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The Effect of Re-randomization in a Smoking Cessation Trial

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Abstract

Objectives: The purpose of this sub-study was to determine whether operating engineers (heavy equipment operators) who failed to quit smoking in a randomized controlled trial would benefit from re-exposure to the interventions one year later.

Methods: Operating Engineers attending workplace safety training groups during the winters of 2010 to 2012 were randomized by training group to either to the Tobacco Tactics Web-based intervention or the 1–800-QUIT-NOW telephone line. Of the 145 original participants, 41 reappeared in training groups one year later and were re-randomized with their group. Seven-day point prevalence quit rates at 30-days and 6-months post-intervention were analyzed using the chi-square test and Fisher’s exact test.

Results: At 30-day follow-up, an additional 9.8% (4/41) of repeaters had quit smoking. At 6-month follow-up, 12.2% (5/41) of repeaters had quit smoking. At 30-day follow-up, increased quitting was more common among those re-randomized to the intervention group than among those who received the control treatment, although this was not statistically significant and was no longer true at 6-month follow-up.

Conclusions: Because many smokers make multiple attempts to quit smoking, re-enrollment of participants in smoking cessation trials may produce additional quitters.

Keywords

randomized controlled trial; smoking cessation; web-based intervention; re-randomization; re-enrollment

Randomized controlled trials (RCTs) are considered the most rigorous study design for testing the efficacy and effectiveness of interventions.¹ Traditional RCT design generally

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Human Subjects Statement

Institutional Review Board approval for this study was received from the University of Michigan. Human studies approval was obtained and all ethical guidelines were followed during the course of this study.

Conflict of Interest Statement

The authors declare that they have no conflict of interest.

does not allow re-randomization because the assumption is that each person participates only once, and therefore, is independent. Re-randomizing and retreating some participants violates this assumption because responses will be correlated from the same person in repeated runs through the trial.^{2,3}

However, a few studies have begun to allow reenrollment, particularly in trials related to pregnancy, trauma, or cancer recurrence.^{4–6} For example, the sequential multiple assignment randomized trial (SMART) research method allows re-randomization to test sequential, individualized treatment, which is a relatively new approach.⁷ Under certain circumstances there are benefits to allowing participants to re-enroll in RCTs, including increased sample sizes, the option to test for the optimum dosages of the intervention, and enhanced therapeutic outcomes in rare, relapsed disorders or chronic diseases, as long as care is taken to reduce errors that might occur by applying suitable statistical techniques.^{1,3} Furthermore, multiple exposures to an intervention may enable researchers to achieve desired clinical outcomes by including patients who need more intensive treatment to reach such outcomes.

Multiple exposures to interventions especially may be helpful in smoking cessation studies, as it takes an average of 7 quit attempts to give up smoking and relapse rates are high.⁸ A review of the literature identified several smoking cessation studies that allowed reentry and re-randomization, but none that we found reported clinical outcomes such as quit rates after re-enrollment.^{9–11}

In our original RCT,¹² which compared the Tobacco Tactics website to the 1–800-QUIT-NOW intervention among operating engineers (heavy equipment operators), (N = 145), quit rates were significantly higher in the intervention group than the control group at the 30-day follow-up, but there was no difference at the 6-month follow-up, suggesting that a higher dosage of the intervention may be needed. Because the trial was still in progress, the participants who had not managed to quit smoking (N = 128) in their first try and who were interested in repeating the study (N = 41) were allowed to re-enroll one year after their first enrollment. These 41 repeaters were re-randomized, along with other new participants, to the 2 study groups in the following 2 years as if they were new participants (Figure 1). The primary aim of this paper is to determine the additional quit rates achieved by allowing participants to re-enroll and re-randomize in the study. A secondary aim is to examine the quit rates among the different randomization combinations.

METHODS

Study Design

The protocol of this study was described in a previous paper.¹³ In brief, Operating Engineers at-tending a required annual training were recruited by approaching their training group. Those who came forward were consented and given a base-line survey. Randomization to either the Tobacco Tactics website intervention or the state-supported 1–800-QUIT -NOW telephone quit line was done at the training group level, rather than the individual level, to prevent possible cross-contamination. Follow-up surveys were mailed at 30 days and 6 months post-enrollment.

Previous participants who failed to quit after the initial treatment based on the 6-month follow-up and appeared in subsequent training groups and asked to re-enroll were allowed to re-enter the trial one year later and were re-randomized along with their safety training group. Because participants were not initially consented to be re-randomized, in a consultation with the institutional review board, we decided that repeaters be treated (approached, consented, surveyed, randomized, provided with interventions, and followed) the same as new participants.

Sample and Setting

Smokers included in the study: (1) were at least 18 years old; (2) had smoked in the past month; (3) were interested in participating in a cessation program; (4) were English speakers; and (5) were not pregnant. Participants were recruited during the winters of 2010 through 2012, when they attended mandatory annual safety trainings at Local 324 Training Center of the International Union of Operating Engineers.

Intervention

The Tobacco Tactics website intervention provided the study participants with access to the Tobacco Tactics website for Operating Engineers, which contained humorous graphics specifically targeted at Operating Engineers, tailored smoking cessation feedback, and follow-up nurse counseling offered via multimedia options, including phone and/or email, as well as an e-community/forum.¹³ The website content, which was written at an 8th grade reading level, provided a series of interactive cognitive behavioral therapy exercises, including a self-assessment of tobacco use, calculation of a score representing the participant's level of nicotine dependence, identification of the participant's smoker type, calculation of money savings, preparation for quitting (for example, cleaning the car of cigarette butts), creation of a change plan work sheet, and tips for coping with relapses.

Interactive components provided mechanisms for tobacco users to assess their smoking habits, set a quit date, review potential cessation medications, and monitor weekly progress via an e-community, as well as nurse monitoring and peer support, both of which are known to be effective for smoking cessation.¹⁴ The e-community/forum was a tab on the Tobacco Tactics website that took the participant to a chat room that met at designated times, 3 times per week, and was led and monitored by the study nurse. Participants were encouraged to interact online to support each other's efforts and share information about smoking cessation strategies. In addition, those randomized to the Tobacco Tactics website intervention received booster nurse telephone and/or email counseling contacts at 2, 7, 14, 21, and 30 days after the initial education session was complete.

Nicotine replacement therapy (NRT) was provided based on the nurse's assessment of the individual and prescribed in accordance with a medication algorithm (also shown on the website). Based on the initial telephone assessment and with input from the participant, the study nurse mailed each participant an 8 to 10 week supply of either over-the-counter: nicotine patch 21, 14, or 7 mg (depending on the patients habit); nicotine gum, or lozenges; or a combination of patch and oral NRT. Those participants who had used NRT in the past

and failed were encouraged to obtain prescription medications such as bupropion or varenicline from their physician.

To make it as equivalent as possible to the Tobacco Tactics website intervention, participants randomized to the 1-800-QUIT-NOW control group were encouraged to call counselors at the time of enrollment during their annual safety training. Participants in the control group also had access to written materials with similar content to the website and follow-up calls and/or emails with a smoking cessation expert. In the 1-800-QUIT-NOW telephone line cessation group, counselors either facilitated obtaining cessation medication through the participants' insurance company or mailed free NRT to those that did not have access to NRT through their insurance company.

Measures

The primary dependent variable was the self-reported, 7-day point prevalence smoking cessation rates at the 30-day and 6-month follow-ups.¹⁵ The secondary dependent variable was a cotinine-verified 6-month smoking status using a mailed NicAlert urinary cotinine test kit.

Nicotine dependence was assessed using the Fagerström Test for Nicotine Dependence (FTND),¹⁶ self-efficacy for quitting was measured by the Smoking Self-Efficacy Questionnaire (SEQ-12),¹⁷ and motivation to quit smoking was measured by the validated question: "Are you thinking of quit-ting in the next: (a) 30 days, (b) 6 months, or (c) not thinking of quitting?"¹⁸ Additional variables known to influence smoking were also measured using validated instruments including problem drinking,¹⁹ social support,²⁰ stress,²¹ depressive symp-toms,²² body mass index (BMI), and demographics.^{23,24}

Data Analysis

Descriptive statistics (means and frequencies), chi-square tests, and t-tests were used to compare demographic characteristics at baseline for repeaters, who participated in the trial twice, and non-repeaters, who took part only once, at 30 days and 6 months. Because the sample size of repeaters was small, Fisher's exact test was used to compare the quit rates of repeaters. The statistical significance level was set as .05, and a 2-tailed test was conducted. The intention-to-treat approach was applied, as is common in smoking cessation research, and penalized imputation was done so that participants who failed to respond at 30 days and 6 months were assumed to be still smoking.

RESULTS

Of the 145 participants who were originally randomized, 41 were re-randomized one year later. The 30-day follow-up rate was 82.9% and the 6-month follow-up rate was 75.6% (Figure 1). As Table 1 shows, there were no significant differences between repeaters and non-repeaters at baseline, albeit race was marginally significant ($p = .074$) with more non-whites (mostly blacks) in the repeater group. The second time around, 4 of 41 (9.8%) self-reported quitting smoking at the 30-day follow-up, and 5 of 41 (12.2%) had quit at the 6-month follow-up (Table 2). Although the sample size was small, the quit rates of repeaters were higher in the intervention than in the control group at the 30-day follow-up (4 of 23,

17.4% versus 0 of 18, 0.0%) (Table 2). The higher quit rate among participants reassigned to the intervention group (3 out of 23, 13.0%) compared to the control group (2 of 18, 11.1%) remained at the 6-month follow-up. Both in our larger trial and this sub-study, only about 20.0% returned the NicAlert cotinine tests; anecdotally, we heard that some of the Operating Engineers were offended by them. Thus cotinine-validated quit rates were not analyzed.

Recognizing that the groups were small, the quit rates were analyzed in 4 groups depending on the different conditions to which repeaters were randomized: (1) intervention then intervention; (2) intervention then control; (3) control then intervention; and (4) control then control (Table 3). In spite of the small sample size ($N = 41$), there were significantly higher quit rates at the 30-day follow-up ($p < .05$) among those who had been re-randomized to the intervention, both in the intervention then intervention group (2/4, 50.0% quit rate) and in the control then intervention group ($N = 2/19$, 10.5%), than in either the intervention then control ($N = 0/9$) or control then control ($N = 0/9$) groups, both of which had a 0.0% quit rate. This trend had changed somewhat by the 6-month follow-up, with the intervention then intervention group ($N = 0/4$) having a 0.0% quit rate, the control then intervention group having a 15.8% quit rate ($N = 3/19$), the intervention then control group ($N = 1/9$) having an 11.1% quit rate, and the control then control group ($N = 1/9$) having an 11.1% quit rate.

DISCUSSION

The most important finding of this study was that allowing participants to be re-randomized yielded additional quitters, supporting the case for re-randomization and increased exposure to interventions. This study shows benefits to participants who were able to quit after being enrolled into the trial again. Because no studies that we are aware of have reported outcomes (quit rates) for smokers that were re-randomized, it is difficult to compare the quit rates we obtained in this study to those reported in previous studies. However, the additional quit rates obtained (9.8% at the 30-day follow-up and 12.2% at the 6-month follow-up) are higher than those reported in other smoking intervention studies enrolling blue-collar workers.²⁷ This is particularly important given that in the United States, blue-collar workers have an unusually high smoking rate of about 35%, almost double the 20% seen in white-collar workers.^{25,26} In addition, about one-third of the 128 smokers who failed to quit in their first trial asked to enroll in the trial for a second time, which is higher than the other trials that re-randomized smokers to quit lines using Inter-active Voice Response (IVR) outreach,^{10,11} suggesting that there was high motivation to quit among this population. Moreover, face-to-face recruitment (versus, for example, IVR outreach) may have enhanced re-enrollment.

Though there were no significant differences between the repeaters and the overall study population (Table 1), there was a marginally significant difference in race with slightly more non-whites (mostly black/African Americans) in the repeaters group. Studies have shown that African-American smokers are highly motivated to quit smoking, make serious attempts, and have strong concerns about the social and health consequences of smoking.^{13,28–30} Despite their high motivation to quit, African-American smokers make more unsuccessful quit attempts than whites,^{31,32} perhaps because minorities are less likely than whites to report receiving cessation intervention, including advice from their healthcare

providers, counseling, and pharmacotherapy.^{33–36} For these reasons, non-whites in this study may have been slightly more likely to re-enroll.

Whereas the sample size in this pilot study was small, there was a trend toward higher quitting rates among those who were re-randomized to the intervention than among those assigned to the control condition. This suggests the potential need to provide a more intensive dosage over a longer period of time, as well as the potential benefit of re-randomization in helping to address hard-to-reach smokers. Smokers often make many attempts to quit before they are successful.⁸ Another reason that quit rates may have been slightly higher in the Tobacco Tactics group is that this intervention content and graphics were tailored specifically to the participants' profession, namely Operating Engineers, whereas the 1-800-QUIT-NOW control intervention was more generic. The specific information related to the Operating Engineers' profession in the Tobacco Tactics intervention may have enhanced the participants' motivation to quit.

Although re-enrolling participants may violate the basic assumption underlying conventional RCTs, these findings highlight the advantages of allowing participants to try again and be re-randomized in smoking cessation trials. Repeated exposure to the intervention may be clinically useful because therapeutic outcomes are not easy to achieve in this area. Nonetheless, several questions about the efficacy of re-randomizing study participants remain.

The first question is how best to perform the re-enrollment (ie, to the same intervention or not). In this study, repeaters were re-randomized as new participants. However, other studies, including most SMART study designs, participants have been allowed to re-enroll into the condition to which they were initially randomized.

The second question has to do with how to treat the data statistically. In studies in which every person is re-randomized and re-treated, this can be handled using a variety of statistical strategies.³⁷ However, when only a minority of participants are re-randomized and re-treated, as was the case here, this is more challenging. In this study the quit rates of repeaters were analyzed depending on their reassigned group.

Despite the high re-enrollment rates and additional quitters obtained, the study has several limitations. Because participants asked us if they could be re-randomized in subsequent years, planning for re-randomization was not done *a priori* and repeaters were treated as new participants. Because we approached training groups and invited interested participants to join the study, we do not know how many potential repeaters were present that did not come forward, although we did enroll about one-third of continuing smokers. The sample size was small; thus, percentages need to be interpreted cautiously. By chance, 46.3% of all participants that re-enrolled were in the control then intervention group versus a far smaller number in the other 3 conditions. It is likely that carry over effects (effects from the prior treatment) are influencing the additional quit rates among the repeaters, although increasing dosage is in essence what we were attempting to evaluate. Smoking status was not biologically validated, although we expect lie rates are low because quit rates are relatively low and are similar to other studies. Unfortunately, there were no qualitative data about their

experiences in the first quit attempt that could help our understanding about why they were willing to re-enroll.

Conclusions

This study showed that allowing participants to re-enroll and be re-randomized in a smoking cessation study produced additional successful quitters. These findings show that allowing participants to be re-randomized to RCTs has the potential to enhance therapeutic outcomes, particularly for behavioral interventions where repeated exposure to the intervention can enhance success rates. Because conducting RCTs is expensive, allowing participants to be re-randomized into an existing trial infrastructure may incur only a minimal additional cost. Additional research needs to be conducted to determine the statistical and therapeutic trade-offs that result from allowing participants to re-enroll in RCTs.

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References

1. Evans D Hierarchy of evidence: a framework for ranking evidence evaluating healthcare interventions. *J Clin Nurs* 2003;12(1):77–84. [PubMed: 12519253]
2. Hozo I, Djulbegovic B, Clark O, Lyman GH. Use of re-randomized data in meta-analysis. *BMC Med Res Methodol* 2005;5(1):17. [PubMed: 15882470]
3. Mills EJ, Kelly S, Wu P, Guyatt GH Epidemiology and re-reporting of randomized trials employing re-randomization of patient groups: a systematic survey. *Contemp Clin Trials* 2007;28(3):268–275. [PubMed: 17067857]
4. Altman D, Carroli G, Duley L, et al. Do women with pre-eclampsia, and their babies, benefit from magnesium sulphate? The Magpie Trial: a randomised placebo-controlled trial. *Lancet* 2002;359(9321):1877–1890. [PubMed: 12057549]
5. Heyn RM, Joo P, Karon M, et al. BCG in the treatment of acute lymphocytic leukemia. *Blood* 1975;46(3):431–442. [PubMed: 1056801]
6. Martenyi F, Brown EB, Zhang H, et al. Fluoxetine v. placebo in prevention of relapse in post-traumatic stress disorder. *Br J Psychiatry* 2002;181:315–320. [PubMed: 12356658]
7. Almirall D, Nahum-Shani I, Sherwood NE, Murphy SA. Introduction to SMART designs for the development of adaptive interventions: with application to weight loss research. *Transl Behav Med* 2014 9;4(3):260–274. [PubMed: 25264466]
8. Zhou X, Nonnemaker J, Sherrill B, et al. Attempts to quit smoking and relapse: factors associated with success or failure from the ATTEMPT cohort study. *Addict Behav* 2009;34(4):365–373. [PubMed: 19097706]
9. Carlini BH, Zbikowski SM, Javitz HS, et al. Telephone-based tobacco-cessation treatment: re-enrollment among diverse groups. *Am J Prev Med* 2008;35(1):73–76. [PubMed: 18541180]
10. Carlini BH, McDaniel AM, Weaver MT, et al. Reaching out, inviting back: using Interactive voice response (IVR) technology to recycle relapsed smokers back to Quitline treatment - a randomized controlled trial. *BMC Public Health* 2012;12(1):507. [PubMed: 22768793]
11. Carlini B, Miles L, Doyle S, et al. Using diverse communication strategies to re-engage relapsed tobacco quitline users in treatment, New York State, 2014. *Prev Chronic Dis* 2015;12:150191.

12. Choi SH, Waltje AH, Ronis DL, et al. Web-enhanced Tobacco Tactics with telephone support versus 1-800-QUIT-NOW telephone line intervention for operating engineers: randomized controlled trial. *J Med Internet Res* 2014;16(11), e255. [PubMed: 25447467]
13. Duffy SA, Ronis DL, Richardson C, et al. Protocol of a randomized controlled trial of the Tobacco Tactics website for operating engineers. *BMC Public Health* 2012;12(1):335. [PubMed: 22569211]
14. Selby P, van Mierlo T, Voci SC, et al. Online social and professional support for smokers trying to quit: an exploration of first time posts from 2562 Members. *J Med Internet Res* 2010;12(3):e34. [PubMed: 20719739]
15. Hughes JR, Keely JP, Niaura RS, et al. Measures of abstinence in clinical trials: issues and recommendations
16. Fagerstrom KO, Heatherton TF, Kozlowski LT. Nico-tine addiction and its assessment. *Ear Nose Throat J* 1990;69(11):763–765. [PubMed: 2276350]
17. Colletti G, Supnick JA, Payne TJ. The Smoking Self-Efficacy Questionnaire (SSEQ): preliminary scale development and validation. *Behav Assess* 1985;7(3):249–260.
18. DiClemente CC, Prochaska JO, Fairhurst SK, et al. The process of smoking cessation: an analysis of precontemplation, contemplation, and preparation stages of change. *J Consult Clin Psychol* 1991;59(2):295–304. [PubMed: 2030191]
19. Saunders JB, Aasland OG, Babor TF, et al. Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO Collaborative Project on Early Detection of Persons with Harmful Alcohol Consumption – II. *Addiction* 1993;88(Suppl 6):791–804. [PubMed: 8329970]
20. Vaglio J, Conard M, Poston WS, et al. Testing the performance of the ENRICH Social Support Instrument in cardiac patients. *Health Qual Life Outcomes* 2004;2(1):24. [PubMed: 15142277]
21. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav* 1983;385–396. [PubMed: 6668417]
22. Radloff LS. The CES-D scale a self-report depression scale for research in the general population. *Appl Psychol Meas* 1977;1(3):385–401.
23. Stump TE, Clark DO, Johnson RJ, Wolinsky FD. The structure of health status among Hispanic, African American, and white older adults. *J Gerontol B Psychol Sci Soc Sci* 1997;52(Spec No): 49–60. [PubMed: 9215357]
24. Gilpin EA, Pierce JP. Demographic differences in pat-terns in the incidence of smoking cessation: United States 1950–1990. *Ann Epidemiol* 2002;12(3):141–150. [PubMed: 11897171]
25. Barbeau EM, Krieger N, Soobader M-J. Working class matters: socioeconomic disadvantage, race/ethnicity, gender, and smoking in NHIS 2000. *Am J Public Health* 2004;94(2):269–278. [PubMed: 14759942]
26. Oliver LC, Miracle-McMahill H, Littman AB, et al. Respiratory symptoms and lung function in workers in heavy and highway construction: a cross-sectional study. *Am J Ind Med* 2001;40(1): 73–86. [PubMed: 11439399]
27. Okechukwu CA, Krieger N, Sorensen G, et al. MassBuilt: effectiveness of an apprenticeship site-based smoking cessation intervention for unionized building trades workers. *Cancer Causes Control* 2009 8;20(6):887–894 [PubMed: 19301135]
28. Boardman T, Catley D, Mayo MS, Ahluwalia JS. Self-efficacy and motivation to quit during participation in a smoking cessation program. *Int J Behav Med* 2005;12(4):266–272. [PubMed: 16262545]
29. Okuyemi KS, Cox LS, Nollen NL, et al. Baseline characteristics and recruitment strategies in a randomized clinical trial of African-American light smokers. *Am J Health Promot* 2007;21(3): 183–191. [PubMed: 17233236]
30. Karvonen-Gutierrez C, Ewing L, Taylor N, et al. Ethnicity predicts perceptions of smoking and smoking cessation among veterans. *J Psychiatr Ment Health Nurs* 2012;19(3):203–210. [PubMed: 22074190]
31. Piper ME, Cook JW, Schlam TR, et al. Gender, race, and education differences in abstinence rates among participants in two randomized smoking cessation trials. *Nico-tine Tob Res* 2010;12(6): 647–657.

32. Holford TR, Levy DT, Meza R. Comparison of smoking history patterns among African American and white cohorts in the United States Born 1890 to 1990. *Nicotine Tob Res* 2016;18(Suppl 1):S16–S29. [PubMed: 26980861]
33. Fu SS, Burgess D, van Ryn M, et al. Views on smoking cessation methods in ethnic minority communities: a qualitative investigation. *Prev Med* 2007;44(3):235–240. [PubMed: 17175016]
34. Houston TK, Scarinci IC, Person SD, Greene PG. Patient smoking cessation advice by health care providers: the role of ethnicity, socioeconomic status, and health. *Am J Public Health* 2005;95(6):1056–1061. [PubMed: 15914833]
35. Cokkinides VE, Halpern MT, Barbeau EM, et al. Racial and ethnic disparities in smoking-cessation interventions: analysis of the 2005 National Health Interview Survey. *Am J Prev Med* 2008;34(5):404–412. [PubMed: 18407007]
36. Fu SS, Sherman SE, Yano EM, et al., A. Ethnic disparities in the use of nicotine replacement therapy for smoking cessation in an equal access health care system. *Am J Health Promot* 2005;20(2):108–116. [PubMed: 16295702]
37. Chakraborty B, Murphy S, Strecher V. Inference for non-regular parameters in optimal dynamic treatment regimes. *Stat Methods Med Res* 2010;19(3):317–343. [PubMed: 19608604]

Figure 1.
CONSORT Diagram

Table 1Comparison of Baseline Characteristics of the Non-repeaters and Repeaters^a

Group	All (N= 145)	Non-repeaters (N _n = 104)	Repeaters (N _r = 41)	P-value ^b
	Frequency (%) or Mean (SD)	Frequency (%) or Mean (SD)	Frequency (%) or Mean (SD)	
Sex (N_n = 104; N_r = 41)				
Men	115 (79.3)	83 (79.8)	32 (78.0)	.814
Women	30 (20.7)	21 (20.2)	9 (22.0)	
Age (N_n = 104; N_r = 41)				
Hispanic or Latino (N _n = 104; N _r = 41)	41.6 (9.5)	41.9 (9.6)	42.1 (9.3)	.928
Race (N_n = 104; N_r = 41)				
White	6 (4.1)	5 (4.8)	1 (2.4)	.676
Non-white (all others, mostly black)	125 (86.2)	93 (89.4)	32 (78.0)	.074
Marital Status (N_n = 102; N_r = 41)				
Married	80 (55.9)	57 (55.3)	23 (57.5)	.815
Not married	63 (44.1)	46 (44.7)	17 (42.5)	.436
Educational Level (N_n = 103; N_r = 41)				
High-school or less than				
High-school	88 (61.1)	65 (63.1)	23 (56.1)	
More than high-school	56 (38.9)	38 (36.9)	18 (43.9)	
Veteran of the U.S. armed forces? (N_n = 101; N_r = 41)				
Do you live alone? (N _n = 101; N _r = 41)	18 (12.7)	12 (11.9)	6 (14.6)	.655
Weight in pounds	21 (14.8)	15 (14.9)	6 (14.6)	.974
(N _n = 104; N _r = 41)	201.0 (46.8)	202.0 (47.6)	198.5 (45.3)	.688
Height in inches	Range: 112–394	Range: 112–280	Range: 112–394	
(N _n = 104; N _r = 41)	69.6 (3.7)	69.8 (3.7)	69.3 (3.8)	.474
BMI	Range: 60–76	Range: 60–76	Range: 60–76	
(N _n = 104; N _r = 41)	29.0 (5.7)	29.0 (5.6)	29.0 (6.1)	.993
Have used any methods before?	Range: 20.4–53.0	Range: 20.4–53.0	Range: 20.4–43.9	

Group	All	Non-repeaters	Repeaters	P-value ^b
	(N= 145)	(N _n = 104)	(N _r = 41)	
	Frequency (%) or Mean (SD)	Frequency (%) or Mean (SD)	Frequency (%) or Mean (SD)	
Quit on own	95 (65.5)	69 (66.3)	26 (63.4)	.738
Pamphlets	8 (5.5)	4 (3.8)	4 (9.8)	.223
Buddy system	7 (4.8)	5 (4.8)	2 (4.9)	1.000
Patch	37 (25.5)	23 (22.1)	14 (34.1)	.135
Gum	38 (26.2)	27 (26.0)	11 (26.8)	.915
Inhaler	14 (9.7)	9 (8.7)	5 (12.2)	.539
Other medications	44 (30.3)	29 (27.9)	15 (36.6)	.305
Fagerström Test for Nicotine Dependence Score (N _n = 101; N _r = 39)	4.7 (2.6) Range: 0–10	4.7 (2.4) Range: 0–9	4.9 (3.0) Range: 0–10	.674
Nicotine Dependence, Fagerström Test for Nicotine Dependence (N _n = 101; N _r = 39)	55 (39.3)	37 (36.6)	18 (46.2)	.301
Smoking Self-Efficacy Questionnaire Score (SEQ-12) (N _n = 104; N _r = 41)	32.7 (10.5) Range: 12–60	33.8 (9.1) Range: 12–60	30.0 (13.3) Range: 12–49	.092
Alcohol Use Disorder Identification Test Score (N _n = 95; N _r = 38)	8.1 (5.6) Range: 1–32	7.8 (5.0) Range: 1–32	9.1 (7.1) Range: 1–32	.299
Alcohol Problem, Alcohol Use Disorder Identification Test (N _n = 104; N _r = 41)	60 (45.1)	43 (45.3)	17 (44.7)	.956
ENRICHED Social Support Inventory Score (N _n = 104; N _r = 41)	25.3 (5.1) Range: 8–32	25.4 (4.8) Range: 8–32	25.0 (5.8) Range: 8–32	.700
Low Social Support, ENRICHED Social Support Inventory (N _n = 104; N _r = 41)	42 (29.0)	29 (27.9)	13 (31.7)	.648
Perceived Stress Scale Score (N _n = 103; N _r = 42)	24.3 (6.8) Range: 2–43	24.0 (6.8) Range: 2–43	25.2 (6.8) Range: 2–43	.363
Center for Epidemiologic Studies Depression (CES-D) Scale Score (N _n = 3; N _r = 41)	13.6 (11.2) Range: 0–44	12.8 (10.6) Range: 0–44	15.6 (11.8) Range: 0–44	.165
Motivation level to quit smoking (Are you currently seriously thinking of quitting smoking or using other tobacco products? (N _n = 104; N _r = 41) Yes, within the next 30 days	76 (52.4)	55 (52.9)	21 (51.2)	.322

Group	All	Non-repeaters	Repeaters	P-value ^b
	(N= 145)	(N _n = 104)	(N _r = 41)	
	Frequency (%) or Mean (SD)	Frequency (%) or Mean (SD)	Frequency (%) or Mean (SD)	
Yes, within the next 6 months	64 (44.1)	44 (42.3)	20 (48.8)	
No, I am not thinking of quitting	5 (3.4)	5 (4.8)	0 (0.0)	

Note.

^a = Subgroups are denoted as: N_n = non-repeaters; N_r = repeaters

Table 2

Quit Rates for Different Repeater Conditions after the Second Treatment^a

Second Treatment	Number of Participants	30-Day Follow-Up		6-Month Follow-Up	
		Quitters (%)	Quitters (%)	Quitters (%)	Quitters (%)
Intervention	N = 23	N = 4 (17.4)	N = 3 (13.0)		
Control	N = 18	N = 0 (0.0)	N = 2 (11.1)		
Total	N = 41	N = 4 (9.8)	N = 5 (12.2)		
p-value^a		0.118	1.000		

Note.

^a = p-values calculated with Fisher's exact test

Table 3Quit Rates for Different Repeater Conditions ^a

Order of Treatment	Number of Participants	30-Day Follow-Up		6-Month Follow-Up	
		Quitters (%)	Quitters (%)	Quitters (%)	Quitters (%)
Intervention then Intervention	N = 4	N = 2 (50.0)	N = 0 (0.0)	N = 0 (0.0)	
Intervention then Control	N = 9	N = 0 (0.0)	N = 1 (11.1)	N = 1 (11.1)	
Control then Intervention	N = 19	N = 2 (10.5)	N = 3 (15.8)	N = 3 (15.8)	
Control then Control	N = 9	N = 0 (0.0)	N = 1 (11.1)	N = 1 (11.1)	
Total	N = 41	N = 4 (9.8)	N = 5 (12.2)	N = 5 (12.2)	
p-value ^a		.030 ^b		.926	

Note.

^a = p-values calculated with Fisher's exact test^b = p < .05