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A school-based peer-led smoking prevention intervention with extracurricular activities: the LILT-LdP cluster randomized controlled trial design and study population

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ABSTRACT

Aims and background. Few school programs are effective in preventing adolescents' tobacco smoking initiation. The "Lega contro i Tumori - Luoghi di Prevenzione" is a cluster randomized controlled trial designed to evaluate a school-based peer-led smoking prevention intervention with extracurricular activities for students aged 14-15 years. This paper presents the study design and the baseline characteristics of the study population.

Methods and study design. Twenty secondary schools located in the Reggio Emilia province took part in the study. Five schools were excluded because they already participated in smoking prevention interventions. The schools were randomized to control or intervention arms. The study population consisted of students attending the first grade. Components of the intervention included 1) the out-of-school "Smoking Prevention Tour" (SPT) at the "Luoghi di Prevenzione" Center, a 4-hour (4 sessions) extracurricular activity; 2) the "Smoke-free Schools" intervention, combining a life–skills-based peer-led intervention at school, an in-depth lesson on one of the SPT sessions, and enforcement surveillance of the school antismoking policy. Tobacco use was studied through a questionnaire administered before and 6 months after the intervention.

Results. Eleven high schools and 9 vocational secondary schools took part in the study for a total of 2,476 out of 3,050 eligible students (81.2%). The proportions of respondents in high schools and vocational secondary schools were 90.9% and 64.5%, respectively (P <0.001). Intervention and control arms showed a different distribution of gender and school type, whereas no difference was observed in any tobacco-use characteristic.

Conclusions. This study is one of the few Italian trials to evaluate the effectiveness of a school-based program for preventing smoking initiation.

Introduction

Youth smoking initiation is an important public health concern, since tobacco use is the leading cause of preventable deaths[1]. According to the Health Behavior in School-aged Chidren (HBSC) study, 20% of Italian students aged 15 years in 2005-2006 smoked at least weekly[2]. According to the European School Survey Project on Alcohol and Other Drugs (ESPAD), in 2007 in Italy 34% of boys aged 15-16 years and 39% of girls of the same age had used cigarettes during the past 30 days, and 23-24% in both genders smoked on a daily basis. Moreover, at the age of 13 or younger 30% of

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boys and 27% of girls had tried cigarettes, and 6% of boys and 5% of girls smoked cigarettes on a daily basis[3]. In the last 3 ESPAD surveys (1999, 2003 and 2007), the lifetime smoking prevalence in Italian adolescents recorded a slight reduction in both genders of about 5%, and more recent smoking (last 30 days) recorded an 8% decrease in boys and a 9% decrease in girls[3].

Schools are a potentially valuable setting for smoking prevention. Systematic reviews have, however, provided varied evidence of the effectiveness of school-based programs for smoking prevention[4-6]. One review indicated Life Skills Training[7-8] as the only program having long-term effectiveness in decreasing the smoking prevalence at age 18[5]. Life Skills Training programs have been proposed to train a comprehensive core of social skills thought to exert a protective effect on youths' smoking initiation. This program teaches goal-setting, problem-solving, decision-making and cognitive skills to resist interpersonal influences, to increase self-esteem and assertiveness, and to cope with stress and anxiety[6]. Recently, a school curriculum based on a comprehensive social-influence approach incorporating Life Skills Training, normative belief, and knowledge about the harmful effects of smoking showed a significant short-term effect 3 months after the end of the program of an about 30% lower prevalence of daily cigarette use in the past 30 days in the intervention group compared with controls[9].

Another approach is using peers to deliver health promotion interventions to young people. Peers may be seen as more credible sources of information than health professionals or teachers, and may be helpful for "at risk" young people[10-12]. A systematic review on peer-led health promotion interventions showed variable evidence of effectiveness[10]. Recently, a randomized controlled trial based on an informal school-based peer-led intervention showed a significant 22% reduction of the odds of being a smoker in intervention schools compared with control schools[13].

School antismoking policies are considered part of a comprehensive approach to preventing adolescent cigarette smoking[14]. Only a few cross-sectional studies have addressed the possible effect of a completely smoke-free school on youth smoking behavior[15]. Strictly enforced antismoking policies bring about changes in students' beliefs about cigarette smoking (tobacco is perceived as less available, more risky, less attractive, and less socially accepted) and a decrease in students' past 30-day smoking[16]. The results of this approach appeared promising, even though more research is required[15].

Little is known about the adjunct to a school-based intervention of a component of extracurricular activities[17-20]. In our study extracurricular activities were conducted in an out-of-school center specifically dedicated to health promotion, the 900 m^2 "Luoghi di Prevenzione" (LdP; Prevention Places) Center funded by the nonprofit organization LILT (Lega contro i Tumori di Reggio Emilia), located in a former national health system hospital in Reggio Emilia, Italy. In this center students can follow 4-hour out-of-school "Health Promotion Tours" delivered by trained educators. Each tour is devoted to a single subject (prevention of smoking, alcohol and substance abuse, and street accidents)[21]. In particular, the "Smoking Prevention Tour" (SPT) was developed to deliver life skills and knowledge about the harmful effects of smoking.

The LILT-LdP study is a cluster randomized controlled trial designed to evaluate the effectiveness of a smoking prevention program for students aged 14 years, characterized by 2 components: 1) participation in the SPT at the LILT-LdP Center and 2) participation in the school-based intervention "Scuole libere da fumo" (Smoke-free Schools) incorporating a peer-led intervention based on life skills, an in-depth school lesson conducted by teachers on one of the SPT sessions, and enforcement surveillance of the school antismoking policy. This paper presents the study design and the baseline characteristics of the study population.

Methods

The LILT-LdP intervention

The components of the intervention included:

1. The out-of-school SPT conducted at the LILT-LdP Center. The 4-hour SPT was divided into four 40-minute sessions. Every class was divided into 2 groups. The 4 sessions were led by LILT-trained health promotion educators and included the following parts: a) a Lab session with 10 minutes dedicated to the physiology of the respiratory system and 20 minutes to laboratory tests for separating substances in cigarette smoke (tar, particulate matter, nicotine, carbon dioxide, nitric oxide) using lab reagents. In the last 10 minutes a portable laser-operated aerosol analyzer with a sampling time of 2 minutes was used in real time to measure particulate matter (PM2.5 and PM10) when a cigarette is lit. Then a student was asked to breathe into the analyzer in order to show that the human respiratory system holds most of the PM2.5 contained in inhaled air; b) a computer session where every student filled in 3 to 5 score tests and calculated his/her scores in each test. These included for all students: tests on physical and psychological wellness and stress levels; for nonsmokers: a test on the curiosity level about smoking; for smokers: the Fagerström Tolerance Questionnaire and a test measuring the motivation to quit; for former smokers: a test measuring the motivation to remain a nonsmoker; c) a creative writing session, which began with a reading about smoking. The session was then divided into 2 parts: in the first

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part, called "Smoking Signs", the students divided a sheet of paper into 4 parts with the following headings: smoking and emotions, thoughts, experiences, and keywords. Every student filled in the 4 parts of the sheet using words and sentences. In the second part, called "Personal Feeling of Smoking", the students divided a paper sheet into 3 parts with the following headings: feelings, beliefs, and experiences. Every student filled in the 3 parts of the sheet using words and sentences; d) an imaginative session: after a few minutes of relaxation and deep breathing in a room with comfortable armchairs, an educator read a novel that described the experience of smoking a cigarette during a Saturday night in a disco club. The students had to identify with the character. In the text of the novel there were questions about the emotions the character felt when smoking and holding a cigarette. This experience was compared with a non-smoker experience.

2. The school-based intervention "Smoke-free Schools" consisted of a) a peer-led intervention in which a group of self-selected 16- and 17-year-old students of schools belonging to the intervention arm (older than those recruited for the study) were trained by LILT educators in three 2-hour sessions at school plus 1 meeting at the LILT-LdP Center. This training served to explain their role in the study, to provide knowledge of the smoking effects on health through participation in the Lab session of the SPT, and to demonstrate the use of the instruments they were asked to use during meetings with students in the intervention arm (role-playing games, brainstorming, creative writing, novels with questions). The trained peers organized two 2-hour meetings in every first class of the intervention arm. In the first meeting the peers had to conduct a brainstorming session on smoking and to administer a questionnaire on the health risks of smoking. In the second meeting the peers had to conduct a discussion with students on positive and negative aspects of smoking, and to conduct a creative writing session on smoking; b) a 2-hour in-depth school lesson on one of the SPT sessions at the LILT-LdP Center. The lesson was conducted by teachers after the students' meetings with peers. Teachers had previously been trained in two 2-hour meetings with LILT educators; c) enforcement surveillance of the school antismoking policy, where school staff established a working group on the surveillance on smoking in school areas (playground, corridors, toilets), proposed and activated a school antismoking policy with clear indications about non-smoking areas, sanctions, and enforcement surveillance. Moreover, the working group checked the enforcement of the smoking regulations at school and the correct positioning of non-smoking signs in school areas.

Study design

This was a 2-arm cluster randomized controlled trial where schools were randomly assigned to the intervention arm, while students remained the units of analysis. The intervention group was compared with a control group (Figure 1).

Units and subjects

The study population consisted of students attending the first grade of secondary schools located in the Reggio Emilia province, Italy. Inclusion criteria for the schools were the presence of at least 3 classes in the target grade; being part of the mainstream national educational system; no participation in any current or recent smoking prevention interventions. Exclusion criteria at the student level were the student's incapability to participate in the survey.

Sample size

With an inflation factor of 1.9 derived from an intra-class correlation coefficient estimate calculated in grade participants to ESPAD surveys[3], assuming a significance level of $\alpha = 0.05$, power of 0.80, prevalence of past 30-day cigarette use of about 15% in the control group, a sample size of about 3,400 students (1,700 per arm) could allow a relative risk of about 0.70[22].

Selection and randomization of schools

Five secondary schools among the 25 secondary schools located in the Reggio Emilia province (population 513,400 in 2008) were excluded because they had participated in school-based smoking prevention programs in the preceding years. The remaining 20 schools took part in the trial. Small annexes of the participating schools with fewer than 3 classes in the target grade and located in peripheral areas of the province were excluded. Participating schools were paired according to the type of school (vocational secondary school or high school) and the size of the

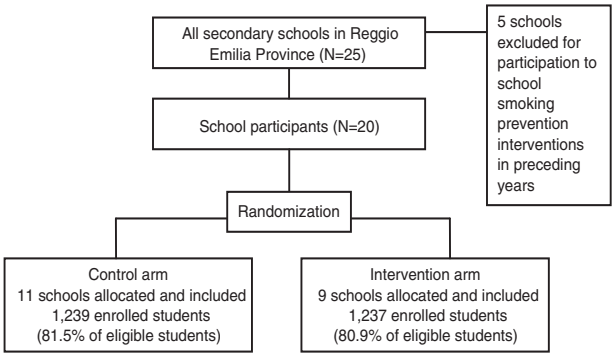


Figure 1 - Flowchart of the enrolment of schools and students in the LILT-LdP study.

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school (number of students attending the first grade in the 2008-2009 school year). One school of each pair was randomized to the intervention arm.

The study was conducted in 2 phases: in the first phase, including 4 school pairs, the pre-intervention survey was conducted from December 2008 to May 2009, whereas for the remaining schools it was conducted from November 2009 to May 2010. The follow-up surveys of both phases were carried out on average 18 months after the baseline surveys and at least 6 months after the end of the intervention.

Outcome assessment

Students in both arms had to fill in a questionnaire before and after the intervention. The questions covered demographic characteristics including gender, age, and origin and education of parents; cigarette use including lifetime cigarette use, cigarette use in the past 30 days, 20 or more days of cigarette smoking in the past 30 days, lifetime use of ≥100 cigarettes; smoking prevalence in parents, siblings and friends; exposure to second-hand smoke at home and in cars; exposure to antitobacco advertisements and smoking scenes in movies and television programs; perceived health consequences from smoking (Do you think people addicted to nicotine smoke at least 20 cigarettes per day? Do you think that breathing passive smoking is dangerous for your health?); intent to use cigarettes in the near future (Do you think you will smoke a cigarette during the next year?); smoking if friends offer a cigarette (If one of your best friends offers you a cigarette, would you smoke it?); perceived social norm (How many adolescents smoke, given as a percentage?); perceived social acceptability of smoking (Do you think people who smoke cigarettes have more friends? Do you think smoking cigarettes makes young people look cool or fit in?); antitobacco industry norms (Do you think that tobacco companies try to get people addicted to cigarettes? Do you think tobacco companies would stop selling cigarettes if they knew for sure that smoking hurts people?).

Confidentiality

In order to ensure rigorously anonymous management of the data while keeping the link between individual information collected during subsequent surveying, the questionnaires were labeled with a 9-digit individual code generated by the student[9].

Ethical aspects

The LILT-LdP study was submitted to and approved by the Ethics Committee of the Local Health Authority of Reggio Emilia, Italy. A policy of informed consent was adopted, and surveys involving students were conducted at school after approval of school boards.

Analysis

We conducted a descriptive analysis of the baseline characteristics of the recruited students in the 20 participating schools. Differences in proportions were analyzed using the chi-squared test.

Results

Twenty schools took part in the study: 11 high schools and 9 vocational secondary schools. One hundred and sixteen out of 123 eligible classes of the target grade (94.3%) participated in the baseline survey with 2,476 out of 3,050 eligible students (81.2%): 1,237 students in the intervention arm (80.9%) and 1,239 in the control arm (81.5%; $P = 0.22$). The proportion of respondents was higher in high schools than in vocational secondary schools (90.9% *vs* 64.5%; $P < 0.001$).

The sociodemographic characteristics that showed a different distribution between the intervention and control arms at baseline were gender (a lower proportion of girls were enrolled in the intervention arm compared to the control arm) and type of school (a lower proportion of students of vocational secondary schools were enrolled in the intervention arm) (Table 1). Prevalence of cigarette use in the past 30 days, 20 or more days of cigarette smoking in the past 30 days, lifetime cigarette use, and lifetime use of at least 100 cigarettes were similar in the intervention and control arms (Table 1).

Discussion

The LILT-LdP study is a trial aiming to evaluate the effectiveness of a school-based peer-led smoking prevention intervention with extracurricular activities. The participation rate of schools was very high, in that all the available secondary schools in the Reggio Emilia province took part in the study and only 5 schools were excluded because they already participated in school-based smoking-prevention programs. Our study recruited 20 schools and 3,050 secondary schools students aged 14 years, corresponding to 87% of the expected study sample (about 3,500 students). It recorded a participation rate in the baseline survey of 81% of enrolled students (2,476 boys and girls). The participation rate in the baseline survey was significantly lower in vocational secondary schools (65%) due to a documented higher proportion of days of school absence among students attending vocational secondary schools than those attending high schools.

The prevalence of current cigarette use in our study (24.5% in both the intervention and control arms) was similar to that recorded in the 2010 HBSC survey among students aged 15 years old from the Emilia-Romagna Region (26.4%)[23] and was lower than the 2007 figures of

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Table 1 - Baseline sociodemographic characteristics and smoking behavior variables in recruited students by study arm

		Intervention N = 1,237 %	Control N = 1,239 %	*P* value
Age				
	<15 years	87.3	84.2	0.103
Gender				
	Girls	47.4	60.2	<0.001
	Boys	51.8	39.8	
Parents' education				
	Both parents with primary or middle school diploma	75.3	76.7	0.438
	At least one parent with high school diploma or university degree	24.7	23.3	
Parents' origin				
	At least one parent born in Italy	81.3	83.2	0.434
	Both parents born abroad	17.1	15.6	
School type				
	Vocational secondary school	22.7	27.1	0.011
	High school	77.3	72.9	
Smoking outcomes				
	Cigarette use (past 30 days)	25.6	23.5	0.296
	≥20 days of cigarette smoking in past 30 days	8.3	8.3	0.951
	Lifetime cigarette use	46.8	45.9	0.665
	Lifetime use of ≥100 cigarettes	8.6	9.8	0.302

the ESPAD survey for Italy (37% in both genders), which involved older students (aged 15 and 16 years)[3].

This study is one of the few trials conducted in Italy to evaluate effectiveness of school-based programs to prevent smoking initiation in adolescents. A limit of the study is that the 2,476 students recruited at baseline amounted to almost three quarters of the estimated sample size (3,500 students). This could result in a lower than expected power of the study.

In conclusion, smoking is currently a predominant health problem in developed countries, accounting for about 71,000 attributable deaths in Italian women and men in 2010[24]. Promoting interventions for smoking prevention is one of the most important strategies to reduce the smoking-attributable mortality in future decades. In order to achieve this goal, the LILT-LdP study evaluated the effectiveness of a school-based peer-led smoking prevention intervention with extracurricular activities.

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