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Randomized Controlled Trial of the ACTION Smoking Cessation Curriculum in Tobacco-Growing Communities

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Abstract

We conducted a group randomized trial of an interactive, games-based, tobacco cessation program (ACTION) designed to help adolescents who live in tobacco-growing communities to stop using tobacco. More than 260 high school students participated in this study, in 14 schools across three states. We collected self-reported measures of cigarette and smokeless tobacco use and conducted biochemical validation of self-reported use at three time points (pre-test, immediate post-test, and 90-day follow-up). We used multi-level modeling to account for intraclass clustering at the school and classroom levels, and we analyzed our results using an intent-to-treat approach and a per protocol approach. Using the per protocol analytic approach, ACTION participants were more likely than comparison participants to achieve abstinence at 90-day follow-up. We found no program effects on our secondary outcomes or mediating factors. This study suggests that ACTION has promise as a relatively effective adolescent cessation program, although the overall limited effectiveness of cessation programs for adolescents must be acknowledged.

Keywords

adolescent; tobacco use; cessation; smoking; smokeless tobacco; cigarettes

1. Introduction

A recent Youth Risk Behavior Survey (YRBS) revealed that 20% of U.S. high school students smoked at least once in the past thirty days, with state rates ranging from 7.9% to 27.6% (Eaton et al., 2008). Not surprisingly, teen smoking rates in tobacco-growing states are generally higher than the national average. The top six tobacco-producing states are North Carolina, Kentucky, Tennessee, South Carolina, Virginia, and Georgia. North Carolina, Kentucky, and Tennessee have 79% of all tobacco farms, and the six states together accounted for 94% of tobacco production in the US in 2002 (Capehart, 2004). Teen smoking rates for five of these states are 26.0% (KY), 25.5% (TN), 22.5% (NC), 18.6% (GA), and 17.8% (SC).¹ Rates of frequent smoking, heavy smoking, and quit attempts among teens are also higher in these states

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¹YRBS data for Virginia are not available.

than the national average (Eaton et al., 2008). Although, nearly 50% of high school smokers tried to quit at least once during the previous 12 months (Eaton et al., 2008), successful quit rates are very low, ranging from 0 to 11% at three to five month follow-up (Sussman, 2001).

Sussman, Sun, & Dent (2006) conducted a first-of-its-kind meta-analysis of 48 teen cigarette smoking cessation studies using multi-level techniques to control for inter-study variability. They concluded that smoking cessation programs are effective, providing a 2.90% absolute advantage in quitting over comparison conditions: on average, 9.14% of students in cessation programs quit smoking, compared to 6.24% of students in comparison conditions, increasing the probability of quitting by 46%. Programs consisting of at least five quit sessions and including a motivation enhancement component, cognitive-behavioral techniques, and social influence approaches had higher quit rates, as did school-based clinic and classroom modalities. Effects were maintained at short-term (1 year or less) and longer term (longer than 1 year) follow ups (Sussman, Sun, & Dent, 2006).

This article presents the results of a randomized controlled study of the effects of a tobacco cessation program, known as ACTION (Adolescent Cessation of Tobacco: Independent of Nicotine), designed specifically for high school youth in tobacco-growing communities, where there is an elevated risk of tobacco use (Noland et al., 1996; Ritchey, Reid, & Hasse, 2001). We randomly assigned schools to either the ACTION condition or the comparison condition and measured several variables related to tobacco use. Our primary hypothesis was that youth assigned to the ACTION condition would be more likely than youth assigned to the comparison condition to stop using tobacco, as measured immediately after the intervention and three months following the end of the intervention. A secondary hypothesis was that youth assigned to the ACTION condition would be more likely than youth assigned to the comparison condition to reduce the frequency and amount of their tobacco use. In addition, we explored the effects of ACTION on several mediating variables (e.g., nicotine dependence, stages of change [Prochaska & DiClemente, 1983], and motivation to quit), as well as the effects of program fidelity on our outcomes measures.

2. Methods

2.1. Participants

Participants were high school students recruited from 14 schools in Kentucky, North Carolina, and Ohio. Each school attempted to recruit two classes of 12 students. To be eligible to participate in the study, the students had to meet the following criteria: 1) had smoked or used smokeless tobacco in the past seven days, 2) were 14 to 18 years of age, and 3) were interested in voluntarily participating in this study of tobacco cessation. We chose “past seven day use” as one of our criteria because there is no consensus regarding a definition of regular tobacco use among adolescents, and because adolescent *daily* tobacco users typically have less success in quitting, are more addicted (Sargent, Mott, & Stevens, 1998), and are harder to recruit. Also, researchers recommend intervening at a lower threshold, before students report daily use (Mermelstein et al., 2002). Each school received an incentive of \$1,000 for its participation in the study and enrollment of 24 students (prorated if enrollment did not reach 24). In addition, each school was allowed to keep a new video camera and tripod that were purchased to record program delivery during each session.

2.2. Procedures

Schools were randomly assigned to receive either the ACTION curriculum or the comparison condition. The randomization was stratified by state to ensure a balance between state and condition. All participating school districts were informed that their high schools would be randomly assigned to either the treatment condition or to the comparison condition.

Data on all outcome measures and mediating factors were collected at three separate time points. Most students in the treatment and comparison groups completed three internet-based surveys using a secure, internet-based data collection program. (Students in two schools relied on paper and pencil surveys for all three waves of data collection.) Students completed the pretest survey up to seven days prior to implementation of the treatment and comparison conditions, the second (posttest) survey six weeks later (no more than 3 days after the treatment and comparison interventions concluded), and then a three month follow-up survey. Because the surveys were internet-based, students completed them in a variety of settings, including the classroom and at home. Questions about smoking cigarettes and using smokeless tobacco were asked separately of all participants. Data on all process measures were collected at immediate post-test only, with the exception of attendance, which was tracked each session by the facilitators who delivered the ACTION and comparison programs.

Given concerns over the accuracy of adolescent self-reports of tobacco use, researchers recommend biochemical confirmation (Mermelstein et al., 2002). We biochemically verified reports of abstinence with salivary cotinine, which is a metabolite of nicotine. This method is preferred to other biological measures (e.g., carbon monoxide and thiocyanate) because saliva cotinine can be detected up to 72 hours after cigarette and smokeless tobacco use (Dolcini, Adler, Lee, & Bauman, 2003). Carbon monoxide, for example, can be detected only up to nine hours after use—and only for cigarettes—thereby hindering the identification of tobacco use by many adolescents (Mermelstein et al., 2002).

We collected saliva samples at all three study time points using a Salivette device (i.e., a cotton pad containing acetic acid to stimulate salivation). Students were told that we were collecting saliva samples to verify their tobacco use for the study. The student placed the pad between his/her gum and cheek, allowing the pad to absorb the saliva. The pad was then placed into a special tube. All saliva samples were sent to a nationally recognized laboratory where they were centrifuged to release the saliva.² Because the saliva specimens were stable at ambient temperatures, they could be sent through the mail. Facilitators were provided with pre-labeled and stamped envelopes, and were instructed to place them in the mail at the end of the day.

As incentives to complete the surveys and saliva tests, students received \$25 gift cards after each wave of data collection. We also offered incentives to the facilitators to help prompt students to complete the on-line surveys and to administer the saliva tests.

2.3. Treatment and Comparison Conditions

The treatment condition consisted of the delivery of the ACTION program, a curriculum based on insights from stages of change theory (Prochaska & DiClemente, 1983), psychosocial theory (Newman & Newman, 2001), and the curriculum designers' qualitative research (Denham, Meyer, & Toborg, 2004; Meyer, Denham, Toborg, & Mande, 2008). Stages of change theory posits that when people make decisions, they move through several stages before they are able to change a health-related behavior and sustain their commitment to the maintenance of the new behavior. ACTION encourages participants to move along these stages of change. Psychosocial theory suggests that a principal developmental hurdle for youth in the targeted age range is group identity; ACTION, therefore, helps students reflect upon a variety of pressures that arise in their communities, families, and among friends and peers that deter them from quitting tobacco.

The program uses interactive games to teach cessation and abstinence skills. Each session consists of games, during which participants accumulate points across the length of the

²The testing technique employed an immunoassay (Chemiluminescence) with a sensitivity of 10 ng/mL.

program. Between sessions, students are asked to practice skills (e.g., making contacts with each other for support or using relaxation techniques) that emphasize the progressive nature of quitting. The program encourages the use of incentives and consists of six 50-minute sessions. The comparison intervention included six sessions, consisting of videos (approximately 20 to 30 minutes in length) and scripted discussion questions about themes portrayed in the videos.³

Most schools scheduled the ACTION and comparison classes during the school day; some schools administered the classes after school. There were no systematic differences in class setting by condition.

2.4. Measures

2.4.1 Primary and Secondary Outcome Measures—The primary outcome of interest was abstinence from tobacco use. We used two measures to assess abstinence. First, we used self-reported abstinence for at least three days, combined with the biochemical verification. Thus, only participants who reported abstaining from cigarettes and smokeless tobacco for at least three days *and* who tested negative for salivary cotinine were considered 3-day abstainers with biochemical verification. Based on previous studies, we considered cotinine values greater than 11.4 ng/ml to be indicative of tobacco use (Caraballo, Giovino, & Pechacek, 2004; Kandel et al., 2006). Second, we examined self-reported abstinence for at least seven days. Although 7-day abstinence could not be biochemically validated, we combined 7-day abstinence with our 3-day biochemical validated to create a measure of self-reported 7-day abstinence plus 3-day biochemical verification. Thus, our two primary cessation outcomes of interest were 3-day abstinence with verification and 7-day abstinence with 3-day verification. We assessed both measures at pre-test, post-test, and 90-day follow-up. We also measured four secondary outcomes—frequency of tobacco use, amount of tobacco use, number of quit attempts, and number of days abstinent—during all three waves of data collection.

2.4.2. Mediators—We measured several mediating factors at all three time points to examine whether the ACTION program would have an effect on them, as well. These mediators—nicotine dependence, stages of change, and motivation to quit smoking—have been identified in the literature as influencing tobacco use behavior. A second reason for gathering data on these mediators was to use them as possible covariates if we found that our ACTION and comparison participants differed on these dimensions.

Nicotine Dependence: To measure nicotine dependence among smokers, we used the 6-item Fagerström Tolerance Questionnaire modified for use with adolescents (m-FTQ), (Prochaska & DiClemente, 1983; Prokhorov et al., 2000; Prokhorov, Pallonen, Fava, Ding, & Niaura, 1996). To measure nicotine dependence among smokeless tobacco users, we used a nine item m-FTQ adapted for smokeless tobacco.⁴

Stages of Change: To assess stage of change we used a 6-item measure validated with adolescents (Pallonen, Prochaska, Velicer, Prokhorov, & Smith, 1998; Prokhorov et al., 2001). We also adapted this instrument for smokeless tobacco users.

³A true, non-intervention control group was considered but recommended against by proposal reviewers and by the study's Advisory Committee because it was felt that the study should control for attention. That is, the study should be able to demonstrate that the program *content* provided to students, not just the attention given to students, would explain any differences compared to the control group.

⁴An additional measure recently reported in the addiction literature, the Fagerström Test for Nicotine Dependence-Smokeless Tobacco (FTND-ST), (Ebbert, Patten, & Schroeder, 2006) was unavailable at the time of this study.

Motivation to Quit Smoking: Participants were asked how motivated they were not to smoke (or use smokeless tobacco) using a 4-point scale, with response ranging from “not at all motivated” to “extremely motivated.”

Exposure Index: We assessed exposure to tobacco users at pretest by asking participants whether their parents, brothers or sisters, and best friends smoke or use smokeless tobacco.

2.4.3. Process Measures—We collected data on three process variables—dosage, participants’ perceptions of the program, and program fidelity. For dosage, teachers recorded student attendance during each session. For perceptions of the program, we asked participants to rate four dimensions of the intervention: situation management (5 items)⁵; cessation skills (9 items); program likeability (3 items); and facilitator likeability (4 items). Cronbach’s alphas were high on all four dimensions, ranging from .85 to .91.

To assess program fidelity, facilitators videotaped all sessions of the treatment and comparison conditions. Immediately after concluding each session, the facilitators mailed videotapes to us in self-addressed, stamped packages provided by the research team. Although we collected tapes from all the sessions for both the treatment and comparison conditions, we developed a rating scale for assessing fidelity to the ACTION program only. Our rating form comprised of three components: adherence to content, addition of material outside the curriculum, and quality of delivery. The adherence-to-content component consisted of a series of Yes/No questions about whether the facilitator delivered 24 specific curriculum elements across five main activities. The addition-of-material component consisted of five items (one after each main activity) asking whether the facilitator added material that was not included in the curriculum. This component was measured on a 3-point scale (none, some, a lot); we did not assess whether the additional material seemed to have a positive or negative impact. We measured quality of delivery with a series of questions about how well the instructor delivered the program (e.g., to what extent did the instructor provide genuine praise and encouragement?), using a four-point scale (very much, somewhat, a little, not very much).

Because of resource limitations, we selected one ACTION session (session five) for detailed review. We selected session five to give students and health educators the chance to become acclimated to the program and the video equipment, and because session five included content that was particularly relevant for the students’ quit attempts. Two researchers viewed and independently rated all the session five tapes using our form. After making their independent ratings, the researchers discussed their ratings and recorded a single rating per item, based on consensus.

3. Data Analysis

For analyses of the primary outcomes we employed an intent-to-treat (ITT) approach which assumed that participants who dropped out of the study and/or who did not provide all the data were unchanged by the intervention. We also employed a per-protocol (PP) approach to analyze primary and secondary outcome variables among participants for whom we had data at two points in time (i.e., pre-test and post-test; pre-test and 90-day follow-up). We acknowledge that this is a less conservative approach, but one that may be better suited for assessing the effects of the intervention among those who comply with the protocol (and provide the data).

Because individuals in the group class mutually interact with each other, the usual assumption of statistically independent outcomes was not justified. A meta-analysis of studies of adolescent smoking found that outcomes of individuals within an intact group were positively correlated,

⁵Situation management is the extent to which the program was helpful in identifying reasons and ways to quit (Stevens et al., 2003).

with average intra-class correlation coefficients for adolescent smoking ranging from 0.01 to 0.025 (Murray et al., 1994). For all inferential statistics, we therefore used mixed model analyses to account for the intra-class correlation (ICC) or non-independence that may have resulted from both randomizing at the school level and student membership in particular classrooms and schools (Raudenbush & Byrk, 2002; Twisk, 2006).

Thus, we treated school as a level-2 random effect in our models of the dichotomous primary outcomes, using SAS PROC GLIMMIX. For continuous outcome measures and mediators we had greater modeling flexibility. We were able to employ three-level mixed models incorporating classroom and school as level-2 and level-3 random effects, and four-level longitudinal (growth) mixed models incorporating time (i.e., repeated observations within students) as a level-1 random effect. All analyses controlled for the within-student fixed effects of pre-test score on the dependent variable, as well as student age and gender.

We also explored whether program fidelity influenced outcomes. We created a fidelity index comprised of the three fidelity components, and each element was given equal weight (i.e., counted for one-third of the index). Scale scores were normalized to 100 for a maximum score of 300. We dichotomized ACTION classes into high and low fidelity, splitting the classes at the median score of 154.2.

4. Results

Of the 268 students, four were subsequently identified as not meeting the age inclusion criteria at pre-test and were dropped from the analysis. An additional three students were dropped from the analysis because of three or more inconsistencies in their demographic data across the three data collection time points. Thus, there were 261 students who contributed data at pretest (24 classes in 14 schools)—123 in the treatment group and 138 in the comparison group. At posttest there were 229 students (24 classes in 14 schools) who contributed data (88% of pre-test)—108 in the treatment group and 121 in the comparison group. At 90-day follow-up, there were 181 students (23 classes in 13 schools) who contributed data (69% of pre-tests)—81 in the treatment group and 100 in the comparison group.⁶

4.1. Sample Demographics and Tobacco Use Characteristics

The only statistically significant pre-test differences in demographic characteristics were more 8th graders and fewer 12th graders in the treatment group at pre-test—although the mean age of the two groups did not differ (Table 1). At posttest there continued to be more 8th graders in the treatment group, but again, no differences in mean age in the two groups at posttest or follow up.

There were no statistically significant between-group differences at pre-test in smoking characteristics (Table 2). Although those in the ACTION group had slightly longer time periods of abstinence during quit attempts in the past three months, this difference was not statistically significant. Notably, 15% of the participants indicated that they were not at all motivated to quit smoking, even though they were voluntarily enrolled in this smoking cessation study. Similarly, nearly one-fourth of participants reported on the stages of change questionnaire that they were not considering quitting during the next six months. Thus, a substantial portion of our sample apparently entered this study with little intention of quitting.

There were no statistically significant between-group differences at pre-test on smokeless tobacco use characteristics. Notably, reflective of the fact that girls rarely if ever use smokeless

⁶At pre-test and at post-test, there were seven ACTION schools and seven comparison schools. At 90-day follow-up, one ACTION school did not contribute data, though it only accounted for two students.

tobacco, less than half of our participants reported using smokeless tobacco during the past 30 days, limiting the likelihood of finding differences among those who actually did use.

4.2. False Reporting of Abstinence

We found a high degree of false reporting about abstinence from tobacco. At post-test, 61% of those who reported abstinence from tobacco use for three or more days had positive (> 11.4 ng/ml) cotinine test results. At 90-day follow-up, 38% of those who reported abstinence from tobacco use for three or more days had positive cotinine test results. There was no difference in false reporting rates between conditions. All reported analyses on our primary outcomes include only students for whom we could biochemically verify had not used tobacco for at least three days.

4.3. Intent-to-Treat Analysis on Primary Outcomes

At post-test, biochemical verification of 3-day abstinence was achieved by 15 of 261 participants (5.7%)—six students in the ACTION condition (4.9%) and nine students in the comparison condition (6.5%). (See Table 3.) Also at post-test, 7-day abstinence with 3-day verification was achieved by 7 of 261 participants (2.7%)—four students in the ACTION condition (3.3%) and three students in the comparison condition (2.2%). At 90-day follow-up, biochemical verification of 3-day abstinence was achieved by 13 students (4.6%)—nine in the ACTION condition (7.3%) and four in the comparison group (2.9%). Also at 90-day follow-up, 7-day abstinence with 3-day verification was achieved by 12 of 261 participants (4.6%)—9 students in the ACTION condition (7.3%) and 3 students in the comparison condition (2.2%).

In mixed models the ICC at both classroom and school levels was 0.00, indicating virtually no class- and school-level clustering. These models, which included the condition variable as the predictor, and age and gender as covariates, found no statistically significant condition effect at post-test or 90-day follow-up. The condition effect for 7-day abstinence with 3-day verification at 90-day follow-up did, however, approach statistical significance [β (SE) = 1.30 (0.68) $p = .08$; OR (CI) = 3.68 (0.83 – 16.39)].

4.3. Per Protocol Analysis

To establish treatment group equivalence at pre-test in the per-protocol population, we compared treatment groups on the pre-test demographic and tobacco use characteristics. This analysis indicated that students in the per-protocol population did not differ significantly by condition assignment at pre-test, except for the following: (1) among the 229 students in the per-protocol population at posttest, there were significantly more 8th graders and fewer 12th graders in the ACTION condition (as was the case for the ITT population); and (2) among both the 229 students in the per-protocol sample at posttest and the 181 students in the per-protocol sample at follow up, ACTION participants reported significantly longer periods of time (in days) in the past three months during which they abstained from cigarettes because they were trying to quit. To control for pre-test group differences, we added motivation to quit as a covariate in all subsequent PP analyses, along with sex, age, and the pre-test score of the dependent variable of interest.⁷

4.3.1. Primary Outcomes—As shown in Table 3, at post-test, biochemical verification of 3-day abstinence was achieved by 15 of 229 participants (6.6%)—six students in the ACTION condition (5.6%) and nine students in the comparison condition (7.4%).⁸ Also at post-test, 7-

⁷We considered using number of days abstinent among those who tried to quit as the covariate, given that the groups differed on this variable. However, this resulted in too many missing cases in subsequent analyses because not all participants had tried to quit.

⁸The positive responses for abstinence did not change between the IT and the PP analyses.; the number of people who did not respond positively changed.

day abstinence with 3-day verification was achieved by 7 of 229 participants (3.1%)—four students in the ACTION condition (3.7%) and three students in the comparison condition (2.5%). At 90-day follow-up, biochemical verification of 3-day abstinence was achieved by 13 students (7.2%)—nine in the ACTION condition (11.1%) and four in the comparison group (4%). Also at 90-day follow-up, 7-day abstinence with 3-day verification was achieved by 12 (6.6%)—9 students in the ACTION condition (11.1%) and 3 students in the comparison condition (3.0%).

In mixed models the ICC at both classroom and school levels was again 0.00, indicating virtually no class- and school-level clustering. We found no statistically significant differences at post-test. Group differences were significant at 90-day follow-up for 3-day abstinence with verification [β (SE) = 1.49 (.72) p = .048; OR (CI) = 4.46 (1.02 – 19.52)] and 7-day abstinence with 3-day verification [β (SE) = 1.49 (.72) p = .049; OR (CI) = 4.44 (1.01 – 19.49)].

4.3.2. Secondary Outcomes—Using 3-level longitudinal mixed models, we assessed differences on the secondary outcomes over time, controlling for age, sex, and motivation to not smoke cigarettes at pre-test. We found no significant condition effects (i.e., no significant condition $\times$ time interaction). However, ACTION students consistently reported slightly more favorable adjusted mean scores on the secondary outcomes, relative to comparison students (see Table 5). We did find a statistically significant effect for data collection time point (that is, improvement in scores for students in both ACTION and the comparison condition over time), for the following secondary outcomes: past 7-day frequency of cigarette use [β (SE) = $-.72$ (.14) p < .001]; past 7-day number of cigarettes smoked per day [β (SE) = $-.72$ (.14) p < .001]; and number of intentional cigarette quit attempts [β (SE) = -1.89 (.41) p < .001].

We found parallel results when looking at our secondary outcomes for smokeless tobacco. That is, we found no significant condition effects (i.e., no significant condition $\times$ time interaction), but students in the ACTION condition consistently reported more favorable least squares mean scores on these secondary outcomes, relative to comparison students. We also found a significant effect of time on past 7-day frequency of use—that is, improvement in scores for students in both the ACTION and comparison conditions over time on this outcome [β (SE) = $-.70$ (.19) p < .001].

4.3.3. Mediators—In 3-level multi-level growth models of the mediator nicotine dependence, controlling for age, sex, and motivation to not smoke cigarettes at pre-test, we found no significant condition effects. We found a significant effect of time, with reductions in nicotine dependence for students in both the ACTION and comparison conditions over time. In 2-level mixed models of the dichotomized outcome variable stage of change regarding readiness to quit smoking or using smokeless tobacco (where 0 = Precontemplation or Contemplation and 1 = Preparation), controlling for the pre-test dichotomized stage of change score, age, sex, and motivation to not smoke cigarettes at pre-test, we found no significant condition effects at post-test or follow up. Again, we found a significant effect of time, with increases in readiness to quit for students in both the ACTION and comparison conditions over time. In 3-level multi-level growth models of the mediator motivation to quit smoking or using smokeless tobacco, controlling for age, sex, and motivation to not smoke cigarettes at pre-test, we found no significant condition effects. We did not find an effect for time on motivation to quit.

4.3.4. Process Measures—T-tests on mean scale scores of our process measures indicated that students assigned the ACTION program had significantly higher acceptability scale scores compared to students in the comparison group, for all four scales: situation management (t = 2.61, p = .01), cessation skills (t = 4.40, p < .001), program likeability (t = 1.99, p = .05), and facilitator likeability (t = 2.79, p = .01), although scores were generally high for both groups.

Of the 209 students supplying attendance data, 184 (88%) completed four or more program sessions. Although students in the comparison condition had slightly higher mean attendance rates, these rates were not statistically different by condition.

We analyzed our fidelity data for 11 of the 12 classes that participated in the ACTION condition.⁹ On average, facilitators covered about half (53%) of the intended content with each class. Across the sites, the content taught ranged from slightly more than one-third (37%) to 80%. In general, the facilitators were liberal with adding material—on average, they introduced additional content to 76% of the activities. In all classes, material was added during at least three of the five activities. In some classes, additional material was introduced with every activity. For quality of delivery, the mean for all groups was 3.4, with a minimum score of 2.3 and a maximum score of 4.0. This indicates strong program quality overall, but it is important to note that only half the curriculum was delivered and, for better or for worse, facilitators exercised great freedom when introducing additional material into each session.

We also examined whether there was a fidelity effect on the primary outcomes. In multilevel models controlling for age, gender, and motivation to quit smoking at pre-test, there were no significant effects of the dichotomized fidelity scores on the primary outcomes. In longitudinal mixed models of the secondary outcomes, controlling for age, gender, and motivation to quit smoking at pre-test, we found two significant effects for the time by fidelity score interaction: students in classrooms in which teachers demonstrated high fidelity to the curriculum reported more days of abstinence from cigarettes; but students in classrooms in which teachers demonstrated high fidelity reported using chewing tobacco *more often* in the past seven days.

5. Discussion

In this group randomized trial of an adolescent smoking cessation, we found two significant program effects. Using a per protocol approach with mixed model analyses, we found that ACTION participants were more likely than comparison participants to achieve 3-day abstinence with verification and 7-day abstinence with 3-day verification at 90-day follow-up. (Using an intent-to-treat approach, 7-day abstinence with 3-day verification approached statistical significance at 90-day follow-up.) We found no differences between our ACTION and comparison students on our secondary outcomes or on our mediating factors. For all the secondary outcomes and mediators, however, ACTION participants reported adjusted means in the more favorable direction than did comparison participants. We found consistent effects for time, with students in the ACTION and comparison condition reporting reduced tobacco use behaviors over time. ACTION students reported higher levels of program acceptability than comparison participants, although both groups' ratings were high. And, finally, we found varying degrees of program fidelity, with only half the content of the ACTION curriculum delivered, on average. Further analyses revealed that fidelity had limited, and mixed, impact on program outcomes.

Despite these equivocal program effects, it is noteworthy that the difference in abstinence rates at 90-day follow-up between the ACTION and comparison conditions was more pronounced than differences reported in the recent meta-analysis conducted by Sussman and his colleagues of 48 teen smoking programs (Sussman et al., 2006), using the ITT approach. In our study, we found that 7.3% of ACTION students and 2.9% of comparison students abstained from tobacco use for at least three days (with biochemical verification) at 90-day follow-up. In Sussman's terms, the net effect (or absolute risk reduction) of the program on 3-day abstinence was 4.4%, with ACTION students experiencing an increased probability of quitting by 152%. This compares favorably to the meta-analysis, which found the average net effect of smoking

⁹One facilitator neglected to send in the tape for one of the classes in the school

cessation programs is 2.9%, increasing the probability of quitting by 46% (Sussman et al., 2006).

One possible reason for the lack of statistically significant findings was that the study was likely underpowered to detect any effects that were present. At the outset of the study, we anticipated recruiting 20 schools (10 per condition) with 20 students per school (after estimated attrition). In the actual study, only 14 schools participated, with an average of 19 students per school at pre-test. In addition, we had predicted a larger difference in abstinence between the treatment and comparison conditions (12 percentage points) based on a 1999 review of the literature by Sussman et al. The more recent meta-analysis revealed a much smaller average difference between treatment and comparison conditions (2.2 percentage points), thereby increasing even more the power necessary to detect significant differences. Nevertheless, had the study reached its recruitment and retention goals, it would have been adequately powered to detect an effect on the primary outcomes with our ITT approach.

It is noteworthy that differences in abstinence rates between ACTION and comparison students were more pronounced at 90-day follow-up than at immediate post-test. This would seem to contradict conventional wisdom that differences between treatment and controls decay over time. In our study, they increased over time. This may partly be the result of having an “active” comparison condition, which may have had a limited and temporary effect on participants. For instance, at post-test, nine comparison participants achieved 3-day abstinence with biochemical verification, but only four achieved abstinence at 90-day follow-up. More telling, however, is the fact that the number of ACTION students who achieved 3-day abstinence with verification actually increased from six at post-test to nine at 90-day follow-up. Thus, it appears that the ACTION program provided students with a set of skills that they were able to practice and carry with them after the intervention ended, unlike the comparison condition.

We also found very high levels of false reporting by students at post-test (61%), but lower levels of false reporting at 90-day follow-up (38%). Students may have been more inclined to provide socially desirable responses for the benefit of the instructor immediately after the sessions ended, but the need to “please” the instructor may have waned after several months (noting, of course, that students’ responses were not known by the instructor at either point in time). The false reporting rates were similar to the 50% rate obtained in a small sample of participants from a recent randomized controlled trial of a smoking cessation program (Robinson, Vander Weg, Riedel, Klesges, & McLain-Allen, 2003) and lends support to the methods used here to verify abstinence reporting.

There were several methodological limitations to this study. The most prominent, perhaps, was the lack of power to detect effects. As the above discussion suggests, future school-based studies of adolescent smoking cessation may need to involve many more schools than had previously been thought, given the lower effect sizes that are now apparent. Another approach to these studies may be to randomize individuals into groups within schools, thereby increasing power by allowing the individual to be the unit of analysis. (This, of course, creates other problems, such as potential contamination between groups.) The second limitation is that we were not able to collect data beyond the 90-day follow-up. Longer-term data collection would have been particularly interesting in this study, given the increased abstinence between post-test and 90-days. The third limitation is that facilitators apparently delivered only about half the intended curriculum. The need for facilitators to deliver programs with fidelity to the program design is well documented (Dusenbury, Brannigan, Falco, & Hansen, 2003), though the best approach for increasing fidelity is not (Ringwalt et al., in press). Nevertheless, the lack of adherence to the curriculum content in this study may have limited the potential strength of the program. Fourth, our sample included a high percent of students who were apparently neither motivated to quit nor even thinking about quitting their tobacco use at the outset of the

study. We had anticipated that nearly all students who enrolled in this voluntary study would have done so because they were ready to begin the process of quitting tobacco use—but that was not the case. In several schools, for instance, participation in the study was evidently offered as an alternative to suspension for a tobacco-use violation on school grounds. In addition, it is possible that the incentives offered to students to participate attracted students who were not actually motivated to quit. Thus, a large portion of our study sample may not have been suited for a study on smoking cessation (although participants in both conditions reported a higher degree of readiness to quit over time). Finally, we did not include any measures of cost-effectiveness of ACTION versus the comparison. Thus, we do not know whether the modest gains achieved with the ACTION program are a worthwhile investment when compared with the cost of delivering the intervention (including facilitator training, as well as student recruitment and retention).

Despite these methodological limitations, there were several strengths to this study. First, it was a group, randomized control study. Only 19 of the 48 “controlled” studies in Sussman’s meta-analysis involved randomization to condition. Thus, this is one of a relatively small number of studies to employ a rigorous research design. Second, we used mixed models in our analyses to account for clustering effects that occur when individuals are randomized by groups. As far as we can tell, this is one of the few group randomized studies to do so. By not accounting for clustering, positive effects found in previous studies may have been overstated. Third, we collected biochemical data from all our participants during all waves of data collection. Again, this appears to be one of the few studies to do so; and the importance of such data was underscored by false reporting rates of more than 60% at post-test. Finally, we collected data on program fidelity, allowing us to determine the extent to which instructors adhered to the ACTION curriculum. This will allow the program developers to further refine the curriculum and provide guidance to instructors on how to better adhere to the curriculum.

This study suggests that ACTION has promise as a relatively effective adolescent cessation program, although the overall limited effectiveness of cessation programs for adolescents must be acknowledged. Further study is warranted, with a longer follow-up period, better facilitator monitoring to increase program fidelity, a cost-effectiveness component, and a more targeted group of adolescents (i.e., more motivated to quit). Such a study could help determine if the program effects found in this study are sustained and whether the modest effect sizes of smoking cessation programs, in general, and the ACTION program, in particular, are more valuable to society than their cost.

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Table 1

Sample demographics by time point

Variable	Pre-test			Post test			Follow up		
	Total (n=261)	ACTION (n=123)	Comp (n=138)	Total (n=229)	ACTION (n=108)	Comp (n=121)	Total (n=181)	ACTION (n=81)	Comp (n=100)
Age, yrs, mean (SD)	16.1 (1.04)	16.0 (1.05)	16.2 (1.03)	16.3 (1.04)	16.2 (1.08)	16.4 (0.99)	16.4 (1.07)	16.3 (1.07)	16.5 (1.07)
Sex, n (%) male	162 (62.1)	77 (62.6)	85 (61.6)	141 (61.6)	67 (62.0)	74 (61.2)	116 (64.1)	57 (69.5)	59 (59.6)
Race, n (%) white	245 (93.9)	118 (95.9)	127 (92.0)	217 (94.8)	104 (96.3)	113 (93.4)	175 (96.7)	79 (96.3)	96 (97.0)
Hispanic, n (%)	6 (2.3)	3 (2.4)	3 (2.2)	3 (1.3)	0 (0.0)	3 (2.5)	4 (2.2)	1 (1.2)	3 (3.0)
Grade, n (%)									
8 th or lower	8 (3.1)	7 (5.7)	1 [*] (0.7)	7 (3.1)	7 (6.5)	0 ^{**} (0.0)	3 (1.7)	2 (2.4)	1 (1.01)
9 th	36 (13.8)	17 (13.8)	19 (13.8)	35 (15.3)	17 (15.7)	18 (14.9)	27 (14.9)	12 (14.6)	15 (15.2)
10 th	89 (34.1)	42 (34.2)	47 (34.1)	78 (34.1)	36 (33.3)	42 (34.7)	61 (33.7)	28 (34.2)	33 (33.3)
11 th	78 (29.9)	40 (32.5)	38 (27.5)	68 (29.7)	31 (28.7)	37 (30.6)	56 (30.9)	30 (36.6)	26 (26.3)
12 th	50 (19.2)	17 (13.8)	33 [*] (23.9)	41 (17.9)	17 (15.7)	24 (19.8)	34 (18.8)	10 (12.2)	24 (24.2)

* p < .05,
*** p < .01

Table 2

Pre-test smoking characteristics

Variable	ACTION (n=123) ^a	Comparison (n=138) ^a
Exposure to cigarettes, mean (SD)	2.4 (0.73)	2.5 (0.67)
Age of first use in years, mean (SD) ^b	11.4 (2.26)	11.1 (2.16)
Past 30 days frequency of use, n (%)		
None	16 (13.0)	18 (13.0)
Weekly or less	8 (6.5)	4 (2.9)
More than weekly, less than daily	24 (19.5)	34 (24.6)
Daily	75 (61.0)	82 (59.4)
Number of quit attempts during past 3 months, n (%) ^b		
0	39 (38.6)	48 (40.7)
1	21 (20.8)	23 (19.5)
2	18 (17.8)	22 (18.6)
3 to 5	14 (13.9)	15 (12.7)
6 to 9	5 (5.0)	5 (4.2)
10 or more	4 (4.0)	5 (4.2)
Longest period of time abstinent in past 3 months during quit attempts, n (%) ^b		
Less than a day	7 (5.4)	8 (6.2)
1 to 2 days	15 (11.5)	24 (18.5)
3 to 7 days	19 (14.6)	22 (16.9)
8 to 30 days	14 (10.8)	9 (6.9)
31 to 60 days	3 (2.3)	2 (1.5)
61 to 90 days	4 (3.1)	3 (2.3)
Number of days since last smoked, n (%) ^b		
More than 3 days ago	6 (5.7)	6 (5.1)
3 days ago	3 (2.8)	3 (2.5)
2 days ago	4 (3.8)	8 (6.8)
1 day ago	11 (10.4)	13 (11.0)
Today	82 (77.4)	88 (74.6)
Stage of change, n (%) ^b		
Precontemplation	24 (24.2)	29 (25.9)
Contemplation	24 (24.2)	22 (19.6)
Preparation	51 (51.5)	61 (54.5)
Action	0 (0.0)	0 (0.0)
Heavy smokers (> 15 cigs/day) n (%) ^b	36 (33.6)	38 (31.9)
Motivation to quit smoking n (%) ^b		
Not at all	18 (17.3)	16 (13.6)
A little	34 (32.7)	45 (38.1)
Moderately	39 (37.5)	41 (34.8)
Extremely	13 (12.5)	16 (13.6)
Modified Fagerstrom score, mean (SD) ^c		
Method A (NCI)	5.5 (1.54)	5.4 (1.68)

Variable	ACTION (n=123) ^a	Comparison (n=138) ^a
Method B (Prokhorov <i>et al.</i> , 2000)	4.7 (1.24)	4.7 (1.33)

^aTotals do not always equal number of participants because not all participants completed every survey item.

^bAmong current smokers.

^c0–2 = no dependence, 3–5 = moderate dependence, and 6–9 = substantial dependence.

Table 3
Frequencies on primary outcomes by condition and time point (ITT and PP population)

Outcome	Condition	Number	ITT		PP	
			OR	CI	OR	CI
POST-TEST (n = 108 ACTION, 121 comparison)						
3-day abstinence	ACTION	6				
	Comparison	9				
	Total	15	0.77	0.24 – 2.54	1.05	0.35 – 3.20
7-day abstinence	ACTION	4				
	Comparison	3				
	Total	7	1.60	0.29 – 8.80	1.56	0.32 – 7.71
90-DAY FOLLOW UP (n = 81 ACTION, 100 comparison)						
3-day abstinence	ACTION	9				
	Comparison	4				
	Total	13	2.66	0.69 – 10.24	4.46	1.02 – 19.52*
7-day abstinence	ACTION	9				
	Comparison	3				
	Total	12	3.68	0.83 – 16.39	4.44	1.01 – 19.49*

*
p<.05

Table 4

Least Squares Means (SEs), Beta coefficients, and p-values for condition effects from 3-level multi-level growth models of cigarette use secondary outcomes, controlling for age, gender, and motivation to not smoke cigarettes at pre-test assessment

Outcome		LS Mean (SE)	Beta (SE)	p-value
Past 7-day frequency of use (days)	ACTION	5.27 (.19)	-.10 (.18)	.5903
	Comparison	5.36 (.18)		
Past 7-day amount used (# of cigarettes per day)	ACTION	9.75 (.64)	-.02 (.55)	.9689
	Comparison	9.95 (.60)		
Number of intentional quit attempts	ACTION	2.85 (.36)	.32 (.25)	.2035
	Comparison	2.08 (.34)		
Number of days abstinent	ACTION	9.24 (1.12)	-.83 (1.74)	.6332
	Comparison	8.07 (1.07)		