A randomized controlled trial of two primary school intervention strategies to prevent early onset tobacco smoking

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Abstract

In this article, we examine the impact of two universal, grade 1 preventive interventions on the onset of tobacco smoking as assessed in early adolescence. The classroom-centered (CC) intervention was designed to reduce the risk for tobacco smoking by enhancing teachers' behavior management skills in first grade and, thereby, reducing child attention problems and aggressive and shy behavior—known risk behaviors for later substance use. The family–school partnership (FSP) intervention targeted these early risk behaviors via improvements in parent–teacher communication and parents' child behavior management strategies. A cohort of 678 urban, predominately African–American, public school students were randomly assigned to one of three Grade 1 classrooms at entrance to primary school (age 6). One classroom featured the CC intervention, a second the FSP intervention, and the third served as a control classroom. Six years later, 81% of the students completed audio computer-assisted self-interviews. Relative to controls, a modest attenuation in the risk of smoking initiation was found for students who had been assigned to either the CC or FSP intervention classrooms (26% versus 33%) (adjusted relative risk for CC/control contrast = 0.57, 95% confidence interval (CI), 0.34–0.96; adjusted relative risk for FSP/control contrast = 0.69, 95% CI, 0.50–0.97). Results lend support to targeting the early antecedent risk behaviors for tobacco smoking. © 2002 Elsevier Science Ireland Ltd. All rights reserved.

Keywords: Randomized clinical trial; Adolescence; Smoking; Survival analysis; Prevention

1. Introduction

The aim of this study is to estimate the efficacy of two primary school preventive interventions designed to ameliorate malleable early antecedents of smoking. The study was organized as a group-randomized controlled trial with intervention and control arms. The conceptual background for this research includes an array of complimentary conceptual models that link early aggression and rule-breaking behaviors with early emergence of youthful drug-taking (e.g. see Kellam and Rebok, 1992; Patterson et al., 1992). The research represents a shift in focus for drug prevention programs. For about 30 years, the field of smoking prevention has been dominated by a 'school-based' drug education paradigm. Before the 1970s, drug education consisted mainly of scare tactics and informational programs that seem to have promoted awareness of tobacco-related harms, but did little or nothing to affect the incidence of teen tobacco smoking (Ennett et al., 1994; Flay, 2000). More recently, social psychological concepts and principles have been used to promote resistance to peer pressure to smoke and to build social skills that might help young people refrain from starting to smoke. Some forms of peer resistance and social skills programs for secondary school students have seen limited success in the delay of adolescent tobacco smoking, at least through follow-up intervals of up to multiple years duration (Ellickson and Bell, 1990; Botvin et al., 1995; Peterson et al., 2000). Nonetheless, even when

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these programs have short-term beneficial impact, they do not seem to work for adolescents who started to smoke before the program (Elickson and Bell, 1990; Jackson et al., 1997). The goal of ‘tobacco-free cohorts’ will require early interventions in place before the pre-teen years.

In complement with secondary school intervention programs, there are some already-developed smoking prevention programs for primary school pupils. Some of these interventions are based upon the proposition that tobacco smoking has identifiable causal antecedents, observable in the early years of primary school, or before school entry. These primary school programs target these early antecedents, seek to modify the antecedents, and thereby aim to delay the onset or prevent the occurrence of tobacco smoking and related behavior. Our research group has described one recent example of this type of intervention, as well as initial evidence of beneficial preventive impact through early adolescence (Kellam and Anthony, 1998). In brief, we targeted early rule-breaking and other socially mal-adaptive behavior in primary school, previously found to help account for tobacco and other drug involvement of teenage boys. At their entry onto the school, or before school entry. These primary school programs target these early antecedents, seek to modify the antecedents, and thereby aim to delay the occurrence of tobacco smoking and related behavior. Our research group has described one recent example of this type of intervention, as well as initial evidence of beneficial preventive impact through early adolescence (Kellam and Anthony, 1998).

Follow-up evidence through age 14 was balanced in favor of beneficial program impact, with reduced risk and delayed onset of tobacco smoking of boys exposed to the GBG intervention (Kellam and Anthony, 1998). From the early days of the GBG study, our research team has been asked whether the same impact could be achieved with just 1 year of GBG programming (during grade 1 of primary school), and whether we might see a greater impact if family resources were brought into play with those of the classroom teacher. A separate randomized controlled trial was designed to address these issues. The goal of this report is to evaluate the impact of a shortened GBG program (Grade 1 only) and a family-school partnership (FSP) intervention on delayed onset of tobacco smoking 6 years after the intervention ended.

As described in detail in Ialongo et al. (1999), the conceptual basis for the interventions was derived from the life course/social fields framework (Kellam and Rebok, 1992) and its integration with Patterson et al.’s (1992) model of the development of antisocial behavior and substance use. Briefly, the CC and FSP interventions were hypothesized to reduce the early antecedent risk behaviors of aggressive and shy behaviors and their distal correlates, such as tobacco smoking, by improving teachers’ and parents’ disciplinary practices, respectively, and through the enhancement of parent–teacher communication in the case of the FSP intervention (see Henderson, 1987; Sattes, 1985). The reductions in the early antecedent risk behaviors were hypothesized, in turn, to lower the risk for antisocial behavior and substance use in adolescence and young adulthood. As reported in Ialongo et al., the CC and FSP interventions had significant impact on the early risk behaviors of attention/concentration problems and aggressive and shy behavior through the Grade 2 follow-up (Ialongo et al., 1999).

2. Methods

2.1. Study participants

In Fall of 1993, a total of 678 pupils started grade 1 in the nine participating Baltimore City public primary schools (Fig. 1). Among eligible pupils, 53% were male, 86% were African-American, with 14% of Euro-American heritage. The students ranged in age from 5.3 to 7.7 years with a mean age of 5.7 years (S.D. = 0.5). Nearly two-thirds of the children (62%) received free or reduced lunch—a proxy for low family income. Three percent of the parents or guardians refused to participate in the parental assessments, or failed to respond to the request for active informed consent and signature for their children to participate in baseline self-report measures. Consent status was not associated with the just described characteristics of the children.

At the 6-year follow-up, active written consent was obtained from parents for their child’s participation in the follow-up assessments. Assent was obtained from the child at the time of the interview. Letters of explanation and consent forms were sent to parents via mail or through teachers and students. Follow-up telephone contacts and home visits were conducted to responded to parents’ concerns and questions about their child’s participation. Ninety-four percent of those parents located at follow-up gave permission for their child to participate, whereas 6% either actively or passively refused participation (i.e. failed to respond to the consent request after repeated consent solicitations).

2.2. Research design

A randomized block design was employed, with each of the nine schools serving as a blocking factor, and with a statistical analysis plan appropriate for group-level interventions. Within each school, children and teachers were randomly assigned to one of two intervention or control classrooms. The interventions were kept in place throughout the Grade 1 academic year,
once the children had completed a pre-program assessment in the early Fall. In the present paper, we examine the impact of the interventions on a distal target, risk of starting to smoke tobacco, 6 years after the end of the intervention programs, when most of the youth were completing Grade 7, or approximately age 12.

2.3. Interventions

2.3.1. The classroom-centered intervention (CC)

The classroom-centered (CC) intervention consisted of three components: (1) curriculum enhancements; (2) enhanced behavior management practices; and (3) back-up strategies for children not performing adequately. Each CC class was divided into three heterogeneous groups, which provided the underlying structure for the curricular and behavioral components of the classroom intervention. The existing school curriculum in language arts and mathematics was enhanced through the addition of new and supplementary curricular materials designed to increase critical thinking, composition, and listening and comprehension skills. Current behavior management practices were enhanced with use of the GBG (Dolan et al., 1989; Kellam et al., 1994) that promoted child social problem solving within a group context (Johnson and Johnson, 1987).

The GBG, developed and found efficacious by Barrish et al. (1969), is a whole-class strategy to decrease aggressive/disruptive behavior and increase time on task. In the GBG, children are assigned to one of three heterogeneous groups in each classroom and points are given to the team for precisely defined good behavior by its members and taken away for off-task and other socially maladaptive behaviors such as starting fights. The points are then exchanged for a variety of tangible rewards in the form of classroom activities, stickers, erasers, etc. Initially, game periods are announced, and the rewards are delivered immediately afterwards. Later, the rewards are delayed to the end of the school day or week. Material reinforcers were accompanied by social reinforcers, with the material rewards gradually phased out over the school year and replaced with social reinforcers. Back up strategies for children not responding to the GBG included creating single member teams for such children. In that way the link between their behavior and rewards and punishments would be more direct and, therefore, more likely to increase the rate of learning appropriate behavior.

2.3.2. The FSP intervention

The FSP intervention was designed to improve achievement and reduce early aggression, shy behavior

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**Fig. 1. Flowchart of enrollment in Grade 1 through follow-up in Grade 7.**
and concentration problems by enhancing parent–teacher communication and providing parents’ with effective teaching and child behavior management strategies. The major mechanisms for achieving these aims were: (1) training for teachers and other relevant school staff in parent–teacher communication and partnership building; (2) weekly home-school learning and communication activities; and (3) a series of nine workshops for parents lead by the first grade teacher and the school psychologist or social worker. The Parents on Your Side program (Canter and Canter, 1991) formed the basis for training teachers in partnership building and parent–teacher communication. The program included a 3-day seminar with follow-up supervisory visits and an explicit training manual that is accompanied by videotape training aides.

The parent workshop series began immediately after the pretest assessments in the Fall of Grade 1 and ran for seven consecutive weeks—one workshop per week—through early December. Two follow-up or booster workshops were held in the winter and spring of Grade 1, respectively. The first two parent workshops aimed at establishing an effective and enduring partnership between parents and school staff and set the stage for parent–school collaboration in facilitating children’s learning and behavior. The next five workshops focused on effective disciplinary strategies. The Parents and Children series, a videotape modeling group discussion program developed by Webster-Stratton (1984), formed the basis for this component of the intervention. These workshops were led by each schools’ psychologist or social worker, with topics that included effective praise, play, limit setting, time-out versus spanking, and problem-solving. In addition to the workshops, a voice mail system, or a ‘Warm Line’, was put in place in each school to maintain parent involvement and to facilitate parent–school communication and collaboration around children’s learning or behavior management difficulties.

2.3.3. Control condition

Children whose random assignment placed them in control classrooms had the benefit of the usual and customary curriculum and parent–teacher communication and interaction (e.g. parent visits, parent–teacher organization meetings), without the special elements of the CC and FSP conditions.

2.3.4. Intervention training and fidelity

Teachers assigned to the CC intervention completed 60 h of CC training and received certification. Similarly, teachers assigned to the FSP condition, and each school social worker or psychologist, completed 60 h of FSP training and received certification. During the intervention period, teachers and school staff met with our intervention experts individually ad lib in order to promote effective program implementation. In addition, all intervention teachers attended monthly meetings to discuss common intervention issues and to receive ongoing support. To prevent ‘spill over’, all participating teachers and school administrators were regularly made aware in planning, training, and supervisory meetings of the need to protect against ‘spill over’ effects to avoid undermining the validity of the study results.

To monitor and sustain the integrity of both the CC and FSP interventions, the training and intervention manuals were precisely delineated and codified, thus standardizing the content of each training and intervention contact. In addition, teachers had a number of materials available designed to foster correct execution of the interventions, including detailed outlines and checklists that prescribe the necessary materials for each intervention contact, the specific themes or tasks that need to be covered, and related information.

In terms of implementation and/or participation checks specific to each intervention, the monitoring of fidelity of implementation for the CC intervention involved three parts: (1) measures of setting up the classroom; (2) classroom observation sessions; and (3) classroom visit record reviews. Information was gathered during monthly supervisory meetings and three classroom visits made over the year. With respect to the FSP intervention, intervenors were required to provide documentation of each contact with parents, including, where appropriate, summaries of what transpired, any unique features, duration of the contacts, parent or child attendance, and level of participation and compliance with ‘homework assignments’. Parents involved in the FSP intervention anonymously reported on their implementation and the usefulness of the techniques taught, and were also asked to report on the family intervenors’ interpersonal and teaching skills. Live and audio taped observations of parent workshops were made to determine the extent to which the intervention protocols were being adhered to and well administered.

2.3.4.1. Level of participation/implementation in the CC and FSP interventions. Each of the nine CC intervention classrooms were assigned a score from 0 to 100 representing the percentage of the teacher’s implementation of the intervention as designed. Scores were based on the three sources of implementation data identified above: (1) measures of setting up the classroom; (2) classroom observation sessions; and (3) classroom visit record reviews. CC implementation scores ranged from 30 to 78%, with a median of 64.4%, and a mean of 59.9% (S.D. = 17.0%). All but two of the nine CC intervention teachers implemented more than 50% of the intervention protocol. In terms of the FSP intervention, parents/caregivers attended on average four (S.D. = 2.4, median 5.0, range 0–7) of the seven core
parenting sessions offered in the Fall of Grade 1, or 57.1% of the available sessions. Just less than 13% (12.7%) of the parents/caregivers failed to attend any of the core workshops, whereas just more than a third (35.3%) of the parents attended at least six of the seven sessions.

2.4. Assessments

2.4.1. Tobacco onset

In this report, the primary response variable was the risk of starting to smoke tobacco or time to the initiation of tobacco smoking. Youth’s self-reported use of tobacco was first assessed 6 years after the end of the intervention year when they were 12 years old on average. Reliable reporting of tobacco smoking has been found among children as young as 8–11 years (Henriksen and Jackson, 1999). Whereas standardized self-administered answer sheets and private confidential interviews have been used in prior evaluations of time to initiation of tobacco smoking, in this study we used the audio computer-assisted self interview (ACASI) method. The ACASI method involves each participant sitting down with a laptop computer, putting on headphones, and both listening and seeing standardized questions and responses as they are streamed in audio and visual displays. The federal government’s evaluation of its mass media anti-drug campaign and the National Household Survey on Drug Abuse (NHSDA) that is conducted each year for a ‘national report card’ on the nation’s drug experiences also use ACASI methods (Office of Applied Studies, 2001). Others have shown the superiority and more complete reporting of sensitive behaviors when ACASI methods are used in place of standard questionnaire and interview methods of assessing youth drug involvement (Turner et al., 1998; Murphy et al., 2000).

Time to initiation of tobacco smoking was assessed via the same standard question used in the NHSDA after a lead question where the youth indicated whether they ever smoked tobacco, even just a puff. This was followed by a question inquiring how old they were the first time they smoked tobacco. There is no bioassay to measure time to initiation to tobacco smoking, and the prevalence of active smoking by African–American students is too low at age 14 to make current smoking a viable outcome measure for a study of this size and statistical power. For this reason we gave special attention to our approach to measure smoking onset, with careful reassurances about privacy and confidentiality.

In order to promote honest reporting, the staff interviewer sat down across from the youth in a private location within the school (e.g., vacant office or classroom). The first part of the session was devoted to developing trust and rapport via informal conversation, followed by an explanation of the ACASI method and completing the formal youth assent process in accord with a protocol approved by the cognizant Institutional Review Board. The interviewer provided assurances that the information would be recorded and treated in a confidential manner. After answering all of the youth’s questions, the ACASI program was started and the laptop was turned to face the youth. Each youth answered the questions without observation of their choices by anyone. The sequence of questions within the ACASI session was designed to promote accurate and complete responding. The interview began with questions on social adaptation, feelings of psychological well-being and perception of control. Questions on tobacco smoking occurred about midway into the 90-min duration of the ACASI session.

A small number of students were not present in school (e.g. home schooled, absent or expelled). These 20 youths (3%) were interviewed at home in a private location, also with the ACASI method described above.

2.4.2. Measurement of covariates

It is possible to evaluate the impact of the CC and FSP interventions with three variables: intervention status as ‘intent to treat’, time to initiation of smoking, and sex (male vs. female). Nonetheless, we attempted to strengthen the evaluation by taking into account several of the behavioral and parenting characteristics previously found to account for youthful drug involvement. These characteristics were measured in the Fall of Grade 1, before the interventions started.

2.4.2.1. Parent reports. A number of family and household characteristics (e.g., marital status, ethnicity) were assessed by parent/caregiver report during an approximately 60-min telephone interview. Eighty-nine percent of the consenting parents in the fall of Grade 1 completed a parent telephone interview at that time. Tobacco use by adult family household members in Fall of Grade 1 was assessed using a standardized item adapted from the National Health and Nutrition Examination interview (Would you say heavy tobacco use affected your family in the last 12 months?) (National Center for Health Statistics, 1990). We also obtained the biological father’s and mother’s involvement in the child’s care giving. A Structured Interview of Parent Management Skills and Practices—Parent Version (SIPMSP) was administered just before the FSP intervention started (Capaldi and Patterson, 1989). It was designed to assess major constructs included by Patterson and colleagues in a model of parenting practices that are important in the development of antisocial behavior in children (Patterson et al., 1992). Subscales for the present study include: (1) parental supervision and monitoring of the child (e.g., ‘How often is child out after dark without an adult present?’); and (2) inconsistent discipline (e.g., ‘How often can child talk
you out of punishing him/her?”). Parents responded to questions in forced choice response formats with a range from 1 (Almost always) to 5 (Never).

2.4.2.2. Teacher reports. Each child was rated by the teacher on adequacy of performance on core classroom tasks using the Teacher Observation of Classroom Adaptation-Revised (TOCA-R) scale (Werthamer-Larsson et al., 1991). A trained interviewer follows a structured script precisely and responds in a standardized way to issues the teacher initiates. The interviewer records the teacher’s ratings on three basic tasks: accepting authority (the maladaptive form being misbehavior, rule-breaking, and aggressive behavior); social participation (socially avoidant, withdrawn, or shy behavior); and concentration and being ready for work (the maladaptive form being concentration problems). Teachers rate the observed child’s adaptation on a frequency scale from 1 to 6 (1 = not at all, 6 = always). Teacher reports were obtained on 100% of the children at the baseline assessment. The TOCA-R score used in this impact analysis was the mean of the items making up the aggression, shy behavior and concentration problems subscales. Our decision to use the total score as opposed to the individual subscales reflected the fact that these maladaptive behaviors typically co-occur, as reflected in an internal consistency reliability statistic of 0.96 (Cronbach’s ) for the total scale.

2.4.3. Sample attrition
As might be expected in a study with a 6-year follow-up interval, many families moved and some families broke up or became disengaged from the school and university connections, making it impossible to secure 100% participation for the ACASI assessments of smoking status (Fig. 1). Nevertheless, it was possible to secure ACASI assessment of 549 out of the original 678 recruited children (81%). This source of missing smoking data at follow-up was well-balanced across the CC, FSP, and control conditions (23, 18, 16%, respectively; \( \chi^2 = 4.1, 2 \) d.f., \( P \)-value = 0.13), and also with respect to all baseline characteristics described in our measurement plan.

2.5. Statistical analysis

2.5.1. A priori projection of statistical power
Based on a standard model for an intent-to-treat analysis, we projected statistical power of at least 80% to detect a between-group difference in cumulative risk of starting to smoke. The specifications for this projection were: (a) 150 children in each condition; (b) mean cumulative risk of 30%; (c) between group control/CC or control/FSP contrast of relative risk = 1.75, (d) \( \alpha = 0.05 \), two-tailed (Egret SIZ, 1993).

2.5.2. Analytic plan
After estimation of cumulative risk of starting to smoke tobacco, and basic contingency table analyses, standard life tables and survival analysis methods were used to compare the estimated risk of starting to smoke tobacco across the study subgroup. Then Cox regression models for time-to-event data were used to estimate the impact of interventions on risk of starting to smoke, in a manner that takes into account the membership of students in their original Grade 1 classrooms (i.e. with risk sets defined by school of origin). Statistical adjustment for baseline covariates was accomplished via elaboration of the Cox regression models. In these analyses, an initial model included dummy-coded indicator terms for the ‘intent to treat’ CC and FSP conditions. Terms for characteristics of the child in Grade 1: age, race, parental monitoring and supervision, family tobacco use, and teacher rating of the TOCA-R score were entered in the next step. We report estimates of intervention impact, and 95% confidence interval (CI), as a measure of uncertainty in the point estimates. \( P \)-values are reported as an aid to interpretation.

3. Results

3.1. Sample characteristics at randomization

Table 1 characterizes children assigned at random to the CC and FSP intervention conditions and the control group. Children in the control group were somewhat less likely to be male and to be of African–American heritage, as compared with children in the CC and FSP conditions. They were somewhat more likely to come from two-parent households. The teacher ratings of problem behavior (TOCA-R summary score) is modestly larger for CC children. We speculate that training of the CC teachers might have sensitized them to these problem behaviors (e.g. in relation to the training for the GBG component of the CC intervention). These between-group differences, though modest, motivated our use of statistical adjustment for covariates on the study’s regression analyses.

3.2. Six-year follow-up

Among the 549 youth assessed in Spring 2000, 6 years after intervention when most of them were completing seventh grade, a total of 156 (28%) reported that they had started to smoke tobacco. Specific for intervention status, these cumulative risk estimates are 33% (56/168) for youth in control classrooms, 26% (49/189) for those in the CC intervention, and 26% (51/192) for the FSP intervention.

Fig. 2 depicts estimates for the cumulative risk of starting to smoke tobacco for each experimental and
Table 1
Characteristics of sample at randomization (Fall Grade 1) by intervention status: Baltimore CC/FSP Prevention Trial 1993–2000

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Percentage distribution</th>
<th>Control (n = 219)</th>
<th>Classroom centered (n = 230)</th>
<th>Family–school (n = 229)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td></td>
<td>51.1</td>
<td>55.2</td>
<td>53.7</td>
</tr>
<tr>
<td>African–American</td>
<td></td>
<td>84.5</td>
<td>88.6</td>
<td>85.5</td>
</tr>
<tr>
<td>Two parent household</td>
<td></td>
<td>44.9</td>
<td>32.7</td>
<td>41.3</td>
</tr>
<tr>
<td>Family smoker</td>
<td></td>
<td>18.3</td>
<td>16.1</td>
<td>16.2</td>
</tr>
</tbody>
</table>

Mean (S.D.)

<table>
<thead>
<tr>
<th></th>
<th>Control (n = 219)</th>
<th>Classroom centered (n = 230)</th>
<th>Family–school (n = 229)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>6.2 (0.4)</td>
<td>6.2 (0.3)</td>
<td>6.2 (0.4)</td>
</tr>
<tr>
<td>TOCA-R summarya</td>
<td>1.5 (0.8)</td>
<td>1.8 (1.0)</td>
<td>1.5 (0.7)</td>
</tr>
<tr>
<td>Parent monitoringb</td>
<td>1.4 (0.3)</td>
<td>1.4 (0.3)</td>
<td>1.4 (0.3)</td>
</tr>
<tr>
<td>Parent disciplineb</td>
<td>2.0 (0.7)</td>
<td>2.1 (0.6)</td>
<td>2.1 (0.7)</td>
</tr>
</tbody>
</table>

*a Measured by teacher observation of classroom adaptation-revised (TOCA-R).

*b Measured by structured interview of parent management skills and practices (SIPMSP).

control group, based upon a basic life table analysis. Table 2 summarizes the estimated impact of the interventions in the form of risk ratios: the estimated risk for CC and FSP youth is about 75% of the expected value, derived on the basis of control group experiences. This modest attenuation in risk does not reflect statistical adjustment for the covariates listed in Table 1. Once these covariates are taken into account, the estimated risk ratio for the CC–control contrast is 0.57 (95% CI = 0.34–0.96; P = 0.03), and the estimated risk ratio for the FSP–control contrast is 0.69 (95% CI = 0.50–0.97; P = 0.03).

We probed for the possibility that the CC and FSP interventions might have had greater impact on boys, as discussed in the introduction, using product terms in an elaboration of the regression models. Based on an evaluation of goodness-of-fit statistics, there was no greater impact of interventions on boys.

4. Discussion

Evidence from the study’s main analyses is consistent with the hypothesized program impact on children’s risk of starting to smoke tobacco during the primary school years. The magnitude of program associated attenuation of risk is modest but noteworthy. It may be remarkable that a single year of preventive effort of this type is associated with even a modest attenuation of risk. The risk attenuation associated with the study’s FSP intervention was almost as great as the attenuation associated with the CC intervention.

Before we discuss these findings in detail, several study limitations must be acknowledged. First, with others, we wonder if these results can be replicated elsewhere. Future research will be needed to answer this question, and future research can clarify whether larger impact is gained by strengthening these Grade 1 interventions (e.g. via booster sessions). Second, we were able to recruit and re-engage 81% of the participating youth 6 years after the end of the intervention, including 20 youth who were no longer in school. Sample attrition was not associated with CC–FSP–control assignments, but this attrition is worrisome nonetheless. Additional logistic regression analysis, not shown, show similar intervention effects for the FSP and CC conditions compared to the control condition even if all the youth lost to follow-up are assumed to have started smoking. In our next wave of follow-up with this sample, we hope to have sufficient resources to push participation closer to 100%. Third, community-based randomized preventive trials represent an especially difficult form of biomedical and public health research. For this reason, it was necessary for practical reasons to work with a sample of only nine schools and only 600–700 children. Clearly, when risk-attenuation is at the 50–70% level this size of sample is not optimal with respect to precision of the study estimates. A study with 1000–2000 children would reduce the uncertainty that is reflected in the 95% confidence intervals of our estimates. Fourth, it might be said that a reduction in cumulative risk from 33 to 26% is not very large.
hoped for more substantial impact, but we are pleased to see evidence of risk attenuation, however modest, 6 years after a Grade 1 intervention. And finally, additional follow-up is warranted in several more years after the entire cohort has passed their peak onset incidence years.

Counterbalancing limitations and concerns of this type, there are some strengths that deserve mention. First, the research design was that of a true randomized experiment to evaluate a primary prevention program. The students were randomly assigned, helping to balance out characteristics that otherwise might lead to distorted estimates of impact. Grouping students and classrooms within risk sets defined by school at entry into Grade 1, and by working within a relatively homogeneous urban community is an advantage. Namely, this approach keeps in check some of the socially shared characteristics that can influence tobacco smoking (e.g., local attitudes and availability of tobacco to minors). In addition, the interventions were school-based, curriculum programs that were designed to be developmentally appropriate, and which can be used by others in replication of this experiment. In addition, there was covariate adjustment for characteristics measured from a variety of sources: teacher, parent, and school records.

Use of the ACASI method to assess time to first tobacco smoking also represents a strength and improvement over prior methods. Some critics might charge that a bioassay method would be preferable, but here we were concerned with time to first smoking and risk of starting to smoke, for which there is no current bioassay. Assessment of intervention impact on persistent or regular daily smoking must await a future follow-up of this sample, when smoking prevalence is larger, or for future experiments with much larger samples. Under these circumstances, the value of bioassays becomes clearer, but will not detract from the importance of measuring risk of starting to smoke. For example, this Grade 1 intervention might influence risk of starting to smoke, but have absolutely no influence on the persistence of smoking once smoking has started or the duration from first tobacco smoking into nicotine dependence.

Considered in light of the study limitations and counterbalancing strengths, the evidence from this experiment is consistent with the tenets of life course social field theory and the organizational theory of development (Cicchetti and Schneider-Rosen, 1984; Kellam and Rebok, 1992). As suggested by others, it is possible that early primary school success in meeting the early demands for authority acceptance, attention to task, and social participation presages later social adaptional success (Jackson et al., 1997).

The observed prevention or delay in onset of use of tobacco may have some importance in relation to the ‘boomerang’ effect of secondary smoking prevention programs. That is, students who start to smoke in primary school tend to be poor responders to later school prevention efforts, and may actually increase their smoking in response to these programs (Ellickson and Bell, 1990). Evidence indicates that delaying the early onset of smoking into later teen years or early adulthood may also prevent the especially pernicious course of smoking (Breslau and Peterson, 1996).

To be clear, we are not suggesting that in and of itself an early preventive approach such as described here is the panacea to prevent tobacco smoking. Rather, early preventive approaches of this type can be strengthened and combined usefully with effective prevention programs for secondary school students as part of a comprehensive approach to the prevention of tobacco smoking. We would not wish to neglect the potential benefit of a mass media campaign, change in policy, increased taxes, restricted availability, and other efforts at the community level to augment the prevention efforts going on at the level of the school and individual child (Pentz et al., 1989; Lantz et al., 2000). Finally, we wonder whether a combination of the full CC and FSP Grade 1 interventions described in this paper might lead to additive or synergistic effects in terms of later socially adaptive behaviors. In turn, one also might find greater impact in terms of the primary prevention or delay of onset of first use of tobacco.

In conclusion, this research provides modest supporting evidence in favor of an early primary prevention strategy to reduce or delay first use of tobacco. This study adds to past evidence that group interventions

Table 2
Estimated relative risk of smoking initiation before and after statistical adjustments: Baltimore CC/FSP Prevention Trial 1993–2000

<table>
<thead>
<tr>
<th></th>
<th>Classroom centered (n = 178)</th>
<th>Family–school partnership (n = 180)</th>
<th>Control (n = 160)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RR (95% CI)*</td>
<td>0.76 (0.52–1.11)</td>
<td>0.77 (0.56–1.05)</td>
<td>1.0</td>
</tr>
<tr>
<td>Adjusted modelb</td>
<td>0.57 (0.34–0.96)*</td>
<td>0.69 (0.50–0.97)*</td>
<td>1.0</td>
</tr>
</tbody>
</table>

* Risk ratio (95% CI), models account for school-level clustering (i.e. students were grouped into risk sets defined by their grade 1 school).

b Adjusted model: adjusted for sociodemographics and baseline family and behavior covariates.

* P = 0.03.
targeting early risk behavior may have wider public health impact on distal targets, such as tobacco smoking (Kellam and Anthony, 1998). The primary school setting can be an excellent venue for promoting the health of children, before truancy and dropping out become major threats to school-based socialization. Interventions such as the CC and FSP programs can be implemented by regular classroom teachers and can reach all children, not just those at the higher levels of risk. In local and national efforts to declare ‘tobacco-free’ cohorts of school children, this type of early drug prevention may prove to be a useful complement to other initiatives.

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References


