginning to promote adoption and sustainability of the program in the long-term.

Acknowledgments: This research was supported by the National Institute on Drug Abuse at the National Institutes of Health (grant DA021729). We would like to acknowledge the hard work of our research team and the YMCA of Greater Providence for partnering with us on this project.

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