

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

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Abstract

Aims and background

Few school programmes are effective in preventing adolescents' tobacco smoking initiation. The "Lega Italiana per la Lotta contro i Tumori - Luoghi di Prevenzione" is a cluster randomized controlled trial designed to evaluate a school-based peer-led smoking prevention intervention with extra-curricular activities for students aged 14-15 years. This paper presents study design, baseline characteristics of the study population, and the monitoring process of the intervention in experimental schools.

Study design

Twenty secondary schools located in Reggio Emilia province participated to the study. Five schools were excluded because already participated to smoking prevention interventions.

Schools were randomized to control or intervention arms. The study population consisted of students attending the first grade. Components of the intervention conducted in 2009-2010 were:

- The out-of-school "Smoking Prevention Tour" (SPT) at the "Luoghi di Prevenzione" Centre, a 4-hours extracurricular workshop;
- The "Smoke-free Schools" intervention, combining a life skills based peer-led intervention at school (i.e. meetings conducted by trained students of the third or fourth grades), an in-depth lesson on one of the SPT sessions, and an enforcement surveillance of the antismoking school policy.

Control schools did not conduct any intervention.

The primary endpoint was ≥ 20 days of cigarette smoking in past 30 days (daily smoking), and 1-19 days of cigarette use in past 30 days (frequent smoking) after the intervention.

Tobacco use was studied through a questionnaire administered before and 6 months after intervention. This study is registered, number ISRCTN 10561880.

Results

Twenty schools, 11 high schools and 9 vocational secondary schools, participated in the study, and 2,476 out of 3,050 eligible students (81.2%) participated in the baseline survey. Proportion of respondents in high schools and vocational secondary schools was 90.9% and 64.5%, respectively ($p < 0.001$). Intervention and control arms showed a different distribution of gender, school type, and period of survey conduction, whereas no differences were observed on any tobacco-use characteristic. All experimental schools completed the most important components of the intervention.

Conclusions

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

Keywords: school-based prevention, tobacco, cluster randomized control trial, youth

Introduction

Youth smoking initiation is an important public health concern worldwide, considering tobacco use is the leading cause of preventable death in the world today¹. While cigarette smoking is highly addictive, individuals who have not initiated smoking by age 21 years are unlikely to ever begin. Further, the younger the age when people initiate, the more likely they will become regular smokers and the less likely it is they will ever quit¹. According to the Health Behaviour in School-aged Children (HBSC) Study, 20% of Italian students aged 15 years in 2005-2006 smoked at least weekly². 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 past 30 days, and 23-24% in both genders smoked on a daily basis. Moreover, at the age of 13 or younger 30% of boys and 27% of girls had tried cigarettes, and 6% of boys and 5% of girls smoked cigarettes on a daily basis³. In the last three ESPAD surveys (1999, 2003, 2007) 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-percent decrease in boys and a 9-percent decrease in girls³.

Schools are potential valuable setting for smoking prevention. Systematic reviews have, however, provided varied evidence of effectiveness of school-based programmes for smoking prevention⁴⁻⁶. One review indicated Life Skills Training⁷ as the only programme having long-term effectiveness in decreasing smoking prevalence at age 18⁵. Life Skills Training programme have been proposed to train a comprehensive core of social skills, thought to exert a protective effect on youths' smoking initiation. This programme teaches generic self-management personal and social skills, such as goal-setting, problem-solving, and decision making, and also teach cognitive skills to resist media and interpersonal influences, to enhance self-esteem, to cope with stress and anxiety, to increase assertiveness, and to interact with others of both genders⁶. Recently, a school curricula 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 programme of about 30-percent lower prevalence of daily cigarette use in past 30 days in the intervention group in comparison to controls⁹.

Another approach is using peers to deliver health promotion interventions to young people. It is based on the assumption that peers may be seen as more credible sources of information than adult, professionally trained, health educators or teachers, and may be particularly helpful in reaching 'at risk' young people^{10,11,12}. Most peer-led health promotion interventions tend to use peers of the same age or slightly older to deliver classroom-based lessons, but a systematic review showed variable evidence of effectiveness and a scarcity of assessments that were methodologically sound¹⁰. Recently, a randomized controlled trial based on an informal school-based peer-led intervention showed a significant 22-percent reduction in the odds of being a smoker in intervention compared with control schools¹³.

School tobacco use policies are often considered to be part of a comprehensive approach to preventing or reducing adolescent cigarette smoking¹⁴. There are only a few cross-sectional studies that have addressed the possible effect of a completely smoke-free school on youth smoking behavior¹⁵. Adolescents who perceived school antismoking policies as strictly enforced also believed tobacco was less available, more risky, less socially attractive, less used by their friends, and less acceptable. These beliefs were directly related to adolescents' past-30-day cigarette smoking. Thus, enforcement of antismoking policies by school may help to shape students' personal beliefs about cigarette smoking and, thus, their smoking behaviour¹⁶. Results of this approach appeared promising, even though more research is required¹⁵.

Little is known about the adjunct to a school-based intervention of a component of extracurricular activities¹⁷⁻²⁰. In our study extracurricular activities were conducted in an out-of-school Centre specifically dedicated to health promotion, the 900-square-meter "Luoghi di

Prevenzione” Centre (Prevention Place) funded by the LILT (Lega Italiana per la Lotta contro i Tumori - Reggio Emilia section) no-profit organization. The Centre is located in a former national health system hospital in Reggio Emilia, Italy. Students can follow four-hour out-of-school “Health Promotion Tours” delivered by trained educators. Each tour is dedicated to a single subject (prevention of smoking, alcohol and substance abuse, street accidents)²¹ In particular, the “Smoking Prevention Tour” (SPT) was developed in order to deliver life skills and knowledge on the harmful effects of smoking.

The LILT-LdP (Luoghi di Prevenzione, Prevention Place) study is a cluster randomized controlled trial designed to evaluate the effectiveness of a smoking prevention programme for students aged 14 years, characterized by two components: the participation to the SPT at LILT-“Luoghi di Prevenzione” Centre and 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 an enforcement surveillance of the antismoking school policy. This paper presents study design, baseline characteristics of the study population, and the monitoring process of the intervention in experimental schools.

Methods

The LILT-LdP Intervention

Components of the intervention were:

1. The out-of-school “Smoking Prevention Tour” (SPT) at the LILT “Luoghi di Prevenzione” Centre was developed in order to deliver life skills and knowledge on the harmful effects of smoking. This 4-hour workshop was divided into four 40-minute sessions led by LILT trained educators: a) Lab session: conduction of laboratory trials to separate different smoking substances using lab reagents; measuring particulate matters when a cigarette is lit using a portable laser-operated aerosol analyzer. b) Computer session: every student filled in 3-5 score tests (tests on physical and psychological wellness and on stress levels, on curiosity

level about smoking; for smokers: the Fagerstrom Tolerance Questionnaire, test on motivation to quit and on motivation to be a sustained non-smokers). c) Creative Writing session: after a reading on smoking, students wrote two structured papers following specific headings, such as emotions and feelings, thoughts, experiences, key-words, beliefs. d) Imaginative session: an educator read a novel on smoking during a Saturday night in a disco-club. Students were invited to identify themselves with the character, comparing this situation with that of a non-smoker.

2. The school-based intervention “Smoke-free Schools” consisted in: a) a 2-hour in-depth school lesson on one of the SPT sessions. Teachers were previously trained in two 2-hour meetings. b) a life-skills peer-led intervention: a group of self-selected 16-17-year-old peers of experimental schools (older than those recruited for the study) were trained in three 2-hour sessions at school plus one meeting at the LILT “Luoghi di Prevenzione” Centre. Trained peers organized two 2-hour meetings in every intervention classes, where they conducted a brainstorming on smoking, a discussion on positive and negative aspects of smoking, a creative writing session on smoking, and administered a questionnaire on health risks of smoking. c) enforcement surveillance of the antismoking school policy: school staff established a working group, revised the school anti-smoking policy, enforced the smoking regulation and the correct positioning of non-smoking signs in school areas.

Control schools did not conduct any intervention. They participated in the baseline and follow-up surveys only.

Process evaluation

We monitored the completeness of the intervention recording the implementation of the components of the intervention in experimental schools.

Study design

It is a two-arm cluster randomized controlled trial where schools were randomly assigned to the experimental arm. The intervention group will be compared with one control group (Figure 1). This study is registered, number ISRCTN 10561880.

Units and subjects

The study population consists of students attending the first class of secondary schools located in Reggio Emilia province, Italy. Inclusion criteria for the schools were: presence of at least three classes in the target grade; to be part of the mainstream national educational system; not current or recent participation to smoking prevention interventions. Exclusion criteria at the students' level were the own incapability to participate in the survey.

Sample size

With an inflation factor of 1.9 derived from an estimate of intra-class correlation coefficient calculated in grade participants to ESPAD surveys³, assuming significant level $\alpha=0.05$, power of 0.80, prevalence of cigarette use in past 30 days of about 15% in the control group, a sample size of about 3,400 students (1,700 per arm) could allow to appreciate a relative risk of about 0.70²².

Selection and randomization of schools

Five secondary schools out of all the 25 secondary schools located in Reggio Emilia province (536,600 inhabitants in 2011) have been excluded since in preceding years they have already participated to school-based smoking prevention programmes. The remaining 20 schools participated to the trial. Small school annexes of the participating schools with less than 3 classes in the target grade and located in peripheral areas of the province were excluded. Participating schools have been paired according to the type of school (vocational secondary school; high school) and the size of the school (number of students attending the first class in the 2008-2009 school-year), in order to obtain similar number of students in each study arm. One school per couple was then randomized to the experimental arm using a random-number generator. After randomization, three schools (2 vocational and 1 high schools) allocated in

the control group refused to be assigned to the control group. Authors then decided to change experimental into control schools and vice-versa in these three pairs of schools. This protocol change will be taken into account in the analyses.

The study was conducted in two waves: in the first wave in four pairs of schools the pre-intervention survey was conducted in December 2008-May 2009, whereas for the remaining schools was conducted in November 2009-May 2010. The follow-up surveys of both waves were carried out on average 18 months after the baseline surveys, taking into account at least 6 months after the end of the intervention.

Outcome assessment

The primary endpoint was 20 or more days of cigarette smoking in past 30 days (daily smoking), and 1-19 days of cigarette use in past 30 days (frequent smoking) recorded in the follow-up survey.

Data collection

Students in both arms had to fill in a questionnaire before and after 6 months from the intervention. Questions covered demographic characteristics: gender, year of age, origin and education of parents; cigarette use (frequent or daily smoking, lifetime cigarette use, lifetime use of ≥ 100 cigarettes); smoking prevalence in parents, siblings and friends; exposure to second-hand smoke at home and in cars; exposure to anti-tobacco advertisements and to smoking scenes in movies and television programmes; 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, in 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?); anti-

tobacco 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 know for sure that smoking hurts people?).

Confidentiality

In order to preserve a rigorously anonymous management of the data, while keeping the link between individual information collected on subsequent survey, the questionnaires were labelled with a 9-digit individual code generated by the student⁹.

Ethical aspects

The LILT-LdP Study was submitted and approved by the Ethics Committee of the Local Health Authority of Reggio Emilia, Italy. A policy of informed consent was adopted, and surveys to students were conducted at school after approval of school-boards. Parents were all informed of the surveys through a letter with an attached declaration form they had to sign and to send to the school principal in the case they did not accept that their offspring participated in the surveys.

Statistical analysis

We conducted a descriptive analysis of the baseline characteristics of recruited students in the 20 participating schools. Differences in proportions were analyzed using the Chi-squared test. The software STATA 11 was used for the analyses.

We planned to measure the effect of the intervention on daily and frequent smoking at six-month follow-up in terms of Odds Ratios. In order to take into account the hierarchical structure of the data, estimates of the intervention effect at six-month follow-up will be obtained with random effects logistic regression models with school as a random effect, and including as covariate past-30-day smoking at baseline and variables with different distribution between intervention and control groups. Analysis will be by intention to treat. After conducting primary outcome analyses, we planned to study secondary endpoints, which are changes on attitudes and beliefs on tobacco smoking and on tobacco industry conduct:

perceived health consequences from smoking, intent to use cigarettes in the near future, smoking if a friend offers a cigarette, perceived social norm, perceived social acceptability of smoking, anti-tobacco industry norms.

Results

Twenty schools participated to the study, 11 high schools and 9 vocational secondary schools. One hundred and sixteen classes 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 experimental arm (80.9%), and 1,239 students of the control arm (81.5%; $p=0.22$). Proportion of respondents were higher in high schools than in vocational secondary schools (90.9% vs. 64.5%, respectively; $p<0.001$).

Socio-demographic characteristics that showed a different distribution between intervention arm and controls at baseline were gender, as lower proportion of girls was enrolled in the intervention arm compared to controls, and type of school, as a lower proportion of students of vocational secondary schools was enrolled in the intervention arm (Table 1). Prevalence of cigarette use in past 30 days, of 20 or more days of cigarette smoking in past 30 days, lifetime cigarette use, and lifetime use of at least 100 cigarettes, were similar in intervention and control arms (Table 1). Moreover, in experimental schools the baseline survey was conducted on average 3 months earlier and the follow-up survey 3 months after in comparison to control schools.

Regarding the monitoring of the process of the programme, all intervention classes completed the peer-led intervention, participated in the SPT workshop, and formed a working-group on the school anti-smoking policy, verified the presence of no-smoking signs, enforced and revised the school anti-smoking regulation. On the contrary, only 5 schools participated in the class lesson on one SPT workshop, and only 3 schools implemented the revised regulation during the study period (Table 2).

Discussion

The LILT-LdP Study is a trial aiming to evaluate the effectiveness of a school-based peer-led smoking prevention intervention with extra-curricular activities. The participation rate of schools was very high: in practice, all the available secondary schools in Reggio Emilia province, participated to the study, except for 5 that were excluded because they already participated to school-based programmes. Our study recruited 20 schools and 3,050 students of secondary schools aged 14 years, corresponding to the 87% of the expected study sample (about 3,500 students), and recorded a participation rate at the baseline survey of 81% of enrolled students (2,476 boys and girls). The participation rate at the baseline survey was significant 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.

Prevalence of current cigarette use in our study (24.5% in both intervention and control arms) was similar to that recorded in the 2010 HBSC survey in students aged 15 years old from Emilia-Romagna Region (26.4%)²³, and was lower in comparison to the 2007 figures of ESPAD survey for Italy (37% in both genders), that was from older students aged 15 and 16 years³.

Regarding the delivery of intervention, main components were implemented in all experimental schools. Even though 5 schools only conducted the 2-hour in-depth school lesson on one of the SPT sessions, this component was considered the less important of the school-based intervention whose main components were the peer-led intervention and the enforcement surveillance of the antismoking school policy. Regarding this part of intervention, all experimental schools formed a working-group, verified the presence of no-smoking signs, and revised the school anti-smoking regulation, but only 3 schools succeeded in implementing the revised school smoking regulation in the study period, since the school approval procedure of the revised regulation required more than one school-year.

This study is one of the few trials conducted in Italy to evaluate effectiveness of school-based programmes for preventing smoking initiation in adolescents. One strength of this study is the completeness of the implementation of the intervention in experimental schools. One limit of this study is that the 2,476 students recruited at baseline were almost $\frac{3}{4}$ of the estimated sample size (3,500 students). This could determine a lower than expected power of the study. In conclusion, smoking is actually the 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 smoking attributable mortality in future decades. In order to achieve this goal, LILT-LdP study evaluated effectiveness of a school-based peer-led smoking prevention intervention with extra-curricular activities.

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Table 1

	I N=1,237 %	C 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

Table 2

Programme components	Schools (%)
Peer Education	9 (100.0)
“Smoking Prevention Tour” workshop	9 (100.0)
Class lesson on one SPT workshop	5 (55.6)
At least one training lesson on SPT workshops for teachers	9 (100.0)
School smoking regulation: control of smoking signs and enforcement surveillance of the school policy; formation of a school working-group; revision of school smoking regulation	9 (100.0)
School smoking regulation: introduction of the revised smoking policy during the study period	3 (33.3)

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

Table 1. Baseline socio-demographic characteristics and smoking behaviour variables in recruited students by study arm (Intervention; Control).

Table 2: Monitoring of the process of the programme in intervention schools.

