

Comparison of Two School-Based Smoking Prevention Programs among South African High School Students: Results of a Randomized Trial

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Abstract:

Background

Smoking rates are projected to increase substantially in developing countries such as South Africa.

Purpose

The aim of this study was to test the efficacy of two contrasting approaches to school-based smoking prevention in South African youth compared to the standard health education program. One experimental program was based on a skills training/peer resistance model and the other on a harm minimization model.

Method

Thirty-six public schools from two South African provinces, KwaZulu-Natal and the Western Cape, were stratified by socioeconomic status and randomized to one of three groups. Group 1 (comparison) schools (n = 12) received usual tobacco use education. Group 2 schools (n = 12) received a harm minimization curriculum in grades 8 and 9. Group 3 schools (n = 12) received a life skills training curriculum in grades 8 and 9. The primary outcome was past month use of cigarettes based on a self-reported questionnaire.

Result

Five thousand two hundred sixty-six students completed the baseline survey. Of these, 4,684 (89%) completed at least one follow-up assessment. The net change in 30-day smoking from baseline to 2-year follow-up in the control group was 6% compared to 3% in both harm minimization (HM) and life skills training (LST) schools. These differences were not statistically significant. Intervention response was significantly moderated by both gender and race. The HM intervention was more effective for males, whereas the life skills intervention was more effective for females. For black African students, the strongest effect was evident for the HM intervention, whereas the strongest intervention effect for “colored” students was evident for the LST group.

Conclusion

The two experimental curricula both produced similar overall reductions in smoking prevalence that were not significantly different from each other or the control group. However, the impact differed by gender and race, suggesting a need to tailor tobacco and drug use prevention programs. More intensive intervention, in the classroom and beyond, may be needed to further impact smoking behavior.

Keywords: Smoking prevention | South Africa | Schools

Article:

Introduction

Whereas adolescent cigarette use has, over the past 20 years, seen a significant decline in resource-rich societies [1–4], among many countries with emerging economies, use has begun to rise [5–7]. The inevitable accompanying increase in tobacco-related diseases will likely have dramatic medical, social, and economic consequences in these societies. One country in the midst of such a tobacco and chronic disease “transition” is South Africa [7–9].

Smoking rates among the more affluent white and so-called “colored” South African adolescents are already as high or higher than teens from resource-rich countries. The 30-day smoking prevalence rates in these two groups were 38% and 40%, respectively, in the most recent national surveillance study [9]. Conversely, 30-day rates among black African adolescents, who represent the overwhelming majority of the population, are considerably lower, 17%. Rates are particularly low among black African females, 10%. There is concern that the increased social and economic liberation as well as the shift from rural to urban living being experienced by many black South Africans may have the unintended consequence of increasing tobacco and other drug use [9].

Although effective tobacco control requires multilevel, integrated programs and policies, (e.g., taxation, limits on advertisement, warning labels, public education, access restrictions, etc.), school-based prevention programs are a potentially important component of a comprehensive tobacco and drug use prevention strategy [10–13].

Despite the substantial number of school-based tobacco use prevention studies that have been conducted in the USA as well as internationally, there have been few controlled trials in developing countries. We could find no controlled intervention studies in central or southern Africa.

Although many school-based social influence and social competence programs have been developed and tested internationally, it cannot be assumed that such programs, even with cultural adaptation, would be equally effective in developing countries. One reason is that the determinants of tobacco and other drug use appear to differ cross-culturally [14, 15], including among South African youth [9, 15], and intervention messages that may be effective in one culture may not be salient in other cultural contexts. For example, messages that emphasize US tobacco industry deception as a reason to not smoke may not generalize outside the USA [16, 17].

The primary aim of the current study was to adapt and test two contrasting school-based approaches to adolescent tobacco use prevention. The primary outcome of the study was any 30-day cigarette use assessed by self-report questionnaire. One intervention was adapted from a widely used social skills/peer resistance program developed in the USA (i.e., Life Skills Training) and the second was based on a harm minimization model, developed and tested in Western Australia, (i.e. “KEEP LEFT”). The long-term goal of the project is to help South African educators, researchers, and policy makers design a tobacco and other drug use prevention strategy that meets the needs of their multicultural and rapidly changing society.

The social influences/social competence program chosen for adaptation, life skills training or LST, has been shown in several randomized trials to reduce tobacco and other substance use behaviors among both inner-city and suburban US youth as well as white, Hispanic, African-American, and Asian students [18–29]. Additionally, whereas the effects of many other tobacco and other drug use prevention programs have been shown to decay after 1 or 2 years post-implementation, the effects of LST have been shown to endure for up to 6 years, (i.e., through the end of high school) [22, 28, 30–34]. The program has been widely adopted in the USA and has been adapted for use in other countries [35].

Despite the positive effects of the LST program, several other social influences and social competence programs have yielded either no short-term positive impact on smoking behavior [36, 37] or they produced short-term impacts that decayed within a few years post-intervention [30, 32, 38–41]. There are also conceptual concerns over the skills component of social competence programs. In several studies that have disentangled the social competence and social influences strategies by creating separate, conceptually distinct curricula, the skills training programs have shown either no effects on substance use [42–46] and in at least once study [47] harmful effects. Moreover, studies have found that self-reported life skills did not mediate smoking and other drug use behaviors among youth receiving such programs [24, 45, 48].

Given the limitations of the social competence paradigm, testing other models of smoking prevention may be warranted. One such novel approach is harm minimization (HM) [49, 50]. HM operates from the assumption that eliminating cigarette and other drug use entirely is neither philosophically tenable nor practically attainable [49–54]. Instead, the focus is on reducing the adverse physical, psychologic, and social consequences of use, in particular heavy use [55]. HM takes a non-moralistic pragmatic approach which, in contrast to zero tolerance abstinence-based models, contends that efforts should be placed on reducing the deleterious consequences of use rather than achieving a “drug-free” society.

Examples of HM outside of tobacco use include methadone maintenance to mitigate the addictive aspects of heroin use and needle exchange and bleach distribution to reduce the transmission of HIV and other blood-borne illnesses [51, 52]. Initiatives to reduce driving under the influence of alcohol represent another application of these principles [53]. With regard to marijuana, in The Netherlands, sale of cannabis is tolerated in selected “Koffeeshops”; however, sales to minors and purchases exceeding 30 g per customer are prohibited [52].

How these concepts may apply to smoking prevention has received little empirical attention. A key concept of HM as it relates to smoking prevention is reducing heavy use and nicotine addiction as opposed to targeting initiation and experimentation. This potential benefit of HM is supported by the dose–response relationship between cigarette and marijuana intake and adverse health effects [56–59]. Additionally, occasional users may be less likely to progress to using “harder” substances [60–65], they may have less difficulty quitting [66–69], and they may exhibit lower rates of school failure and other illegal/antisocial behaviors (i.e., social morbidity) [63, 70].

Potential HM strategies relevant to adolescent cigarette use include avoiding addiction and regular smoking, delaying initiation, reducing the number of cigarettes smoked, limiting the times, days, and locations when and where smoking occurs, preventing progression into use of other drugs, and reducing exposure to environmental tobacco smoke.

There has been one experimental study testing the effects of a HM approach to smoking prevention, the KEEP LEFT study [71]. The trial was conducted in Perth, Western Australia between 1999 and 2002. Thirty public high schools (14 intervention and 16 comparison) were randomized to receive either the standard Western Australian substance use curriculum or the KEEP LEFT, HM intervention. The KEEP LEFT intervention comprised eight 1-hr lessons over 2 years, quitting support from school nurses and enactment of policies to support program components. Comparison schools implemented the standard abstinence-based curriculum and policies.

At immediate post-test (20 months post-baseline), after accounting for baseline differences and school-level clustering effects, students in the HM schools were significantly less likely to have smoked within the previous 30 days (OR = 0.69, 95% CI = 0.53, 0.91) than students in the

standard intervention schools [71]. Additionally, smoking initiation was no higher in the HM group than controls [72].

The current study was designed to determine which, if either, of the two approaches to smoking prevention would be most effective for South African youth and to explore potential subgroups that may respond differently to either type of intervention.

Method

Sampling Framework

All public schools in two of South Africa's nine provinces, KwaZulu-Natal and the Western Cape, were enumerated. Because of the substantially higher smoking rates among "colored" youth previously established [9], schools with predominantly "colored" students were oversampled. These two provinces were selected because the Western Cape has a much higher proportion of "colored" residents, whereas KwaZulu-Natal has a predominantly black African population, the largest ethnic group in SA.

Schools in these provinces were categorized by ethnic composition, size, as well as socioeconomic status (SES) using data supplied by South Africa's National Department of Education. School-level poverty data provided by the Department of Education were used to dichotomize schools into low and middle/high SES. Poverty index scores incorporated physical condition, infrastructure, and crowding of the school. Each school is assigned a number from 0 to 1 by the Department, with scores closer to 1 indicating higher levels of poverty. School poverty scores were ranked into terciles, and schools in the top tercile were, for purposes of stratification, considered low SES and all others middle/upper SES. Only schools within 50 km of project offices and those with more than 100 students in grade 8 were included. Schools were considered large if there were more than 200 grade 8 students enrolled; otherwise, they were classified as small.

Schools were then randomly selected within each ethnicity, size, and SES strata. The target sample was 36 or 12 per experimental group. A total of 39 schools were approached, of which, three refused. The 36 public schools recruited from the two provinces (18 per province) were then randomly assigned to one of three experimental groups. Group 1 (comparison) schools ($n = 12$) received usual tobacco and substance use education, which involves little specific smoking prevention programming. Group 2 schools ($n = 12$) received the South African version of the "KEEP LEFT", harm minimization curriculum beginning in grade 8 and continuing through grade 9. Group 3 schools ($n = 12$) received the South African version of the "life skills training" curriculum beginning in grade 8 and continuing through grade 9.

Curriculum Adaptation

Both the LST and HM curricula required significant adaptation for South African students and the South African educational system. Prior to designing the curricular lessons, we conducted a series of focus groups with students (nine groups; 69 total participants) and teachers (seven groups; 54 total participants) from South African public schools. Focus groups for students addressed perceived norms regarding tobacco and other drug use, gender and cultural aspects of tobacco and other drug use, and perceived motivation for using and not using tobacco and other drugs. For teachers, groups addressed perceived gender and cultural aspects of tobacco and other drug use as well as experience and preferences regarding health education curricula.

Key findings from students included strong social stigma of smoking among black African girls that contrasted with a high degree of perceived prevalence and acceptability of smoking among “colored” and white youth. Teachers expressed interest in both the skills-based and HM approaches to smoking prevention and they requested individual student workbooks, something rarely provided in their educational system.

Local curriculum writers familiar with school health education and the state requirements for health-related student outcomes were employed to develop the curricula. A graphic artist was hired to design the two curricula and generate required photographic and drawn images. In addition, contributors to original versions of the US LST and the Australian KEEP LEFT programs served as consultants and co-writers to maximize conceptual integrity of the two adapted interventions.

The two curricula were designed to be taught by life orientation (LO) teachers. LO is a separate mandatory topic in SA schools similar to health education in the USA which includes student outcomes for health behaviors and social skills development. Both curricula utilized interactive strategies such as role playing, small group activities, and skill practice.

Initial drafts of lessons were pretested during focus groups with LO teachers and then revised, and then the two curricula were pilot-tested by LO teachers in six schools (KEEP LEFT) and four schools (LST), respectively, over a 2- to 3-month period. Although the primary language used was English, most lessons included optional adaptations for Zulu and Xhosa youth, the two main cultural groups of black South Africans as well as Afrikaans. For example, educators were provided with alternatives for words such as dagga (marijuana), which in Zulu is insango. Students were also asked to translate key concepts and words into their native language. Additionally, graphic images were created for the project that predominantly represented black and “colored” youth. Finally, Xhosa and Zulu culturally specific risk and protective factors related to smoking and substance use, such as “embarrassment to the family” and smoking as an indication of “poor moral character”, were incorporated into the teacher training. Teachers were provided with interactive activities to help students address how cultural values might serve to either promote or discourage smoking and other drug use and how positive aspects of culture can be retained during the process of economic and social liberation.

Prior to implementing the final curriculum, teachers participated in a 3-day in-service training during which they learned about the theoretical underpinnings of their respective curricula, practiced sample lessons, and planned their implementation schedule for the upcoming year.

LST Intervention

The LST curriculum comprised eight units for each of grades 8 and 9. In both years, students were provided with individual workbooks and teachers were provided with an educator's manual. Most units contained more than one activity and therefore may have required more than one classroom session to complete. Content focused on building general and substance use specific life skills including decision making, stress management, affect management, assertive communication, and resisting peer pressure.

HARM Minimization Intervention, aka KEEP LEFT

Similar to the LST program, the KEEP LEFT curriculum comprised eight units for each of grades 8 and 9 and students were also provided with a workbook and teachers were provided with an educator's manual. Most units contained more than one activity and could be taught over multiple classroom sessions.

KEEP LEFT provides a decision-making framework for reducing the physical, social, and psychologic harms associated with tobacco and other drug use. Using a continuum of risk, youth were encouraged to minimize their risk at every level of use. The primary message is that at all levels of use, moving to the LEFT (i.e., reducing risk is beneficial). Those who were never users were encouraged to remain so. However, for those who have initiated use, activities focussed on addiction prevention, reducing intake, or quitting.

Youth were taught to analyze the context and cues of their smoking; for example, some youth smoke primarily at parties and other social gatherings (but rarely alone), while others are more solitary smokers. KEEP LEFT helps youth devise strategies for limiting the frequency and intensity of their smoking to avoid further addiction, with a long-term goal of eventual cessation. Although both LST and KL provide decision-making skills, unlike in the LST program, in KL, there are no general social skills lessons related to stress management, affect management, assertive communication, or resisting peer pressure.

Measures

Tobacco and Other Drug Use

The primary outcome was past month use of cigarettes. This, as well as secondary outcomes of lifetime cigarette use, frequent cigarette use (>20 days per month), past month marijuana (aka "dagga") use, past month binge drinking (defined as consumption of five or more drinks within a few hours), and an index of past month illicit drug use were assessed with a self-report questionnaire adapted from prior studies conducted in South Africa and elsewhere [7, 9, 73].

Each of these indicators was recoded into a binary variable with 0 = nonuse and 1 = use. Due to the low rates of “hard” or “illicit” drug use, we created an aggregate index indicating past month use of either cocaine/crack, “mandrax” (methaqualone), and “tik” (methamphetamine). Use of any one of these substances was coded as “1” for the illicit drug use index.

Psychosocial Variables/Mediators

Perceived harm of ever and regular use of tobacco, marijuana, and alcohol was assessed using a three-point scale with the following response categories: no harm, slight harm, and great harm, coded 1, 2, and 3, respectively. Alpha for the ever use items was 0.73, and alpha for the regular use items was 0.88. Perceived refusal skills for five substances [i.e., cigarettes, alcohol, marijuana (dagga), cocaine, and inhalable drugs] was assessed by querying; “would you be able to say no if someone tried to get you to use (insert substance).” Responses ranged from “definitely would” to “definitely would not,” coded 1–5, respectively. Alpha for the scale was 0.97. Smoking attitudes was assessed with a ten-item measure adapted from a previous South African survey that tapped positive expectancies of smoking. Sample items include smoking helps you cope with stress, smoking helps you enjoy a party, and smoking helps people feel more relaxed. Items were answered on a four-point scale ranging from strongly agree to strongly disagree, coded 1–4, respectively. Alpha for the scale was 0.88.

Scanable questionnaires were administered in the classroom by trained research assistants. Student names were not included in the questionnaire. Each student was assigned a confidential identifying number which was prewritten on their questionnaire. Teachers were asked to vacate the room during the questionnaire administration.

Active written consent was obtained from parents. The study was approved by the Human Investigations Committees from the University of Michigan and the South African Medical Association Ethnic Committee.

Curriculum Implementation

To maximize curriculum implementation, each teacher was visited at least four times over the 2-year period by study staff. During these visits, the teacher’s implementation of the lesson was rated on several dimensions including classroom management, how well questions were answered, overall implementation of the lesson, and the extent to which the specific lesson objectives was taught. Teachers were given feedback about their classroom lessons and offered technical assistance where indicated.

To assess teacher implementation of the HM and LST classroom curricula, at the end of grades 8 and 9, ten student workbooks were collected from each teacher. Workbooks were examined for evidence that lessons were completed. If more than half of the activities in a lesson were completed in at least five of the workbooks audited, the lesson was considered taught by that teacher that year. The total percent of lessons taught by each teacher was calculated over the

2 years of intervention, and students were assigned an “implementation” score (ranging from 0% to 100%) based on the percent of lessons taught by their teachers over the 2 years of intervention.

Students receiving at least 50% of the planned 16 sessions over 2 years were classified as “high exposure,” and this variable was used to explore dose–response effects of the intervention. This secondary analysis is presented after the primary intent to treat analyses.

Assessment Schedule

Students completed questionnaires on three occasions: (1) Baseline at the beginning of eighth grade, (2) posttest 1 at the end of eighth grade, and (3) posttest 2 at the end of ninth grade. For the two posttest assessments, only individuals who were in the school at the beginning of grade 8 and who completed the baseline evaluation were asked to complete questionnaires.

Analytic Model

Primary Outcomes

The primary statistical approach to examine intervention effects was a random coefficient model specifying both the intercept and slope for time as random rather than fixed effects. To account for the design effect of randomizing schools rather than individuals to treatments, the model nested students within schools within treatment condition. The model included values at three time points: baseline, posttest 1, and posttest 2. All available data at all time points were used in the analyses. Analyses were conducted using PROC MIXED in SAS (version 9.1). All outcome analyses, a priori, examined potential moderating effects of gender and race. The study was powered to detect a 6% to 7% difference in 30-day smoking at posttest between either the HM or LST groups and the control group. Psychosocial variables were analyzed using the same mixed regression approach discussed above.

Results

Sample Description

A total of 5,266 eighth grade students completed the baseline survey. Based on the school rosters provided, there were 5,685 eligible eighth grade students, which equates to a response rate of 93%. Of these, 4,684 (89%) completed at least one of the two posttest assessments. As shown in Table 1, at baseline, the three intervention groups did not differ on any of the sociodemographic or substance use variables. Dropouts, defined as students with baseline data but no data at either follow-up, were significantly different from cohort members (baseline and at least one follow-up) for each of the substance use variables. In every instance, dropouts were significantly more likely to have been baseline substance users. Thus, there was selective attrition in the study, which limits external validity. Dropouts between intervention groups did not differ for any of the variables in Table 1, thus indicating that differential attrition did not threaten internal validity.

Table 1 Sample description: cohort and dropouts by intervention group

	Cohort				Dropouts ^a			
	Control (<i>n</i> = 1,404)	Harm Min (<i>n</i> = 1,751)	Life skills (<i>n</i> = 1,529)	Total (<i>n</i> = 4,684)	Control (<i>n</i> = 167)	Harm Min (<i>n</i> = 227)	Life skills (<i>n</i> = 188)	Total (<i>n</i> = 582)
Gender, (% Male)	48.1	55.1	47.5	50.5	55.7	66.1	50.5	58.1
Age mean (SD)	14.0 (1.2)	14.1 (1.2)	14.1 (1.2)	14.1 (1.2)	14.6 (1.4)	14.7 (1.2)	14.7 (1.5)	14.7 (1.3)
Ethnicity								
% Black	55.7	61.0	61.7	59.7	40.7	51.1	52.7	48.6
% “Colored”	28.6	26.3	24.6	26.4	35.3	42.1	39.2	39.2
% White	9.4	9.4	11.1	9.9	3.0	5.8	6.5	5.2
Cigarette use (%)								
Ever	28.6	27.1	30.4	28.6	43.4	49.1	48.4	47.2*
30-day	16.2	14.2	15.3	15.2	36.1	41.2	34.2	37.5**
Heavy	4.6	4.7	3.7	4.3	15.7	20.6	19.8	18.9**
Other drug use (%)								
30-Day binge drinking (5+)	11.8	11.1	12.9	11.9	21.3	31.4	27.9	27.4**
30-Day marijuana	4.5	5.1	3.8	4.5	13.9	19.1	12.3	15.4**
30-Day “hard” drug	3.3	4.2	2.6	3.4	7.6	17.9	12.1	13.1**

MJ marijuana, *Harm Min* harm minimization

* $p < 0.05$, chi-square comparing dropouts to cohort members

** $p < 0.01$, chi-square comparing drop outs to cohort members

^aDropouts defined as having baseline but neither post 1 or post 2

30-Day Smoking

Considering the entire sample, rates of 30-day cigarette use in the control group at baseline, year 1 follow-up, and year 2 follow-up were 18%, 21%, and 24%, respectively. The corresponding rates in the HM group were 17%, 18%, and 20% and in the life skills training group, 17%, 20%, and 20%. The net change from baseline to 2-year follow-up in the control group was 6% compared to 3% in both HM and LST schools. The treatment by time interaction, however, was not statistically significant. Restricting the sample to baseline nonsmokers yielded a similar pattern of results.

Treatment Moderators

The treatment × time × gender interaction was significant ($F = 5.7, p < 0.01$), as was the treatment × time × race interaction ($F = 2.8, p = 0.01$). Therefore, we present results stratified by gender and race. As shown in Table 2, the HM intervention was more effective for male students, whereas the life skills intervention was slightly more effective for female students. The treatment group differences within gender, after accounting for clustering, were not, however, statistically significant.

Table 2 30-Day cigarette use at baseline and follow-up by intervention group and gender

	Control			Harm Min			Life skills		
	Baseline (<i>n</i> = 1,569)	Year 1 (<i>n</i> = 1,340)	Year 2 (<i>n</i> = 1,011)	Baseline (<i>n</i> = 1,974)	Year 1 (<i>n</i> = 1,697)	Year 2 (<i>n</i> = 1,177)	Baseline (<i>n</i> = 1,701)	Year 1 (<i>n</i> = 1,519)	Year 2 (<i>n</i> = 1,079)
Males	0.22	0.24	0.25	0.20	0.20	0.20	0.23	0.26	0.25
Females	0.15	0.19	0.22	0.14	0.15	0.19	0.12	0.14	0.16
Totals	0.18	0.21	0.24	0.17	0.18	0.20	0.17	0.20	0.20

Harm Min harm minimization

With regard to race effects, as shown in Table 3, for black African students, the strongest effect was evident for the HM intervention. Specifically, over the 2-year intervention period, rates increased 3% in the control and LST groups, but dropped 2% in the HM group. Conversely, the strongest intervention effect for “colored” students was evident for the LST group. Specifically, 30-day smoking rates increased for “colored” students by 13% in the control schools and 11% in the HM schools, but only 4% in LST schools. For Indian and white students, neither curriculum appeared to positively impact smoking rates. None of the treatment group differences within race groups were statistically significant after accounting for clustering.

Table 3 30-Day cigarette use at baseline and follow by intervention group and ethnicity

	Control			Harm Min			Life skills		
	Baseline (n = 1,569)	Year 1 (n = 1,340)	Year 2 (n = 1,011)	Baseline (n = 1,974)	Year 1 (n = 1,697)	Year 2 (n = 1,177)	Baseline (n = 1,701)	Year 1 (n = 1,519)	Year 2 (n = 1,079)
Black	0.09	0.12	0.12	0.12	0.11	0.10	0.10	0.14	0.13
Colored	0.37	0.40	0.50	0.32	0.37	0.43	0.36	0.40	0.40
White/Indian/Other	0.16	0.18	0.14	0.07	0.08	0.13	0.11	0.10	0.15

Secondary Outcomes

As shown in Table 3, considering male and female students together, lifetime smoking rates increased 15% in the control condition compared to 10% and 11% in the HM and LST groups, respectively. Frequent smoking increased 2% in the control and LST groups compared to a 1% decrease in the HM schools. Past month dagga use increased 3% in control schools compared to 1% and 2% in the HM and LST schools, respectively. Past month binge drinking increased 8% in control schools compared to 10% and 7% in the HM and LST schools, respectively. Finally, 30-day illicit drug use decreased 4% in control schools compared to a decrease of 6% and 4% in the HM and LST schools, respectively. None of these between-group differences were statistically significant.

We also explored gender and race interactions for the secondary outcomes. For all but lifetime and frequent smoking, gender was a significant treatment moderator. For 30-day dagga use, the HM intervention appeared to be more effective for male students, whereas for female students, both curricula had similar impacts. For binge drinking, the interaction effect was driven by a greater increase in use among HM and LST males than controls. For illicit drug use, the effect appeared to be driven by both a greater decrease in use among control males as well as a greater decrease in use among females in HM schools (see Table 4).

Table 4 Secondary outcomes at baseline and follow by intervention group and gender

	Control			Harm Min			Life skills		
	Baseline (n = 1,569)	Year 1 (n = 1,340)	Year 2 (n = 1,011)	Baseline (n = 1,974)	Year 1 (n = 1,697)	Year 2 (n = 1,177)	Baseline (n = 1,701)	Year 1 (n = 1,519)	Year 2 (n = 1,079)
Lifetime cigarette									
Males	0.35	0.41	0.47	0.33	0.40	0.43	0.40	0.49	0.48
Females	0.25	0.35	0.43	0.25	0.32	0.37	0.25	0.32	0.39
Total	0.30	0.38	0.45	0.30	0.36	0.40	0.32	0.40	0.43
Frequent cigarette ^a									

Males	0.08	0.06	0.09	0.07	0.05	0.06	0.08	0.07	0.09
Females	0.03	0.04	0.06	0.06	0.04	0.06	0.03	0.04	0.06
Total	0.06	0.05	0.08	0.07	0.05	0.06	0.05	0.05	0.07
30-Day marijuana ^b									
Males	0.09	0.06	0.12	0.09	0.10	0.10	0.08	0.11	0.12
Females	0.02	0.04	0.07	0.04	0.04	0.05	0.02	0.03	0.03
Total	0.06	0.05	0.09	0.07	0.07	0.08	0.05	0.07	0.07
30-Day binge drinking (5+) ^{b,c}									
Males	0.18	0.18	0.23	0.16	0.21	0.27	0.20	0.26	0.28
Females	0.08	0.13	0.18	0.10	0.14	0.19	0.10	0.13	0.17
Total	0.13	0.15	0.21	0.13	0.18	0.23	0.15	0.19	0.22
30-Day “hard” drug ^b									
Males	0.12	0.05	0.02	0.12	0.05	0.05	0.09	0.04	0.03
Females	0.02	0.03	0.03	0.08	0.03	0.02	0.02	0.01	0.01
Total	0.07	0.04	0.03	0.10	0.04	0.04	0.06	0.02	0.02

Harm Min harm minimization

^aUse >20 days per month

^bInteraction of gender and treatment group significant, $p < 0.05$

^cInteraction of race and treatment group significant, $p < 0.01$

With regard to race, the only secondary outcome that significantly interacted with treatment group was binge drinking. Among control black African students, binge drinking rates increased 12% from baseline to 2-year follow-up compared to an increase of 7% and 10% over the 2 years in the HM and LST schools, respectively. Conversely, for “colored” students, rates increased 4% in control schools compared to 11% and 0% in the HM and LST schools, respectively. Thus, similar to the pattern observed for 30-day smoking, the HM program appeared to be more effective for black African students, whereas the LST program appeared to be more effective for “colored” students (data not shown).

Dose Effects

We examined treatment effects amongst the subgroup of students who received at least 75% (i.e., 12) of the planned 16 lessons over the two-year intervention based on workbook audit. Overall, for LST and HM, 85% and 93%, respectively, of students received at least 75% of the planned lessons. For this sub-analysis, we included all control students. As indicated in Table 2, for the full sample, the increase in 30-day smoking was 3% for both the HM and LST group. However, for the restricted “high exposure” sample, the increases were 4% and 2%, respectively, for the

HM and LST groups (Data not shown). Thus, there was little evidence for a “dose–response” effect. However, this conclusion should be tempered by the observation that restricting the analysis to only “high exposure” students resulted in a sample with lower baseline smoking rates (15% for HM and 14% for LST) than the 17% rate observed at baseline for both HM and LST groups in the unrestricted sample.

Psychosocial Outcomes

Overall, there were no significant treatment \times time effects for perceived harm (ever or regular use), self-efficacy, or drug attitudes. For perceived harm of ever use, however, there was a significant treatment \times time \times gender interaction ($p < 0.001$). For all three intervention groups, males showed larger increases than females in perceived harm of ever use over time (see Table 5). For perceived harm of regular use, there was a significant interaction with both gender and race ($p < 0.001$). Males showed larger increases than females in perceived harm of regular use over time in the KEEP LEFT and control conditions, but not LST. With regard to race, black youth in the KEEP LEFT schools showed a larger increase in perceived harm of regular use than white and colored youth, whereas in LST, black and colored youth showed larger increases in perceived harm of regular use than whites.

Table 5 Psychosocial outcomes by gender, race, and intervention group

	Control			Harm Min			Life skills		
	Baseline (<i>n</i> = 1, 420)	Year 1 (<i>n</i> = 1, 308)	Year 2 (<i>n</i> = 9 98)	Baseline (<i>n</i> = 1, 339)	Year 1 (<i>n</i> = 1, 243)	Year 2 (<i>n</i> = 9 75)	Baseline (<i>n</i> = 1, 415)	Year 1 (<i>n</i> = 1, 306)	Year 2 (<i>n</i> = 1, 007)
Perceived harm of ever use ^a									
Gender									
Males	2.1 (0.66)	2.1 (0.59)	2.1 (0.58)	2.0 (0.68)	2.1 (0.52)	2.0 (0.52)	2.2 (0.54)	2.2 (0.49)	2.1 (0.54)
Females	2.2 (0.60)	2.2 (0.54)	2.1 (0.55)	2.2 (0.67)	2.2 (0.48)	2.1 (0.47)	2.3 (0.51)	2.2 (0.50)	2.1 (0.53)
Race									
White/Indian/Other	2.0 (0.55)	2.1 (0.58)	2.0 (0.56)	2.0 (0.65)	1.9 (0.58)	1.8 (0.53)	2.2 (0.52)	2.0 (0.51)	2.0 (0.51)
Colored	2.1 (0.58)	1.9 (0.56)	1.9 (0.50)	2.2 (0.60)	2.0 (0.48)	2.0 (0.48)	2.1 (0.50)	2.1 (0.48)	2.0 (0.56)
Black	2.2 (0.69)	2.3 (0.53)	2.2 (0.58)	2.1 (0.72)	2.3 (0.47)	2.2 (0.46)	2.3 (0.52)	2.2 (0.50)	2.1 (0.53)
Perceived harm of regular use ^a									
Gender									
Males	2.4 (0.66)	2.5 (0.55)	2.6 (0.50)	2.4 (0.68)	2.6 (0.42)	2.6 (0.46)	2.6 (0.46)	2.6 (0.46)	2.6 (0.47)
Females	2.5	2.6	2.6	2.5	2.7	2.6	2.7	2.7	2.6

	(0.56)	(0.46)	(0.51)	(0.68)	(0.40)	(0.44)	(0.40)	(0.39)	(0.47)
Race									
White/Indian/Other	2.6 (0.50)	2.7 (0.40)	2.7 (0.34)	2.6 (0.52)	2.7 (0.32)	2.7 (0.35)	2.7 (0.38)	2.7 (0.35)	2.7 (0.34)
Colored	2.5 (0.58)	2.4 (0.61)	2.5 (0.58)	2.5 (0.58)	2.5 (0.51)	2.5 (0.55)	2.6 (0.45)	2.6 (0.44)	2.6 (0.49)
Black	2.4 (0.66)	2.6 (0.45)	2.6 (0.50)	2.3 (0.73)	2.7 (0.38)	2.7 (0.41)	2.6 (0.43)	2.7 (0.43)	2.6 (0.49)

^aHigher values indicate higher levels of perceived risk

Harm Min harm minimization

Student Perceptions

To explicate the ethnic differences in study outcomes, we examined student perceptions of the primary focus of the HM and LST programs. At program end, among students in the HM schools, black African youth were significantly ($p < 0.01$) more likely than “colored” youth to indicate that the primary aim of the curriculum was to reduce the social, physical, and psychologic harm of tobacco use, 38% vs. 18%, respectively, that is, they were more likely to interpret the program as focusing on HM. Conversely, in LST schools, “colored” youth were significantly ($p < 0.01$) more likely than black African youth to indicate that the primary aim of the program was to teach methods of coping with stress to avoid tobacco use, 50% vs. 32%, respectively, that is, they were more likely to receive the skills training message. Moreover, even in the LST schools, black African youth were still more likely than “colored” youth to indicate that the primary aim of the LST program was to reduce the social, physical, and psychologic harm of tobacco use, 23% vs. 13%, whereas “colored” youth in the HM schools were more likely than black African youth to perceive that the primary aim of the HM program was to teach stress coping skills, 35% vs. 23%.

Discussion

The primary outcome of 30-day smoking did not differ significantly between any of the three experimental groups. Thus, the overall effect of the two experimental curricula was null. Insufficient implementation is an unlikely explanation, as across the two curricula, more than 80% of students received at least 75% of the planned lessons based on an objective workbook audit. However, there are several other explanations for the lack of statistically significant effects that deserve further consideration. One explanation for the lack of statistical significance stems from the large intra-class correlation (ICC) observed in our data. For cluster randomized designs, the appropriate statistical model requires that the standard error of the estimated individual-level effects be inflated depending on the degree of non-independence of observations within schools. In school-based smoking prevention studies, the ICC has typically been in the range of 0.001 to 0.05, and its impact on statistical significance has been small to moderate [71, 72] due to the small “ n ” per cluster, the small number of clusters, or the small ICC. However, in our study, the

ICC for 30-day smoking at 2-year posttest was 0.14. The ICC was also higher than expected for past month marijuana use (0.05) and binge drinking (0.04). For psychosocial outcomes, the observed ICCs ranged from 0.05 to 0.19. The higher than anticipated ICC for 30-day smoking, 0.14 at posttest 2, is likely due to greater cultural and/or psychologic homogeneity within South African schools present at randomization rather than school-level variation in teacher implementation and/or intervention effects. This is based on the observation that ICCs for 30-day smoking were similarly high at baseline (0.13) and at posttest 1 (0.12), which suggests that the clustering was due to sampling effects rather than post-randomization factors. Schools were largely homogeneous with regard to race; 24 schools comprised at least 70% from one racial group, and race is strongly associated with smoking. Thus, it is difficult to tease out race effects from other sources of clustering.

Our power calculations assumed an a priori ICC of 0.02. With approximately 100 students per school, our higher ICC effectively (using the standard design effect formula¹) [74] reduced our sample size by a factor of 14 for smoking and even more so for psychosocial outcomes. In other words, for significance testing, the ICC adjusted sample size was essentially 1/14th or smaller of the sample size actually measured. The study then could be considered a case of possible type II error. On the other hand, the study was powered to detect a between-group difference in 30-day smoking of 6–7%, which we did not attain. If clustering is ignored and the data are analyzed on the individual level, some of our between-group differences, for example, the positive effect on 30-day smoking of the HM program for boys and the LST program for colored youth would be significant. All psychosocial outcomes would have been significantly different for HM and LST versus controls.

Given that both the original LST and KEEP LEFT programs were shown to produce significant reductions in smoking behavior in prior studies, lack of effects in this study may have been, at least in part, the result of a flawed adaptation for South African youth. Although we conducted considerable formative research and pre-testing during the curriculum development process, it remains possible that the resulting curricula were not culturally appropriate and/or did not adequately translate the core intervention strategies. Conversely, the adaptations might have been true to the original programs and culturally appropriate, but the strategies contained in these programs may simply not be effective in South African youth.

Finally, insufficient dose may have been a factor. Given that several prior successful smoking prevention programs, including LST, incorporated booster sessions after 1 or 2 years of initial intervention, absence of such a booster intervention might have limited intervention impact [29, 75–78]. Additionally, the number of lessons for the adapted South African LST program was approximately half that of the original US version.

Another implication of our findings, consistent with several expert recommendations, is that prevention of smoking and other drug use behavior requires comprehensive programs beyond a

classroom curriculum, which may include community-based intervention, mass media, parents, taxation, and legal restriction on access and use [34, 77, 79–81].

Despite the lack of significant between-group effects, using the relative reduction formula described by Flay [34] and others [82], the two interventions both led to an approximate 13% relative reduction in 30-day smoking rates compared to the control group, computed as 6–3%/24%. This degree of reduction, although on the low end of effectiveness, might be considered of some public health significance, particularly when included as part of a more comprehensive prevention strategy.

The impact of the two curricula differed significantly by gender and race. For the primary outcome of 30-day smoking, the harm minimization curriculum appeared to work better for boys, whereas the skills-based program appeared to have a greater impact on girls. For 30-day marijuana use, the HM program also appeared to be more effective for boys, whereas LST appeared somewhat more effective for girls. This pattern was also evident in attitudes toward regular drug use. Although these gender effects were not anticipated, they merit comment.

Key themes of the HM curriculum included not “preaching” abstinence and supporting autonomy around substance use decisions. These themes may have particularly resonated with boys for whom assertive independence and rebellion may be more central to their social development and their smoking uptake [83,84]. Additionally, given that boys were more likely to be already using tobacco and other drugs at baseline, a harm minimization approach might be more applicable to their current smoking status than a peer refusal model. Conversely, girls were more likely to be non-users at baseline, and therefore, the peer refusal approach might be a better fit for their current level of use. In addition, the LST program focuses more on the social interactions around substance use and the skills to refuse appeals to use. Prior studies, including research in South Africa, suggest that girls start smoking for different reasons than boys and therefore they may respond differently to intervention. In particular, they may be more likely to smoke to manage mood and stress, and their smoking may be more affected by social influences than boys [83, 85–91]. Thus, the LST program may have been better matched to their etiologic predisposition. In one prior LST study, there was a greater impact on smoking amongst girls in some analyses [92].

With regard to race effects, for black African students, the strongest effect on 30-day smoking was observed in the HM schools, whereas for “colored” students, the strongest effect was evident in LST schools. A similar pattern by race was also observed for binge drinking and attitudes toward regular drug use. Given that schools were randomized to treatment group and they were largely homogenous with regard to race, these effects may reflect school differences rather than race differences. For example, the teachers in “colored” schools as well as substance use policies in these schools may differ from those in schools with a higher percentage of black African or white students. Given our school randomized design, it is difficult to tease out race effects from school effects; school and race are highly confounded.

Interestingly, regardless of which curriculum they received, black African youth were more likely to perceive a HM message, whereas “colored” youth were more likely to perceive coping skills messages. Thus, preexisting cultural differences among students may offer some insight as to why the two programs had a differential impact by race. Why black African youth may be predisposed to receiving and responding to a HM approach and “colored” youth a skills training approach merits additional research. One difference is that “colored” youth are generally more influenced by European (e.g., Dutch, German, and British) cultures (perhaps characterized by assertive independence and individual accountability) and Christianity, whereas African black culture remains more rooted in the indigenous principle of Ubuntu-humaneness and interconnectedness [93, 94].

Our primary aim was to determine how two evidence-based smoking prevention programs would work in a diverse sample of South African youth. We found that the overall intervention effects were smaller than those observed in prior studies in the USA and Australia, and there were significant treatment moderators (i.e., gender and race). Assuming the observed gender and ethnic effects are valid, to disseminate the curricula, one option might be to combine the two curricula into a composite program so that the needs of each gender and ethnic group could be met. However, given their contrasting theoretical and pedagogical approaches, it is possible that the combined program could be less effective than either one alone. That is, a canceling effect might occur. Alternatively, perhaps both curricula could be made available, as separate programs and local schools could choose the program that best matches the needs and background of their students. Although neither program yielded statistically significant results, perhaps if taught over multiple years, rather than only two, if used as part of a more comprehensive multicomponent intervention, and if it were better matched to student cultural and learning needs, greater reductions in tobacco and other drug use might be achieved.

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Footnotes

1^{\wedge} = Design Effect is $1 + \rho (m - 1)$ where m = average number of subjects per school and ρ is the computed intracluster correlation coefficient.