

Preventing adolescent substance use through an evidence-based program:

Effects of the Italian adaptation of Life Skills Training

Veronica Velasco^a, Kenneth W. Griffin^{b,c}, Gilbert J. Botvin^{b,c},

Corrado Celata and Gruppo LST Lombardia*

^a ATS della Città Metropolitana di Milano, Rete Regionale Prevenzione e Promozione della salute, Ss

Gestione Attività e Progetti Prevenzione specifica, Dipartimento Dipendenze, Milan, Italy

^b Weill Medical College of Cornell University, Department of Healthcare Policy and Research, New York, NY
(United States)

^c National Health Promotion Associates, White Plains, NY (United States)

Corresponding author: Veronica Velasco, vero.velasco@gmail.com

* Gruppo LST Lombardia is made up of the regional staff of the project and the representatives of each organization involved:

Regional staff: Corrado Celata, Veronica Velasco, Mariella Antichi, Francesca Mercuri, Elena Paganini, Sandro Brasca, Elena Giovanetti and Riccardo Valenti;

Health Units and Regional Network for Addiction Prevention representatives: Luca Biffi, Margherita Marella, Walter De Agostini, Leone Lisè, Carlo Pellegrini, Celeste Zagheno, Valter Drusetta, Paola Duregon, Alessandra Meconi, Ornella Perego, Elisabetta Mauri, Valentina Salinetti, Laura Randazzo, Manuel Benedusi and Marina Salada;

Health Units local managers: Barbara Lamera, Stefania Vizzardi, Lisa Impagliazzo, Adelia Corbani, Rosa Pancera, Sandro Brasca, Elena Bertolini and Sandra Lunari;

Regional School Department: Bruna Baggio

Local School Departments: Antonella Giannellini, Federica Di Cosimo, Laura Peruzzo, Tullia Guerrini Rocco, Jessica Sala, Claudia Zoppi, Barbara Artioli, Laura Stampini, Giulia Fontana, Emanuela Farina, Daniela Marchesi, Linda Casalini

Abstract

Evidence-based preventive interventions for adolescent substance use, violence, and mental health issues are increasingly being adapted and disseminated internationally. In the present paper, we report the results of an effectiveness study that was part of a comprehensive initiative by a coalition of health promotion organizations in the Lombardy region of Italy to select, culturally adapt, implement, evaluate, and sustain an evidence-based drug abuse prevention program developed in the U.S. Findings are presented from a large-scale effectiveness study of the Life Skills Training prevention program among over 3,000 students attending 55 middle schools in Italy. The prevention program taught drug refusal skills, antidrug norms, personal self-management skills, and general social skills. Relative to comparison group students, students who received the prevention program were less likely to initiate smoking at the post-test and two-year follow-up, and less likely to initiate weekly drunkenness at the one-year follow-up. The program had direct positive effects on several cognitive, attitudinal, and skill variables believed to play a protective role in adolescent substance use. The findings from this study show that a drug abuse prevention program originally designed for adolescents in the U.S. is effective in a sample of Italian youth when a rigorous and systematic approach to cultural adaptation is followed that incorporates the input of multiple stakeholders.

Keywords: evidence-based program; drug abuse prevention; cultural adaptation; effectiveness; evaluation

Introduction

Over the past 30 years, a growing number of evidence-based preventive interventions for adolescent substance use, violence, and other health behaviors have been rigorously designed and tested in large scale trials, mostly in the United States. In recent years, there has been a rapid increase in the globalization of evidence-based prevention, in recognition that such programs may have the capacity to produce similar outcomes in cultures and contexts that differ from those where the program was first developed (Catalano et al., 2012; Sundell & Ferrer-Wreder, 2014). In order to maintain behavioral effects and maximize the dissemination potential of evidence-based programs exported across international borders, a variety of researchers, practitioners, policy makers, and other stakeholders have emphasized the importance of culturally adapting programs in a systematic fashion (August, Gewirtz, Realmuto, 2010; Backer, 2001; Bernal, Jiménez-Chafey, & Domenech Rodríguez, 2009; Stirman, Miller, Toder & Calloway, 2013). In studies examining international replications of evidence-based programs, the evidence suggests that such efforts have a mixed record of success. A number of factors can contribute to the failure of such efforts, including methodological differences across trials, ambiguities in the cultural adaptation process, or poor implementation in the new setting (Sundell, Ferrer-Wreder, & Fraser, 2014). Conversely, a comprehensive approach to adapting a prevention program for a specific culture or population is likely to have several positive effects that increase the likelihood of success. Such an adaptation may improve initial buy-in by local stakeholders, increase acceptability by the target population, enhance implementation fidelity, strengthen program effects, and increase the potential that the intervention will be institutionalized.

The LST Lombardia Project

In the present paper, we report the results of an effectiveness study that was part of a comprehensive initiative in the Lombardy region of northern Italy to select, culturally adapt, implement, evaluate, and sustain an evidence-based drug abuse prevention program developed in the U.S. The LST Lombardia project began as an effort by public health and social service organizations in the Lombardy region to improve the quality of drug prevention programming (Velasco, Griffin, Antichi & Celata, 2015). Prior to this initiative, several drug prevention interventions and life skills education activities were implemented but few were evaluated and none

were evidence-based (Celata, Gelmi, Lavatelli, Picozzi, Velasco, 2008; Celata, Gelmi, Velasco, 2010; Leone and Celata, 2006; TTRP, 2010). After a rigorous review of evidence-based programs, the Lombardian Government and the other relevant stakeholders selected the Life Skills Training (LST) program (Botvin, Baker, Dusenbury, Botvin, & Diaz, 1995) because of its' strong evidence-base of effectiveness, theoretical foundation, and fit with local needs and Italian professionals' values. First, based on patterns of substance use onset and escalation in Italy (OReD, 2013), stakeholders recognized the importance of implementing drug use prevention programs in middle schools in order to address the problem before students begin to experiment with drugs. Second, consistent with the broader life skills education strategy that is popular in Italy, the stakeholders sought to identify an educational approach to prevention that focuses on enhancing students' social and personal skills. Third, the stakeholders considered several criteria for effective drug prevention with the goal of identifying an evidence-based program (Regione Lombardia, 2007, 2008; NIDA, 2003). Fourth, they evaluated the potential for adaptation and sought a program that could be modified to meet the local needs, traditions, and guidelines with regards to prevention education in Lombardy. LST met each of these criteria. The conceptual model underlying LST was seen as relevant because the developmental tasks of early adolescence, and corresponding risk and protective factors for engaging in substance use and other health risk behaviors, were seen as more similar than different across the U.S. and Italy. Some cultural differences needed to be addressed in the adaptation process, but the core elements of the program are well defined and we implemented rigorous guidelines for adaptation that took cultural and contextual characteristics into consideration. Moreover, LST is an evidence-based prevention program which has been extensively tested and shown to reduce alcohol, tobacco, drug abuse, and violence by targeting major social and psychological factors that promote the initiation of substance use and other risky behaviors.

A key reason for the selection of LST was the extensive body of scientific evidence published in over 30 peer reviewed journal articles (reviewed in Botvin & Griffin, 2015). Findings from these studies show that LST is highly effective, typically reducing alcohol, tobacco, marijuana, and other illicit drug use by 50% or more among diverse U.S. samples. In a study of over 3,500 predominantly suburban white youth attending 56 junior high schools in the U.S., LST produced durable reductions in tobacco, alcohol, marijuana use, and polydrug use

that lasted until the end of high school (Botvin, Baker, Dusenbury, Botvin, & Diaz, 1995). Other evaluation studies conducted in the U.S. have shown positive prevention effects for predominantly minority youth. In a study of over 3,500 economically disadvantaged urban minority youth attending 29 middle schools in the U.S., students who received the LST program reported less smoking, drinking, drunkenness, inhalant use, and polydrug use relative to controls at the posttest and one-year follow-up assessments (Botvin, Griffin, Diaz, & Ifill-Williams, 2001a). Intervention youth also reported a 50% reduction in binge drinking compared to controls (Botvin, Griffin, Diaz, & Ifill-Williams, 2001b). In a separate study of over 4,800 predominantly minority youth attending 41 urban middle schools in the U.S., students who received LST reported less verbal and physical aggression, fighting, and delinquency compared to control group participants (Botvin, Griffin, & Nichols, 2006). Furthermore, the LST middle school program, initially developed and tested in the U.S., has been recognized as a model or exemplary program by an array of government agencies. While the program has been adopted and implemented internationally in over 30 countries, LST has not been evaluated in an international context. The present study represents the first rigorously designed evaluation of LST outside of the U.S.

The LST Lombardia project was initiated in Italy by the Regional Observatory on Drug Addiction (OReD) on behalf the Regional Government in collaboration with the Health Units and the Schools Department of the region. It is now managed by a regional governmental network that is charged with supporting and improving policies and programming in the field of prevention and health promotion. Moreover, the LST implementation has been included in the Regional Prevention Plan, a strategic document which defines prevention policies and actions, and LST is now one of the main programs of the Regional Health Promoting School Network. Currently, the LST Lombardia project involves 300 health professionals, 230 schools, 4,180 teachers and about 41,000 students. Before the dissemination, the program was adapted to address cultural differences between Italy and U.S. and to maximize the fit between LST and the Italian culture. Adaptations were related to maximizing fit with the Italian health promotion culture, organization of schools, teacher training and background, and alcohol and drug culture. To guide these adaptations, a scientific agreement was made with the developer of the program and a research project focusing on the adaptation process was established with researchers at Cornell University. The adaptation project included of a series of focus groups, key informant

interviews, and group discussions on adaptation, and a pilot test of the adapted intervention. The collaboration with the author of the program, the use of research data to adapt the program, and the inclusion of input from key stakeholders helped to ensure that the program's core elements and theoretical background were maintained. The present paper reports on the effects of the Italian-adapted LST on students' behavioral, cognitive, attitudinal, skill variables and substance use behaviors comparing a subset of schools participating in the larger project along with a matched set of comparison group schools.

Method

Sample

A total of 3,048 students in the first year of middle school from 55 schools participated in the study. The sample size for the number of schools and students required for the study was determined using a statistic power calculator for clustered designs (Campbell, Thomson, Ramsay, MacLennan, & Grimshaw, 2004). The sample was 51% girls and 49% boys with a mean age of 11.1 years. About 90% of students were born in Italy. Of the baseline sample, 2,364 (78%) students from 53 schools and 127 classes (92%) were in the panel sample for this prevention effectiveness study, and provided data at the pretest and posttest, during the first year of the study. Of these, 1,586 (67% of Level 1 students) from 48 schools and 106 classes provided data at the one- and two-year follow-up assessments. The final sample included all students from classes that completed implementation of the intervention and for whom data were available. Over 90% of the classes involved in pretest and posttest provided data at one-year follow-up and the 83% at the two-year follow-up.

Research Design

The study was a quasi-experimental design that included 31 intervention group schools and 24 comparison group schools. Because LST is being implemented as part of the Regional Prevention Plan, a randomized trial was not feasible. A CONSORT diagram describing the flow of participants through the study is provided in Figure 1. Intervention schools were randomly sampled from the set of schools participating in the larger implementation of LST in Italy, after being stratified by geographic area in order to be representative of the schools and health districts in the Lombardy region. From the initial sample, six schools declined to participate in the study because of organizational problems or because they had already implemented some units.

These schools were substituted randomly with other schools in the same geographic area. For the comparison group, schools with similar characteristics (e.g., municipality size, school size, and students' demographics) as the intervention schools were selected in each health district. All comparison schools were not involved in other drug prevention interventions. Three classes were randomly selected in each intervention or comparison group school; all students of each class were involved in the study. During the first year of middle school, students ($n = 1,350$) in the intervention schools received fifteen LST sessions while students ($n = 1,014$) in the comparison schools did not receive any intervention about drug use. Ten booster sessions were implemented during the second year of middle school and nine during the third year of middle school.

--- Insert Figure 1 About Here ---

Procedure

Participants were administered the pretest assessment prior to the beginning of the intervention and a posttest assessment was conducted after the first year of intervention (about 8 months later). Additional follow-up assessments were conducted at the one- and two-year follow-ups, after the booster sessions were implemented in each subsequent academic year. Data were collected following a detailed protocol that was shared with all health units and local managers of the project. Unique identification codes were utilized rather than names to permit linkage of pretest, posttest, and follow-up responses, while preserving the confidential nature of the survey. Questionnaires were administered during a regular 50-minute classroom period by trained health professionals belonging to the public health units. The procedure was approved by the Regional Educational Authority, each school principal consented to participate in the study, and the project was approved by school collective bodies which are tasked with monitoring and approving activity and research in schools in Italy. Each school decided on whether to use active or passive parental consent procedures in accordance with their own autonomous policies. Students could refuse to participate in the study at any time. Schools did not receive any incentive for participating in the study.

Prevention Program

Life Skills Training (LST) is an evidence-based program that targets key etiologic factors associated with the initiation and escalation of substance use, using a conceptual framework derived from social learning

theory (Bandura, 1977) and problem behavior theory (Jessor & Jessor, 1977). The LST program is designed to target social and intrapersonal factors by providing the knowledge, attitudes, and skills necessary to actively resist social influences to engage in substance use; reduce susceptibility to negative influences and increase resilience; and decrease motivation to engage in substance use. These skills are taught by trained classroom teachers who implement the program using a combination of interactive teaching techniques including group discussion, demonstration, modeling, behavioral rehearsal, feedback and reinforcement, and behavioral “homework” assignments for out-of-class practice. The LST program consists of fifteen class periods in the first year, ten class periods in the second year, and nine class periods in the third year. Intervention materials included a teacher’s manual with detailed lesson plans and student guides for each year. All materials used were translated into Italian, adapted to the Italian culture, and integrated with existing complementary instructional materials. Some adaptations were made to the content of the program in order to address cultural differences regarding alcohol, drugs, about violent behaviors and to make behavioral rehearsal and other activities culturally appropriate for Italian students. Additional adaptations were made in training and technical support services for health professionals and teachers within the regional infrastructure that disseminates the program.

The program was delivered by regular classroom teachers who had attended an LST teacher training workshop aimed to familiarize the teachers with the content of the program and to provide an opportunity for teachers to learn and practice the skills needed to successfully implement the prevention program. Teachers also participated in technical assistance workshops delivered by health professionals. Teachers’ training, technical assistance, and ongoing support were adapted to address local needs, to promote high quality implementation, to integrate the program within local organizational contexts, and to strengthen the infrastructure which uses and disseminates the program in order to promote sustainability (Velasco, Griffin, Antichi & Celata, 2015).

Measures

Many of the measures used were derived from well-known and widely used instruments or skills measures developed to reflect the content of the prevention program (Epstein et al, 1997; Macaulay, Griffin & Botvin, 2002). These measures have been used in several previous prevention studies in U.S. with white adolescents and minority adolescents. All items were translated into Italian using a back-translation method.

First, Italian and U.S. researchers worked together to select the scales to be included. Second, items were translated into Italian and back-translated into English. Finally, the instrument was pilot tested in a study that included 23 middle schools in Milan. Some translations were modified for clarity and a few additional psychosocial outcomes were integrated in the questionnaire. The pilot study demonstrated that the instruments were appropriate for Italian students. Data collectors emphasized the confidential nature of the data being collected. Below, each scale is described and alphas from the present study are reported.

Demographic Data. Data concerning the characteristics of the participants were collected using standard survey items concerning gender, age, nationality and ethnicity.

Life Skills. Students were assessed with respect to a variety of social and personal competence skills that were taught in the prevention program. First, a series of 21 true-false questions assessed student's knowledge and awareness about skills, their effects on daily life and about the techniques to improve those skills. Second, specific scales assessed students' skills and abilities on a 5-point Likert scale anchored by 1 (never) and 5 (always). Assertiveness was assessed using 10 items from the Gambrill and Richey Assertion Inventory (Gambrill & Richey, 1975), which measures ability to assert one's rights (5 items; $\alpha=.73$; e.g. "Ask people to give back things that they have borrowed, if they forget to give them back to you") and social skills (5 items; $\alpha=.68$; e.g. "Keep a conversation going by asking questions"). Decision-making was assessed using five items ($\alpha=.80$) from the Coping Assessment Battery (Bugen & Hawkins, 1981), which measures applied information-gathering strategies that individuals may use when confronted with a specific problem (e.g., "I get the information I need to make the best choice"). Advertising resistance skills were assessed using 3 items ($\alpha=.69$) that measure the ability to use critical thinking in evaluating advertisements. Anxiety reduction skills were assessed using five items ($\alpha=.67$) that measure relaxation skills (e.g., "When I feel anxious, I imagine myself in a quiet, peaceful place"). All life skills scores were recoded such that higher scores reflected greater skills.

Psychosocial Outcomes. Students' distress ($\alpha=.81$; e.g. "I felt lonely") and well-being ($\alpha=.81$; e.g. "I generally enjoyed the things I did") were assessed using 12 items from the Mental Health Inventory (Veit & Ware, 1983) on a 5-point Likert scale anchored by 1 (all of the time) to 5 (none of the time). In addition, risk-taking was assessed using six items ($\alpha=.69$) from the Eysenck Personality Inventory (Eysenck & Eysenck,

1975), which measures the tendency to engage in daring behavior (e.g. “I get bored more easily than most people”) on a 5-point Likert scale anchored by 1 (strongly disagree) to 5 (strongly agree).

Beliefs about Substance Use. A series of 14 true–false questions assessed students’ knowledge of the physiological effects of substance use (7 items) and student’s beliefs about myths and misconceptions about drugs (7 items). Higher scores represented greater drug knowledge. Respondents’ attitudes about smoking and drinking, the characteristics of users and the perceived social benefits of using these drugs were assessed by two parallel measures derived from the Teenager’s Self-Test: Cigarette Smoking (U.S. Public Health Service, 1974). Five items were used to assess favorable attitudes about smoking ($\alpha=.78$) and five for alcohol ($\alpha=.74$). Responses were indicated on five-point Likert scales anchored by 1 (strongly disagree) to 5 (strongly agree); higher scores reflected greater antidrug attitudes. In addition, normative expectations related to tobacco and alcohol use were assessed in terms of perceived prevalence of drug use among adults.

Substance Use. Smoking, alcohol use and drunkenness were measured using a 9-point frequency response scale anchored by 1 (*never*) and 9 (*more than once a day*). Scores were recoded to identify students who initiated alcohol or tobacco use (*never vs more than once in lifetime*), and those who transitioned from less than weekly use to weekly use in order to verify the effectiveness of the program in preventing the initiation or the regular use of these substances.

Implementation Fidelity

Teachers completed program implementation forms after the implementation of each LST session in every implementation class. These forms were translated and adapted from the original ones used in U.S. and focused on prevention objectives covered during each LST session, activities implemented, methodologies used, and strengths and obstacles in rolling out the session. The forms were used to monitor the implementation of all mandatory units and to guarantee fidelity adherence. Health professionals periodically reviewed the completed forms and provided feedback to help teachers adhere to fidelity guidelines.

Data Analysis

Data were analyzed using SPSS 22 including the statistical procedures for chi-square test, t-test, and generalized estimating equations independent method (GEE). The effectiveness of the prevention program was

examined by comparing post-test and follow-ups means across the two conditions after adjusting for pre-test scores and additional demographic covariates (gender and age). Because the intervention was provided at the school level and individual students were the unit of observation, it was necessary to control for school-level clustering effects, otherwise clustering can bias estimation of program effects leading to false positives and pose a threat to internal validity (Murray, 1998). In all analyses of intervention effects, we used GEE to account for the clustering or nested structure of the data. The GEE approach is appropriate when group variance is small due to a large number of groups per condition (i.e., more than 20) and members per group (Varnell, Murray, Janega & Blitsein, 2004). The GEE procedure enables the researcher to estimate models at the individual level, corrects the estimated standard errors for the magnitude of clustering, is robust to misspecification, does not make strict distributional assumptions, and handles any type of categorical, continuous, and dichotomous outcome (Zeger, Liang, & Albert, 1988; Murray, 1998). The GEE method adjusts the estimated standard error to account for the within-cluster correlation and generally provides for a more conservative test of the hypothesis when a positive ICC is present.

Results

Pretest Equivalence

A series of chi-square analyses and t-test revealed that there were no pretest differences between the intervention and comparison groups in terms of school characteristics (municipality size and school size) and any of the demographic variables (gender, age, nationality). In addition, there were no differences in terms of substance use (tobacco, alcohol or drunkenness). This indicates a high degree of comparability between conditions prior to the intervention. Table 1 reports the percentages, the means and the p-values of the pre-test comparisons.

--- Insert Table 1 About Here ---

Attrition Analysis

Several analyses were conducted to determine if there was differential attrition between the intervention and comparison groups. A series of two-way chi-squares and t-tests (pretest status X condition) were conducted for each of the main measures at baseline. Significant differences were found in attrition rates between

intervention and comparison group ($\chi^2(1) = 12.817, p < .001$), with comparison group students having higher attrition rates than intervention group. However, no differences in attrition were found between the intervention and comparison groups with regards to baseline well-being or substance use. Missing data for both smoking and alcohol use variables were 1.1% at pre-test and 0.8% at post-test.

Intervention Effects

Several analyses were conducted to examine the effects of the intervention at the post-test and at the one- and two-year follow-ups. Separate GEE-independent analyses were conducted for each dependent variable that included condition as the independent variable, along with demographic covariates (gender and age). Table 2, 3 and 4 report the adjusted means and the p-values, adjusted for the ICC.

Post-Test. The GEE analyses indicated that fewer students initiated smoking in the intervention group compared with those in the comparison group during the first year of middle school ($\chi^2(1) = 10.07, p < .01$). The intervention had significant effects on the life skills taught in the program at the post-test (Table 2). Students who participated in the intervention reported higher rates of awareness about the importance of life skills, their effects on daily life, and the techniques to improve these skills ($\chi^2(1) = 16.05, p < .0001$), higher levels of asserting rights abilities ($\chi^2(1) = 3.80, p < .05$) and better anxiety reduction skills ($\chi^2(1) = 27.01, p < .0001$). No effects were found for decision-making or advertising resistance. At the post-test, the intervention group reported lower levels of distress ($\chi^2(1) = 6.31, p < .001$) and of risk-taking ($\chi^2(1) = 5.84, p < .05$). Finally, the intervention group reported higher knowledge of the physiological effects of substance use ($\chi^2(1) = 131.90, p < .0001$) and lower normative expectations about adults' smoking ($\chi^2(1) = 30.34, p < .0001$) and drinking ($\chi^2(1) = 11.10, p < .001$).

--- Insert Table 2 About Here ---

One-Year Follow-Up. Table 3 reports data on the one-year follow-up, assessed at the end of the second year of LST (10 booster sessions). The GEE analyses indicated that the proportion of students who initiated weekly drunkenness was lower in the intervention group compared with comparison group ($\chi^2(1) = 4.40, p < .05$). Furthermore, the intervention group reported higher levels of awareness about life skills ($\chi^2(1) = 11.82, p < .001$), of asserting rights abilities ($\chi^2(1) = 4.58, p < .05$) and anxiety reduction skills ($\chi^2(1) = 22.17, p < .0001$) compared

to the comparison group. Moreover, significant intervention effects were observed for distress ($\chi^2(1) = 5.73$, $p < .05$) and for beliefs about substance use. Students who participated in the project reported higher rates of knowledge of physiological effects of substance use ($\chi^2(1) = 55.56$, $p < .0001$) and also a better understanding of the myths and misconceptions about drugs ($\chi^2(1) = 11.73$, $p < .001$). Also the effects on normative expectations were maintained, both regarding smoking ($\chi^2(1) = 15.46$, $p < .0001$) and alcohol use ($\chi^2(1) = 5.36$, $p < .05$).

--- Insert Table 3 About Here ---

Two-Year Follow-Up. Table 4 reports findings at the two-year follow-up, assessed at the end of the third year of LST (9 booster sessions). GEE analyses indicated that fewer intervention students initiated smoking between the second and third year of middle school when compared to comparisons ($\chi^2(1) = 5.94$, $p < .05$). Furthermore, students who participated in the intervention reported higher rates of skill awareness ($\chi^2(1) = 6.73$, $p < .01$) and anxiety reduction skills ($\chi^2(1) = 6.94$, $p < .01$) compared to students in the comparison group. Students who participated in the intervention reported greater knowledge of physiological effects of substance use ($\chi^2(1) = 28.25$, $p < .0001$) and more accurate beliefs and fewer misconceptions about drugs ($\chi^2(1) = 20.10$, $p < .0001$). Moreover, positive attitudes about smoking were lower in the intervention group relative to comparisons ($\chi^2(1) = 6.25$, $p < .05$). The normative expectations were lower for the intervention group compared to comparisons both in terms of smoking ($\chi^2(1) = 36.00$, $p < .0001$) and alcohol use ($\chi^2(1) = 36.33$, $p < .0001$). However, the intervention group unexpectedly reported lower assertive skills ($\chi^2(1) = 4.81$, $p < .05$) compared to the comparison group at this time point.

--- Insert Table 4 About Here ---

Table 5 reports adjusted means at post-test, one and two-year follow-up by condition. With regards to tobacco, results showed lower normative beliefs and positive attitudes among intervention group compared to comparison group both short-term and long-term. Moreover, fewer intervention students initiated smoking at the first year of middle school and fewer non-smokers initiated smoking at the third year compared to comparisons. Smoking initiation and transition rates are lower in the intervention group than comparison group in all assessments. With regards to alcohol use, intervention students reported lower normative expectations about adults' drinking and fewer students reported weekly drunkenness. Other differences were not significant but

descriptive analysis showed lower rates of weekly drinking among intervention students compared to comparisons; significant effects could be found at more long distance.

Discussion

The present study reports on the effects of the adapted version of Life Skills Training in northern Italy on student outcomes and is the first rigorously designed evaluation of LST outside of the U.S. LST is an evidence-based prevention program which has been extensively tested and disseminated in the U.S. The Italian adapted version of the program was tested in a large-scale effectiveness study assessing students' skills, psychosocial outcomes, beliefs and drug use before the intervention and over the three years of middle school. The findings indicate that the project was effective for a variety of outcomes. Students in the intervention group who received the LST prevention program reported less use of tobacco and alcohol compared to students in the comparison group. Intervention students improved knowledge and beliefs about substance use and reported lower normative expectations about adults' smoking and drinking. Students who received the LST prevention program also had significantly higher levels of specific life skills (e.g. skill awareness, anxiety reduction or assertiveness) and well-being. The differences between the intervention and comparison group were significant at the post-test and at 1- and 2- year follow-up assessments. The results of this study are important because they show that the LST prevention approach developed in U.S. produces prevention effects in a different culture and context when a comprehensive approach to adaptation is followed (Velasco, Griffin, Antichi & Celata, 2015).

Findings indicated significant effects not only on substance use behaviors and related variables, but also on general protective factors like normative beliefs, life skills, and other psychosocial outcomes. These effects on hypothesized mediators suggest that, despite the linguistic and cultural differences between the U.S. and Italy, the conceptual model behind the LST program appears to be relevant for youth in Italy. LST is based on a conceptual framework that incorporates social learning theory (Bandura, 1977) and problem behavior theory (Jessor & Jessor, 1977). The LST model posits that (1) social factors and the modeling of substance use and other health risk behaviors by peers and high status role models are powerful influences on teen's attitudes and behaviors; and (2) intrapersonal factors (such as knowledge, attitudes, skills, and personality characteristics) affect motivation to engage in these behaviors and interact with social factors to increase susceptibility to those

negative influences. LST is designed to target key social and intrapersonal factors from the perspective of a positive youth development and general competence enhancement framework. The findings of the present study suggest that the etiologic factors and conceptual frameworks that have been used to explain adolescent substance use behavior are more similar than different among early adolescents in the U.S. and Italy.

The study has several strengths and limitations. Strengths of the study include the rigorous adaptation process used. As part of a large-scale regionally funded collaboration in the Lombardy region of Italy, a diverse team of stakeholders selected, translated and culturally adapted, planned, implemented and evaluated the LST program. Few large international initiatives conduct rigorous evaluations to examine the effectiveness of adapted programs. We used psychometrically valid assessment instruments, appropriate outcome variables, standardized data collection procedures, and well-accepted analytic methods. However, a limitation is that the study was a quasi-experimental design, in which intervention schools were matched to comparison group schools. The selection of these schools followed specific criteria, but they were not randomly assigned and thus can be unintentionally influenced by stakeholders. Another limitation of the present study is that we did not use an intent-to-treat analysis; some schools that did not implement the program were not included in the analysis. A related limitation concerns attrition and the fact that data was not available for all schools at all time-points. However, these problems are common in real-world effectiveness studies.

The results of this study provide additional evidence of the effectiveness of a school-based prevention approach focusing on social influences and generic competence skills. They extend prior research by demonstrating its effectiveness in a different culture and context. Moreover, they show the importance of a comprehensive approach to adapt an evidence-based program including program content adaptations, provider training adaptations and program infrastructure ones and incorporating the input of multiple stakeholders. Future research is warranted to determine the durability of these prevention effects with longer term follow-up assessments and to replicate the study after a long-term implementation of the program.

Acknowledgements

Authors want to thank all health professionals and teachers who have been involved in the project and who make it possible. A special thanks to Alayne MacArthur for her support and feedback.

Compliance with Ethical Standards

- a. Funding: the project was funded and supported by the Lombardy Region. The project was managed by the Regional Observatory on Drug Addiction (OReD) in collaboration with the Health Units and the Schools Department of the Region.
- b. Disclosure of potential conflicts of interest: Dr. Botvin has a financial interest in the Life Skills Training (LST) program and he is president of National Health Promotion Associates (NHPA), which provides teacher training and technical assistance for LST. Dr. Griffin is a senior research scientist with NHPA. Other authors declare that they have no conflict of interest.
- c. Ethical approval: the project and all activities were approved by the Regional Educational Authority of the National Ministry of Education, Universities and Research. which monitors and approves local policies, research projects and initiatives in Lombardy. Moreover, each school principal consented to participate in the study and the project was approved by school collective bodies which are tasked with monitoring and approving activity and research in each school. Finally, the assessment was managed by health professionals of the public Health System and by teachers in accordance with their professional ethics. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.
- d. Informed consent: The procedure for research at school defined by the Italian Data Protection Authority (2016) was followed. Informed consent was obtained from all school principals and school collective bodies. Each school decided on whether to use active or passive parental consent procedures in accordance with their own autonomous policies. The confidential nature of the survey was preserved and students could refuse to participate to the study at any time.

References

- August, G. J., Gewirtz, A., & Realmuto, G. M. (2010). Moving the field of prevention from science to service: Integrating evidence-based preventive interventions into community practice through adapted and adaptive models. *Applied and Preventive Psychology, 14*, 72–85.
- Backer, T. E. (2001). *Finding the Balance: Program Fidelity and Adaptation in Substance Abuse Prevention: A State-of-the-Art Review*. Rockville, MD: Center for Substance Abuse Prevention.
- Bandura, A. (1977). *Social learning theory*. Englewood Cliffs, NJ: Prentice-Hall.
- Bernal, G., Jiménez-Chafey, M. I., & Domenech Rodríguez, M. M. (2009). Cultural adaptation of treatments: A resource for considering culture in evidence-based practice. *Professional Psychology: Research and Practice, 40*(4), 361.
- Botvin, G. J., & Griffin, K. W. (2015). Preventing tobacco, alcohol, and drug abuse through Life Skills Training. In: L. M. Scheier (Ed.), *Handbook of drug abuse prevention research, intervention strategies, and practice*. Washington DC: American Psychological Association.
- Botvin, G. J., Baker, E., Dusenbury, L., Botvin, E. M., & Diaz, T. (1995). Long-term follow-up results of a randomized drug abuse prevention trial in a white middle-class population. *Journal of the American Medical Association, 273*(14), 1106–1112.
- Botvin, G. J., Griffin, K. W., & Nichols, T. R. (2006). Preventing youth violence and delinquency through a universal school-based prevention approach. *Prevention Science, 7*, 403-408.
- Botvin, G. J., Griffin, K. W., Diaz, T., & Ifill-Williams, M. (2001a). Drug abuse prevention among minority adolescents: One-year follow-up of a school-based preventive intervention. *Prevention Science, 2*, 1-13.
- Botvin, G. J., Griffin, K. W., Diaz, T., & Ifill-Williams, M. (2001b). Preventing binge drinking during early adolescence: One- and two-year follow-up of a school-based preventive intervention. *Psychology of Addictive Behaviors, 15*, 360-365.
- Bugen, L. A., & Hawkins, R.C. (1981). *The Coping Assessment Battery: Theoretical and Empirical Foundations*. Paper presented at the meeting of of the American Psychological Association, Los Angeles, CA.

- Campbell, M. K., Thomson, S., Ramsay, C. R., MacLennan, G. S., & Grimshaw, J. M. (2004). Sample size calculator for cluster randomized trials. *Computers in Biology & Medicine*, 34(2), 113-125.
- Catalano, R. F., Fagan, A. A., Gavin, L. E., Greenberg, M. T., Irwin, C. E., Ross, D. A., & Shek, D. T. (2012). Worldwide application of prevention science in adolescent health. *The Lancet*, 379, 1653-1664.
- Celata, C., Gelmi, G., & Velasco, V. (2010). *HBSC e le abitudini di salute degli adolescenti lombardi Edizione 2007–2008*. In Osservatorio Regionale sulle Dipendenze.
- Celata, C., Gelmi, G., Lavatelli, M., Picozzi, O., & Velasco, V. (2008). La prevenzione delle dipendenze a scuola. In L. Fornari & B. Peraboni (Eds.), *P.R.A.S.S.I. Prevenzione al Rischio di Assunzione di Sostanze con Sensibilita` Interculturale. Riflessioni sulla sperimentazione di un modello in ambito scolastico*. Trento: Editrice UNI Service.
- Epstein, J. A., Botvin, G. J., Diaz, T., Baker, E., & Botvin, E.M. (1997). Reliability of social and personal competence measures for adolescents. *Psychological Reports*, 81, 449-450.
- Eysenck, S. B. J., & Eysenck, H. J. (1977). The place of impulsiveness in a dimensional system of personality description. *British Journal of Social and Clinical Psychology*, 16, 57–68.
- Gambrill, E. D., & Richey, C. A. (1975). An assertion inventory for use in assessment and research. *Behavior Therapy*, 550-561.
- Italian Data Protection Authority (2016). *La scuola a prova di privacy*. Roma: Garante per la protezione dei dati personali.
- Jessor, R., & Jessor, S. L. (1977). *Problem behavior and psychosocial development: A longitudinal study of youth*. New York, NY: Academic Press.
- Leone, L., & Celata, C. (2006). *Per una prevenzione efficace. Evidenze di efficacia, strategie di intervento e reti locali nell'area delle dipendenze*. Milano: Il Sole 24 ORE.
- Macaulay, A. P., Griffin, K. W., & Botvin, G. J. (2002). Initial internal reliability and descriptive statistics for a brief assessment tool for the Life Skills Training drug abuse prevention program. *Psychological Reports*, 91, 459-462.

- Murray, D. M. (1998). *Design and analysis of group-randomized trials* (Vol. 29). Oxford University Press, USA.
- National Institute of Drug Abuse (2003). *Preventing drug use among children and adolescents. A research-based guide for parents*. Services, Department of Health and Human: NIH Publication.
- ORed (2013). *Generazione 20.10: comportamenti di salute, contesti di vita e livelli di benessere degli studenti lombardi. Indagine Health Behaviour in School-aged Children (HBSC) Lombardia 2009-2010: stili di vita e salute degli studenti di 11, 13 e 15 anni. Rapporto finale*. Milano: Éupolis Lombardia.
- Regione Lombardia (2007). *Prevenzione delle diverse forme di dipendenza nella popolazione preadolescenziale e adolescenziale*. Linee Guida Regionali Regione Lombardia.
- Regione Lombardia (2008). *Prevenzione delle diverse forme di dipendenza nella popolazione generale*. Linee Guida Regionali Regione Lombardia.
- Stirman, S. W., Miller, C. J., Toder, K., & Calloway, A. (2013). Development of a framework and coding system for modifications and adaptations of evidence-based interventions. *Implementation Science*, 8(1), 65.
- Sundell, K., & Ferrer-Wreder, L. (2014). The transportability of empirically supported interventions (pp 41-58). In: A. Shlonsky & R. Benbenishty (Eds.), *Evidence to outcomes in child welfare: An international reader*. Oxford: Oxford University Press.
- Sundell, K., Ferrer-Wreder, L., & Fraser, M. W. (2014). Going Global: A model for evaluating empirically supported family-based interventions in new contexts. *Evaluation & the health professions*, 37(2), 203-230.
- Tavolo Tecnico Regionale Prevenzione (2010). *Gruppo di lavoro tematico: Fare prevenzione a scuola, nella scuola, con la scuola: potenzialità, limiti e opportunità*. Regione Lombardia.
- U.S. Public Health Service (1974). *Teenager's Self-Test: Cigarette Smoking*, U.S. Public Health Service.
- Varnell, S. P., Murray, D. M., Janega, J. B., & Blitstein, J. L. (2004). Design and analysis of group-randomized trials: a review of recent practices. *American Journal of Public Health*, 94(3), 393-399.
- Veit, C. T., & Ware, J. E. (1983). The structure of psychological distress and well-being in general populations. *Journal of Consulting and Clinical Psychology*, 51, 730-742.

Velasco, V., Griffin, K. W., Antichi, M., & Celata, C. (2015). A large-scale initiative to disseminate an evidence-based drug abuse prevention program in Italy: Lessons learned for practitioners and researchers. *Evaluation and program planning*, 52, 27-38.

Zeger, S. L., Liang, K. Y., & Albert, P. S. (1988). Models for longitudinal data: a generalized estimating equation approach. *Biometrics*, 1049-1060.

Figure 1: CONSORT flowchart of study

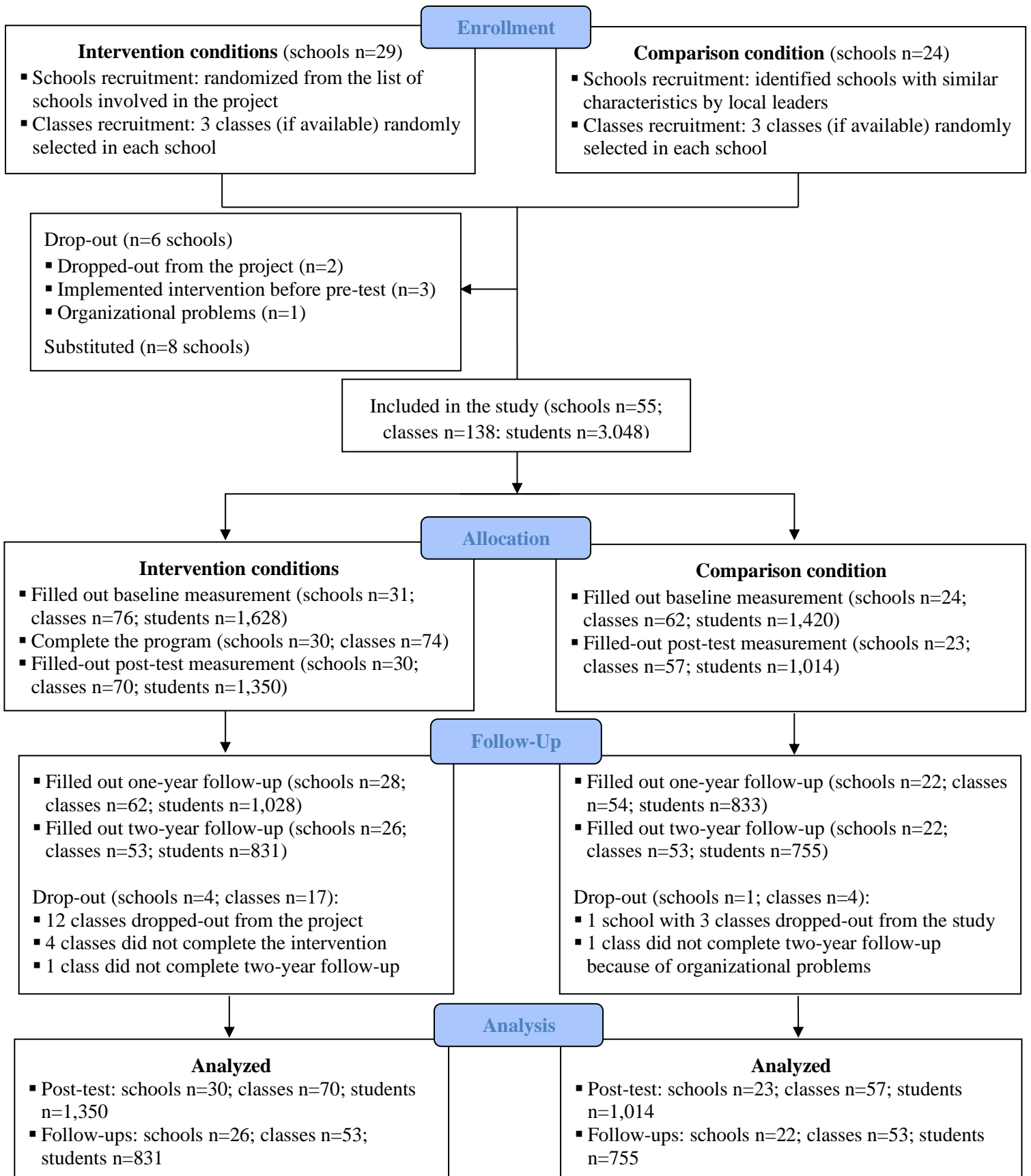


Table 1: Pretest comparability of intervention and comparison conditions

	Intervention group	Comparison group	Chi-square/ T-test		
	% - Mean (SE)	% - Mean (SE)	χ^2 - t	df	p-value
<i>School characteristics</i>					
Municipality size					
Small (<10.000 inhabitants)	25.8%	29.2%	1.39	2	0.500
Medium (>10.001 inhabitants)	25.8%	37.5%			
Large (metropolitan area)	48.4%	33.3%			
School size					
Small (1-3 classes)	35.5%	41.7%	0.43	2	0.806
Medium (4-5 classes)	41.9%	33.3%			
Large (6 or more classes)	22.6%	25.0%			
<i>Demographic variables</i>					
Sex (female)	51.1%	50.9%	0.01	1	0.933
Age	11.05 (0.36)	11.04 (0.39)	0.82	2362	0.415
Nationality (Italian)	91.6%	89.6%	2.79	1	0.097
<i>Substance use (yes/no %)</i>					
Tobacco	3.4%	4.3%	1.47	1	0.229
Alcohol	10.1%	11.5%	1.16	1	0.309
Drunkenness	2.5%	2.8%	0.28	1	0.602

Table 2: Adjusted Means at Post-Test by Quasi-Experimental Condition

	Intervention group		Comparison group		GEE		
	Mean	SE	Mean	SE	χ	df	p-value
<i>Life Skills</i>							
Skill awareness	68.81	0.04	65.68	0.04	16.05	1	0.000
Assertiveness – rights	4.18	0.26	4.10	0.27	3.80	1	0.051
Assertiveness – social skills	3.77	0.28	3.76	0.28	0.09	1	0.759
Decision-making	3.74	0.21	3.75	0.21	0.13	1	0.714
Advertising resistance	3.60	0.24	3.63	0.24	0.44	1	0.508
Anxiety reduction	2.97	0.19	2.78	0.18	27.01	1	0.000
<i>Psychosocial Outcomes</i>							
Distress	3.53	0.24	3.63	0.23	6.31	1	0.012
Well-being	2.53	0.18	2.53	0.17	0.00	1	0.975
Risk taking	2.68	0.21	2.77	0.21	5.84	1	0.016
<i>Beliefs about Substance Use</i>							
Drug knowledge – effects	59.09	0.04	47.45	0.04	131.90	1	0.000
Drug beliefs – myths	82.58	0.04	81.43	0.04	2.53	1	0.112
Positive Attitudes – tobacco	1.45	0.18	1.50	0.18	3.58	1	0.058
Positive Attitudes – alcohol	1.46	0.18	1.50	0.18	2.08	1	0.149
Normative Belief – tobacco	3.12	0.26	3.49	0.25	30.34	1	0.000
Normative Belief – alcohol	3.26	0.20	3.47	0.21	11.10	1	0.001
<i>Substance Use Behavior</i>							
Initiation – tobacco	0.98	0.03	0.96	0.05	10.07	1	0.002
%	2.5		4.7				
Initiation – alcohol	0.92	0.08	0.92	0.08	0.09	1	0.763
%	8.7		8.1				
Transition (weekly) – tobacco	0.99	0.01	0.99	0.02	1.40	1	0.237
%	0.8		1.4				
Transition (weekly) – alcohol	0.99	0.02	0.98	0.03	2.92	1	0.088
%	1.3		2.5				
Transition (weekly) – drunkenness	0.99	0.01	0.99	.002	1.65	1	0.199
%	0.8		1.5				

Note: N=2364 (1350 intervention group and 1014 comparison group); covariates for all analyses were gender and age; the GEE *p*-values represent two-tailed significance levels after adjusting for ICCs at the school level

Table 3: Adjusted Means at the One Year Follow-Up by Quasi-Experimental Condition

	Intervention group		Comparison group		χ	GEE	
	Mean	SE	Mean	SE		df	p-value
<i>Life Skills</i>							
Skill awareness	73.09	0.03	70.03	0.03	11.82	1	0.001
Assertiveness – rights	4.28	0.19	4.20	0.19	4.58	1	0.032
Assertiveness – social skills	3.85	0.20	3.91	0.21	3.71	1	0.054
Decision-making	3.76	0.22	3.78	0.22	0.21	1	0.647
Advertising resistance	3.57	0.32	3.65	0.33	1.98	1	0.160
Anxiety reduction	2.89	0.25	2.73	0.26	22.17	1	0.000
<i>Psychosocial Outcomes</i>							
Distress	3.40	0.22	3.49	0.22	5.73	1	0.017
Well-being	2.56	0.19	2.51	0.19	0.98	1	0.321
Risk taking	2.78	0.27	2.85	0.28	3.16	1	0.075
<i>Beliefs about Substance Use</i>							
Drug knowledge – effects	57.19	0.05	48.20	0.05	55.56	1	0.000
Drug beliefs – myths	84.10	0.04	80.74	0.04	11.73	1	0.001
Positive Attitudes – tobacco	1.49	0.21	1.58	0.21	3.36	1	0.067
Positive Attitudes – alcohol	1.49	0.20	1.57	0.19	3.16	1	0.076
Normative Belief – tobacco	3.37	0.35	3.61	0.33	15.46	1	0.000
Normative Belief – alcohol	3.53	0.37	3.67	0.37	5.36	1	0.021
<i>Substance Use Behavior</i>							
Initiation – tobacco	0.94	0.06	0.92	0.08	1.63	1	0.202
%	6.4		8.3				
Initiation – alcohol	0.87	0.11	0.86	0.12	0.33	1	0.569
%	13.6		15.0				
Initiation booster/L1 – tobacco	0.95	0.05	0.92	0.08	2.86	1	0.091
%	5.4		8.4				
Initiation booster/L1 – alcohol	0.88	0.11	0.88	0.12	0.02	1	0.900
%	12.8		12.8				
Transition (weekly) – tobacco	0.99	0.02	0.99	0.04	1.08	1	0.300
%	1.0		1.8				
Transition (weekly) – alcohol	0.99	0.02	0.98	0.03	0.30	1	0.586
%	1.6		1.9				
Transition (weekly) – drunkenness	1.00	0.00	.99	0.03	4.40	1	0.036
%	0.4		1.0				

Note: N=1586 (831 intervention group and 755 comparison group); covariates for all analyses were gender and age; the GEE *p*-values represent two-tailed significance levels after adjusting for ICCs at the school level

Table 4: Adjusted Means at Two-Year Follow-Up by Quasi-Experimental Condition

	Intervention group		Comparison group		χ	GEE	
	Mean	SE	Mean	SE		df	p-value
<i>Life Skills</i>							
Skill awareness	74.35	0.03	72.03	0.03	6.73	1	0.010
Assertiveness – rights	4.25	0.18	4.20	0.18	2.98	1	0.084
Assertiveness – social skills	3.81	0.23	3.90	0.23	4.81	1	0.028
Decision-making	3.74	0.20	3.80	0.20	1.14	1	0.285
Advertising resistance	3.47	0.35	3.57	0.35	1.91	1	0.167
Anxiety reduction	2.74	0.22	2.61	0.22	6.94	1	0.008
<i>Psychosocial Outcomes</i>							
Distress	3.29	0.18	3.32	0.18	0.63	1	0.426
Well-being	2.70	0.24	2.67	0.22	0.97	1	0.324
Risk taking	2.87	0.26	2.90	0.24	0.31	1	0.576
<i>Beliefs about Substance Use</i>							
Drug knowledge – effects	57.51	0.04	50.91	0.04	28.25	1	0.000
Drug beliefs – myths	83.60	0.04	79.74	0.04	20.10	1	0.000
Positive Attitudes – tobacco	1.59	0.18	1.72	0.19	6.25	1	0.012
Positive Attitudes – alcohol	1.62	0.21	1.68	0.20	1.48	1	0.225
Normative Belief – tobacco	3.31	0.31	3.74	0.29	36.00	1	0.000
Normative Belief – alcohol	3.49	0.28	3.81	0.27	36.33	1	0.000
<i>Substance Use Behavior</i>							
Initiation – tobacco	0.83	0.11	0.80	0.12	1.27	1	0.260
%	16.9		20.4				
Initiation – alcohol	0.75	0.18	0.74	0.15	0.12	1	0.729
%	25.2		26.3				
Initiation booster/L1 – tobacco	0.99	0.02	0.97	0.04	5.94	1	0.015
%	1.2		3.2				
Initiation booster/L1 – alcohol	0.95	0.07	0.95	0.07	0.02	1	0.902
%	6.0		5.4				
Transition (weekly) – tobacco	0.93	0.08	0.92	0.09	0.49	1	0.482
%	6.7		8.1				
Transition (weekly) – alcohol	0.97	0.04	0.96	0.06	2.10	1	0.147
%	2.8		4.5				
Transition (weekly) – drunkenness	0.99	0.17	0.99	0.16	0.04	1	0.849
%	0.7		0.8				

Note: N=1586 (831 intervention group and 755 comparison group); covariates for all analyses were gender and age; the GEE *p*-values represent two-tailed significance levels after adjusting for ICCs at the school level

Table 5: Adjusted Means and SEs at Post-Test, One and Two-Year Follow-Up by Quasi-Experimental Condition

	Intervention group			Comparison Group		
	Post-Test	One-Year Follow-Up	Two-Year Follow-Up	Post-Test	One-Year Follow-Up	Two-Year Follow-Up
<i>Tobacco</i>						
Positive attitudes	1.45 (0.18)	1.49 (0.21)	1.59 ^a (0.18)	1.50 (0.18)	1.58 (0.21)	1.72 ^a (0.19)
Normative belief	3.12 ^a (0.26)	3.37 ^b (0.35)	3.31 ^c (0.31)	3.49 ^a (0.25)	3.61 ^b (0.33)	3.74 ^c (0.29)
Initiation	2.5% ^a	6.4%	16.9%	4.7% ^a	8.3%	20.4%
Initiation booster/L1		5.4%	1.2% ^a		8.4%	3.2% ^a
Transition (weekly)	0.8%	1.0%	6.7%	1.4%	1.8%	8.1%
<i>Alcohol</i>						
Positive attitudes	1.46 (0.18)	1.49 (0.20)	1.62 (0.21)	1.50 (0.18)	1.57 (0.19)	1.68 (0.20)
Normative belief	3.26 ^a (0.20)	3.53 ^b (0.37)	3.49 ^c (0.28)	3.47 ^a (0.21)	3.67 ^b (0.37)	3.81 ^c (0.27)
Initiation	8.7%	13.6%	25.2%	8.1%	15.0%	26.3%
Initiation booster/L1		12.8%	6.0%		12.8%	5.4%
Transition (weekly)	1.3%	1.6%	2.8%	2.5%	1.9%	4.5%
<i>Drunkness</i>						
Transition (weekly)	0.8%	0.4% ^a	0.7%	1.5%	1.0% ^a	0.8%

Note: Values with the same superscript within a row are significantly different ($p < .05$)