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Addressing Challenges in Adolescent Smoking Cessation: Design and Baseline Characteristics of the HS Group-Randomized Trial

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Abstract

Objective—Well-documented challenges have hampered both intervention development and research in teen smoking cessation. Addressing these challenges, the Hutchinson Study of High School Smoking (HS Study), the largest group-randomized trial in adolescent smoking cessation to date, incorporates several design innovations to investigate the effect of a counselor-initiated, individually tailored telephone counseling smoking cessation intervention for older adolescents. This paper presents and discusses these innovative design features, and baseline findings on the resulting study population.

Method—The trial used a population-based survey to proactively identify and recruit all high school juniors who had smoked in the past month—potentially expanding intervention reach to all smokers, even those who smoked less than daily and those not motivated to quit. For ethical and intervention reasons, some nonsmokers were enrolled in the intervention, also. Other important design features included the random allocation of schools into experimental conditions (intervention vs. no-intervention control) and a multi-wave design.

Results & Conclusion—The design innovations address problems and challenges identified in adolescent smoking cessation literature. The heterogeneous baseline characteristics of the study population, well-balanced between the two arms, have three significant implications: They (1) demonstrate the effectiveness of the trial's design features, (2) highlight several intervention-related issues, and (3) provide assurance that the trial's evaluation of intervention effectiveness will be unbiased.

Keywords

adolescent; smoking cessation; randomized trial; group-randomized; cessation intervention; proactive intervention; telephone counseling; youth

Introduction

Despite an 8-year gradual decline, U.S. adolescent smoking rates remain unacceptably high: One in four high school seniors smokes at least monthly, and 15% smoke daily (Johnston et

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al., 2005). These rates are alarming because adolescents who smoke regularly are at increased risk for a variety of health problems. Moreover, their risk of serious health consequences increases with the length of time and amount they smoke (U.S. Department of Health and Human Services, 1989; Hozawa et al., 2006), and for the majority of adolescent smokers, smoking will be a long-term addiction (Chassin et al., 1996; Chen and Kandel, 1995; Kandel and Logan, 1984; Bachman et al., 1997; Pierce and Gilpin, 1996).

Many young smokers, however, want to quit and seriously attempt to do so (Centers for Disease Control and Prevention, 2006; Allen et al., 1993; Burt and Peterson, 1998). Unfortunately, their self-initiated cessation rate is low (Zhu et al., 1999; Sussman et al., 1998; Stanton et al., 1996), and quitting grows more difficult with age as the amount smoked and level of dependence increase (COMMIT, 1995; U.S. Department of Health and Human Services, 1989). Young smokers' desire to quit, the low rates of abstinence achieved without assistance, and the consequences of smoking into adulthood all support the need for strong, theory-based cessation interventions and rigorous randomized trials to evaluate their effectiveness.

Despite this pressing need, multiple, well-documented challenges have hampered development of interventions for teen smokers. First, teens smoke with greater variability and irregularity than adults: While some youth are regular, daily smokers exhibiting symptoms of addiction, many are light or infrequent smokers, and still others smoke only under limited circumstances (Mermelstein, 2003; Backinger, McDonald et al., 2003; Mermelstein et al., 2002; Baillie et al., 2005; Kishchuk et al., 2004). Also, some adolescents do not view their smoking as a serious problem, and even those who want to quit have been unenthusiastic about potentially helpful cessation strategies (Balch, 1998; Patten et al., 2004; Balch et al., 2004; Massey et al., 2003; Leatherdale and McDonald, 2005). Other noted intervention obstacles include adolescents' concerns regarding privacy (McCormick et al., 1999; Massey et al., 2003; Gillespie et al., 1995; Balch, 1998; Moolchan and Mermelstein, 2002) and loss of autonomy (Balch, 1998; Balch et al., 2004), and limited relevance and accessibility to teens of cessation programs (Balch, 1998; Patten et al., 2003; Balch et al., 2004; Massey et al., 2003; Leatherdale and McDonald, 2005).

Conducting methodologically rigorous research with adolescent smokers has also been a challenge. First, identifying and reaching teen smokers is difficult: Prior teen smoking cessation studies have been conducted primarily in self-selected or convenience samples of small size (McDonald et al., 2003; Sussman 2002), limiting the trials' generalizability. Second, past adolescent cessation studies have mostly focused on daily smokers, with little attention paid to infrequent smokers (Backinger, Fagan et al., 2003): In a recent meta-analysis of 48 adolescent cessation trials, the level of baseline smoking averaged 10.44 cigarettes per day (Sussman, 2006), reflecting the prevalent research interest in daily smokers. Because infrequent smokers constitute a sizable portion of adolescent smokers (Centers for Disease Control and Prevention, 2006; Johnston et al., 2006; Mowery et al., 2004), are at high risk of smoking escalation and adult smoking (Bricker et al., 2006; Centers for Disease Control and Prevention, 1998; Choi et al., 1997; Chassin et al., 1990), and have difficulties quitting smoking (CDC, 1994), expanding research to include infrequent smokers is an important next step. Third, much of the published literature on adolescent smoking cessation consists of uncontrolled, nonrandomized, or single-group studies (Sussman, 2002), providing weak tests of program effectiveness. Finally, in-depth reporting of study populations, methods and outcomes is often neglected, despite its importance for research communication and assessment. Underreporting of such important information has impeded comprehensive literature reviews (McDonald et al., 2003; Sussman 2002) and meta-analyses (Sussman 2006), and has limited knowledge accumulation in the field of adolescent smoking cessation.

Designed to overcome identified methodological challenges and rigorously test an innovative smoking cessation intervention for older adolescents, the Hutchinson Study of High School Smoking (HS Study) is the largest group-randomized trial in adolescent smoking cessation to date, with 2,151 adolescent smokers from 50 high schools. The trial used a population-based survey to proactively identify and recruit all high school juniors who had smoked in the past month, thus potentially expanding intervention reach to all smokers and capturing a heterogeneous sample of older teen smokers. With its rigorous group-randomized design, the study will evaluate the extent to which a counselor-initiated, individually tailored telephone counseling intervention can effect smoking cessation among a heterogeneous population of older adolescent smokers.

This paper presents the trial's intervention and experimental design, with a focus on innovative features that were developed to overcome the identified challenges, and describes the resulting study population of older teen smokers and the degree of balance in important baseline characteristics of these teens between the two experimental conditions.

Intervention Design

The smoking cessation intervention incorporates multiple strategies to address known intervention obstacles (Kealey et al., 2007), including (1) *proactively* identify smokers in the population and directly invite their participation; (2) include *both* smokers and nonsmokers as participants to protect smokers' privacy; (3) use the *telephone* to proactively deliver the intervention; (4) allow *unlimited* calls to reach adolescents; (5) *tailor* the intervention to the individual; and (6) communicate *respect* for adolescents and their choices.

The intervention, based on Social Cognitive Theory (Bandura, 1977, 1986), incorporates both Motivational Interviewing (MI) (Miller and Rollnick, 1991, 2002), to increase smokers' own motivation and commitment for quitting smoking, and cognitive behavioral skills training (Baer et al., 1999), to build skills for smoking cessation and relapse prevention. MI was chosen for its early promise in reducing adult smoking (Zhu et al., 1996; Britt et al., 1994; Curry et al., 1995), and its nonjudgmental, nonprescriptive style is appropriate for adolescent smokers (Lawendowski, 1998).

The intervention was delivered via counselor-initiated telephone calls, providing the privacy and personalization of face-to-face counseling but at a lower cost. Also, because many teens have continuous access to a telephone, proactive telephone interventions make participation easy for teens, and allow programs to involve *all* smokers, including precontemplative and infrequent smokers who typically are not reached by cessation programs that respond to teen initiative. Furthermore, personalized counseling tailored the intervention's content and dose to each smoker's needs and readiness to quit, thereby enhancing relevance, and increasing teen receptivity.

The intervention was implemented (in the experimental condition) during the participants' senior year of high school. Prior to contacting adolescents, consent for intervention participation from parents of minor-age teens was obtained via mail, with telephone follow-up. Informed consent was conducted with adolescents via the telephone, following receipt of an informational mailer.

As noted, smokers in the trial were identified via a confidential baseline survey and then invited to participate in the intervention. Such a proactive approach enables the recruitment of a wide array of adolescent smokers; however, if self-reported survey data were used to contact *only* smokers, the confidentiality of those data could be breached, because contacting a smoker trial participant would reveal to an observer, e.g. anyone in the household, that the participant was smoker (Moolchan & Mermelstein, 2002). Including nonsmokers in the intervention, so it's

understood that both smokers and nonsmokers will be contacted, is an innovation designed to overcome this obstacle. (In accordance with this design feature, parents of trial participants were informed that both nonsmokers and smokers were enrolled in the intervention.) In addition, contacts with nonsmokers served two significant *intervention* functions: (1) to reinforce smoking abstinence among nonsmokers, and (2) to build motivation, skills and confidence for *supporting peers' efforts to quit smoking*, thus capitalizing on positive social interactions among teens.

Experimental Design

The experimental design of this two-arm group-randomized trial, shown in Figure 1, is described below.

Study population

To provide a population basis for evaluating the intervention effectiveness, 50 high schools were randomly selected from 168 Washington State public high schools that met the study's eligibility criteria: located within 200 miles of the Fred Hutchinson Cancer Research Center and with an enrollment of 100–500 seniors. In the 50 participating high schools, 12,141 (93.1% of 13,042 eligible) high school juniors completed the baseline survey. (Ineligible for survey were 1,188 juniors who were foreign exchange students, enrolled only in off-campus classes, or unable to read/understand English). Through the baseline survey, all smokers who were currently smoking at least monthly or had smoked in the past 30 days were identified for inclusion, based on a positive response to any of the following three survey items: (a) How often do you currently smoke cigarettes? (responded, “once a month or more”); (b) Have you smoked one or more cigarettes in the last 30 days? (responded, “yes”); (c) When was the last time you smoked, or even tried, a cigarette? (responded, “within the past 30 days”).

The selected sample of nonsmokers consisted of former smokers (those who reported they had smoked regularly before but had been abstinent for at least three months) and never smokers (those who reported smoking no more than two cigarettes in their lifetime, and none in the past month). To capitalize on the existing social network and positive social interactions, nonsmokers were preferably selected who self-reported having more smoking friends, higher level of willingness to help friends quit smoking, and greater interest in knowing more about how to help friends quit smoking.

A total of 2,175 smokers and 745 nonsmokers were identified and selected. Excluding 24 smokers and 2 nonsmokers who declined further contact in the baseline survey, the trial cohort consisted of 2,151 smokers and 743 nonsmokers.

Experimental unit and conditions/random assignment

The experimental unit is the high school. This design choice not only prevented possible contamination due to social mixing of intervention-exposed students and unexposed students, but also enabled the trial to target all high school juniors in the school, and to capitalize on the interaction among smokers, and the interaction between nonsmokers and smokers as possible enhancement of intervention effectiveness. The 50 participating high schools were randomly assigned to either the experimental or control condition. To further ensure balance beyond what the randomization achieves between the two conditions, the randomization of schools was pair-matched by prevalence of smoking, number of smokers, cessation stage and percentage of students eligible for free/reduced-price school meals. The matched random assignment was performed via a computerized coin flip for each randomly ordered pair.

Baseline data collection

Baseline data were collected on both schools and students. Information on school demographics and smoking-related characteristics (e.g., rural/urban composition, staff smoking) was obtained via the Survey of High School Principals, which was mailed to each principal, with mail and telephone follow-up of non-responders.

The Survey of High School Juniors was used to collect baseline information on older teens' smoking as well as to identify trial participants. The in-class survey was administered in regular school classrooms by trained study staff, with a scripted explanation of survey procedures and study information. "Bogus pipeline" saliva samples were collected to encourage accurate self-reporting of smoking behavior (Murray et al., 1987; Murray and Perry, 1987). Students absent from the initial survey were contacted 2 weeks later for an in-class clean-up survey; those still absent were asked to complete a mailed or telephone survey.

Prior to the baseline survey, parents/guardians were mailed a letter describing the study, the survey, the saliva sample procedure, the confidential treatment of the data collected, and the voluntary nature of participation. The letter invited them to call a toll-free telephone number with questions or to decline their teen's participation.

Follow-up and outcomes

Multiple outcomes, including abstinence at 7 days, 1, 3 and 6 months, will be collected at approximately 6 months post intervention to answer the trial's main scientific questions. Follow-up procedures were designed to attain the highest possible response rates and minimize attrition, essential for reducing bias in the trial's findings.

Evaluation methods

Intervention effect, represented by differences between the two arms in endpoint outcomes (e.g. 6-month abstinence rate, 3-month abstinence rate), will be evaluated by group permutation-based methods (Lehman, 1975; Edgington, 1987; Gail et al., 1992). The permutation method of analysis acknowledges the intraclass correlation within individuals in the same school by permuting school, as opposed to individual, among a set of all possible intervention assignments, to calculate the test statistics and form a null distribution. The test statistic observed on the basis of the actual assignment is then referenced against this null distribution for hypothesis testing. Such analytic method avoids modeling and distribution assumptions, relying solely on the random assignment of intervention, and is flexible for covariate adjustment (Gail et al., 1996; Murray et al., 2006). Analysis of subgroups will also be conducted on the basis of strong empirical or theoretical evidence to detect differential intervention impact in specific subgroups.

Sample size calculation

The trial design acknowledged the group nature of the experimental unit and accounted for the within-school intraclass correlation in its sample size calculation, which used the following parameters: (1) 6-month abstinence rate of 0.06 at the study endpoint in the control group (Sussman et al., 1999; U.S. Department of Health and Human Services, 1989; Lando et al., 1992), (2) 90% participation rate in endpoint data collection, based on prior experience on the Hutchinson Smoking Prevention Project (HSPP), a 12-year trial on adolescent smoking (Peterson et al., 2000), (3) intraclass correlation coefficient for cessation among high school senior smokers, conservatively estimated as 0.025 from the prior HSPP data on cessation among high school seniors, (4) resulting variance inflation factor of 2.11, (5) two-sided test that accommodates the intraclass correlation, and (6) $\alpha = .05$. Thus, the trial has included enough schools and trial participants to evaluate intervention effectiveness. Specifically, 50

high schools with 2,150 smoker trial participants (43 per school) provide a statistical power of 89% for a cessation fraction of .12 in the intervention arm.

Phase-in of trial activities

The trial used a “wave” design in which recruitment of high schools and subsequent activities were phased-in over 3 years. A total of 14 high schools with 515 smoker trial participants were recruited in the first year (2002), 20 schools with 966 smokers in the second year and 16 schools with 670 smokers in the third year.

Human subject approval

The HS Study intervention, experimental design, procedures and instruments were reviewed and approved by the Hutchinson Center’s Institutional Review Board.

Baseline Results

Baseline characteristics

All the percentages reported below used the number of valid responses as denominator. Unless stated otherwise, percentages of valid data range from 86% to 100%.

The 50 participating high schools had an average enrollment of 1,224 students (SD: 527.7), ranging from 204 to 2,376 students. The percentage of students eligible for free/reduced price school meals is one indication of a school’s socioeconomic status; the average of this percentage for participating schools was 24.6% (SD: 13.7%). For 21 (46.7%) high schools, more than 50% of families lived in rural areas; for 18 (40%) high schools, fewer than 25% of families did so.

Almost half (49.4%) of the 12,141 baseline survey respondents were female. Race/ethnic composition was 73.5% White, 7.2% multiple races/ethnicity, 6.4% Asian, 6.1% Hispanic, 2.9% Black, 1.4% Native Hawaiian or other Pacific Islander, 1.3% American Indian, and 1.5% other. Almost all (94.9%) survey participants were age 16 or 17 at the time of survey; only 28 (.2%) were younger than 16, and 597 (4.9%) were older than 17. Among these high school juniors, 2,175 (17.9%) were identified as smokers; 794 (6.8%) reported at least daily smoking.

Baseline data on important variables (i.e., population descriptors, known predictors of adolescent smoking cessation) are presented in Table 1 for the 2,151 smoker trial participants. Characteristics of smoker trial participants in each condition, as well as overall, are presented side-by-side, so that the degree of balance between the two arms can be observed. Because the randomization ensures that the null hypothesis of balance except for chance variation is true (Donner & Klar, 2000; Murray, 1998), statistical tests for such a null hypothesis are not needed. Nonetheless, at the suggestion of a referee, *p*-values are provided to show where in the randomized distribution the differences between experimental and control condition lie. They were calculated on the basis of two-sample *t*-test using school as the unit of analysis, appropriate for the group nature of the random assignment.

As shown in Table 1, the smoker trial participants have diverse smoking patterns. With regard to cumulative use of cigarettes, about as many (52.4%) reported having smoked more than 100 cigarettes as reported having smoked 100 cigarettes or fewer (47.6%). With regard to smoking frequency, 37.2% of these smokers were smoking at least daily, with 62.8% smoking less than daily, and a sizeable 28.2% smoking less than monthly. A majority of smokers (69.9%) reported having strong or medium motivation to quit, but a significant minority (30.1%) lacked motivation. Only 11.4% of these smokers reported wanting help with quitting.

Examination of the two rightmost columns in Table 1 indicates that the smoker trial participants in experimental and control conditions were very similar with regard to most characteristics. One exception is the percentage of daily smokers (39.9% in experimental vs. 34.5% in control).

In light of the diversity of smoking frequency among smokers, Table 2 presents quitting variables (e.g., past quit attempt, motivation to smoke in the future) by smoking frequency. Almost 60% of daily smokers reported past quit attempts, compared to 34.2% of less-than-monthly smokers and 36.5% of monthly-but-not-weekly smokers. However, a majority (73.3%) of the less-than-monthly smokers reported no intentions to smoke in the future, while almost half (48.8%) of daily smokers reported intentions to do so. Higher-frequency smokers consistently reported lower motivation to quit and lower self-efficacy for quitting.

Nonsmoker trial participants consisted of 419 (56.4%) never smokers and 324 (43.6%) former smokers. Over half (58.3%) of them were female. The ethnic distribution was diverse: 71.7% White, 8.5% multiple ethnicity, 6.9% Hispanic, 5.1% Asian, 2.8% Black, 2% American Indian, 2% Native Hawaiian or other Pacific Islander, and 1% other. The majority (91.4%) of nonsmoker trial participants were 16 or 17 years old.

Discussion

Experimental design

The HS Study, involving 2,151 older adolescent smokers from 50 high schools, is the *largest* group-randomized trial in adolescent smoking cessation to date. Among the many design features included in the trial to overcome problems identified in adolescent smoking cessation literature, two major innovations are (1) proactive identification of smokers and (2) use of a liberal definition for smokers. The combination of these two innovations expanded intervention reach to even low-frequency teen smokers and smokers who were unmotivated to quit. To the authors' knowledge, the HS Study is the *first* adolescent smoking cessation trial to use a population-based survey to proactively identify and recruit participants to the intervention, and is also one of a very few studies that targeted daily and less-than-daily smokers (Sussman, 2002).

The proactive identification of teen smokers enables the recruitment of a population-based sample of teen smokers, *but* it also carries responsibilities for protecting the rights of study participants. If provisions were not made to avoid it, the use of self-reported data to contact individual smokers identified as such by the data would constitute a breach of confidentiality (Moolchan & Mermelstein, 2002). One such provision is to have both smokers and nonsmokers in the trial. In addition, including nonsmokers provides the intervention an opportunity to harness nonsmokers' support in helping their smoking friends to quit and, more important, an opportunity to evaluate the effectiveness of their doing so. Finally, as it turned out, including nonsmokers may have boosted recruitment of smokers to the intervention (Kealey et al, 2007).

The "Phase-in" or "Wave" design in the trial has provided significant advantages for management and design robustness. From the management/quality aspect, the use of Wave design is invaluable for it has (1) enabled project staff to participate fully in recruiting and establishing vital collaborative relationships with schools, (2) allowed the project to operate efficiently with high quality work, (3) reduced the annual cost of the study, and (4) permitted interim evaluation of the intervention process, and incorporation of refinements into subsequent waves as needed. From the aspect of experimental design, recruitment by wave enabled secular trends in population attributes used for sample size calculations to be accommodated. Specifically, in this trial, when a lower-than-expected smoking prevalence was identified in Wave I, the estimate of teen smoking prevalence used at the design stage was

updated using the actual prevalence observed in Wave I, and then the sample size calculations were updated accordingly. This corrective action led to the addition of four more schools in Wave II, and an entire new Wave (III) of 20 schools—sufficient for attaining the desired statistical power. In sum, this favorable experience from the trial supports the use of a Wave design in large group-randomized trials. It not only improves trial management and quality, but also provides a study design with the robustness to handle eventualities—either ones like those encountered in this trial, or others not anticipated at the start.

It is important to note that the experimental condition in this trial is an intervention with multiple components, while the control condition is a no-intervention control. Such design provides a rigorous framework to evaluate the impact of an intervention as a whole, but it is not intended for separating the effects of the various intervention components. In particular, as pointed out by a referee, this study can not separately investigate the effectiveness of the telephone *contact* and the effect of the intervention *content* during telephone contact. In contrast, this two-arm design is used to address first the fundamental question of whether the intervention, with all the components combined, works. Once evidence of overall effectiveness becomes established, subsequent studies could be conducted to distinguish the effect of the intervention components.

Baseline characteristics

One significant result of the trial's important design innovations is a heterogeneous study population of older adolescent smokers with varying rate and frequency of smoking, different level of motivation to quit, and various degree of receptivity to cessation assistance. The baseline findings describing the characteristics of this large and diverse population of older teen smokers not only provide valuable information for understanding young smokers, but also highlight intervention-related issues and challenges, many of which may have relevance to other studies in adolescent smoking cessation.

For example, over one-third of less-than-daily smokers reported having made at least one quit attempt in the past 12 months. That they were still smoking at the time of survey confirms the need to intervene with infrequent smokers. Additionally, the baseline survey found that infrequent smokers differed from frequent smokers with regard to their quitting behaviors and beliefs: More daily smokers at baseline had experience in trying to quit. Their past experience and knowledge in quitting could increase the probabilities of their achieving abstinence in the future (Redmond, 2002; Zhu et al., 1999); although infrequent smokers had less quitting experience than daily smokers, they reported stronger intentions not to smoke in the future, higher motivation to quit, and higher quitting self-efficacy, all strong predictors of successful quitting (Solomon et al., 2005; Redmond, 2002; Engels et al., 1998, Sussman et al., 1998; Zhu et al., 1999). Interventions with either one or both of these groups of teen smokers should be tailored to capitalize on their different quitting behaviors and beliefs.

The baseline results confirm data from previous studies that a majority of teen smokers do not want help with quitting (Balch et al., 2004; Leatherdale and MacDonald, 2005; Balch, 1998; Gillespie et al., 1995; Lynch and Bonnie, 1994). Interestingly, despite their self-reported resistance to cessation assistance, smokers in the experimental arm were receptive to proactive intervention recruitment (Kealey et al., 2007). Specifically, among eligible smokers who were successfully contacted, 81% participated in the intervention.

It is also noteworthy that the baseline survey observed a 30-day smoking prevalence of 17.9% among the high school juniors who participated in the survey (17.2%, 19.1%, 16.9% for Wave I in 2002, II in 2003 and III in 2004, respectively). These percentages were not only lower than expected, as discussed earlier, but also substantially lower than the national estimates for 12th graders (26.7% in 2002, 24.4% in 2003 and 25% in 2004 from Monitoring the Future Study)

(Johnston et al., 2005). This observed difference may be due to Washington's Tobacco Prevention and Control program: Cigarette smoking among Washington State youth has dropped by 48% since the program's launch in 2000 (Washington State Department of Health, 2005). Indeed, similar lower magnitudes in adolescent smoking prevalence have been observed in other states as a result of statewide tobacco control programs (Pierce et al., 2005; Siegel, 2002). While tobacco control efforts in Washington State may provide a more favorable social environment for this smoking cessation trial, another implication is that the remaining adolescent smokers may be more resistant to cessation efforts.

Baseline comparability

Examination of the smoker baseline characteristics between experimental and control conditions indicates that the randomized assignment of high schools generally resulted in good balance between the two conditions. Some mild imbalances between the two arms were identified, mainly in the percentage of daily smokers. However, given that multiple baseline variables are reported here, it is not surprising that a few imbalances are observed (Altman, 1985); the random assignment ensures that these small imbalances have arisen purely by chance (Assmann et al., 2000; Pocock et al., 2002). Nevertheless, such baseline imbalance will be accounted for in outcome data evaluation with covariate adjustments.

Summary

The Hutchinson Study of High School Smoking is the largest group-randomized trial to test a smoking cessation intervention among older adolescents. The study population was proactively identified and a liberal definition was used to pursue older teens who smoked at various levels. For ethical and intervention reasons, nonsmokers were also included as intervention target. Other design features with significant benefits include the group (school) randomization and the multi-wave design. Finally, the heterogeneous baseline characteristics of the study population, well-balanced between the two arms, have three important implications: First, they demonstrate the usefulness and effectiveness of the trial's experimental design features; Second, they highlight several intervention-related issues that would be encountered in other adolescent smoking cessation studies; Third, they provide assurance that the trial's evaluation of intervention effectiveness will be unbiased.

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¹ Absent during the in-class survey and did not reply to subsequent mailed/telephone surveys.

² Twenty-four smokers and two nonsmokers who declined further contact were excluded.

Figure 1.

Table 1
Baseline characteristics of 2,151 smoker trial participants^a, HS Study, WA, 2000–2008

Variable	All (%) (n = 2,151)	Control (%) (n = 1,093)	Experimental (%) (n = 1,058)
Demographic variables			
Gender			
Female	1,017 (47.3%)	505 (46.2%)	512 (48.4%)
Male	1,134 (52.7%)	588 (54.5%)	546 (51.6%)
<i>p-value for gender: 0.647</i>			
Ethnicity/Race			
White	1,583 (74.9%)	796 (72.1%)	787 (75.9%)
Multiple Races/Ethnicity	153 (7.2%)	78 (7.3%)	75 (7.2%)
Hispanic (unknown race)	114 (5.4%)	50 (4.7%)	64 (6.2%)
Asian	103 (4.9%)	67 (6.2%)	36 (3.5%)
American Indian or Alaska Native	54 (2.6%)	27 (2.5%)	27 (2.6%)
Black or African American	53 (2.5%)	32 (2.9%)	21 (2.0%)
Native Hawaiian or other islander	29 (1.4%)	12 (1.1%)	17 (1.6%)
<i>p-value for % of white: 0.612^b</i>			
Age at baseline data collection ^b			
<16 years old	2 (0.1%)	2 (0.2%)	0 (0.0%)
16 years old	656 (30.5%)	309 (28.3%)	347 (32.8%)
17 years old	1,333 (62.0%)	695 (63.6%)	638 (60.3%)
> 17 years old	160 (7.4%)	87 (8.0%)	73 (6.9%)
<i>p-value: 0.064</i>			
Current smoking and smoking history			
Number of cigs smoked in lifetime			
≤1	144 (6.9%)	71 (6.7%)	73 (7.0%)
2–100	865 (41.0%)	463 (43.4%)	402 (38.7%)
101–400	379 (18.0%)	199 (18.6%)	180 (17.3%)
> 400	723 (34.2%)	336 (31.4%)	387 (37.1%)
<i>p-value for % of ≥ 100 cigs: 0.226</i>			
Smoking frequency			
< Monthly	593 (28.2%)	314 (29.4%)	279 (26.9%)
≥ Monthly, < weekly	367 (17.4%)	190 (17.8%)	177 (17.1%)
≥ Weekly, < daily	362 (17.2%)	195 (18.3%)	167 (16.1%)
≥ Daily	782 (37.2%)	368 (34.5%)	414 (39.9%)
<i>p-value for % of daily smokers: 0.019</i>			
Current use of other tobacco products ^c			
Not at all	902 (43.6%)	463 (44.2%)	439 (42.9%)
Less than monthly	520 (25.1%)	261 (24.9%)	259 (25.3%)
At least monthly, but not daily	412 (11.3%)	214 (20.5%)	198 (19.3%)
Daily	237 (11.4%)	110 (10.5%)	127 (12.4%)
<i>p-value for % of no use: 0.659</i>			
Nicotine dependence among daily smokers ^d			
No symptoms	96 (12.5%)	47 (13.0%)	49 (12.1%)
1 or 2 symptoms	186 (24.3%)	90 (24.9%)	96 (23.7%)
3 or 4 symptoms	485 (63.2%)	225 (62.2%)	260 (64.2%)
<i>p-value for % of having 3 or 4 symptoms: 0.795</i>			
Age at first use			
≤ 8	153 (8.0%)	73 (7.6%)	80 (8.5%)
9–12	572 (30.0%)	267 (27.8%)	305 (32.4%)
13–16	1,008 (52.8%)	532 (55.0%)	476 (50.6%)
> 16	175 (9.2%)	95 (9.8%)	80 (8.5%)
<i>p-value for % of first use before 13 yrs: 0.371</i>			
Quitting variables			
Made at least 1 quit attempt in the last year ^e	872 (47.2%)	420 (44.9%)	452 (49.6%)
<i>p-value: 0.810</i>			
Longest quit attempt in the last 12 months			
> 3 months	155 (19.4%)	79 (20.5%)	76 (18.3%)
> 1 month, ≤ 3 months	168 (21.0%)	79 (20.5%)	89 (21.4%)
> 1 week, ≤ 1 month	246 (30.7%)	120 (31.2%)	126 (30.3%)
> 1 day, ≤ 1 week	209 (26.1%)	100 (26.0%)	109 (26.2%)
≤ 1 day	23 (2.9%)	7 (1.8%)	16 (3.8%)
<i>p-value for % of quit attempt lasted > 1 month: 0.334</i>			
Plan to stop smoking entirely someday?			
In the next 30 days	365 (19.8%)	183 (19.5%)	182 (20.1%)
1 – 6 months from now	340 (18.5%)	166 (17.7%)	174 (19.2%)
Not in the next 6 months/No	698 (37.9%)	360 (38.4%)	338 (37.4%)
Don't know	438 (23.8%)	228 (24.3%)	210 (23.2%)
<i>p-value for % of having plan in next 6 months: 0.617</i>			
Intention to smoke in the future			

Variable	All (%) (n = 2,151)	Control (%) (n = 1,093)	Experimental (%) (n = 1,058)
No	1,008 (48.5%)	510 (48.3%)	498 (48.7%)
Yes	687 (33.1%)	357 (33.8%)	330 (32.3%)
Don't know	382 (18.4%)	188 (17.8%)	194 (19.0%)
<i>p-value for % of no intention: 0.683</i>			
Motivation to quit ^f			
Strong	563 (31.0%)	266 (29.0%)	297 (33.1%)
Medium	706 (38.9%)	368 (40.1%)	338 (37.7%)
Weak	546 (30.1%)	284 (30.9%)	262 (29.2%)
<i>p-value for % of strong motivation: 0.423</i>			
Quitting self-efficacy ^g			
Strong	1,279 (69.3%)	665 (71.2%)	614 (67.4%)
Medium	446 (24.2%)	208 (22.3%)	238 (26.1%)
Weak	120 (6.5%)	61 (6.5%)	59 (6.5%)
<i>p-value for % of strong efficacy: 0.192</i>			
Other smoking-related variables			
Often & sometimes around smokers age over 25	1522 (73.2%)	764 (72.5%)	758 (74.0%)
<i>p-value: 0.816</i>			
Often & sometimes around high school smokers	1823 (87.8%)	913 (86.7%)	910 (88.9%)
<i>p-value: 0.082</i>			
Number of friends who smoke			
0	188 (9.0%)	101 (9.5%)	87 (8.5%)
1 or 2	688 (33.0%)	360 (34.0%)	328 (31.8%)
3 or more	1210 (58.0%)	598 (56.5%)	612 (59.6%)
<i>p-value for % of having ≥3 friends who smoke: 0.197</i>			
Desire for help with quitting			
Yes	208 (11.4%)	106 (11.5%)	102 (11.3%)
No	1371 (75.1%)	699 (75.9%)	672 (74.3%)
Don't know	247 (13.5%)	116 (12.6%)	131 (14.5%)
<i>p-value for % of wanting help: 0.509</i>			

^a All percentages use the number of valid responses as the denominator. Valid percentages for demographics, smoking, and other smoking-related variables range from 96% to 100%. Valid data on smoking history and quitting were obtained on 84% to 89% of the smoker trial participants. The latter variables were designed specifically to be answered by those who self-reported having smoked one or more cigarettes in the last 30 days. Some smoker trial participants skipped these questions, either by mistake, intentionally, or simply perceiving themselves as not fitting the statement—even though they were identified by one or more of three questionnaire items as smokers.

^b The baseline data collection date varied over a three-month range within Wave.

^c Current use of other tobacco products: Measured the consumption frequency of chewing tobacco/snuff, cigars, bidis or clove cigarettes, pipe tobacco.

^d Nicotine dependence among daily smokers: Presence of the following nicotine-dependent symptoms: (1) Smokes >10 cigarettes per day; (2) Experiences urge to smoke within 2 hours after waking; (3) Smokes first cigarette of the day within 2 hours after waking; (4) Smokes first cigarette of the day within 2 hours after leaving home in the morning (Rojas, et al., 1998; Nonnemaker et al., 2004; Etter, et al., 2003).

^e Respondents were asked: “Think back over the last 12 months. Did you try to stop smoking completely anytime in the last 12 months?” Those who responded “Yes, I did try to stop smoking completely in the last 12 months” were directed to an open-ended question: “How many times did you try to stop smoking completely in the last 12 months?” Those who responded “one” or a larger number were in this category.

^f Motivation to quit: Mean score of 2 items, “How important is it for you to stop smoking completely?” and “How committed are you to becoming a nonsmoker someday?” Min = 0 (weak), max = 1 (strong); presented using 3 categories: strong (.67~1), medium (.34~.66), weak (0~.33).

^g Quitting self-efficacy: Mean score of 2 items, “Do you think that if you put your mind to it, you could stop smoking?” and “If you were to try to stop smoking, how confident are you that you could keep from smoking for at least 6 months?” Min = 0 (weak) and max = 1 (strong); presented using 3 categories: strong (.67~1), medium (.34~.66), weak (0~.33).

Table 2Baseline quitting variables of smoker trial participants by smoking frequency ^{a,b}, HS Study, WA, 2000–2008

Variable	< Monthly <i>n</i> = 593 (%)	≥ Monthly, < Weekly <i>n</i> = 367 (%)	≥ Weekly, < Daily <i>n</i> = 362 (%)	≥ Daily <i>n</i> = 782 (%)
Made ≥ 1 quit attempt in the last year	133 (34.2%)	112 (36.5%)	146 (42.4%)	454 (59.1%)
Plan to stop smoking entirely someday?				
In the next 30 days	166 (43.0%)	70 (22.6%)	56 (16.2%)	63 (8.3%)
1 – 6 months from now	29 (7.5%)	48 (15.5%)	70 (20.3%)	183 (24.1%)
Not in the next 6 months/No	79 (20.5%)	101 (32.6%)	136 (39.4%)	370 (48.7%)
Don't know	112 (29.0%)	91 (29.4%)	83 (24.1%)	144 (18.9%)
Intention to smoke in the future				
No	421 (73.3%)	182 (50.8%)	154 (44.1%)	233 (30.9%)
Yes	64 (11.1%)	111 (31.0%)	127 (36.4%)	368 (48.8%)
Don't know	89 (15.5%)	65 (18.2%)	68 (19.5%)	153 (20.3%)
Motivation to quit				
Strong	174 (45.1%)	90 (29.7%)	89 (26.3%)	191 (25.5%)
Medium	125 (32.4%)	121 (39.9%)	146 (43.1%)	302 (40.3%)
Weak	87 (22.5%)	92 (30.4%)	104 (30.7%)	256 (34.2%)
Quitting self-efficacy				
Strong	355 (90.3%)	267 (86.1%)	264 (76.7%)	369 (48.6%)
Medium	29 (7.4%)	38 (12.3%)	69 (20.1%)	297 (39.1%)
Weak	9 (2.3%)	5 (1.6%)	11 (3.2%)	93 (12.3%)

^a All percentages use the number of valid responses as the denominator. Ranges of valid percentages for each of the following groups were 65% – 95.1% for less than monthly smokers, 82.6% – 97.5% for at least monthly but not weekly smokers, 93.4% – 96.4% for at least weekly but not daily smokers, and 95.8% – 98.2% for daily smokers.

^b Smoking frequency was determined by one survey item: “How often do you currently smoke cigarettes?” Although smoking less than monthly, 593 respondents also reported that they smoked one or more cigarettes in the past 30 days, and therefore, they were still considered as smokers by the trial’s definition.