Effects of Physical Activity on Teen Smoking Cessation

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KEY WORDS

tobacco use cessation, youth tobacco use, physical activity, smoking-cessation intervention

ABBREVIATIONS

BI—brief intervention
CO—carbon monoxide
N-O-T—Not on Tobacco
RR—relative risk
CI—confidence interval
FIT—Physical Activity Module

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WHAT'S KNOWN ON THIS SUBJECT: Studies of adult smokers have suggested that enhanced physical activity during attempts to quit may decrease withdrawal symptoms and cigarette cravings. Other studies have suggested that physical activity prescribed as part of adult smoking-cessation interventions may help sustain cessation over time.

WHAT THIS STUDY ADDS: Adding physical activity to a youth smoking-cessation program may enhance cessation success, particularly among boys.

abstract

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OBJECTIVE: To understand the influence of physical activity on teen smoking-cessation outcomes.

METHODS: Teens (N = 233; 14–19 years of age) from West Virginia high schools who smoked >1 cigarette in the previous 30 days were included. High schools with >300 students were selected randomly and assigned to brief intervention (BI), Not on Tobacco (N-O-T) (a proven teen cessation program), or N-O-T plus a physical activity module (N-O-T+FIT). Quit rates were determined 3 and 6 months after baseline by using self-classified and 7-day point prevalence quit rates, and carbon monoxide validation was obtained at the 3-month follow-up evaluation.

RESULTS: Trends for observed and imputed self-classified and 7-day point prevalence rates indicated that teens in the N-O-T+FIT group had significantly higher cessation rates compared with those in the N-O-T and BI groups. Effect sizes were large. Overall, girls quit more successfully with N-O-T compared with BI (relative risk [RR]: >∞) 3 months after baseline, and boys responded better to N-O-T+FIT than to BI (RR: 2–3) or to N-O-T (RR: 1–2). Youths in the N-O-T+FIT group, compared with those in the N-O-T group, had greater likelihood of cessation (RR: 1.48) at 6 months. The control group included an unusually large proportion of participants in the precontemplation stage at enrollment, but there were no significant differences in outcomes between BI and N-O-T (z = 0.94; P = .17) or N-O-T+FIT (z = 1.12; P = .13) participants in the precontemplation stage.

CONCLUSIONS: Adding physical activity to N-O-T may enhance cessation success, particularly among boys. *Pediatrics* 2011;128:e801–e811

Although there is a growing body of literature on effective smoking-cessation interventions,[1] there is limited knowledge regarding the factors that mediate cessation among teen smokers. Emerging literature suggests that physical activity, that is, bodily movements that enhance or maintain physical fitness and overall health, may mediate smoking cessation.[2–4] Potential mediating mechanisms include reductions in weight gain, withdrawal symptoms, and cigarette cravings; notably, the latter 2 factors are known contributors to cessation resistance and smoking relapse.[4–8] Studies on the relationship between physical activity and smoking among adults have reported both significant and nonsignificant findings. A systematic review of 13 randomized controlled trials by Ussher et al[3] found mixed results for physical activity interventions as catalysts for smoking abstinence. Three studies showed significantly higher smoking abstinence rates among participants who received the physical activity intervention, compared with control subjects, at the end of the intervention period. At the 12-month observation, however, only 1 of the 13 trials showed significance for exercise as a predictor of smoking cessation. In contrast, an extended adult intervention study using pedometers and fitness counseling found that moderate/vigorous physical activity was positively associated with sustained smoking abstinence at 24 weeks.[9] Interestingly, women had significantly higher quit rates in a cessation intervention, compared with programs with no fitness component.[4] Ultimately, Ussher et al[3] concluded that there is no harm in encouraging physical activity as a smoking-cessation aid, because there is no evidence that it interferes with cessation. Dual intervention efforts seem logical, because a majority of youth and adult smokers are physically inactive[9] and a large body of evidence demonstrates the critical importance of physical activity for health throughout the life span.[2]

The research described above focused exclusively on adults, but there is evidence that physical activity, ranging from aerobic activities (eg, team sports) to less-vigorous activities (eg, walking), is protective against smoking initiation and acceleration among youths.[10–12] Rodriguez et al[13] posited that, when physical activity is prescribed for teens, it may be important to consider how youths interpret or perceive the experience. The authors found, for example, that the effects of interscholastic sports participation on adolescent smoking might be related to how competent teens feel after the activity. Those findings suggest that motivation and self-efficacy may be important considerations for implementation of physical activity adjuncts to smoking interventions. To our knowledge, no published research has examined the value of physical activity in conjunction with teen smoking-cessation efforts. Importantly, the teen years are a time when physical activity often decreases significantly; this may particularly true for teen smokers.[14]

The present study developed a physical activity component (FIT) as an adjunct for an evidence-based teen smoking intervention, Not on Tobacco (N-O-T).[15] We used a randomized group design with 3 conditions, that is, brief intervention (BI) versus N-O-T versus N-O-T+FIT. We hypothesized that youths who received N-O-T+FIT would show significantly higher smoking-cessation rates than those who received N-O-T or BI. Consistent with previous N-O-T research,[16] we also predicted that youths who received any exposure to N-O-T (whether as N-O-T or as N-O-T+FIT) would have higher quit rates than their counterparts who received BI. N-O-T was selected as the program of use because it has been demonstrated to be effective and cost-efficient.[17–19] The program has been adopted by the American Lung Association and has received several federal designations.[20] Enhancing the potential applicability of our findings, a study found N-O-T to be the most widely used teen smoking intervention in the nation.[21]

METHODS

Participants

Participants were enrolled from West Virginia public high schools between 2006 and 2009. The study included teens (14–19 years of age) who volunteered to participate. Our recruitment emphasized daily smokers but, given the variability in how teens perceive smoking status, we maintained a flexible inclusion criterion of $\geq$1 day of smoking in the previous 30 days, which is a well-established standard definition of a current smoker.[22] Study procedures received West Virginia University institutional review board approval, with active parental consent and youth assent.

Intervention Conditions

Table 1 describes the study conditions for N-O-T+FIT, N-O-T, and BI. Extensive N-O-T program descriptions are available elsewhere.[23,24–26] Although the core N-O-T curriculum includes content related to healthy lifestyles, such as generally increasing physical activity, improving nutrition, managing stress, and obtaining social support, the physical activity module (FIT) is more detailed, theoretically and empirically driven, gender-tailored, and linked specifically to N-O-T on a session-by-session basis.

Study Design

Of the 123 high schools in West Virginia, 99 public schools met the inclusion criterion of having $\geq$300 enrolled

TABLE 1 Description of Study Conditions

BI	N-O-T	N-O-T+FIT
Groups of youths (n = 5–17 per group)	Groups of youths (n = 3–10 per group)	Groups of youths (n = 3–10 per group)
1 group per school	1 group per school (according to gender)	1 group per school (according to gender)
Trained facilitator	Trained facilitator	Trained facilitator
One 10–15-min brief advice session at baseline	One 10–15-min brief advice session at baseline	One 10–15-min brief advice session at baseline
NA	Youths offered core N-O-T sessions once per week for 10 wk	Youths offered core N-O-T sessions once per week for 10 wk
NA	NA	Youths received a challenge log and a pedometer, which they kept with them throughout the study. The logs incorporated weekly goals, tips, and self-monitoring strategies reinforced in the group sessions. Teens recorded daily steps (measured with pedometers) and other daily minutes of activity not measured as steps. A "tear-off" record of activity was collected at each session for research purposes
NA	NA	Youths received an additional 5 min of encouragement and instruction by facilitators, as part of each standard N-O-T session. Generally, this included standardized prompts on fitness and health, tailored for each session (dO It!: general instructions; F-I-T challenge: weekly reinforcement of challenge log goals; health tip: how exercise helps mind and body; quit perk: how exercise helps teens quit smoking; remember: other things to keep in mind)

BI included scripted advice about the harmful effects of smoking and its long-term consequences, potential withdrawal symptoms upon quitting, and a widely available brochure on how to quit smoking. NA indicates not applicable.

students. Randomly selected schools were assigned randomly to 1 of the 3 study conditions (BI, N-O-T, or NOT+FIT) by using an assigned code in a SPSS database (SPSS Inc, Chicago, IL) (Fig 1). Of 60 schools that were selected randomly in 3 waves, 40 agreed to participate; schools were then assigned randomly. After random assignment but before study onset, 21 schools dropped out, citing recruitment challenges and time constraints. Schools dropped out equally across conditions, leaving a total of 19 schools. Our final teen sample included 233 participants.

Facilitator Training

School staff members and/or principals helped to identify facilitators across conditions. The research team and American Lung Association West Virginia provided training to facilitators (N = 25) according to condition. According to the American Lung Association protocol, N-O-T facilitator training occurred over a 1-day (8-hour) period; an additional half-day (4 hours) focused on the research protocol.[27] Training topics included teen smoking

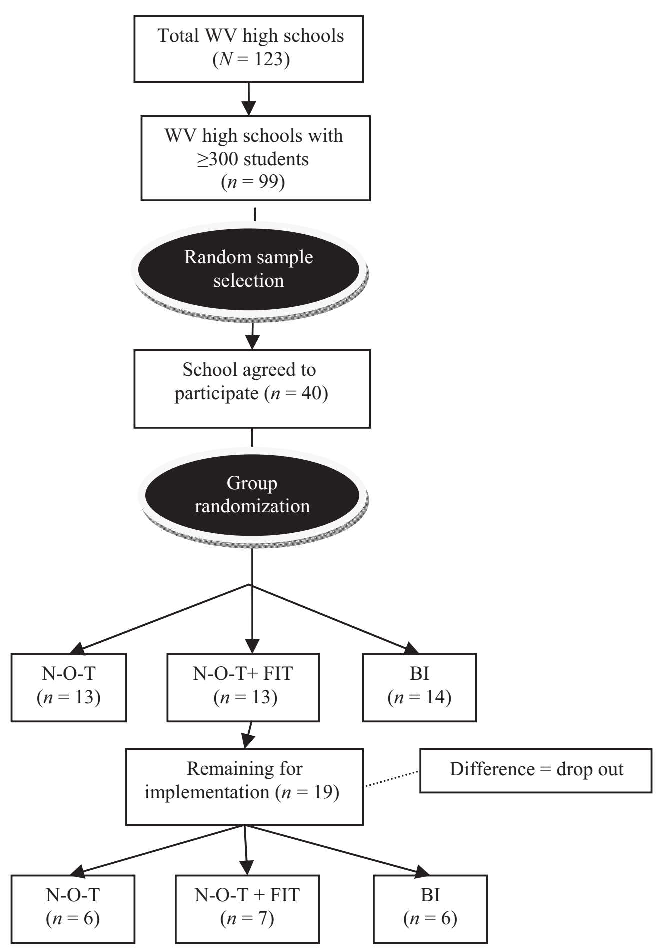

FIGURE 1
Random selection and assignment process. WV indicates West Virginia.

and nicotine dependence, research basics, and National Institutes of Health ethics certification. The BI training lasted <3 hours and focused primarily on the research protocol. Trained facilitators initiated recruitment in their respective schools and provided interested students with the institutional review board–approved consent/assent forms, to be signed by guardians and teens and returned before enrollment in any condition (Table 2).

Data Sources

Researchers collected participant baseline data before the onset of intervention (±2 weeks). Follow-up evaluations occurred 3 and 6 months after the baseline assessment (±3 weeks), equivalent to 1 and 4 months after the quit date, respectively, for all conditions. In this article, we describe only measures relevant to the primary hypothesis for quit outcomes. Table 3 provides a summary of the 18 key variables used to assess the participants' baseline similarity, selected on the basis of their potential relationships to our primary outcomes.[15,19,28,29]

In addition to collecting data on daily cigarette use at the follow-up evaluations, we asked participants to classify themselves as "quit" or "not quit." Smoking abstinence was verified with exhaled carbon monoxide (CO) readings, which are valid for a few hours. A digital CO monitor provides a reading of CO levels in the body. As in previous N-O-T studies and other teen smoking studies,[30,31] our study applied a CO cutoff reading of <9 ppm to corroborate self-reports at the 3-month follow-up evaluation.

Analyses

The appropriate definition of cessation is subject to debate, especially in youth

TABLE 2 Targeted Individual Enrollment

Study Condition	Baseline		3 mo After Baseline		6 mo After Baseline	
	No. of Teens	No. Targeted	No. of Teens	Proportion Retained, %	No. of Teens	Proportion Retained, %
N-O-T	90	100	77	86	56	62
N-O-T+FIT	80	100	59	74	51	64
BI	63	100	38	60	39	62
Total	233	300	174	75	146	63

TABLE 3 Key Variables for Baseline Comparisons

Variables	BI		N-O-T		N-O-T+FIT	
	Female	Male	Female	Male	Female	Male
Demographic summary						
Age, mean ± SD, y	16.88 ± 1.21	16.87 ± 1.38	16.15 ± 1.18	16.74 ± 1.43	16.00 ± 1.38	16.84 ± 1.22
Grade						
Mean ± SD, y	11.06 ± 1.16	10.97 ± 1.05	10.35 ± 1.14	10.71 ± 1.18	10.31 ± 1.12	10.82 ± 1.06
Ninth grade, %	18.75	12.90	25.00	18.42	35.71	18.42
10th grade, %	6.25	16.13	30.77	31.58	11.90	10.53
11th grade, %	25.00	32.26	21.15	10.53	38.10	42.11
12th grade, %	50.00	38.71	21.15	39.47	14.29	28.95
White, %	93.75	93.55	76.92	97.30	76.19	86.84
Living with father and mother, %	12.70	17.46	25.56	16.67	17.50	20.00
Baseline smoking history						
Age at first try, mean ± SD, y	11.91 ± 2.40	11.14 ± 3.23	11.98 ± 2.17	11.08 ± 2.94	11.14 ± 2.79	11.76 ± 2.66
Used smokeless tobacco, %	19.35	50.00	16.67	50.00	7.50	69.44
Smoked cigars, %	23.33	65.38	34.69	51.61	41.46	59.46
Nicotine dependence score, mean ± SD	4.60 ± 2.24	5.52 ± 2.11	4.78 ± 2.14	4.22 ± 2.22	4.56 ± 2.46	5.05 ± 2.68
Previous quit attempts, %	80.65	70.97	76.92	68.42	71.43	78.38
Smoking by parents, %	64.52	70.00	82.69	59.46	75.61	68.42
Smoking by siblings, %	65.63	48.39	76.92	54.05	73.17	47.37
Smoking by friends, %	100.00	96.67	96.08	94.59	100.00	100.00
No. of cigarettes smoked per weekday, mean ± SD	8.16 ± 4.22	12.97 ± 9.24	9.18 ± 6.86	8.22 ± 7.01	10.69 ± 7.98	12.11 ± 15.46
No of cigarettes smoked per weekend day, mean ± SD	14.09 ± 7.67	15.93 ± 9.45	12.85 ± 10.51	14.35 ± 13.76	15.76 ± 11.52	14.61 ± 13.49
No. of cigarettes smoked per day, mean ± SD	9.85 ± 4.76	13.64 ± 8.89	10.30 ± 7.52	9.75 ± 8.38	12.14 ± 8.43	12.82 ± 14.01
BI readiness						
Important to quit score, mean ± SD	5.77 ± 2.31	4.70 ± 2.47	6.39 ± 2.68	6.08 ± 2.33	6.52 ± 2.36	6.69 ± 2.30
Confident to quit score, mean ± SD	4.41 ± 2.50	5.13 ± 3.39	4.73 ± 2.79	6.19 ± 2.92	5.07 ± 2.82	5.58 ± 2.58
Stages of change						
Score, mean ± SD	1.88 ± 0.94	1.80 ± 1.13	2.39 ± 0.96	2.51 ± 0.93	2.51 ± 0.93	2.49 ± 0.69
Precontemplation, %	40.63	60.00	17.65	13.51	12.20	5.41
Contemplation, %	40.63	13.33	41.18	37.84	41.46	45.95
Preparation, %	9.38	13.33	25.49	32.43	29.27	43.24
Action, %	9.38	13.33	15.69	16.22	17.07	5.41

cessation studies.[32–34] In alignment with emerging field standards,[31] we examined 2 categories of quitting, that is, self-classified point prevalence (the proportion of teens who reported being a quitter at the assessment, regardless of the number of days since the last cigarette) and 7-day point prevalence (the proportion of teens who reported having no cigarette use in ≥7 days at the assessment). Both criteria used the CO-validated, intent-to-treat sample with both observed and imputed data (described below).

Little attention has been given to missing data in published teen smoking-cessation studies. Most studies report outcomes by using intent-to-treat or compliant (ie, completers) subsample analyses and view any missing data as "failure." Research shows that missing values in cessation trials can lead to biased estimates of outcomes that do not represent accurately the potential enrolled population.[16] Popular methods for dealing with missing data to produce complete data sets have serious drawbacks.[35] List-wise deletion can introduce biased estimates and reduced power, and simple mean replacement leads to reduction of the SE estimates. Similar to procedures used by Joffe et al[16] in a 2-armed randomized trial of N-O-T, the multiple-imputation procedure described by Rubin[36] replaces missing values with a set of plausible values, eliminating uncertainty about which are the correct values to impute. The procedure introduces "error" while maintaining adequate power.

An important step in multiple imputation is determining the "missingness" of the data, particularly data used to calculate the key outcomes. Three months after baseline, we obtained data from 75% of our subjects (174 of 233 subjects). Rates of missing data for our 3 key outcome variables (quit status, CO reading, and days since the last cigarette) ranged between 25% and 39%. At 6 months after baseline, we obtained data from 63% of our subjects (146 subjects), with missing data rates of 37% to 74%. At 6 months after baseline, many youths had graduated and did not have the opportunity to complete the CO record in person (including the date of the last cigarette), which resulted in high rates of missing values. Therefore, we did not apply imputation, and we reported self-classified point prevalence only.

Consistent with past N-O-T research,[15] reasons for missing data were not predictably related to smoking status (eg, transfer to a different school, need to be at work, illness, or graduation). Following the recommendations of Rubin,[35] we regarded these data as missing at random or missing completely at random. Our reference sample included 233 qualified participants. SAS procedure Proc MI (SAS 9.2 added; SAS Institute, Cary, NC) was used to perform the multiple-imputation method. We used the default Markov chain Monte Carlo method, because the missing data pattern was arbitrary.

We included 44 of 485 available variables in the imputation model, paying attention to those that might be used in subsequent analyses of the imputed data sets.[35] We included the dependent variable in the imputation model to reduce any artificial inflation of the relationship between the independent and dependent variables. The imputed values of the dependent variable did not provide additional error.[37] Therefore, we calculated our primary outcomes by using the 3 key variables (quit status, CO reading, and days since the last cigarette) with their imputed values for observed self-classified and 7-day prevalence quit rates from an average of 5 imputation series, which allowed for an SD 5% wider than if we had used an infinite number of imputations.

We applied standard analytic techniques to our final observed and imputed data sets. A relative risk (RR) of >1 means that continued smoking is less likely to occur in the N-O-T or N-O-T+FIT group. We used a 2-proportion z test to determine statistical differences in quit rates between groups as follows: $z = (p_1 - p_2)/\text{SE}$, where $\text{SE} = \sqrt{[p_1(1 - p_1)/n_1 + p_2(1 - p_2)/n_2]}$, p_1 is the sample proportion from population 1, p_2 is the sample proportion from population 2, n_1 is the size of sample 1, and n_2 is the size of sample 2.

RESULTS

Youths smoked approximately one-half of a pack of cigarettes per day (mean: 10.13 cigarettes per day; SD: 9.18 cigarettes per day) on weekdays and almost 1 pack per day (mean: 14.47 cigarettes per day; SD: 11.29 cigarettes per day) on weekends at program enrollment, which was consistent with our efforts to recruit daily teen smokers; 96% of youths smoked daily. We found moderate/high nicotine dependence scores. The mean age of the participants was 16.53 years (SD: 1.34 years) (Table 3).

Because of limited time in the funding period and the potential for cohort effects over an extended recruitment period, the final number of schools per condition was not ideal. Given the small number of schools for each treatment condition (BI: $N = 6$; N-O-T: $N = 6$; N-O-T+FIT: $N = 7$), we were limited in our approach to controlling for the clustering in the design. The majority of approaches to control for clustering, such as multilevel modeling and generalized estimating equations, require a larger number of units per condition for adequate power. Therefore, we did not use those analytic approaches. In an attempt to determine whether outcomes might have been attributable to school-level differences rather than intervention effects, we conducted a series of analyses of variance to examine whether there were significant baseline differences in 4 key variables (age, age at first cigarette use, nicotine dependence scores, and numbers of cigarettes per day) between schools, both within each treatment condition and between conditions. Within-group results suggested that 1 school in the BI group had a significantly lower average age, which was the result of having only 2 enrolled individuals, both 15 years of age ($F_{5,57} = 7.26$; $P < .01$); therefore, the school's average age was 15 years, with an SD of 0 years. Similarly, 1 N-O-T+FIT school had 3 enrolled individuals with an average age of 15.33 years (SD: 0.58 years), and 1 N-O-T+FIT school had 3 enrolled individuals with an average age of 15 years (SD: 1.00 years; $F_{6,73} = 5.64$; $P < .01$). There were no significant between-group differences ($F_{2,16} = 0.81$; $P = .46$). With respect to the age at first cigarette use, there were no significant differences either within groups (BI: $F_{5,55} = 1.75$; $P = .14$; NOT: $F_{5,82} = 1.68$; $P = .15$; N-O-T+FIT: $F_{6,73} = 2.01$; $P = .08$) or between schools ($F_{2,16} = 1.17$; $P = .34$). With respect to within-group levels of nicotine dependence, 1 N-O-T+FIT school had nicotine dependence scores significantly higher than average (mean: 7.67; SD: 0.58), and 1 school had nicotine dependence scores lower than average (mean: 4.00; SD: 2.52; within-group $F_{6,69} = 3.04$; $P = .01$). These differences in the N-O-T+FIT schools were attributable to 1 school having no female participants (the school with higher-than-average nicotine dependence scores) and the other school having no male participants (the school with lower-than-average nicotine dependence scores). There were no significant between-group differences in levels of nicotine dependence ($F_{2,16} = 2.62$; $P = .10$). Finally, 1 BI school had a lower-than-average value for the number of cigarettes per day ($F_{5,55} = 2.60$; $P = .04$), which was the result of the school enrolling 2 individuals, 1 who smoked an average of 4.3 cigarettes per day and 1 who smoked an average of 2.3 cigarettes per day. There were no other within-group differences in the numbers of cigarettes per day (N-O-T: $F_{5,81} = 1.13$; $P = .35$; N-O-T+FIT: $F_{6,73} = 1.52$; $P = .19$). There were no between-group differences in the numbers of cigarettes per day ($F_{2,16} = 1.98$; $P = .17$). Overall, these results suggested that the schools were largely equivalent with respect to key predictor variables, both within and between conditions, which increased our confidence that the results were not likely attributable to school-level effects.

Visual inspection of the data revealed an unusual distribution of participants in the precontemplation stage of change, particularly in the BI group (Table 3). To explore this issue, we conducted a series of *t* tests to determine whether the differences in the stages of change between groups were statistically significant. Results demonstrated that the BI group had significantly lower scores for stage of change, compared with the N-O-T group ($t_{151} = -3.72$; $P < .001$) and the N-O-T+FIT group ($t_{141} = -4.17$; $P < .001$). There was no significant difference between the N-O-T and N-O-T+FIT groups with respect to stage of change ($t_{168} = -0.37$; $P = .71$). Two-proportion *z* scores confirmed that there were significantly more participants in the precontemplation stage in the BI group, compared with the N-O-T group ($z = -5.5$; $P < .001$; RR: 2.49) and the N-O-T+FIT group ($z = -6.29$; $P < .001$; RR: 2.50). There were no significant differences in the numbers of participants in the precontemplation stage in the N-O-T and N-O-T+FIT groups. Further examination of the data showed that 1 BI school had a large number of boys in the precontemplation stage. To explore the potential effects of this confounding, we examined whether the large number of participants in the precontemplation stage in the BI group influenced quit outcomes in the BI group versus the other groups. Findings revealed that there were no significant differences in cessation outcomes between participants in the BI and N-O-T groups in the precontemplation stage ($z = 0.94$; $P = .17$) or between participants in the BI and N-O-T+FIT groups in the precontemplation stage ($z = 1.12$; $P = .13$).

In support of the primary study hypothesis (Table 4), the observed CO-validated, self-classified and 7-day point prevalence quit rates were consistent with our predicted trends 3 months after baseline. The 7-day quit rates were 4.76% for the BI group, 11.11% for the N-O-T group, and 13.75% for the N-O-T+FIT group. Imputed values for the BI, N-O-T, and N-O-T+FIT groups were 12.7%, 20.00%, and 33.75%, respectively. Overall, as predicted, the addition of the FIT adjunct decreased the risk of continued smoking twofold. Moreover, the RR values were >1 for both N-O-T and N-O-T+FIT groups, compared with the BI group, which indicated that youths in the BI group had a higher likelihood or risk of continuing to smoke after intervention than did youths in the N-O-T group (Table 5). The self-classified quit rates at 6 months after baseline were 15.87% for the BI group, 21.11% for the N-O-T group, and 31.25% for the N-O-T+FIT group. Although all groups showed increased proportions of abstainers, youths in the N-O-T+FIT group maintained a higher likelihood of quitting, compared with the risks of continued smoking in the BI group (RR: 1.97). Consistent with our hypothesis, youths in the N-O-T+FIT group had a greater likelihood of cessation, compared with those in the N-O-T group (RR: 1.48). Although the differences between the N-O-T and BI conditions were not statistically significant at 6 months, there

TABLE 4 Quit Rates

	n (%)								
	BI			N-O-T			N-O-T+FIT		
	Female (*N* = 32)	Male (*N* = 31)	All (*N* = 63)	Female (*N* = 52)	Male (*N* = 38)	All (*N* = 90)	Female (*N* = 42)	Male (*N* = 38)	All (*N* = 80)
3 mo after baseline[a]									
Self-classified	0 (0)	3 (9.68)	3 (4.76)	9 (17.31)	6 (15.79)	15 (16.67)	5 (11.90)	10 (26.32)	15 (18.75)
Imputed	4 (12.50)	5 (16.13)	9 (14.29)	13 (25.00)	11 (28.94)	24 (26.67)	12 (28.57)	20 (52.63)	32 (40.00)
≥7 d	0 (0)	3 (9.68)	3 (4.76)	7 (13.46)	3 (7.89)	10 (11.11)	2 (4.76)	9 (23.68)	11 (13.75)
Imputed	3 (9.38)	5 (16.13)	8 (12.70)	11 (21.15)	7 (18.42)	18 (20.00)	8 (19.05)	19 (50.00)	27 (33.75)
6 mo after baseline, self-classified[b]	4 (12.50)	6 (19.35)	10 (15.87)	12 (23.08)	7 (18.42)	19 (21.11)	11 (26.19)	14 (36.84)	25 (31.25)

[a] Intent to treat, with CO validation.
[b] Intent to treat.

TABLE 5 RRs Overall and According to Gender

	BI vs N-O-T			BI vs N-O-T+FIT			N-O-T vs N-O-T+FIT		
	z Score	*P*	RR	*z* Score	*P*	RR	*z* Score	*P*	RR
3 mo after baseline									
All									
Self-classified	2.502	.006	3.50	2.731	.003	3.94	0.355	.361	1.13
Imputed	1.930	.027	1.87	3.657	<.001	2.80	1.854	.032	1.50
≥7 d	1.489	.068	2.33	1.915	.028	2.89	0.520	.302	1.24
Imputed	1.228	.110	1.58	3.119	.001	2.66	2.033	.021	1.69
Male									
Self-classified	0.769	.221	1.63	1.870	.031	2.72	1.135	.128	1.67
Imputed	1.296	.097	1.79	3.492	<.001	3.26	2.164	.015	1.82
≥7 d	0.259	.398	0.82	2.124	.017	2.44	1.933	.027	3.00
Imputed	0.251	.401	1.14	3.238	.001	3.10	3.077	.001	2.71
Female									
Self-classified	3.299	<.001	∞	2.382	.009	∞	0.746	.228	0.69
Imputed	1.492	.068	2.00	1.767	.039	2.29	0.388	.349	1.14
≥7 d	2.844	.002	∞	1.449	.074	∞	1.510	.066	0.35
Imputed	1.538	.062	2.26	1.216	.112	2.03	0.254	.400	0.90
6 mo after baseline									
All, self-classified	0.831	.202	1.33	2.218	.013	1.97	1.505	.066	1.48
Male, self-classified	0.098	.461	0.95	1.655	.049	1.90	1.835	.033	2.00
Female, self-classified	1.280	.100	1.85	1.529	.063	2.10	0.348	.364	1.13

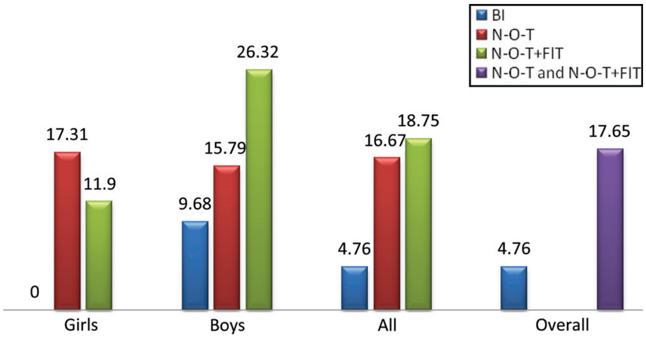

FIGURE 2
Observed self-classified point prevalence rates 3 months after baseline. All values are percentages.

was a large effect in favor of N-O-T (RR: 1.33) (Figs 2 and 3).

With consideration of all quit rate calculations at the 3-month follow-up assessment, there were marginally significant differences between boys in the N-O-T and BI groups. When we examined the N-O-T+FIT component, however, the added effect for boys was striking. For example, 7.89% of boys in the N-O-T group, compared with 23.68% of boys in the N-O-T+FIT group, reported 7-day point prevalence cessation (RR: 3.00). Imputed 7-day point prevalence values were 18.42% for the N-O-T group and 47.37% for the N-O-T+FIT group (RR: 2.71). In contrast, the corresponding observed 7-day quit rates for girls were 13.46% for the N-O-T group and 4.76% for the N-O-T+FIT group; the imputed values were 21.15% for the N-O-T group and 19.05% for the N-O-T+FIT group. Both calculations revealed RR values of <1.0, which suggests that the addition of

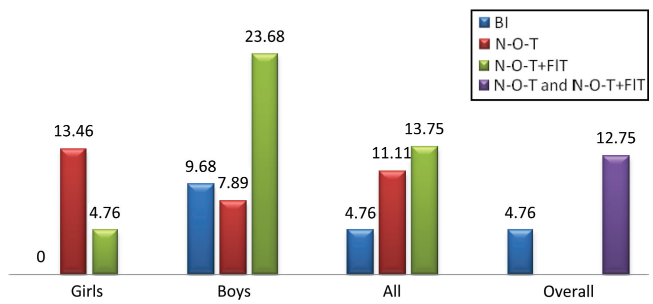

FIGURE 3
Observed 7-day point prevalence rates 3 months after baseline. All values are percentages.

physical activity to N-O-T did not decrease the risk of continued smoking for girls.

Across all measurement points and types of analyses, girls in the N-O-T group reported significantly higher quit rates than did girls in the BI group. The 7-day observed and imputed values for N-O-T and BI comparisons revealed remarkable RRs of $\geq\infty$. The observed 7-day values showed that >13 times more girls in the N-O-T group, compared with girls in the BI group, quit smoking. Data strongly support the efficacy of N-O-T for smoking cessation among girls, with or without the physical activity supplement. However, the addition of more structured physical activity to N-O-T did not boost female cessation rates at the 3-month follow-up assessment. Similar trends were observed at the 6-month follow-up assessment. Depending on which quit rate calculation was used, it might be contended that the FIT component actually moderated quitting among girls.

DISCUSSION

Beyond examination of the influence of physical activity on cessation, this study served as an opportunity to examine quit rates under numerous conditions, including analyses similar to those used by Joffe et al[16] in their randomized controlled trial of N-O-T. With the use of conservative nonimputed techniques, both N-O-T and N-O-T+FIT conditions showed consistently higher overall rates of biochemically validated cessation than did BI. The overall risk of continued smoking among youths in the BI group was almost 3 times higher. When we aggregated data across N-O-T conditions (N-O-T and N-O-T+FIT) and compared those data with data for the BI group, the observed 7-day quit rate for the aggregated N-O-T group was significantly higher than that for the BI group (BI: 4.76%; N-O-T/N-O-T+FIT combined: 12.35%; $z = 2.061$; $P = .020$; RR: 2.59). The imputed 7-day point prevalence values showed similar results (BI: 12.70%; N-O-T/N-O-T+FIT combined: 26.47%; $z = 2.555$; $P = .005$; RR: 2.08).

When we analyzed data according to gender, we discovered that the N-O-T+FIT component decreased the risk of continued smoking fourfold among boys. This finding is consistent with evidence showing that physical activity is protective against smoking initiation and increased smoking levels among youths.[10–12] In contrast to adult studies, these data provide further justification for enhancing physical activity as part of the N-O-T program for male participants. Our findings are consistent with other independent N-O-T investigations at comparable time points. A similar analysis by Joffe et al[16] revealed statistically significant treatment effects of the N-O-T program on self-reported quit rates at the end of the program (RR: 1.26 [95% confidence interval CI]: 1.10–1.43), at 1 month (RR: 2.07 [95% CI: 1.68–2.56]), and at 12 months (RR: 1.58 [95% CI: 1.22–2.04]). A N-O-T study by Kohler et al[38] in Alabama demonstrated a positive effect of the N-O-T program on 30-day, self-reported, quit rates at the end of the program, by using a conservative intent-to-treat analysis; youths in the N-O-T program had 4.2 times the odds of quitting, compared with control subjects. It is important to point out that the variations in quit rates were contingent on the criteria used (eg, self-classified versus 7-day and observed versus imputed). Although different classifications yielded slightly different rates, the trends were consistent. Equivalent to the $\geq$24-hour rates reported in previous N-O-T studies,[18,19] the self-classified point prevalence rates were slightly higher than the 7-day rates. Point prevalence captures whether a participant is smoking at a particular point in time, and results can be validated biochemically, as in our study.[32] The 7-day rates do not allow for slips, which often accompany cessation behavior. Moreover, although we measured CO levels, it is generally difficult to validate smoking behavior biochemically beyond 24 hours. Among the biochemical measurements to confirm smoking status, cotinine measurements, although they are expensive, are preferred by researchers because of cotinine's 17-hour half-life. CO has a shorter half-life of 1 to 4 hours.[39] The various methods used to report quit rates cause some confusion regarding which reflect program outcomes most accurately. Point prevalence rates, such as the self-classified rates reported here, reflect real-time estimates of quit status and should be given consideration as a type of assessment of program impact. As presented by Hughes et al,[40] we contend that multiple measures of outcomes provide a more accurate picture of effect size and that the effect size (and not simply the abstinence measure) should be a "major criterion for success" and clinical relevance. Because we found baseline differences in stages of change (ie, readiness), we examined cessation rates according to stage within each condition. We found a higher-than-expected frequency of subjects in the precontemplation stage in the BI group, especially among boys. We are not certain how to interpret these findings; it is plausible that in 1 BI school there was a "piggyback" effect with boys. These differences, however, provided us with an opportunity to explore outcomes according to stage. As reported by Cahill et al,[41] the added value of adapting interventions to a smoker's stage of change is tentative. In their recent review, those authors reported that the evidence does not support the restriction of interventions only to smokers perceived to be in the preparation and action stages. Our study, in fact, found that both the BI and N-O-T conditions led to cessation across stages of change. In a N-O-T study by Dino et al,[42] participants in the BI group in the preparation stage were 25 times more likely to have quit smoking at postbaseline assessments than were participants in the contemplation or precontemplation stages. In contrast, N-O-T was effective for youths regardless of baseline stage. Although our present study used a randomized design, the BI sample had a greater proportion of participants in the precontemplation stage, particularly in 1 school. The teens in the BI group who quit smoking represented all stages of readiness equally. Logically, N-O-T was more effective than BI for those in the preparation stage and beyond.

This study included only West Virginia youths, which might limit the generalizability of the findings. For instance, opportunities for physical activity in this rural mountainous state may be more limited than in other geographic areas. Moreover, West Virginia has among the highest US teen smoking rates and lowest physical activity rates.[43] We must replicate the study with diverse groups of teens. Future studies also should give attention to co-occurring external influences on the intervention within the schools or communities. It is possible that the physical activity adjunct, rather than physical activity itself, was more culturally suitable for boys than for girls. The stage of change baseline difference also is a consideration for overall treatment effects, biased toward unusually high cessation outcomes for the boys in the BI group. Other unmeasured factors might be at play. Although we made great efforts to recruit and to randomize carefully, our sample size was small, as reflected in small numbers of participants per group and per condition. It has been suggested that designs such as that used in our study would benefit from addressing of intraclass correlations between randomized groups through analyses such as generalized estimating equations.[44] When the numbers of randomized groups (schools in the present study) are small (eg, $<$20), however, generalized estimating equations and similar techniques are inappropriate.[44,45] In such circumstances, generalized estimating equations are known to result in biased estimates of effects.[46,47] The availability of intraclass correlation estimates for smoking outcome variables in school-based smoking interventions is limited. However, a few studies showed that school-level intraclass correlations for smoking and other health behaviors ranged from 0 to 0.075.[48–50] Intraclass correlation coefficients in relevant school-based studies often are small,[51] which enhances our confidence in our treatment effects.

CONCLUSIONS

We conclude that the N-O-T+FIT component had a large effect for boys, decreasing the risk of continued smoking almost fourfold by the end of the program. We also found significant overall effects of N-O-T, compared with BI, on quit status. With consideration of both the imputed and observed data, the overall, CO-validated, 7-day quit rates were between 13.75% and 33.75% for N-O-T+FIT, between 11.11% and 19.78% for N-O-T, and between 4.76% and 13.33% for BI. The effect sizes were large, in favor of the intervention conditions. Overall, girls quit more successfully with N-O-T, compared with BI (RR: $>\infty$), 3 months after baseline, and boys responded better to N-O-T+FIT than they did to BI (RR: 2–3) or to N-O-T (RR: 1–2). In this study, the $\leq$5 minutes per session of additional effort by N-O-T facilitators to bolster physical activity had a significant program impact. A forthcoming article will explore whether the FIT component enhanced physical activity for N-O-T participants, paying particular attention to gender.

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