ARTICLES

Hutchinson Smoking Prevention Project: Long-Term Randomized Trial in School-Based Tobacco Use Prevention—Results on Smoking

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Background: **No long-term impact has yet been observed with the use of the social-influences approach to school-based smoking prevention for youth. However, whether this lack of impact is due to methodologic problems with the studies or to the failure of the interventions is unclear. The Hutchinson Smoking Prevention Project (HSPP), conducted from September 1984 through August 1999, aimed to attain the most rigorous randomized trial possible to determine the long-term impact of a theory-based, social-influences, grade 3–12 intervention on smoking prevalence among youth.** ***Methods:*** **Forty Washington school districts were randomly assigned to the intervention or to the control condition. Study participants were children enrolled in two consecutive 3rd grades in the 40 districts (n = 8388); they were followed to 2 years after high school. The trial achieved high implementation fidelity and 94% follow-up. Data were analyzed with the use of group-permutation methods, and all statistical tests were two-sided.** ***Results:*** **No significant difference in prevalence of daily smoking was found between students in the control and experimental districts, either at grade 12 (difference [Δ] = 0.2%, 95% confidence interval [CI] = −4.6% to 4.4%, and *P* = .91 for girls; Δ = 0.3%, 95% CI = −5.0% to 5.5%, and *P* = .89 for boys) or at 2 years after high school (Δ = −1.4%, 95% CI = −5.0% to 1.6%, and *P* = .38 for girls; Δ = 2.6%, 95% CI = −2.5% to 7.7%, and *P* = .30 for boys). Moreover, no intervention impact was observed for other smoking outcomes, such as extent of current smoking or cumulative amount smoked, or in subgroups that differ in *a priori* specified variables, such as family risk for smoking.** ***Conclusion:*** **The rigor of the HSPP trial suggests high credence for the intervention impact results. Consistent with previous trials, there is no evidence from this trial that a school-based social-influences approach is effective in the long-term deterrence of smoking among youth. [J Natl Cancer Inst 2000;92:1979–91]**

Cigarette smoking remains the number one cause of preventable, premature death in the United States today, annually killing more than 400 000 persons in the United States *(1–2)* and each year costing the nation more than $50 billion in health care costs *(3)*. Current levels of smoking among youth suggest that these trends will continue: Since 1991, smoking prevalence among adolescents has been rising, with 23% of high school seniors now smoking at least daily, up from 18.5% in 1991 *(4)*. These prevalence rates are alarming because health risks from early onset of smoking are particularly severe *(2)* and because smoking in youth overwhelmingly leads to smoking in adulthood *(5–8)*. Without reversal of these smoking trends, an estimated five million of today's youth will die prematurely of smoking-related illnesses *(9)*.

Since the early 1980s, the National Cancer Institute (NCI), Bethesda, MD, has sponsored an extensive program of research to address the problem of smoking among youth *(10)*. This research has resulted in new knowledge about acquisition of smoking among youth, including the identification of risk factors for smoking initiation and escalation. A major focus of this research has been school-based smoking prevention. Nearly all children can be reached through schools *(11)*, which are primary vehicles for their health education [e.g., *(12)*]. Unfortunately, randomized trials aimed at evaluating school-based smoking prevention interventions have had disappointing results. These have shown short-term (i.e., immediately after intervention) impact on smoking prevalence *(13–16)*; however, with one exception *(17)*, to our knowledge, no long-term intervention impact has been observed to date *(18–20)*. In addition, because of the challenges inherent in the school setting and in the youth populations themselves *(13,19,21–32)*, school-based trials have suffered various methodologic difficulties. These difficulties include 1) sample sizes too small to accommodate positive intraclass correlation between outcomes within group, 2) poor intervention fidelity (i.e., poor provider compliance), 3) less than optimal rates of outcome ascertainment (i.e., high attrition rates), and 4) social mixing of study participants between the experimental and control conditions during the postintervention follow-up years (as has occurred in studies that randomized junior high schools, in which experimental and control students intermingled during follow-up in high school). Consequently, it has been difficult to determine whether the lack of a long-term intervention impact is a result of methodologic or intervention failures.

In accordance with a long-standing NCI priority for school-

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See "Notes" following "References."

based intervention research and in response to an NCI request for applications "to [determine] the long-term impact of . . . school-based interventions" *(33),* the 15-year Hutchinson Smoking Prevention Project (HSPP) randomized trial was initiated in September 1984 to address the challenges of trial design and execution in the school setting. The trial had two goals: 1) to attain the most rigorous school-based, randomized trial possible and 2) to use the trial to answer the scientific question, "To what extent can a state-of-the-art, theory-based, social-influences smoking prevention intervention that spans the elementary, junior high, and high school grades reduce smoking among youth at grade 12 and beyond?" All HSPP intervention and data collection activities in the schools were completed in 1997, and follow-up to endpoint and associated data collection were completed in August 1999.

The HSPP was the first randomized, controlled trial of smoking prevention among youth to start early (i.e., at grade 3), to study a comprehensive grade 3–12 social-influences intervention, and to follow participants to 2 years after high school. In this article, we present the HSPP trial's results for intervention impact on smoking at grade 12 and at 2 years beyond high school.

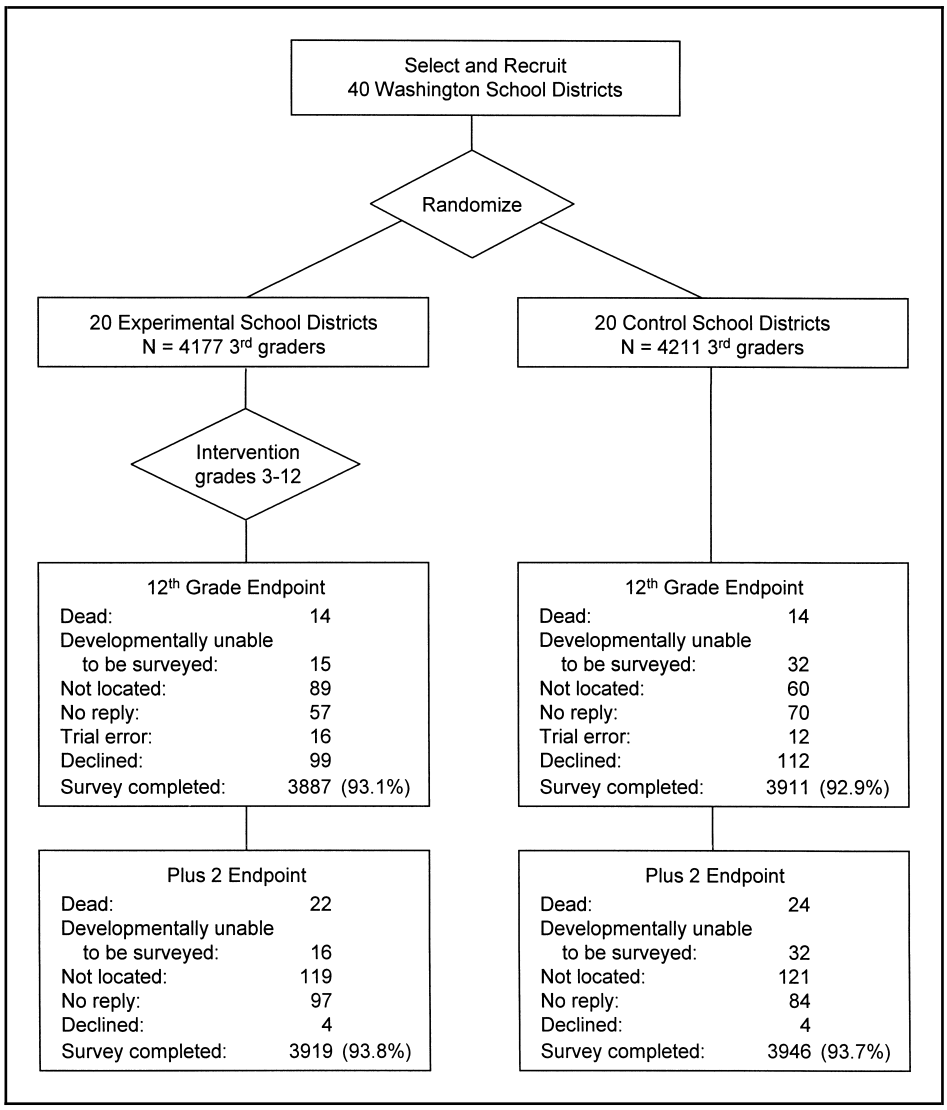

Fig. 1. Experimental design of the Hutchinson Smoking Prevention Project and extent of follow-up.

Subjects and Methods

The HSPP trial used a group-randomized, matched-pair design, with the school district as the experimental unit, a feature that permits the evaluation of an intervention that spans elementary school, junior high school, and high school, and that minimizes social mixing during the trial between control and experimental students. Of 40 participating school districts, 20 were randomly assigned to the experimental (intervention) condition and 20 were randomly assigned to the control (no HSPP intervention) condition. No restrictions were placed on the health promotion or tobacco use prevention activities of the control districts, thus enabling the schools to continue whatever health curricula were normally offered. The lack of restrictions placed on control districts makes the trial's scientific question relevant to the real world: For achieving long-term reduction of smoking, to what extent is the HSPP experimental intervention more effective than the usual activities in the schools? The main endpoints were daily smoking at grade 12 and at 2 years after high school. All members of the original trial cohort were targeted for tracking and follow-up to endpoint. The HSPP experimental design and the extent of follow-up are shown in Fig. 1. The HSPP experimental design and procedures were reviewed and approved in advance and annually throughout the trial by the Institutional Review Board of Fred Hutchinson Cancer Research Center, Seattle, WA. Additional details about the HSPP design are published elsewhere *(34).*

Study Population and Sample Size

The HSPP trial cohort (n = 8388) consists of two consecutive, entire 3rd grade enrollments in 40 collaborating school districts, with the exception of 42 children considered by their schools to be developmentally unable to learn. The HSPP school districts and population encompass a wide spectrum of communities, school districts, families, and children. The communities are small to medium in size and are located in rural and suburban settings throughout Washington State. The children who comprise the HSPP trial cohort are representative of the state population of children, and they are similar to the national population of children with respect to percent female, percent total minority, percentage of households headed by a single parent, and percentage of parents having at least a high school education *(35).* For trial management reasons, school districts eligible for collaboration were limited to those within 200 miles of the Fred Hutchinson Cancer Research Center, with 50–250 students per grade level, with a self-contained feeder system consisting of at least one elementary and at least one junior high/middle school and only one high school, and with a pre-trial grade 3–7 attrition of less than 35%.

During the implementation period of the trial (1984 through 1997), tobacco control in Washington State consisted primarily of the following: 1) tobacco-free school grounds, implemented in 1991; 2) statewide compliance checks to educate cigarette retailers about avoiding sales to minors, begun in 1989; and 3) local health department sponsorship of community-based activities (e.g., youth peer leadership training) using funds from the American Stop Smoking Intervention Study. The state did not require schools to teach tobacco use prevention.

The sample size of 40 school districts and 8388 children is sufficient to accommodate intraclass correlation of outcome within school district, and it provides 86% and 95% statistical power to detect in girls and boys, respectively, a 30% nominal relative reduction in smoking prevalence *(34).* Following the "intent-to-treat" tenet *(36,37)* of good experimental design, the 8388 students enrolled in HSPP, including those who dropped out of school or otherwise left their original collaborating school district, remained part of the trial throughout.

HSPP recruited school districts in three waves over the first 3 years of the trial (1984 through 1986). The trial cohort in each school district consisted of two consecutive grade 3 enrollments *(34,38)*. Thus, the project was phased in over a 4-year period.

Randomized Assignment

A matched-pair randomization was performed for each of 20 district pairs matched on prevalence of high school tobacco use (ascertained immediately after district recruitment), school district size, and location (i.e., east or west of Washington's Cascade Mountains). For each matched pair of school districts, the two members of the pair were randomly ordered and then one was randomly assigned to the experimental condition by a computerized coin flip that was performed openly and witnessed, recorded, and signed by two Fred Hutchinson Cancer Research Center (non-HSPP) scientists *(34)*. To promote each school district's adherence to its randomized assignment, HSPP staff explained to district administrators both the randomized nature of the intervention assignment and the importance of randomization to the success of the study during school district recruitment. Also, immediately after randomization was done, the principal investigator telephoned the superintendent of each collaborating school district to communicate the results and to reinforce the importance of the randomization and each school district's role to the integrity of the trial *(34)*.

Intervention

The HSPP intervention uses an enhanced social-influences approach [e.g., *(13)*] that includes the 15 "essential elements" for school-based tobacco prevention recommended by a national Expert Advisory Panel convened by the NCI *(39)*. It also meets the guidelines for planning and implementing effective school-based (kindergarten to grade 12) programs for the prevention of tobacco use recommended by the Centers for Disease Control and Prevention (CDC), Atlanta, GA *(40,41)*. In accordance with the social-influences approach, the intervention's behavioral components feature 1) skills for identifying social influences to smoke (e.g., tobacco advertising and marketing strategies; peer influence), 2) skills for resisting influences to smoke (e.g., advertising analysis and resistance skills), and 3) information for correcting erroneous normative perceptions regarding smoking *(42)* and for promoting tobacco-free social norms. Three additional HSPP intervention components extend the standard social-influences approach: 1) motivating students to want to be smoke free as a precursor to skills training *(43–46)* and distinguishing between what the adolescent "wants to do" and what he/she is "able to do" *(45,46);* 2) promoting self-confidence in one's own abilities to refuse pressures or influences to smoke (i.e., self-efficacy); and 3) enlisting positive family influences *(47)*.

The intervention's theoretical design incorporates multiple social learning constructs (e.g., behavioral capability, observational learning, and self-efficacy) *(48–50)* and the concept, from attribution theory, that attributing desirable and rewarding nonsmoking motivations to students can reinforce nonsmoking behavior and can increase self-efficacy *(51)*. (This positive approach, i.e., to reinforce nonsmoking, is supported by the intervention's early start: Because very few children are smoking at the 3rd grade, students' tobacco-free behavior can be accurately acknowledged.) These theories guided all intervention development, including the teacher-training program designed to enhance teacher motivation, compliance, and fidelity *(52)*.

The HSPP intervention is a teacher-led, grade 3–10 tobacco use prevention curriculum together with unit-specific teacher training. There are a total of 65 classroom lessons in the HSPP curriculum: nine lessons in each of grades 3–5, 10 lessons in each of grades 6 and 7, eight lessons in grade 8, and five lessons in each of grades 9 and 10. (There are no classroom lessons in grades 11 and 12.) The length of the classroom lessons varies with the lesson and the grade, ranging from 30 to 50 minutes; the total classroom minutes in grades 3–10 is 2805 (46.75 hours). The curriculum is supplemented by two additional high school components: 1) self-help tobacco use cessation materials to help motivate smokers in grades 9–12 to think about quitting and to make attempts to quit and 2) biannual newsletters informing high school teachers about tobacco education resources and tobacco current events as well as about ways to incorporate these resources into various course subjects in high school.

The intervention's early start and 10-year time span across grades 3–12 provide opportunities to target each of the stages of the smoking acquisition process and to address age-specific interests and developmental capabilities of students. Accordingly, the level of emphasis placed on each of the intervention's behavioral components varies with grade level. For example, the strategy of enlisting positive family influences is included in the primary grades but not in later grades, to take advantage of the period of childhood when parental influence is stronger than the influence of peers *(47)*. Similarly, to capitalize on young children's interest in how their bodies work, the primary grade units lay a strong foundation of knowledge about how avoiding tobacco use and tobacco smoke helps their bodies. In contrast, the junior high/middle school units focus on issues relevant to middle schoolers: immediate health, cosmetic and social benefits of not using tobacco, identifying peer and media influences to use tobacco, and building skills for resisting such influences. Over the course of the eight units, the total amount of classroom time devoted to each behavioral component varies from 682 to 1783 minutes, depending on the component, as shown in Table 1.

The curriculum is designed for all students, not just students at high risk for smoking. Nonetheless, some content is designed to influence high-risk youth within a diverse student audience [e.g., *(53)*] by targeting the stages of the smoking acquisition process—i.e., preparation, initiation, experimentation, regular use, and addiction *(46,54)*—and by addressing risk factors for smoking initiation and escalation *(55)*. These risk factors, summarized extensively in the 1994 Surgeon General's Report *(56),* fall into four broad categories: 1) personal factors (e.g., perception that smoking enhances self-image, susceptibility to peer pressure, and deficiencies in self-control), 2) behavioral factors (e.g., prior experimentation with tobacco, alcohol, or other drugs; risk-taking or rebellious behavior), 3) environmental factors (e.g., having friends who smoke, perception that the majority of peers and adults smoke, and exposure to tobacco advertising), and 4) sociodemographic factors (e.g., low socioeconomic status and gender). For example, to harness adolescents' rebelliousness and redirect it against the actions of the tobacco industry, the curriculum incorporates classroom activities featuring evidence of wrongdoing by tobacco companies. To target risk-takers, the intervention employs messages that are high in stimulus value and that emphasize exciting alternatives to smoking *(57)*. To engage students, address varied learning styles, and encourage students to express their own opinions and feelings about tobacco, lessons rely on a variety of creative communication methods (e.g., vivid images, video and other media, current events, and humor) and direct student involvement (e.g., discussing, reporting, playwriting and acting, and taking anti-tobacco action). A breakdown of the communication/teaching methods employed in each grade unit is shown in Table 2.

Finally, the intervention was developed to be practical in the real-world setting of the schools: In addition to using teachers as providers, the units were designed to fit easily into school routines, to be interesting and engaging to both teachers and students, and to be accurate, developmentally and age appropriate, and relevant with regard to the educational objectives of schools.

Implementation

The HSPP curriculum was implemented by HSPP-trained classroom teachers to the experimental cohort of 4177 students in the 20 intervention districts as they progressed through grades 3–10. Teachers were selected to implement HSPP if they taught subjects that were required of all students at a particular grade level (hence ensuring that the entire HSPP experimental cohort would be exposed to the intervention*) (52)*. Because elementary school teachers typically teach all required subjects to their classes, it was routine for every elementary teacher (for grades 3 and up) to receive training and teach the HSPP unit. In contrast, in junior high/middle schools and in high schools, students typically have different teachers for every subject. Therefore, to capture the study cohort, for each grade level, school principals identified a course required of all students and assigned teachers of this course to attend in-service training and to teach the HSPP curriculum as part of their course subject. Anticipating the need to support the teachers in courses other than Health, which is not required in all secondary schools, the units for grades 6–10 were developed with some educational content to help meet learning objectives for Social Studies and Language Arts. Teacher compliance was assessed by self-report and by classroom observations conducted by trained HSPP staff data collectors in accordance with established trial protocol, as described elsewhere *(52)*.

The supplemental high school components were implemented as follows: Motivational and self-help cessation materials were placed in public areas (e.g., the library) of the high schools in experimental districts, and school newspaper ads and posters, placed by HSPP staff, promoted the presence/availability of the cessation materials. In addition, volunteers from the high school faculty received a brief (1-hour) training in how to encourage and support teens' smoking cessation efforts. The biannual newsletters were mailed to high school offices for distribution to all faculty and librarians.

Table 1. Hutchinson Smoking Prevention Project intervention: total classroom minutes that address each behavioral component, by grade unit

Behavioral component	No. of minutes								Intervention totals	
	Grade 3	Grade 4	Grade 5	Grade 6	Grade 7	Grade 8	Grade 9	Grade 10	Minutes	%*
Build motivations									1783	63.5
General health motivations	265	270	195	45	5	0	0	0	780	27.8
Long-term health	35	20	35	50	53	15	5	15	228	8.1
Short-term health	40	25	38	40	30	25	5	5	208	7.4
Cosmetic/social	15	15	23	30	45	20	10	5	163	5.8
Physical fitness/sports	10	0	5	25	0	20	0	2	62	2.2
Monetary	0	0	0	10	0	10	0	0	20	0.7
Addiction	10	10	0	5	7	15	35	10	92	3.3
Environmental tobacco smoke	70	40	0	5	0	15	5	5	140	5.0
Effect on family	0	0	40	10	30	0	0	10	90	3.2
Teach skills for identifying social influences to smoke									682	24.3
Peer influence	0	0	0	0	70	45	0	10	125	4.5
Advertising/media influences	12	20	10	50	5	30	15	15	157	5.6
Actions of the tobacco industry	0	0	15	0	35	75	135	140	400	14.3
Teach skills for resisting influences to smoke									919	32.8
Advertising analysis	35	40	25	115	17	10	10	5	257	9.2
Resistance/refusal skills	22	0	0	0	210	90	0	50	372	13.3
Helping others avoid tobacco	5	0	30	100	90	45	20	0	290	10.3
Correct misperceptions about societal norms/promote tobacco-free norms									847	30.2
Correct normative misperceptions	10	0	95	65	22	25	10	15	242	8.6
Promote tobacco-free norms	35	0	55	125	120	65	110	95	605	21.6
Build self-efficacy for nonsmoking	70	77	50	115	135	130	65	55	697	24.9
Enlist positive family influences†	Yes	Yes	Yes	Yes	No	No	No	No		
Total‡	385	360	390	435	430	355	225	225	2805	100.0

*Percent of total (length in minutes) of curriculum. Because some curriculum minutes address more than one component (*see* ‡ *below*), these percentages do not add up to 100%.

† "Yes" indicates family activities were part of the unit.

‡ This is the total number of minutes in the unit; it is not the sum of the numbers above. By design, some lesson activities address more than one behavioral component. Each number of minutes reported in the body of the table represents the time for the indicated behavioral component, even when the same minutes may also address another behavioral component. Consequently, the total number of classroom minutes for each unit cannot be calculated from this table by adding together the number of minutes for each of the individual behavioral components.

Table 2. Hutchinson Smoking Prevention Project intervention communication/teaching methods, by grade unit

	No. of minutes								Grade 3–10 intervention totals	
	Grade 3	Grade 4	Grade 5	Grade 6	Grade 7	Grade 8	Grade 9	Grade 10	Minutes	%
Communication/teaching methods										
Discussion activities	145	150	213	192	140	156	83	85	1164	41.5
Media (e.g., video) activities	15	18	28	0	30	34	37	15	177	6.3
Hands-on (e.g., drama, art) activities	210	163	130	238	248	160	88	110	1347	48.0
Didactic activities	15	29	19	5	12	5	17	15	117	4.2
Total minutes per unit	385	360	390	435	430	355	225	225	2805	100.0

Follow-up and Data Collection

To minimize the potential for attrition bias *(36,37),* the trial followed the cohort of 8388 children to the main outcomes at grade 12 and at 2 years after high school ("Plus 2"). Follow-up procedures were applied to all members of the cohort, both those who remained in the original school district through grade 12 ("non-outmigrators") and those who dropped out of school or otherwise left their original collaborating school district ("outmigrators"). It is well known that outmigrators are different from non-outmigrators—e.g., with regard to smoking prevalence *(19,58)*—and, thus, must be included in the follow-up to ensure scientific integrity *(36,37).* Standard tracking strategies and methods were applied and are discussed elsewhere *(34,59,60).*

For those trial cohort members still enrolled as 12th graders in an HSPP school district (48.6% of the trial cohort), the grade 12 survey was conducted primarily by in-class data collections. For those cohort members not enrolled as 12th graders in an HSPP district (51.4% of the trial cohort), the grade 12 survey was conducted primarily by telephone survey. For all study participants, the Plus 2 survey was conducted by a mailed survey, with mail and telephone follow-up of nonresponders. Consent was obtained from all participants. Survey and informed consent procedures were based on those proven successful in this and other settings *(59,61–63)* and have been described in more detail elsewhere *(34).*

To maximize the validity of self-reported tobacco use, data collection sessions were unannounced and were designed to develop rapport and to build trust with study participants. They were administered entirely by trained HSPP staff, who emphasized the need for accurate reports and the important role of participants, promised complete confidentiality, and made no mention of the intervention. Also, the data collection materials and questionnaires were developed to be professional looking, engaging, and easy to complete. Because misreporting of tobacco use is a possibility among adolescents *(64–66),* each 12th grader was asked as part of the in-class survey to provide a saliva specimen for cotinine

analysis. The in-class data collection process included an explanation of the test for saliva cotinine and a demonstration of its collection. A 12.6% random sample[1] of the saliva specimens was submitted along with blind controls (which looked similar to the samples from the study participants, but with known cotinine concentration) to a laboratory willing to abide by HSPP "acceptance/rejection" criteria in which specimen results were accepted only if cotinine results for the blind controls were within certain limits *(67)*. Cotinine was assayed by a gas chromatography method designed to detect 5 ng/mL or more *(68,69)*.

Measures

The trial's main outcomes are current daily smoking at grade 12 and at Plus 2. Supplementary main outcomes, which were chosen to cover a range of smoking behaviors, include 1) other binary measures of current smoking frequency (whether the student smokes at all, whether the student smokes at least monthly, and whether the student smokes at least weekly); 2) an ordinal measure of current smoking frequency (grade 12 scale: 1 = never smoked or don't smoke now, 2 = smokes less than once per month, 3 = smokes once per month, 4 = smokes more than once per month but less than once per week, 5 = smokes once per week, 6 = smokes more than once per week but less than once per day, 7 = smokes one to three cigarettes per day, 8 = smokes four to 10 cigarettes per day, 9 = smokes 11 to 20 cigarettes per day, and 10 = smokes >20 cigarettes per day; Plus 2 scale: 0 = never smoked or don't smoke now, 1 = smokes less than once per week, 2 = smokes at least once per week but less than once per day, 3 = smokes one to 10 cigarettes per day, 4 = smokes 11 to 20 cigarettes per day, and 5 = smokes >20 cigarettes per day); 3) an ordinal measure of the student's smoking acquisition stage (scale: 1 = never smoked, 2 = tried once, 3 = tried more than once but quit, 4 = smokes less than once per week, 5 = smokes at least once per week but less than once per day, 6 = smokes one to 10 cigarettes per day, and 7 = smokes >10 cigarettes per day) *(70);* 4) a binary measure of cumulative lifetime smoking (whether total amount smoked is >100 cigarettes); 5) number of cigarettes smoked per day, among daily smokers; and 6) grades in school when monthly, weekly, and daily smoking were first reported. Outcome measures were derived from survey items (Table 3) adapted from those developed in 1985 by a consensus of NCI tobacco prevention research grantees.

Statistical Methods

For group-randomized trials, it is essential to use analysis methods that account for intraclass correlation of endpoint between individuals within school district; i.e., it is the variation in smoking prevalence among school districts (not among individual students) against which the intervention impact must be measured for the purpose of tests of statistical significance and confidence intervals (CIs) [e.g., *(71–75)*]. Such methods accommodate variation among school districts that results from differences in district characteristics, from social interactions (e.g., peer influence) among individuals in the districts, and from district-specific commonalities of the intervention implementation.

To accommodate the variation among school districts, this trial used group-randomization-based permutation inference *(76–79)* with 2^{20} = 1 048 576 permutations corresponding to the trial's randomized 20 pairs of school districts. The use of permutation inference for group-randomized trials has become well known after its use in the Community Intervention Trial for Smoking Cessation group randomized trial *(78,79)*. This method acknowledges the school district as the experimental unit (i.e., accommodates the intraclass correlation within school districts) by permuting the school districts, as opposed to individuals, in accordance with the group-randomized design. The use of permutation inference is especially suited to randomized trials because the validity of the inference relies solely on the randomized assignment of intervention and needs no distributional or modeling assumptions. For simplicity of interpretation and good efficiency, the permutation test statistic used is the difference in overall averages between the control and experimental conditions.

To maintain randomization as the basis for intervention and, in particular, to avoid the possibility of bias [e.g., *(80)*], the main analyses of impact compared the experimental and control groups as determined by the original randomized assignment ("intent to treat") and not by the extent of the actual intervention exposure.

Three variables were identified in advance to investigate *a priori* hypotheses about differential intervention impact in specified subgroups. These variables are as follows: 1) child/family risk for smoking *(18),* with low-risk children defined as those who, at baseline, had never smoked, did not have smoking parent(s), and did not have an older sibling who smoked *(38);* 2) enrollment in grades 3–10, with full enrollment defined as children with full (grades 3–10) enrollment in collaborating school districts during the trial's duration; and 3) school risk for smoking *(81),* with high-risk schools defined as schools with a monthly smoking prevalence of greater than 2.2% (median split) among (non-cohort) students who were in grade 5 when the first cohort entered the trial as 3rd graders. Thus, the first set of subgroups is based on *personal/family* variables, the second set is based on an *exposure* variable, and the third set is based on a *school/environment* variable.

The number of main endpoints is small, and the number of intervention conditions being compared is only two. Accordingly, for ease of presentation and interpretation, nominal two-sided *P* values and 95% CIs are reported, unadjusted for multiple comparisons.

Table 3. Survey items for main and supplementary main endpoints

Item	Response choices
On grade 12 instrument	
How often do you currently smoke cigarettes?	Have never smoked cigarettes. Don't currently smoke cigarettes at all. Less than once a month. Once a month. More than once a month, but less than once a day. 1 to 3 cigarettes per day. 4 to 10 cigarettes per day. 11 to 20 cigarettes per day. More than 20 cigarettes per day.
Have you ever smoked or tried a cigarette?	No, never. Not even one puff. Yes, but just one puff. Yes, but only 1 cigarette. Yes, 2–5 cigarettes. Yes, more than 5 cigarettes.
In the last seven days, how many cigarettes have you smoked or tried?	None. Never tried a cigarette, not even one puff. Just one puff. One cigarette.
How many cigarettes have you smoked or tried in your lifetime?	None. Never tried a cigarette, not even one puff. Just one puff. One cigarette. Two cigarettes. 3 to 5 cigarettes. 6 to 10 cigarettes. 11 to 20 cigarettes. 21 to 60 cigarettes. 61 to 100 cigarettes. More than 100 cigarettes.
On Plus 2 instrument	
How often do you currently smoke cigarettes?	Not at all. Less than once a week. Once a week, but not daily. Daily: 1–10 cigarettes per day. Daily: 11–20 cigarettes per day. Daily: More than a pack a day.
How many cigarettes have you smoked in your lifetime?	None. One cigarette or less. 2–20 cigarettes. 1–5 packs. More than 5 packs.
In the last seven days, how many packs of cigarettes have you smoked? (*Asked of those reporting any level of current smoking.*)	____ packs

Reporting the Design and Results of the Trial

The HSPP trial was conducted over a 15-year period in 40 school districts in 40 diverse communities. To help protect the investment in this large long-term

trial from any possibility of degradation from external influences, trial policy was established to wait until all intervention and data collection activities were completed before publishing or otherwise publicizing the trial.

Results

Forty (97.6%) of 41 school districts invited to join the project were successfully recruited. All 40 (100%) participated fully for the duration of the trial.

Baseline Comparability

A comparison of the distribution of the baseline tobacco use and demographic variables between experimental and control conditions shows that the randomized assignment of school districts provided a very good balance between the two conditions *(38).* For example, control and experimental district students were similar with regard to percent having tried tobacco prior to the 3rd grade (10.8% and 11.8%, respectively), percent with one or more parents smoking (44.6% and 46.4%, respectively), and percent living in a single-parent household (22.3% and 23.3%, respectively) *(38).* Also, with regard to ongoing tobacco prevention efforts, there was little difference in the average number of hours of non-HSPP tobacco use prevention in schools (2.9 and 3.2 hours per grade, respectively, for control and experimental school districts).

Implementation Compliance

During the course of the project, 640 teachers from 72 elementary schools, middle schools, and high schools were assigned to teach the HSPP curriculum *(52).* The teachers ranged in age from 22 to 59 years and had from 1 to 33 years of teaching experience. Sixty percent of the teachers were female. At the time of implementation, 61% of the teachers were never smokers, 32% were former smokers, and 7% were current smokers *(52).*

As reported previously *(52),* all assigned teachers participated in the HSPP staff-led in-service training, and virtually all trained teachers (>99%) implemented the units in their classrooms. Overall, implementation results as assessed during classroom observations were positive (e.g., teachers effectively communicated the lessons' key concepts in 80% of lessons observed).

Follow-up/Data Acquisition Rates

Of the 8388 trial cohort members identified at baseline, 7798 (93.0%) completed a grade 12 survey and 7865 (93.8%) completed a Plus 2 survey. A total of 590 trial cohort members (7.0%) did not complete a 12th grade survey: 28 (0.3%) had died prior to data collection, 47 (0.6%) were developmentally unable to take part, 149 (1.8%) could not be located, 127 (1.5%) did not reply, 28 (0.3%) were missed because of trial error, and 211 (2.5%) actively declined (parent or teen decision). A total of 523 trial cohort members (6.2%) did not participate in the Plus 2 survey: 46 (0.5%) had died prior to the survey, 48 (0.6%) were developmentally unable to take part, 240 (2.9%) could not be located, and 181 (2.2%) did not reply. Only eight (0.1%) actively declined *(58).* Of survey respondents, a small percentage did not reply to pertinent current smoking questions: 75 (1.0%) at grade 12 and 90 (1.1%) at Plus 2. As shown in Fig. 1, rates of survey completion, study participant declines, and deaths were similar for the control and experimental groups. There was also no evidence of any difference between the control and intervention groups for high school dropout rate (17.44% and 17.43%, respectively; $P = .997$), death (0.57% and 0.53%, respectively; $P = .83$), or age at death (16.6 years of age and 16.7 years of age, respectively; $P > .99$).

Cotinine Validation of Self-Reported Tobacco Use

Cotinine was measured on a 12.6% random sample of saliva specimens collected at the grade 12 in-class data collection. The slope of a linear regression of self-reported level of tobacco use versus the cotinine value was 0.074 in the control group and 0.076 in the experimental group, with a difference in slopes of −0.002 (95% CI = −0.008 to 0.003; $P = .46$). The fraction of observations that were positive outliers (overreports) were six (1.5%) of 413 and seven (1.8%) of 392, respectively, in the control and experimental groups; difference (Δ) between control and experimental = −0.3% (95% CI = −2.1% to 1.4%; $P = .71$). The fraction of observations that were negative outliers (underreports) were five (1.2%) of 413 and five (1.3%) of 392, respectively, in the control and experimental groups; Δ = −0.1% (95% CI = −1.6% to 1.5%; $P = .93$). In sum, these comparisons between control and experimental conditions of the relationship between self-reported level of tobacco use and cotinine value revealed no evidence of differential bias in self-reported tobacco use between the control and experimental conditions.

Results at Grade 12

Daily smoking prevalence at grade 12—for girls, for boys, and for girls and boys together—was highly variable among the school districts (Table 4). Among the 20 control school districts, the average smoking prevalence was 24.7% (range = 0%–41.9%) among the girls and 26.7% (range = 14.2%–46.3%) among the boys. Among the 20 experimental school districts, the average smoking prevalence was 24.4% (range = 15.5%–34.2%) among the girls and 26.3% (range = 10.3%–41.7%) among the boys. The overall difference in prevalence of daily smoking between the control and experimental school districts was 24.66% − 24.41% = 0.25% ($P = .91$) for girls and 26.65% − 26.32% = 0.33% ($P = .89$) for boys. Thus, the difference in daily smoking prevalence between the control and experimental conditions is small; there is no evidence of an intervention impact on the prevalence of daily smoking at grade 12, either for girls or for boys.

There was also no evidence of an impact of the intervention on the supplemental main endpoints (Table 5). For the seven measures of current smoking, for the single measure of cumulative smoking, and for the grades at which students first reported monthly, weekly, and daily smoking, the results for the control school districts are close to those for the experimental school districts. For example, the largest difference for the binary measures (lines 1–4 and 8 of Table 5) is just 2.1% (i.e., 36.0%–33.9%, for percent of boys having smoked >100 cigarettes in their lifetime). Also, the data do not suggest any intervention impact on the grades in school at which students first reported (monthly, weekly, and daily) smoking. For girls and boys considered together, however, there is a small, statistically significant difference in the number of cigarettes smoked per day among daily smokers: 10.4 and 9.6, respectively, for stu-

Table 4. Prevalence (Prev) of daily smoking at grade 12

	Girls (n = 3831)					Boys (n = 3892)					Girls and boys together (n = 7723)				
	Control (n = 1910)		Experimental (n = 1921)			Control (n = 1966)		Experimental (n = 1926)			Control (n = 3876)		Experimental (n = 3847)		
Pair	No.	Prev, %	No.	Prev, %	Δ,* %	No.	Prev, %	No.	Prev, %	Δ,* %	No.	Prev, %	No.	Prev, %	Δ,* %
1	66	28.8	58	15.5	**13.3**	65	35.4	64	31.3	**4.1**	131	32.1	122	23.8	**8.3**
2	68	27.9	66	33.3	**–5.4**	75	21.3	68	17.6	**3.7**	143	24.5	134	25.4	**–0.9**
3	87	19.5	101	21.8	**–2.2**	108	25.0	100	22.0	**3.0**	195	22.6	201	21.9	**0.7**
4	114	29.8	152	34.2	**–4.4**	116	34.5	154	20.8	**13.7**	230	32.2	306	27.5	**4.7**
5	210	27.1	256	20.7	**6.4**	182	24.7	236	25.4	**–0.7**	392	26.0	492	23.0	**3.1**
6	86	41.9	209	23.9	**17.9**	95	29.5	218	29.8	**–0.3**	181	35.4	427	26.9	**8.4**
7	73	27.4	49	30.6	**–3.2**	90	30.0	47	29.8	**0.2**	163	28.8	96	30.2	**–1.4**
8	88	18.2	48	31.3	**–13.1**	79	30.4	36	41.7	**–11.3**	167	24.0	84	35.7	**–11.8**
9	156	28.2	125	19.2	**9.0**	191	36.1	124	25.0	**11.1**	347	32.6	249	22.1	**10.5**
10	117	22.2	93	21.5	**0.7**	102	34.3	83	12.0	**22.3**	219	27.9	176	17.0	**10.8**
11	39	12.8	35	17.1	**–4.3**	44	15.9	39	10.3	**5.7**	83	14.5	74	13.5	**0.9**
12	170	21.8	138	31.2	**–9.4**	187	26.2	152	28.3	**–2.1**	357	24.1	290	29.7	**–5.6**
13	90	21.1	88	20.5	**0.7**	77	26.0	95	18.9	**7.0**	167	23.4	183	19.7	**3.7**
14	31	19.4	42	19.0	**0.3**	32	25.0	62	22.6	**2.4**	63	22.2	104	21.2	**1.1**
15	101	19.8	122	25.4	**–5.6**	124	23.4	106	36.8	**–13.4**	225	21.8	228	30.7	**–8.9**
16	124	16.1	80	20.0	**–3.9**	120	14.2	63	27.0	**–12.8**	244	15.2	143	23.1	**–7.9**
17	60	0.0	32	25.0	**–25.0**	42	14.3	30	26.7	**–12.4**	102	5.9	62	25.8	**–19.9**
18	151	31.1	93	24.7	**6.4**	159	15.1	99	27.3	**–12.2**	310	22.9	192	26.0	**–3.1**
19	37	35.1	43	18.6	**16.5**	37	29.7	63	38.1	**–8.4**	74	32.4	106	30.2	**2.2**
20	42	38.1	91	28.6	**9.5**	41	46.3	87	36.8	**9.6**	83	42.2	178	32.6	**9.6**
Overall	1910	24.66	1921	24.41	**0.25**†	1966	26.65	1926	26.32	**0.33**‡	3876	25.7	3847	25.4	**0.3**§
	95% confidence interval (CI) = **–4.6 to 4.4**					95% CI = **–5.0 to 5.5**					95% CI = **–3.5 to 3.7**				

*Δ = difference: prevalence in control school district minus prevalence in paired experimental school district (positive values of Δ are in the direction of a positive intervention effect).

†P = .91 (two-sided permutation test).

‡P = .89 (two-sided permutation test).

§P = .86 (two-sided permutation test).

Table 5. Other smoking endpoints at grade 12

	Girls				Boys				Girls and boys together			
	Control	Experimental	Δ,* %	95% confidence interval	Control	Experimental	Δ,* %	95% confidence interval	Control	Experimental	Δ,* %	95% confidence interval
Current smoking												
Any smoking, %	37.7	38.0	**–0.3**	–4.7 to 3.2	39.8	40.2	**–0.5**	–5.9 to 4.8	38.7	39.1	**–0.4**	–4.3 to 3.1
At least monthly smoking, %	32.9	34.0	**–1.1**	–5.0 to 2.2	35.1	35.4	**–0.3**	–6.1 to 5.5	34.0	34.7	**–0.7**	–4.6 to 2.9
At least weekly smoking, %	28.2	28.3	**–0.047**	–4.5 to 3.7	30.7	31.2	**–0.5**	–6.1 to 5.2	29.5	29.7	**–0.2**	–3.9 to 3.1
At least daily smoking, %	24.7	24.4	**0.2**	–4.6 to 4.4	26.7	26.3	**0.3**	–5.0 to 5.5	25.7	25.4	**0.3**	–3.5 to 3.7
Smoking frequency†	3.13	3.13	**0.0**	–0.30 to 0.26	3.37	3.34	**0.03**	–0.39 to 0.45	3.25	3.23	**0.02**	–0.26 to 0.28
Smoking acquisition stage‡	3.25	3.25	**0.0**	–0.23 to 0.18	3.46	3.45	**0.01**	–0.25 to 0.26	3.36	3.35	**0.01**	–0.18 to 0.17
No. of cigarettes per day§	9.3	8.9	**0.4**	–0.4 to 0.9	11.3	10.2	**1.1**‖	–0.3 to 2.2	10.4	9.6	**0.8**¶	0.03 to 1.4
Cumulative smoking: smoked >100 cigarettes in lifetime, %	30.4	29.3	**1.2**	–4.1 to 5.6	36.0	33.9	**2.1**	–3.6 to 7.3	33.2	31.6	**1.7**	–2.6 to 5.1
Grade when first reported smoking#												
Monthly	10.14	10.10	**0.04**	–0.20 to 0.33	10.20	10.12	**0.08**	–0.19 to 0.35	10.17	10.11	**0.06**	–0.13 to 0.29
Weekly	10.41	10.32	**0.09**	–0.14 to 0.33	10.51	10.43	**0.08**	–0.14 to 0.29	10.46	10.38	**0.08**	–0.08 to 0.26
Daily	10.66	10.57	**0.09**	–0.13 to 0.32	10.80	10.68	**0.12**	–0.10 to 0.33	10.74	10.63	**0.11**	–0.05 to 0.27

*Δ = difference: prevalence or average in control school districts minus prevalence or average in experimental school districts.

†Average of scale for smoking frequency with level-of-daily smoking refinement. Scale: 1 = never smoked or don't smoke now; 2 = smokes less than once per month; 3 = smokes once per month; 4 = smokes more than once per month but less than once per week; 5 = smokes once per week; 6 = smokes more than once per week but less than once per day; 7 = smokes 1–3 cigarettes per day; 8 = smokes 4–10 cigarettes per day; 9 = smokes 11–20 cigarettes per day; 10 = smokes more than 20 cigarettes per day.

‡Average of scale for stage of acquisition. Scale: 1 = never smoked; 2 = tried once; 3 = tried more than once but quit; 4 = experimenter (smokes less than once per week); 5 = regular weekly smoker (at least once per week but less than once per day); 6 = light daily smoker (1–10 cigarettes per day); 7 = heavy smoker (more than 10 cigarettes per day).

§Based on last 7 days' use among daily smokers, truncated at 20 cigarettes per day.

‖P = .11 (two-sided permutation test).

¶P = .04 (two-sided permutation test).

#Among those who ever reported smoking at or above level indicated.

Table 6. Prevalence (Prev) of daily smoking at 2 years after high school

	Girls (n = 3877)					Boys (n = 3898)					Girls and boys together (n = 7775)				
	Control (n = 1926)		Experimental (n = 1951)			Control (n = 1968)		Experimental (n = 1930)			Control (n = 3894)		Experimental (n = 3881)		
Pair	No.	Prev, %	No.	Prev, %	Δ,* %	No.	Prev, %	No.	Prev, %	Δ,* %	No.	Prev, %	No.	Prev, %	Δ,* %
1	67	25.4	64	28.1	**–2.8**	69	47.8	66	30.3	**17.5**	136	36.8	130	29.2	**7.5**
2	69	26.1	65	38.5	**–12.4**	73	38.4	70	24.3	**14.1**	142	32.4	135	31.1	**1.3**
3	92	21.7	102	22.5	**–0.8**	106	30.2	111	26.1	**4.1**	198	26.3	213	24.4	**1.8**
4	117	35.0	160	33.8	**1.3**	118	41.5	153	30.1	**11.5**	235	38.3	313	31.9	**6.3**
5	216	27.3	257	21.8	**5.5**	183	28.4	243	27.6	**0.8**	399	27.8	500	24.6	**3.2**
6	90	36.7	210	29.5	**7.1**	96	37.5	223	32.3	**5.2**	186	37.1	433	30.9	**6.1**
7	75	36.0	53	39.6	**–3.6**	87	36.8	49	24.5	**12.3**	162	36.4	102	32.4	**4.1**
8	89	20.2	52	30.8	**–10.5**	83	36.1	40	35.0	**1.1**	172	27.9	92	32.6	**–4.7**
9	151	27.2	128	25.0	**2.2**	193	43.0	122	28.7	**14.3**	344	36.0	250	26.8	**9.2**
10	116	22.4	96	25.0	**–2.6**	105	33.3	86	25.6	**7.8**	221	27.6	182	25.3	**2.3**
11	38	15.8	33	18.2	**–2.4**	45	13.3	40	30.0	**–16.7**	83	14.5	73	24.7	**–10.2**
12	168	19.6	139	27.3	**–7.7**	189	25.9	140	33.6	**–7.6**	357	23.0	279	30.5	**–7.5**
13	89	23.6	87	24.1	**–0.5**	77	33.8	90	18.9	**14.9**	166	28.3	177	21.5	**6.8**
14	32	21.9	42	14.3	**7.6**	33	27.3	61	24.6	**2.7**	65	24.6	103	20.4	**4.2**
15	102	28.4	118	25.4	**3.0**	118	28.8	103	34.0	**–5.2**	220	28.6	221	29.4	**–0.8**
16	127	18.1	83	25.3	**–7.2**	120	20.8	60	28.3	**–7.5**	247	19.4	143	26.6	**–7.1**
17	62	4.8	33	27.3	**–22.4**	41	22.0	30	33.3	**–11.4**	103	11.7	63	30.2	**–18.5**
18	149	30.2	95	28.4	**1.8**	155	25.2	97	39.2	**–14.0**	304	27.6	192	33.9	**–6.2**
19	35	40.0	42	35.7	**4.3**	38	36.8	61	39.3	**–2.5**	73	38.4	103	37.9	**0.5**
20	42	28.6	92	23.9	**4.7**	39	46.2	85	32.9	**13.2**	81	37.0	177	28.2	**8.8**
Overall	1926	25.6	1951	27.0	**–1.4**†	1968	32.5	1930	29.9	**2.6**‡	3894	29.07	3881	28.42	**0.65**§
	95% confidence interval (CI) = **–5.0 to 1.6**						95% CI = **–2.5 to 7.7**						95% CI = **–2.8 to 3.8**		

*Δ = difference: prevalence in control school district minus prevalence in paired experimental school district.
†P = .38 (two-sided permutation test).
‡P = .30 (two-sided permutation test).
§P = .68 (two-sided permutation test).

Table 7. Other smoking endpoints at 2 years after high school

	Girls				Boys				Girls and boys together			
	Control	Experimental	Δ,* %	95% confidence interval	Control	Experimental	Δ,* %	95% confidence interval	Control	Experimental	Δ,* %	95% confidence interval
Current smoking												
Any smoking, %	37.9	38.0	**–0.1**	–3.5 to 2.8	44.5	41.6	**2.9**†	–1.6 to 7.7	41.2	39.8	**1.4**	–1.3 to 4.0
At least weekly smoking, %	30.6	31.2	**–0.5**	–4.1 to 2.3	37.9	34.9	**2.9**	–2.1 to 7.9	34.3	33.0	**1.3**	–2.0 to 4.1
At least daily smoking, %	25.6	27.0	**–1.4**	–5.0 to 1.6	32.5	29.9	**2.6**	–2.5 to 7.7	29.1	28.4	**0.6**	–2.8 to 3.8
Smoking frequency‡	1.05	1.07	**–0.02**	–0.13 to 0.06	1.36	1.26	**0.1**	–0.1 to 0.3	1.21	1.16	**0.04**	–0.06 to 0.14
Smoking acquisition stage§	3.41	3.42	**–0.01**	–0.19 to 0.13	3.79	3.69	**0.1**	–0.1 to 0.3	3.61	3.56	**0.05**	–0.11 to 0.18
No. of cigarettes per day‖	11.6	11.4	**0.2**	–1.0 to 1.3	14.2	14.0	**0.2**	–0.6 to 1.1	13.0	12.7	**0.3**	–0.3 to 0.9
Cumulative smoking: smoked >100 cigarettes in lifetime, %	42.0	41.1	**1.0**	–4.0 to 4.9	49.1	45.2	**3.9**¶	–0.9 to 8.6	45.6	43.1	**2.5**#	–1.6 to 5.9
Grade when first reported smoking**												
Weekly	11.17	11.21	**–0.04**	–0.31 to 0.27	11.41	11.20	**0.20**	–0.04 to 0.46	11.30	11.20	**0.09**	–0.09 to 0.28
Daily	11.42	11.44	**–0.02**	–0.27 to 0.22	11.66	11.47	**0.19**	–0.04 to 0.42	11.54	11.45	**0.09**	–0.05 to 0.25

*Δ = difference: prevalence or average in control school districts minus prevalence or average in experimental school districts.
†P = .19 (two-sided permutation test).
‡Average of scale for smoking frequency with level-of-daily smoking refinement. Scale: 0 = never smoked or don't smoke now; 1 = smokes less than once per week; 2 = smokes at least once per week but less than once per day; 3 = smokes 1–10 cigarettes per day; 4 = smokes 11–20 cigarettes per day; 5 = smokes more than 20 cigarettes per day.
§Average of scale for stage of acquisition. Scale: 1 = never smoked; 2 = tried once; 3 = tried more than once but quit; 4 = experimenter (smokes less than once per week); 5 = regular weekly smoker (at least once per week but less than once per day); 6 = light daily smoker (1–10 cigarettes per day); 7 = heavy smoker (more than 10 cigarettes per day).
‖Based on last 7 days' use among daily smokers, truncated at 30 cigarettes per day.
¶P = .11 (two-sided permutation test).
#P = .20 (two-sided permutation test).
**Among those who ever reported smoking at or above level indicated.

Table 8. Prevalence (Prev) of daily smoking by *a priori*-hypothesized subgroups, girls and boys analyzed together

Subgroup	Control No.	Control Prev, %	Experimental No.	Experimental Prev, %	Δ,* %	95% confidence interval	*P*
At grade 12							
Child/family risk for smoking							
High†	1381	34.5	1464	34.3	**0.2**	−4.1 to 4.5	.93
Low‡	1536	17.3	1460	17.5	**−0.2**	−5.0 to 3.9	.92
Unknown§	542	25.8	581	19.3	**6.6**	0.9 to 12.2	.025
Unknown‖	417	27.3	342	31.3	**−3.9**	−13.0 to 6.0	.41
Enrollment in grades 3–10¶							
Partial enrollment	1434	33.1	1614	32.9	**0.2**	−4.4 to 4.1	.91
Full enrollment	2442	21.3	2233	19.9	**1.4**	−3.3 to 5.8	.53
School risk for smoking#							
High**	1579	28.1	1670	26.0	**2.0**	#	.25
Low††	1828	23.6	1720	25.2	**−1.7**	#	.25
Unknown§	469	25.8	457	23.4	**2.4**	#	.5
At 2 years after high school							
Child/family risk for smoking							
High†	1374	37.5	1458	36.3	**1.2**	−2.6 to 5.0	.50
Low‡	1533	19.7	1474	20.6	**−0.9**	−5.8 to 3.6	.68
Unknown§	544	31.3	596	27.9	**3.4**	−1.2 to 8.1	.13
Unknown‖	443	32.7	353	29.5	**3.3**	−5.0 to 11.5	.41
Enrollment in grades 3–10¶							
Partial enrollment	1435	37.4	1628	36.1	**1.2**	−3.4 to 5.3	.57
Full enrollment	2459	24.2	2253	22.9	**1.4**	−2.3 to 5.0	.45
School risk for smoking#							
High**	1588	31.4	1696	29.2	**2.2**	#	.13
Low††	1830	26.5	1707	27.8	**−1.3**	#	.25
Unknown§	476	31.1	478	27.6	**3.5**	#	.25

*Δ = difference: prevalence in control school districts minus prevalence in experimental school districts.

†Smoked one or more cigarettes at or prior to baseline, or one or both parents smoked at baseline, or one or more siblings smoked at baseline.

‡Didn't smoke at or prior to baseline, no parent smoked at baseline, and no sibling smoked at baseline.

§Survey not attempted, per design or other reason.

‖Survey attempted, but data not obtained (e.g., no reply).

¶Partial enrollment = experienced fewer than 8 years of enrollment in a Hutchinson Smoking Prevention Project (HSPP) cohort class between grades 3 and 10, inclusive; full enrollment = experienced at least 8 years of enrollment in HSPP cohort class between grades 3 and 10, inclusive.

#School risk is a school district-level variable. A 95% confidence interval does not exist because there are too few pairs of school districts in which both school districts are at the same risk level.

**2.2% or more of older students (grade 5) smoke at baseline.

††Fewer than 2.2% of older students (grade 5) smoke at baseline.

dents in the control and experimental school districts ($\Delta = 0.8$ cigarette per day; $P = .04$).

Results at 2 Years After High School (Plus 2)

The intervention impact results at 2 years after high school are similar to those reported at grade 12: The differences between control and experimental school districts are small and are not statistically significant (Tables 6 and 7). A notable difference between the daily smoking prevalence at grade 12 versus that at Plus 2 is that daily smoking prevalences are higher at Plus 2 than at the 12th grade (compare Tables 5 and 7).

Results for *a Priori*-Hypothesized Subgroup Variables

Intervention impact results by the three *a priori*-hypothesized subgroup variables are reported in Table 8. With one possible exception, there is no evidence of an intervention impact in any of the subgroups, either at grade 12 or at Plus 2. The one exception is at grade 12 for one of the unknown subgroups for child/family risk for smoking: those students whose entry into the study predated a baseline survey of parents to determine their smoking behavior. For this group of students, the difference in prevalence of daily smoking between the control and experimental group was 6.6% ($P = .025$), but this effect was smaller and not statistically significant ($P = .13$) at Plus 2.

Discussion

Our results indicate that there was no substantial difference in smoking prevalence for students in the control and experimental conditions, as assessed at grade 12 and at 2 years after high school, either for girls or for boys. Indeed, at grade 12 and at Plus 2, there was a remarkable similarity between the control and experimental conditions, both for girls and for boys, for all smoking endpoints covering a range of smoking behaviors and for all of the *a priori* subgroups. The observed effect sizes were very small. For daily smoking, girls and boys together, the difference was 25.7%–25.4% = 0.3% (95% CI = −3.5% to 3.7%) at grade 12 (Table 4) and 29.07% − 28.42% = 0.65% (95% CI = −2.8% to 3.8%) at 2 years after high school (Table 6).

Because of the randomized nature of the assignment of intervention condition and because of the experimental rigor of the HSPP trial, the lack of difference in smoking prevalence be-

tween the control and experimental conditions leads to the conclusion that the HSPP intervention had very little or no impact on smoking prevalence. The alternative possibility—that the intervention may actually have affected smoking prevalence but that the effect was canceled and, thus, unobserved because of chance or bias favoring the control group—is not plausible for the following seven reasons: 1) Chance cannot explain the null results. The trial was adequately powered, with a sample size (40 school districts and 8388 children) sufficient to accommodate intraclass correlation among individual student outcomes within school district and to investigate intervention impact for girls and boys separately. Moreover, the 95% CIs, which assess the range of possible effect sizes consistent with the data, show that the possibility of moderate effect sizes is not consistent with the data. 2) The randomized assignment was maintained: Each of the 40 school districts accepted and maintained its randomized assignment and participated fully in all research activities during the 12-year collaboration. 3) Because the school district was the experimental unit, there was minimal (<1.7%, data not shown) social mixing during the trial between students in the experimental and control conditions. 4) The 6% non-survey rate is unlikely to have resulted in substantial bias in the overall results. Not only is a 6% non-survey rate very small, but also only 9.7% of the students not surveyed were exposed to the full intervention, and only 28% were exposed to half or more of the intervention. Thus, those not surveyed would be expected to be those who would benefit *least* from the intervention. Moreover, little difference in results was observed between those difficult to follow and those easy to follow among the 94% successfully followed-up (data not shown). 5) The control and experimental groups were well matched at baseline *(38).* 6) Poor compliance with intervention implementation, which has dogged some other trials, was not present in this trial *(52).* 7) The statistical method chosen for analysis for this group-randomized trial—randomization-based permutation tests—is one that accounts for the school district as the experimental unit (i.e., accommodates intraclass correlation within school districts), takes full advantage of the fact of randomized intervention assignment as the basis for inference, and has good efficiency.

In sum, because of the high degree of rigor achieved in the design and execution of this trial, the failure to observe reduced smoking prevalence in the experimental group is attributable only to the failure of the intervention and not to these alternative possibilities. We must conclude, then, that the HSPP school-based, enhanced social-influences smoking prevention intervention that started early, and that was sustained throughout the period of smoking acquisition, did not work.

The implications of our results for the field of smoking prevention among youth are considerable. These disappointing results raise serious concerns about the social-influences approach as presently conceived and applied to smoking prevention in the school/classroom setting, including those school-based interventions that comply with CDC's "best practices" guidelines for comprehensive tobacco control programs *(41).* The HSPP intervention spans grades 3–12, covering virtually the entire period of smoking onset *(40,82).* It includes all of the components recommended by the NCI-sponsored Expert Advisory Panel *(39)* and by the CDC's guidelines for school tobacco use prevention programs *(40).* It was well implemented by trained classroom teachers and was evaluated rigorously. Nevertheless, the intervention had no impact on smoking prevalence among youth. The HSPP results thus suggest that current school program "best practices" are not strong enough to deter adolescent tobacco use.

A new round of theory development and empirical basic research appears essential to gain additional insights into mechanisms of smoking initiation among youth and strategies for its prevention. Important goals of such research would include the following: 1) identification of risk factors that are highly predictive of subsequent smoking by children; 2) identification of those highly predictive risk factors that are theoretically modifiable; 3) assessment of the extent to which changing these risk factors might be expected to reduce smoking acquisition among youth; and 4) critical re-evaluation of current behavior change strategies, together with the development and testing of new strategies for changing the identified predictive risk factors and, ultimately, reducing smoking among youth.

Also indicated is further investigation of intervention strategies that provide a broad array of life-skills training. Such strategies have already been investigated by Botvin and colleagues *(17,30,83),* who reported a positive long-term impact of life-skills training on smoking among youth.

Further critical evaluation of the various possible venues (e.g., school, families, and youth clubs) and providers (e.g., teachers, parents, peers, and media) that can effectively gain the attention and trust of youth, especially those at high risk for smoking, is also needed. For example, although schools have many logistical advantages for youth intervention, they also have some disadvantages for reaching high-risk youth, many of whom are rebellious, indifferent to academics, at risk for illegal drug use, chronically absent, or otherwise not engaged by the schools or their teachers *(84).*

An intervention approach that combines school-based components with community-based components (e.g., mass media) might be worthy of consideration. Investigations of such approaches have started [e.g., *(85–87)*], albeit only with nonrandomized and/or very few *(2–6)* experimental units. To date, there have been no randomized trial results that show long-term (i.e., through grade 12) effectiveness of such a combined approach. Such trials may be helpful sometime in the future, especially once school-based components with long-term effectiveness have been identified.

Our judgment is that, given this major failure of the social-influences approach despite the extensive nature of the intervention, the remedy should not be more of the same (e.g., starting earlier, lasting longer, or combining unproven components with other approaches). It may be time for an altogether new approach that incorporates different theories, different intervention strategies, different venues, and/or different providers.

Finally, secondary analyses of the HSPP data are needed to investigate why the intervention did not work. First, investigations of the extent to which the HSPP intervention succeeded in changing targeted factors (e.g., beliefs and attitudes about smoking/nonsmoking, perceived norms of youth/adult smoking prevalence, antipathy toward the actions of the tobacco industry, knowledge of immediate and long-term physical and social consequences of smoking, identification of social influences to smoke, skills and self-confidence to resist such social influences, and intentions to smoke in the future) would suggest to what extent the behavior-change strategies were successful or unsuccessful. Second, investigations of the extent to which changes in the targeted factors predicted abstinence from smoking would

contribute to the critical evaluations, suggested above, of our current understanding of the smoking acquisition process and of the risk factors thought to be highly predictive for subsequent smoking. Third, an investigation of characteristics of those school districts and cohorts within school districts for which extremely low or extremely high smoking prevalences were observed might provide additional clues about which aspects of the school, family, peers, or community environment are conducive to smoking and which are deterrent. For example, among girls in one district, the prevalence of daily smoking was 0.0%; in another district, it was 41.9% (Table 4). Fourth, investigation of the rise in smoking prevalence between grade 12 and 2 years after high school, including distinguishing between new initiation and cessation, would help us understand the personal and environmental factors responsible for the continued rise in smoking after high school.

In conclusion, as a result of experimental design features and methodologic successes, the HSPP is the most rigorous study to date in school-based smoking prevention; thus, high credence is suggested for the trial results concerning intervention impact. Unfortunately, and consistent with previous randomized trials in school-based smoking prevention that have used the social-influences approach and that have followed children to grade 12, there is no evidence from the HSPP trial that a school-based social-influences approach is effective in deterring smoking among youth, either overall or for low- or high-risk children.

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NOTES

[1]A 12.6% sample was chosen to allow a 4% absolute difference in misreporting fraction between experimental and control study participants to be detected with probability 90%.

Supported by Public Health Service grants R01CA38269, P01CA34847, and R01CA57388 from the National Cancer Institute (NCI), National Institutes of Health, Department of Health and Human Services; and by a donation from the Northern Life Insurance Company.

We acknowledge with deep appreciation the children (now young adults), parents, teachers, administrators, and school staff who participated in this trial and the leadership, support, and collaboration of the 40 participating Washington State school districts. Contributing to the initial experimental design and providing wise counsel throughout were Ross L. Prentice, Maureen M. Henderson, and Terry Janicki. Also contributing to the experimental design and methods were the trial's scientific consultants: J. Allan Best, K. Stephen Brown, David Murray, Vaughn Call, and Don Dillman. Members of an external advisory panel for minimizing contamination were Donald Iverson, David Murray, and Terry Pechacek. Invaluable encouragement and counsel were generously provided by the trial's NCI Project Officer, Thomas J. Glynn.

Manuscript received July 5, 2000; revised September 14, 2000; accepted October 17, 2000.